MANAGEMENT OF MEDICINES BENEFIT PROGRAMS IN LOW- AND MIDDLE-INCOME SETTINGS



Adapting Approaches from High-Income Countries

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Management Sciences for Health

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ABBREVIATIONS AND ACRONYMS

ADDO	accredited drug dispensing outlet
CEO	chief executive officer
CFO	chief financial officer
CIO	chief information officer
DUR	drug use review or drug utilization review
ID	identification
LMIC	low- and middle-income countries
MBP	medicines benefit program or plan
MSH	Management Sciences for Health
NGO	nongovernmental organization
NHIS	national health insurance scheme
OECD	Organization for Economic Cooperation and Development
PEPFAR	US President's Emergency Plan for AIDS Relief
PBM	pharmacy (or pharmaceutical) benefits manager
PTC	Pharmacy and Therapeutics Committee
SMS	short message service
STG	standard treatment guideline
UHC	universal health coverage
WHO	World Health Organization

GLOSSARY

Actuaries
Insurance professionals who perform mathematical analyses for setting insurance premium costs, calculating the expected costs and revenues of the benefit plan and determining what level and scope of coverage can be provided, given resources available.

Actuarial equivalence
Situation where two different benefit plans may not have the same premiums, cost sharing requirements, or benefits, but expected overall spending by the plans is projected to be about the same.

Adjudication
The process of analyzing claims from providers or beneficiaries for eligibility, validity, completeness, and compliance with plan policies, and preparing the claim for payment or denial.

Adverse selection
The problem faced when plan beneficiaries are sicker (more costly) than the general population, and lower-risk members (less costly) opt out of the plan.

Attachment point
A term used in reinsurance; it is the size or value that a claim must reach before reinsurance kicks in. For example, if the attachment point was $100,000, any claim up to $100,00 would be paid by the primary insurer, but claims in excess of $100,000 would be reimbursed by the reinsurance firm.

Authorization process
The requirement to obtain approval from the plan or benefit manager before a claim is paid. **Prior authorization** means approval is required before the service is provided. **Concurrent authorization** means approval is requested when treatment is already underway but not completed. **Retrospective authorization** means approval is requested after the service has been completed before the request is submitted. **Sub-authorization** means that if one product or service is approved, then another service that would normally require approval is automatically authorized (usually applicable in hospital settings).

Beneficiary
Also known as a plan "member." An individual covered by the benefit plan; includes the primary subscriber, a dependent, and family members covered by the plan.

Bundled charges (bundled billing)
Is a contractual arrangement whereby an all-inclusive charge covers all services provided during an episode of care, including medicines and other health technologies; most often applicable in the hospital or dispensing doctor setting, but increasingly considered for outpatient services in some low- and middle-income country benefit plans.

Capital reserves
Readily available funds that the insurance/benefit plan retains to pay for unforeseen requirements and future liabilities that are higher than available operating funds. The amount (or percentage of revenue) required for capital reserves may be stipulated in national laws and regulations.

Capitation
A payment method whereby the benefit plan pays a service provider a monthly or annual amount per beneficiary to cover all services provided to a set of beneficiaries for a specified length of time (usually a year), with the payment amount fixed, no matter how many services are provided to an individual beneficiary. The fixed payment amount may be the same for all beneficiaries or may vary based on actuarial projections of service utilization.

Carved-in model
Can refer to either the basic plan design (all health benefits including both medical services and medicines are covered under a single plan) or to payment terms (whereby all services including medicines are paid for under the basic contract terms).

Carved-out model
A set of benefits (such as medicines) are not provided as part of the basic health plan, but are provided through a separate plan. In many countries, the medicine benefit may be "carved out" and managed by a separate company under contract to the benefit plan. As applied to payment terms, the carved-out charges for specific services (or medicines) are not covered by the standard payment terms and are charged separately (mostly applicable to capitation and "bundled billing" contracts).

Claim
A bill to the health plan or benefit manager submitted by either a provider or beneficiary to obtain payment for the service or medicines provided to the beneficiary.

Closed formulary
A specific list of medicines that are eligible for payment under a medicine benefits plan. Medicines not on the list will not be covered unless approved through a formal authorization process.

Closed model
In this context, it refers to a model of providing access to services and medicines exclusively through facilities and outlets that are owned and operated by the insurance scheme or benefit plan. Beneficiaries must visit one of these facilities to obtain services and medicines.

Closed network
Refers to a network of designated and contracted preferred providers who are pre-authorized to provide services and medicines to beneficiaries. Payment will not be made to providers who are not in the network unless an exception is approved through the authorization process.

Co-contracting
An arrangement between two or more benefit plans whereby both plans agree to contract with the same network of providers to provide services to beneficiaries of both plans.

Co-insurance
A cost-sharing provision in a benefit plan whereby the beneficiary is responsible for paying out-of-pocket a percentage of the charges for health services or medicines provided. For example, the plan might pay 80% of charges and the beneficiary 20% if the service comes from an authorized provider. Obviously these provisions place a heavy burden on less-wealthy segments of the beneficiary population and can significantly reduce access to services and medicines.

Co-payments
Another form of cost sharing, whereby the beneficiary plays a fixed amount to the provider out-of-pocket to the provider at the time services are provided. In some plans, the amount paid is the same for all patients and all medicines. For plans with tiered co-payments, the amount paid can be based on the level of health facility providing the service or on the type of medicine prescribed. For example, generic medicines or those on the MBP formulary would require lower co-pays than branded or non-formulary products.

Deductibles
A cost-sharing provision that requires beneficiaries to pay a fixed charge for services and medicines out-of-pocket before insurance coverage kicks in.

Deductions
This refers to payroll deductions that are used to pay for insurance coverage. They are usually deducted on a monthly basis, and the deduction may be a fixed amount for all beneficiaries or may be based on a percentage of salary. Total annual deductions may be capped at a specified total annual amount (as in MEDICARE in the United States) or uncapped meaning that the deduction is applied on the total annual salary.

Discounts
Negotiated reductions in fees for services (such as dispensing fees) and/or charges for medicine ingredient costs which are then specified in contracts between the benefit plan and service providers.

Dispensing fee
The negotiated amount specified in contracts that is paid to a service provider to cover the costs of processing and filling prescriptions. The fee is added to the charge for medicine ingredient costs.

Essential medicines
In the benefit management context, essential medicines are those medicines that are indispensable and necessary for the health needs of the majority of the beneficiary population and which should be accessible in the proper dosage form to all beneficiaries.

Exclusions
Health conditions, health services, or medicines and technologies which will not be covered by the benefit plan. In some plans, coverage for excluded conditions, services, or commodities may be allowed through the authorization process.

Exemptions
Exceptions to plan policies, such as cost sharing, which may be granted to targeted classes of beneficiaries. Exempt beneficiaries may be fully or partially excused from paying co-payments, co-insurance, premiums, or other financial contributions normally required for participation in the plan.

Formulary
The list of medicines and related health commodities that the MBP approves for prescribing and dispensing to beneficiaries and which are eligible for payment or reimbursement by the MBP.

Generic medicines
Products from non-originator companies that are approved to be marketed under the international nonproprietary name (INN) or another brand name. Ideally they should have been certified by the national drug regulatory authority as being equivalent in safety, purity, strength, and effectiveness to a brand-name medicine. In most markets, once generic equivalent medicines are approved, they are less expensive than the branded equivalent product, although that may not be true in countries where prices are regulated at the national level.

Informal sector
The parts of society and the economy that are not registered with the government and are not subject to public regulation and taxation, and which therefore are not formally entitled to benefit from most government services.

Ingredient cost
The acquisition cost that the service provider pays for the medicine or product being dispensed or administered to a patient, without any added markup or fee. For reimbursement purposes, the ingredient cost may be the actual acquisition cost, an estimated or average acquisition cost, or a standard stipulated cost value established for the product through policy or regulation.

In-house services
A service delivery model in which health services and/or medicines are provided to beneficiaries by staff employed by the benefit plan in facilities operated by the plan (also known as a closed model).

Interactive voice response system (IVRS)
A telecommunications system in which a computer operated by the benefit plan or benefit manager fields telephone calls from service providers and beneficiaries and allows the caller to obtain or enter standard categories of information. The caller enters information and responds to questions from the IVRS either by spoken words or entries using the telephone keypad. IVRS can also be used to provide reminders to members regarding prescription status or to promote services such as immunization or other preventive services.

Leakage
Loss of funds or commodities due to diversion or theft.

Means testing
One approach to determining eligibility of beneficiaries for targeted financial exemptions or subsidies, based on beneficiary income and assets. **Direct means testing** involves actual collection and verification of information from the beneficiaries, which can be a complex and expensive process. **Proxy means testing** uses indicators such as location and quality of beneficiary's home, number of children, visible assets, occupation, or educational levels, rather than directly collecting the information from individuals.

Mobile applications
Systems and software that allow benefit plans and managers to communicate via radio and/or wireless mobile devices including phones. These applications have a variety of potential uses in a benefit plan to facilitate claims and claim processing, manage the authorization process, share information on medical/medication use and history, and provide targeted information to service providers and beneficiaries.

Monopoly
A situation where there is no competition (or very limited competition) among service providers or vendors of an essential product or service, and therefore anyone wishing to purchase those services or products is forced to deal with the dominant entity. Usually leads to significantly higher costs for the product or service compared to a situation where there is strong competition among vendors.

Moral hazard
Changes in behavior or in consumption of a product or service due to the presence of insurance that increases costs to the insurer. This may manifest in higher use of available services by beneficiaries, and demands for excessively expensive tests and medicines (demand side moral hazard) as well as in inappropriately high levels or quantities of services and medicines provided (and billed for) by service providers (supply side moral hazard).

Negative list
A list of medicines, procedures, and services that are excluded from plan coverage and from payment by the benefit plan, unless an exception has been approved through the benefit plan's authorization process.

Online portal
An Internet website operated by a benefit plan or benefit management firm that allows access to the benefit plan's on-line information services.

Open access
Beneficiaries can go to any appropriately licensed service provider to receive medical services and medicines, with or without a contractual agreement in place between the service provider and the benefit plan or benefit manager.

Open model
The opposite of closed model, in which services and medicines are provided exclusively in-house. In an open model, health services and medicines are provided through contracts with a variety of service providers, including public and private hospitals and health centers, physicians and physician groups, private pharmacies and pharmacy chains, mail order or courier pharmacies (where available), and in some cases, nongovernmental organization health facilities. The open model could be expanded to include contracts with licensed drug sellers to provide certain medicines and other health commodities.

Open network
A beneficiary can obtain medical services and medicines from any licensed provider who is willing to accept the medicines benefit plan's terms and conditions (known as "any willing provider"). An open network still requires that the provider sign a contract with the benefit plan to get claims paid, but the option must be open to any willing provider who meets the criteria.

Open unlimited formulary
Any medicine registered in the country is eligible for some level of payment coverage unless the medicine or the category of medicines is expressly excluded in the plan design. As new medicines are registered, they automatically become eligible for coverage unless they are in an excluded therapeutic category.

Over-the-counter
Refers to medicines and health commodities that do not require a prescription (by law) to sell or dispense to consumers.

Performance-based contracts
Contracts with a service provider or benefit management firm where fees may be increased through achievement of specified objectives or decreased due to failure to achieve specified objectives.

Pharmacy benefits management
An alternate term for medicines benefits management, which is used widely in settings where private firms often manage the medicines benefit on behalf of insurers. These private firms are called pharmacy benefit managers or PBMs.

Positive list
The list of medicines, health commodities, medical services, and procedures that are covered by the benefit plan and which are eligible for payment without any further authorization.

Preferred medicine list
Also known as a tiered formulary list. It is the list of medicines that can be prescribed and dispensed to plan patients with the lowest level of co-payment and without any further authorization process. Similar to an essential medicines list, it is meant to provide cost-effective access to medicines that are necessary for the health needs of the majority of the beneficiary population.

Premiums
Money paid to a health insurance entity or benefit plan for coverage. It may be paid by individual beneficiaries or by employers, government agencies, or other organizations that sponsor the coverage for beneficiaries.

Provider
An organization or individual that provides medical services and procedures and related health care services, medicines, and other health-related products to the benefit plan and its beneficiaries.

Rebates
Payment from a provider of services, medicines, or other products to the purchaser (or in some cases, consumer) of the products. With respect to medicines, the manufacturer or distributor provides a rebate based on a percentage of the nominal purchase price and the volume of specific products purchased. The rebase is provided to the health plan or benefit manager, usually through a contractual arrangement. In some settings, a percentage rebate may be mandated for government-funded benefit programs.

Rescission
The abrogation or cancellation of a contract effective back to the initial date of the contract, meant to nullify all transactions under the contract. In insurance, it relates to retroactive rejection of approval for insurance coverage based on an undisclosed pre-existing health condition.

Reinsurance
Insurance purchased by a health insurance organization or benefit plant to protect itself against extremely high-cost individual claims.

Reserve fund (or institutional reserve fund)
Funds kept aside by an insurance or benefit plan to cover future obligations, both anticipated costs and currently unforeseeable future liabilities. Laws and regulations often stipulate the amount required in the reserve fund.

Risk equalization fund
Funding to cover costs of high-risk populations. It may involve a transfer of funds from insurers with low-risk populations to insurance plans with high-risk populations. Commonly in low- and middle-income countries, risk equalization funding comes from the government.

Skimming
The situation when an insurer or benefit plan denies coverage or charges extremely high prices for coverage of high-risk populations, with the intent of providing coverage only to relatively low-risk populations who use less health care services.

Sliding scale
A policy whereby required co-payments or co-insurance amounts vary according to the beneficiaries' income or assets. Similarly, other exemptions and subsidies may be allowed based on a sliding scale.

Social targeting
The primary methods of social targeting are categorical, geographic, and means tested. In **categorical targeting,** specific categories of individuals are given the subsidy or preference, without requiring means testing (or determining if someone qualifies for assistance). For example, demographic categories may include groups such as children, the elderly, disabled, or pregnant. Disease-based categories might afford preferences to patients with specific diseases, such as tuberculosis or HIV and AIDS. Other categories might be based on occupation, such as military, teachers, or other government employees. Categorical preferences could also be extended to the defined immediate family of the eligible individual. In **geographic targeting,** the preference goes to individuals living in a specific geographical area, such as urban slums or rural areas with little formal economy or access to care. This method can be combined with some form of means testing to better target the poor in those areas. **Means-tested targeting** is defined earlier in the glossary.

Specialty pharmacy
A pharmacy that provides specialized "high cost, high touch" medicines, such as new cancer therapies, new "biological" medicines, etc. These medicines require special handling or special considerations in preparing and administering the medicines, often including direct clinical support during administration. Specialty pharmacies may have a direct relationship with the manufacturers and distributors of these high- cost medications and function as a promoter of preferred products in addition to providing clinical services to beneficiaries. In addition to pharmacies, he scope of these providers may extend to new, high-cost medical devices, both diagnostic and therapeutic.

Sponsor
The institution responsible for arranging for insurance and benefit coverage for a set of beneficiaries. The benefit plan sponsor may be a government, a social security institution, a union, a private employer, a group of employers, etc. The plan sponsor may directly operate the benefit plan or may contract with insurance firms and benefit managers to operate and manage the plan on behalf of the sponsor.

Step therapy
Based on the concept of standard treatment guidelines. The medical provider is encouraged (or required) to start treatment of a given health problem with a preferred medicine, usually a cost-effective generic medicine, and only progress to prescribing a higher-cost medicine if the patient failed to respond to the first step of therapy. Compliance with the policy can be encouraged by requiring higher co-payment levels or higher co-insurance percentages if the provider does not adhere to the step therapy approach.

Targeting benefits
Targeting is the process for determining which segments of the beneficiary population should receive special benefits and/or financial benefits though exemptions and subsidies, and then designing the benefit plan to cover the targeted populations. **Social targeting** is the process of designing the benefit plan so that disadvantaged and high-risk segments of the population can participate and access benefits. This is a basic requirement for plans contributing to universal health coverage. **Political targeting** involves targeting the plan and its benefits toward politically favored segments of the population. This kind of

targeting may effectively shut-out access for non-favored segments.

Therapeutic substitution

A policy that authorizes or mandates that the pharmacist or dispenser provide a preferred cost-effective medicine in the same therapeutic category as the prescribed medicine, but not necessarily the same generic medicine as that prescribed. For example, for high blood pressure, the preferred angiotensin converting enzyme inhibitor (ACE) medicine might be captopril; however, if lisinopril—which is in the same ACE therapeutic category, but is a different generic molecule—is prescribed, captopril would be substituted and dispensed. In countries with this policy, there are usually authorization processes that provide for exceptions for specific circumstances.

Tiered open formulary

A formulary model in which non-excluded medicines may be eligible for payment, but the amount reimbursed may be lower or the cost share higher than for preferred medicines in the same generic or therapeutic category. See also preferred drug list.

Tiering

Categorizing coverage, benefits, co-payment amounts, or providers into different tiers. Tier 1 medicines would have a lower cost-sharing amount than tier 2 medicines, which are lower than tier 3 medicines. For patients, accessing a tier 1 health care provider might require minimum or no cost sharing whereas going to a tier 2 or 3 provider would invoke higher cost-sharing requirements.

Universal health coverage

The WHO World Health Report of 2008 defined universal health coverage (UHC) as achieving access for all people to key promotional, preventive, curative, and rehabilitative health interventions at an affordable cost, thereby achieving equity in access. The ultimate UHC goal is ensuring that all people obtain needed health services, including medicines and other essential health technologies, without suffering financial hardship when paying for them.

Some of these definitions are adapted in part from the following sources, which offer more comprehensive glossaries of terms used in insurance and managed care.

- Kongstvedt, P.R. 2013. Essentials of Managed Care, 6th Edition. Burlington, MA: Jones and Bartlett.
- Navarro, R. ed. 2009. Managed Care Pharmacy Practice. Sudbury, MA: Jones and Bartlett.
- Preker, A, M., Lindner, D. Chernichovsky, O. Schellekins eds. 2013. Scaling Up Affordable Health Insurance – Staying the Course. Washington, D.C.: World Bank.

INTRODUCTION TO THE MANUAL

HEALTH INSURANCE AND MEDICINES BENEFITS IN THE CONTEXT OF UNIVERSAL HEALTH CARE

A medicines benefit program (MBP) is the component of a health insurance plan that covers some or all medicines prescribed and dispensed to plan beneficiaries. Although this manual focuses primarily on medicines, other health technologies, such as diagnostics and vaccines, fall into the same category, with similar decision-making processes. Here, we focus on MBPs offered by insurance mechanisms—public and private and for-profit and nonprofit entities.

Many low- and middle-income countries (LMICs) provide medicines to patients through nationalized public sector health programs or social security systems that maintain their own health facilities, employ their own doctors and pharmacists, and dispense medicines to patients exclusively through these in-house facilities. This manual does not cover that type of medicines benefit. The issues related to managing medicines in those types of health systems are covered in *MDS-3: Managing Access to Medicines and Health Technologies*.[1]

Here, we focus on management systems that insurance programs use to provide medicines to beneficiaries through contracts with outside service providers and then pay for the providers' services based on claims submitted by the provider (or in some cases by the beneficiary). The service providers may be public or private entities.

PURPOSE OF THIS MANUAL

We developed this manual in response to discussions at a conference that Management Sciences for Health (MSH) hosted in June 2013 called "Universal Health Care and Medicines: the Start of a Dialogue." Although meeting participants generally agreed that a medicine benefits component is essential for

achieving universal health coverage (UHC), discussions made it clear that we lack a common understanding of which elements of an MBP are truly essential and which options and design elements should be considered when implementing or revising an MBP.

The companion to this manual, the *MSH Medicines Benefit Program Assessment Tool for Developing Countries*, contains key questions to ask and data collection templates to use when considering options for developing or revising a medicines benefit program. We have used the tool in three countries, Ghana, Namibia, and South Africa.

We created the manual as a primer for managers or consultants who are tasked by a government or other institution with designing or implementing an MBP or with supporting these efforts, such as international development professionals.

The manual introduces common design and management elements that every MBP must address. It helps readers identify the basic options and trade-offs to consider when designing or revising each aspect of the plan. Because each country context is unique, the manual cannot specify any combination of program elements that will fit a specific country situation, much less lay out a single program design fitting all situations.

This guide does not include detailed templates, algorithms, or samples of the analytical tools and approaches discussed in the text, but makes readers aware of alternatives to consider and points out sources for useful tools and templates. When we do discuss specific tools or we include citations in the reference section that provide practical details and examples of tools and templates that can be adapted to a specific country situation.

The manual highlights the sections that correspond to relevant chapters in MDS-3 that provide more information.

Many of the specific management approaches described here (particularly those related to claims processing) are drawn from approaches that pharmacy benefit management (PBM) companies in North America, South Africa, and Namibia use to manage medicines benefits for insurance programs. These approaches are not the only way to effectively address management challenges, but they are well documented and proven in their own settings and can be adapted to fit LMICs. This first version of the manual includes relatively few case studies from medicines benefit programs in LMICs because we found little information on the management specifics of current LMIC programs in the published and gray literature.

The manual is a work in progress—it will be revised periodically with feedback from colleagues working in international organizations, those working directly in LMIC programs, and from experiences gained in supporting medicines benefit programs in LMICs. We hope that future versions of this manual will include many more concrete examples of how MBPs in LMICs are handling the challenges involved in implementing and sustaining a viable program and more substantive discussion of the issues specific to accessing innovative health technologies in general.

MSH's Systems for Improved Access to Pharmaceuticals and Services Program (funded by USAID) will be working with selected LMICs to assess their status and consider options for MBPs. We will incorporate lessons learned from these activities into future editions of the guide.

CAVEAT—THE CHALLENGES FACING LMICS IN IMPLEMENTING AND SCALING-UP MBPS

Most Organization for Economic Cooperation and Development (OECD) countries have implemented national health insurance coverage that includes medicine benefits. In most, the public sector plays a primary role in financing coverage for beneficiaries, determining which medicines will be covered, paying for claims when services are provided by non-staff prescribers and dispensers, and managing the bureaucracy around the programs.

Some middle-income countries have a combination of national health insurance and large social security programs that cover medicine benefits, and many of these programs provide access to much of the target population.

In the United States and some other middle- to high-income countries, the private sector also manages MBPs, with financing through a combination of employer-funded insurance, government-funded programs, and private insurance paid out-of-pocket.

For many lower-income countries, UHC with comprehensive national medicine benefit coverage is not a realistic goal, even if they can combine features of the public and private systems used in higher-income countries. This guide discusses approaches to mitigating these and other barriers, but the challenges should not be minimized because the barriers are high.

Major barriers are related to—

- **Financial resources.** Few LMICs have the funds and recurrent revenue to finance universal coverage with medicine benefits. And health systems that depend on out-of-pocket payments from beneficiaries to supplement available medicine benefits will limit access for the poor.
- **Human resources**. Many LMICs lack the skilled personnel needed to staff and manage an effective and efficient large-scale insurance system with medicine benefits.
- **Information technology**. Modern large-scale insurance and MBPs in high- and even middle-income countries depend heavily on computerized systems and reliable electronic communications to manage beneficiary and provider relationships, oversee medicines distribution, and process claims. These automated systems are expensive to implement and maintain and require a national infrastructure that many low-resource countries lack. While managing an MBP with paper-based systems is possible, such systems are vulnerable to fraud and abuse and delays in claim approvals and payments, which limit the buy-in of both beneficiaries and service providers.
- **Access to information**. Related to the information technology deficit, many LMICs lack access to data on the countries' epidemiology, target populations, such as unique identifiers, and other information needed to design and manage a large-scale MBP effectively.

However, there is hope for improvement. Computerization and reliable electronic communication technology will increase in LMICs, and the spread of mobile technology may allow management of beneficiary and provider services where land-line communications are not well developed.

One simple option might be a combination of vouchers with smart phone applications that help beneficiaries and providers access information on the benefits program and manage payments

from patients (for co-pays/co-insurance) and from the program (to reimburse for claims). Another potential option is for private sector PBM companies (existing companies or new entities) to extend their services to additional LMICs to overcome issues of limited management resources and technology. Although few PBM companies are operating in LMICs (Namibia is one example where these services exist), that may change as companies explore the potential for new markets. Of course, private sector PBM services will need to be economically viable for both the insurance programs and the PBMs, and political factors may restrict the possibility in some countries.

Assuming PBM companies do investigate these new markets, some LMIC insurance programs may determine that this contracting option is more cost-effective and efficient than managing their MBPs in-house—similar to the tradeoffs involved with maintaining a centralized pharmaceutical supply chain or contracting out to the private sector.

The bottom line is that as donors and LMICs continue to consider options for achieving UHC, including medicine benefit coverage, they need to be realistic when designing new benefit programs or reforming existing programs. The essential thing is to design and implement programs that provide equitable access to a defined set of benefits that can be sustainably financed and managed. Starting with smaller-scale, but manageable, benefit programs is better than embarking on a national-scale program that strives to cover the entire population for all diseases and medicines, but that cannot be resourced, managed, or sustained.

CONTENTS AND ORGANIZATION

The manual has four main sections with several annexes—

Section I is an overview of the essential concepts related to health insurance and to medicine benefit programs and the components needed for a sustainable program, no matter what its size or scope. Referrals point to sections of the guide where these components are discussed in more detail.

Section II discusses the key factors involved in designing or revising an MBP, including program benefits and risks, major design elements, scope and scale, and revisions.

Section III describes the practical aspects of managing the benefit program—how services will be delivered, program governance and administration, claims processing systems, information technology, beneficiary services, provider contracts, selection of medicines, negotiation with manufacturers, and information and educational programs.

Section IV looks at performance monitoring and utilization review, which are critical components for successfully maintaining an MBP.

Annex 1 provides a list of evaluation criteria to consider when contracting with service providers for dispensing services.

Annex 2 includes selection criteria for contracting with pharmacy benefit management firms.

Annex 3 offers examples of monitoring and evaluation indicators for measuring performance of the MBP itself, as well as the performance of service providers and beneficiaries.

Annex 4 describes examples of fraud and abuse that have been encountered in MBPs in all countries.

Annex 5 summarizes a useful review of the various managed market entry programs in Europe.

REFERENCES

1. Management Sciences for Health. 2012. MDS-3: Managing Access to Medicines and Technologies. Arlington, VA.: MSH.

KEY CONCEPTS AND CONSIDERATIONS IN MEDICINES BENEFIT MANAGEMENT

I

I.A. HEALTH INSURANCE CONCEPTS

Health insurance programs comprise the major financing strategy recommended for countries to achieve universal health coverage.[2] The ultimate UHC goal is ensuring that all people obtain needed health services, including medicines and other essential health technologies, without suffering financial hardship.

The two primary components of any health insurance program are risk pooling and prepayment. Risk pooling means spreading financial risk associated with health care costs among large groups of beneficiaries. The more extensive and heterogeneous the pool of beneficiaries, the more the risks and costs can be shared, which minimizes the financial risk for any individual member. Prepayment means that expenditure for health care is paid by individual beneficiaries, employers, or the government before it is needed, rather than paying the full cost of health services out-of-pocket when they are delivered.

Risk pooling combined with prepayment effectively redistributes health care expenditures among individuals with high and low health risks and high and low incomes. However, this formula only promotes UHC when the total risk pool that is covered includes all segments of the population—the young as well as the old, the wealthy, middle class, and poor, and the healthy and chronically ill. Because some beneficiaries will not be able to afford coverage at market rates, additional funding will be needed to subsidize their coverage. This funding is sometimes known as a risk equalization fund. It may come from government or from other sources, depending on the nature of the insurance program.

A variation of prepayment without risk pooling is a medical savings account, whereby individuals are encouraged or mandated to set aside money for future health expenses. Medical savings accounts may be government run, such as in China and Singapore, or they may be administered privately, often through employers, as in the United States and South Africa. Because these programs are not insurance programs per se, they cannot protect individuals who incur extremely high health costs. Therefore, from a UHC perspective, medical savings accounts need to be complemented by other forms of insurance.

I.B. HEALTH INSURANCE TYPES

There are four general types of insurance programs that are important for UHC.[3]

National health insurance programs are typically managed by the government and funded through government budgets. These programs may cover the whole population or specific segments, such as government workers, police, or the military. The government may provide health services directly or through contracts with nongovernmental organizations (NGOs), private providers, or a combination of both. In the case of contracted services, the government is deemed the single payer for those services, although beneficiaries may be allowed to purchase private insurance supplements. In the United States, the Medicare program for senior citizens is an example. In such instances, it is critical to clarify which is the primary and which is the secondary insurer and to have regulations regarding whether and how providers can bill for services not covered under the primary insurance.

Social health insurance funds may be managed by autonomous or semiautonomous agencies such as social security institutes or sickness funds, which are typically funded by payroll deductions and cover only formal sector workers. Such schemes often operate their own system of health facilities and pharmacies but may contract for certain types of services or geographic coverage.

Community-based health insurance programs are typically managed by nonprofit community organizations and target rural, poor, and informal populations. Participation in such programs is voluntary and eligibility may be based on geography, income level, profession, or proximity to a health care facility.

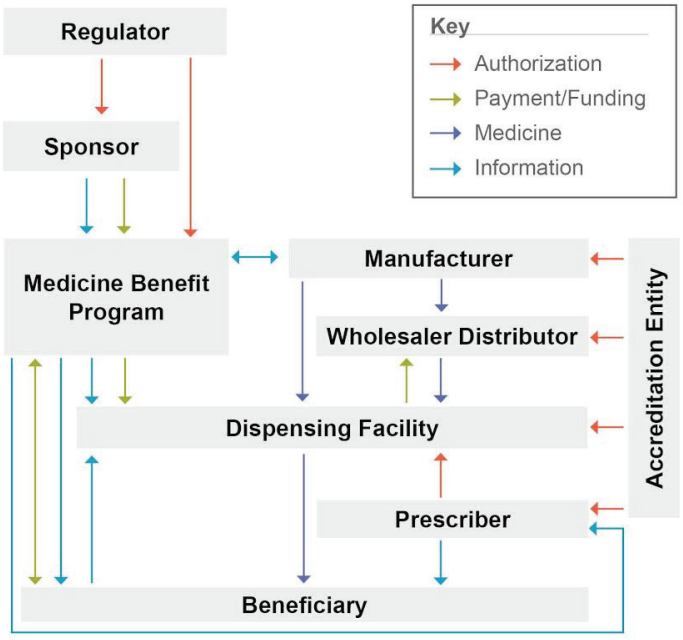
Private insurance is managed by private, usually for-profit companies, although they can be NGOs. The funders (sponsors) may be a group, such as an employer or union, or an individual. In some settings, a private company or union may establish a separate insurance program that covers only employees and their families. These private programs may provide services through contracts with private health care providers, an in-house network of facilities and providers, or a combination. They may also contract with the government to allow their beneficiaries to access public sector health services.

All of these types of insurance mechanisms can include benefits for medicines, and although certain program features may be mandated by the nature of the insurance mechanism behind the benefit program, many options must still be considered when structuring and designing the essential elements of an MBP. The table on the next page illustrates the characteristics and examples of each type.

Characteristics and Examples of Four Types of Health Insurance Programs[4,5,6]

Type of Health Insurance Program	Implementer/ Administrator	Financing	Coverage (% of total country population)	Service Providers
NATIONAL	National government	Government revenues/ budgets	Up to nationwide coverage	Government- or NGO-run facilities
Example: Ghana	*National Health Insurance Authority*	*Tax revenue (primary), employee contributions, and premiums*	*52%*	*Accredited private and public sector facilities*
SOCIAL	**Semi- or fully autonomous government agency (e.g., social security)**	**Payroll deductions**	**Typically formal sector workers**	**Program-specific providers with some services contracted out**
Example: Colombia	*General System of Social Security in Health (SGSSS)*	*Payroll taxes (primary), employer contributions*	*92%*	*Accredited private and public sector facilities*
COMMUNITY-BASED	**Non-profit community organizations**	**Tax revenues, voluntary contributions**	**Informal-sector workers, low income and rural groups**	**Public or private providers**
Example: India	*Aarogyasri Health Care Trust*	*Tax revenues from Andhra Pradesh state*	*< 10% (targeted at low-income residents)*	*Private and public sector facilities that meet program standards*
PRIVATE	**Private companies (for-profit and non-profit)**	**Usually voluntary contributions**	**Plan contributors (typically formal sector workers)**	**In-network providers, contracted providers, or both**
Example: South Africa	*Multiple private health insurance companies*	*Member contributions, premiums, direct payments*	*16%*	*Private sector facilities*

The graphic at right illustrates the roles of major actors involved in a typical MBP. Every country context is different, and the roles played by each entity may differ from country to country, but the major issues discussed here must be addressed by every MBP—large or small, automated or paper based. In the discussion, we try to point out how technology can enhance the program, but we also try to include adaptations when robust information technology is not available.



Medicines Benefit Environment

The following table lists the important considerations along with a reference to the section in the manual that covers it. Paramount among these considerations is feasibility. Setting up and running a national benefit program with or without state-of-the-art technology is a complex and expensive proposition that requires access to specialized human resources. When considering options for implementing an MBP, it is absolutely essential that plan designers and policy makers (and their consultants) estimate as accurately as possible the costs of setting up the system, operating the different management systems, and paying for services and medicines. Plan designers must ensure that financial resources are available to cover projected costs, that skilled human resources are available to design and manage the components, and that the health systems can effectively distribute medicines to all beneficiaries and attempt to assure that they are appropriately prescribed, dispensed, and used.

» See chapter on Pharmaceutical Benefits in Insurance Programs in MDS-3.

Major Design Factors and Functions of the MBP

Program Elements		Where Discussed in the Manual
Country context	The benefit program must be appropriate for the political, legal, and regulatory context and have (or develop) support from key stakeholders.	Section II.B
Plan design	Scope of the benefit program and coverage must be adjusted based on need and equity considerations as well as available financing and health care delivery options, but the program must be scaled to fit within available funding.	Section II.C
Funding for equity	Subsidies will likely be needed to support coverage for target populations who are unable to access coverage otherwise.	Section II.C
Management and governance	The MBP must have appropriate management and governance structures to ensure that the plan operates effectively and efficiently with a focus on serving all intended beneficiaries.	Section III.B
Claims processing	When medicines are provided through contracts with outside providers, a reliable and timely claims processing system is needed.	Section III. C
Information systems	The success of any MBP depends on reliable information management systems. Modern, automated information systems enhance efficiency, but the MBP must adapt its processes to fit the technology available and the information systems must evolve to monitor and manage the MBP effectively as it expands.	Section III.D
Beneficiary services	A robust system to manage beneficiary enrollment and beneficiary services is essential—again—adapted to the information technology available.	Section III.E
Delivery of medicines to beneficiaries	A system must be in place to enable reliable medicine delivery to all plan beneficiaries through in-house facilities, contract providers, or a combination. This includes systems to manage both prescribing and dispensing.	Sections II.B and III.F

Program Elements		Where Discussed in the Manual
Formulary management	A well-designed and managed formulary system that defines the medicines the program covers is essential to good patient care and the program's financial sustainability. In some country contexts, formulary systems may need to address traditional medicines as well as allopathic medicines.	Section III.G
Medicine purchasing strategies	The program may be able to access favorable pricing through mandated or negotiated discount or rebate programs or by negotiations with suppliers or pooling procurement.	Section III.H
Information and education programs	The MBP needs outreach and educational programs for service providers and beneficiaries.	Section III.I
Utilization review and performance monitoring	MBPs must monitor utilization of medicines and services by providers and beneficiaries and the overall performance of the MBP to detect and correct problems. The systems must be adapted to the information technology environment.	Section IV + Annexes

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II BENEFIT PROGRAM SCOPE AND DESIGN

In efforts to achieve UHC, the goals of a medicines benefit program should be to ensure that quality medicines are accessible to and appropriately used by those who need them, without creating financial hardship for households, but yet keep health financing systems sustainable.

II.A. POTENTIAL BENEFITS AND RISKS WITH MEDICINE BENEFITS PROGRAMS

As pointed out by Wang et al.,[7] implementing a health insurance system that covers medicines and other health technologies offers potential benefits and potential risks, which must be considered in its design.

Potential goals and benefits include—

- Protecting beneficiaries from hardship or inability to afford care.
- Increasing national access to health services.
- Improving quality of services and consumer use of services.
- Leveraging private sector resources to support public health.
- Generating additional resources for priority health services.
- Extending access to underserved populations.
- Facilitating redistribution of resources and services to promote equity.
- Minimizing misuse or overuse of certain medicines.
- Providing oversight for quality improvement and risk management in medicines use.

The following is a list of the potential risks—

- Program design may prioritize curative care leading to a decline in preventive health care services.
- Lack of management capacity and systems may result in program inefficiencies that compromise service quality; increase waste, fraud, and abuse; and cause service providers and consumers to abandon the system.

- The insurance mechanism may be unable to find enough high-quality service providers who can provide access to the entire target population.
- The pool of service providers may be too small to permit competition, leading to monopoly by some providers and inability to control costs.
- Provider payment mechanisms that are not properly designed and implemented threaten service quality, access, equity, and solvency.
- Moral hazard, the overuse of covered services by beneficiaries, must be managed in any form of health insurance.
- Adverse selection can threaten sustainability. It occurs when a multitude of high-risk beneficiaries participate in the plan, while low-risk and high-income individuals opt out.
- Skimming is the denial of coverage or charging exorbitant prices to higher risk groups. It must be recognized and mitigated, particularly in private health insurance, to prevent the exclusion of certain groups.
- Cost-sharing programs such as deductibles and co-payments may drive poorer consumers out of the program or leave them unable to access needed health care.
- Low payment levels or long payment lead times may drive service providers out of the system, leading to reduced access and equity for beneficiaries.
- New resources from insurance systems may induce the government to reduce public health spending, thereby decreasing access and equity.
- Corruption or leakage can occur unless strong governance mechanisms are in place and working.
- Benefits may flow to higher income and urban populations without proper mechanisms that target poor and rural populations and workers in the informal sector.
- If the program is not effectively explained and marketed to target populations (particularly the poor and informal sector workers), they may not choose to participate, particularly where the level of trust in the government or in the insurance provider is low.
- If the benefit program is too expansive and costs and financial risks are not properly projected during the design phase, the insurance program may become insolvent or need to be downsized, bringing consumer and provider frustration and adverse political consequences.

II.B. MAJOR PROGRAM DESIGN ELEMENTS

This section focuses on designing MBPs as part of insurance mechanisms that are working toward UHC. The general goals of access to high-quality services and medicines, equity, and financial sustainability apply to all MBPs.

Although a medicine benefits program may be offered as part of any of the four types of health insurance programs, it does not have to be linked directly with a specific scheme. For example, an MBP could serve multiple insurance mechanisms through contracts.

Designing or revising an MBP is a complicated effort requiring collaboration between policymakers, technical experts, and other stakeholders to develop the best options for financing expanded

benefits for underserved populations as well as improving performance of any existing programs. As we will discuss, the design process has to balance the goals of equity, access, and sustainability with political and financial reality.

The major design elements for the MBP include—

- Purpose and goals
- Political and legal contexts
- Financing options
- Cost sharing and user fees
- Health care delivery systems
- Pharmaceutical distribution channels
- Scope of coverage for the plan



Goal and Purpose of the Medicines Benefit Program

As mentioned, the primary purpose of an MBP's contribution to UHC is to improve equitable access to medicines for the entire population, which results in a healthier population that is protected from financial disaster. Equitable access also requires aligning medicines benefits policies and programs to the priority diseases affecting the population and putting in place a system to update medicines coverage to meet its changing needs.

Although access is often equated with availability of medicines, other dimensions of access must be considered, as shown in the framework.

As this diagram illustrates, access to medicines has multiple characteristics—

Availability—products and services are available to consumers where and when they are needed.

Affordability—prices are affordable and consistent with the ability of the users or the MBP to pay for needed products and services.

Accessibility—locations where products and services are provided are accessible to all users.

Acceptability—the characteristics of the products and services provided meet expectations of informed users.

Quality—the cross-cutting characteristic of access. Assuring access requires that the products and services be of high quality; access to substandard products and services is not real access.

Legal and Political Framework

A country's political and legal or regulatory context will determine the kinds of MBPs that are feasible and may mandate or eliminate certain options for plan design unless the conflicting laws and regulations can be changed.

This section discusses some of the key political factors, the types of laws and regulations that will affect the MPB design, and the issues related to changing policies, laws, or regulations.

Developing political will through stakeholder involvement

When working on the MBP design or revision, an evaluation is needed to determine which potential design features are politically feasible. For example, political realities may ultimately control whether a publicly financed MBP can contract with private or NGO providers for prescription services to improve access and which segments of the population the program must cover.

To evaluate the political feasibility of MBP features, it is critical to understand the attitudes of major stakeholders, which typically include—

- Government executive leaders
- Government ministries such as health, finance, industry, technology, labor
- Regulatory agencies including the drug regulatory agency, insurance supervisor or equivalent, consumer protection, and others with regulatory authority over key program elements
- Boards of medicine and pharmacy
- Public sector unions and employee associations
- Social insurance programs
- Community-based insurance programs
- Private insurance companies and their associations
- Pharmaceutical manufacturers and their associations (local and international companies active in the country)
- Manufacturers and suppliers of other health technologies, such as diagnostics and devices
- Pharmaceutical and health technology importers, wholesalers, distributors, and their associations
- Physicians and physician associations
- Health care organizations and companies (group practices, specialty providers, clinics, hospitals) and associations
- Pharmacists and pharmacy associations, including retail chains or networks
- Licensed drug sellers and their associations
- Key donors supporting local public health initiatives
- International agencies and organizations providing technical support to public health initiatives
- National and international NGOs active in providing health care services
- Consumer and patient advocacy organizations
- Company self-insurance programs (e.g., mining companies that provide health benefits to employees and dependents)

The assessment tool provides a template for mapping stakeholder interests and attitudes. The process for developing and carrying out a structured approach to this sort of assessment is described in MDS-3.

» See chapter on Pharmaceutical Supply Systems Assessment in MDS-3.

As an example of how politics comes into play, strong public worker unions or powerful politicians who rely on the support of public sector health workers may make it difficult or impossible to get approval to allow a government-supported MBP to contract for prescription services, even if public sector health facilities are clearly unable to provide adequate medicine access. There is also a strong bias against private sector health care in some LMICs which can have an effect. Moreover, politics rather than rigorous actuarial analyses often determine the initial scope and coverage of a government-supported MBP. As a result, the program may be overstretched and financially unsustainable from the

start or be unable to properly prioritize and finance access for underserved populations.

Relevant laws and regulations

Several categories of laws and regulations may affect MBPs. Descriptions of some of the most important of these follow.

Laws and regulations governing insurance and related benefit programs

The regulatory agencies overseeing insurance providers may have a special insurance office within the ministry of health or the ministry of finance. Insurance legislation should specify the roles and responsibilities of the various agencies. These laws and regulations may mandate, or in some cases prohibit or restrict, certain types of coverage for some or all of the eligible population. The regulations often specify the management structures and the level of financial reserves required.

Laws and regulations governing prescribing and dispensing of medicines

In most countries, national laws and regulations specify which types of providers can legally prescribe and dispense certain categories of medicines. This will determine which categories of health care providers can formally serve the MBP. Larger countries may also have state or provincial regulations that govern prescribing and dispensing. In these settings, the states or provinces often manage and enforce provider practices.

Laws and regulations regarding generic substitution, where the dispenser provides a generically equivalent medicine to replace a more expensive brand originally prescribed, is an important cost control strategy in medicine benefits programs. Therapeutic substitution takes a further step by authorizing or mandating substitution with a different medicine in the same therapeutic category if it is more cost-effective.

Ideally, for the benefit program to implement either of these substitution strategies, they should be explicitly authorized by laws, regulations, and policies governing pharmaceuticals (or at least not forbidden). If necessary, political efforts to change restrictive regulations should be considered.

Laws and regulations regarding sourcing of medicines, procurement, importing, and distribution of medicines

Most national pharmaceutical laws and regulations stipulate that all medicines sold in a country must be registered by the government. If the registration and product quality assurance regulations are well designed and enforced, they can help protect public health. However, such laws may also restrict the benefit program's capacity to access some products that might be needed for specific users or that offer significant public health impact or cost savings. In some cases, waivers from registration requirements may be allowed for MBPs operated or supported by the government.

Policies, laws, and regulations governing prices of medicines

Most industrialized countries and LMICs have made some effort to control the sales prices of medicines to conserve resources and make them more affordable for health programs and consumers. Section III.F discusses several different variations on price regulation as applied to reimbursement in MBPs. Currently, the most widely used approaches include—

- Managed market entry, which determines whether a medicine is covered by a national insurance/MBP, and in most cases, the price at which it will be reimbursed.
- Reference pricing that sets the allowable sales price (or reimbursement price) for a medicine based on average market prices either within the country, from selected countries, or from various international price reporting systems

(e.g., South Africa and Namibia's single exit price system that sets the allowable price of medicines).

- Regulation of markup on cost (or allowable profit margin) at manufacturer, distributor, or retailer levels. A variation is "cost plus" pricing, which attempts to determine the actual cost of production and other supply-related costs to establish the base cost on which to apply allowable markups.
- Mandatory rebates from manufacturers whose products are dispensed to public sector program beneficiaries.

Although not strictly a form of price regulation, the policies and laws regarding import tariffs and taxes on medicines at each level of the distribution system also directly affect sales prices. It should be noted that taxes and tariffs on medicines affect the poorer segments of the population more because they pay disproportionate fractions of their income for medicines out-of-pocket; most international agencies do not consider these sorts of taxes to be sound public policy.

Updating policies, laws, and regulations

In many LMICs, the laws and regulations governing the distribution and use of pharmaceuticals are relatively outdated and unenforced. In addition, laws and regulations relating to insurance may not adequately cover the types of benefit programs being implemented.

Assuming a country has modern laws and regulations governing registration, marketing, and distribution of medicines, or can feasibly update them, ensuring that these laws are rigorously enforced remains challenging. The drug regulatory authority may be underfunded, lack the political mandate, or have insufficient capacity to properly enforce regulations. Besides the obvious effect on public health, lack of enforcement can negatively affect benefit program performance. For example, if the public perceives that product quality standards are not enforced, patients and service providers may not accept mandatory generic or therapeutic substitution. Consequently, without those sorts of cost control mechanisms, managing a financially viable medicine benefits program will be difficult.

The reform process—changing laws, regulations, and policies

If national policies, laws, or regulations significantly limit the scope and viability of the MBP, it may be feasible to amend them. The following five phases must be completed to get political approval for policy reform[8]—

- Review policies, laws, and regulations to determine what changes might be needed and feasible
- Advocate for getting policy change on the political agenda
- Technically design the reform proposal
- Work to introduce legislation or get policy approval
- Obtain financing
- Implement policy change and monitor impact

Policy reform can be derailed at any of these stages, particularly if critical stakeholders are not included in the process. Fox and Reich call these "veto points." Even if senior health policy makers agree that a change in laws and regulations is needed, succeed in getting the change on the political agenda, and develop a strong technical design, the measure may never get legislative or executive approval or appropriations.

The process of policy reform is complicated, laborious, and fraught with many obstacles. A thorough discussion of the relevant policies and options for reform is beyond the scope of this manual, but readers are encouraged to review Part 1 of MDS-3.[9]

See chapter on Policy and Legal Framework in MDS-3.

Financing Options for the Insurance-Based Medicines Benefit Program

The financing options for an MBP will be tied to the national health financing situation, including insurance mechanisms and donor financing. As mentioned, the four major types of health insurance are national, social, community-based, and private; however, most countries use a combination of these.

Hybrid model

In most LMICs, no single financing option will cover an MBP for the entire population. To achieve universal coverage, it will probably be necessary to implement a hybrid model, whereby some segments of the population are covered through government revenue, some under social insurance schemes, some though community-based health insurance, and some through private insurance. Although necessary, a hybrid introduces a major challenge of establishing effective coordination between the different systems. Policy makers and their advisors should map existing benefit programs and identify the gaps in coverage and access that need to be addressed.

National health insurance

For MBPs associated with national health insurance systems, the primary financing mechanism is the government budget, which draws on taxation and other available revenue streams. In many cases, participation in the health insurance system is mandatory, meaning that all of the population is expected to receive health services and medicines through the system. Unfortunately, government revenue sources in most LMICs, particularly in Africa, are not enough to support full national access to essential health services and medicine benefits. In many countries, the informal economy (which does not contribute to tax revenue) outstrips the formal economy. In addition, LMICs typically have large populations of young and low-income individuals. The health care costs for these groups are usually more than they are able to contribute through taxation, limiting the capacity of the national health insurance scheme to finance UHC. While many UHC advocates argue that national governments are obligated to increase taxation and commit greater shares of national resources to fund national health insurance and UHC, this is easier said than done.

Social health insurance

Under large-scale social health insurance plans, such as social security systems, revenue for medicine benefits is primarily drawn from beneficiaries' mandatory contributions to the system, often through fixed payroll deductions. Deductions can also be based on a fixed percentage of salary, and total deductions for a year may be capped or uncapped. Capped deductions mean a percentage of salary is deducted until a fixed annual cap amount is reached, such as the Medicare tax in the United States. Payroll deductions can also be uncapped with a fixed percentage deducted from the total annual salary. Uncapped payroll deductions are easier to administer in principle and would theoretically provide more cross-subsidization between higher and lower wage earners and between single workers and workers with large families. But this may also impel single workers and higher earners to evade the tax or opt out of the program if possible.

Coverage in large social health insurance schemes typically is limited to formal sector workers or, in some cases,

to specific groups of workers such as government employees, police, union members, or military personnel. A country may have multiple social health insurance mechanisms that cover different groups of workers. These programs are not usually designed to cover the informal sectors because of the difficulty of collecting premiums or payroll taxes. In some countries, the government budget supports the inclusion of some low-income or informal sector workers in the benefit plan. A recent Oxfam report reviews this issue in multiple countries, making the case that governments must find ways to provide revenue to supplement payroll-based social health insurance systems in order to achieve UHC. [10]

Community-based health insurance

Community-based health insurance schemes often aim at rural populations and informal sector workers, and medicine benefits are usually limited. In some cases, such as in Ghana (prior to the roll out of the national health insurance scheme) and Rwanda, the government may provide financial or administrative support to the plans.

Assuming it is legal, an MBP that is part of a community-based health insurance scheme, social insurance plan, or private insurance program can establish contracts with the government, employers, or unions to provide medicines benefits for people who are not directly eligible for the MBP itself. These contracts could cover the full range of medicines or could cover only certain types of medicines for specific diseases and provide an additional source of financing for the MBP. Similarly, contracts can be established with health programs financed by donors, such as the Global Fund to Fight AIDS, Tuberculosis and Malaria or the President's Emergency Plan for AIDS Relief (PEPFAR), to provide medicines to patients covered by those programs.

Private health insurance

Medicine benefits in private insurance plans are financed by premiums paid directly by the beneficiary or by his or her employer. These private plans in LMICs mainly cover wealthier urban populations and are not available or affordable for rural or low-income populations, except in plans managed by private companies for their employees. In an effort to scale-up coverage, many countries have adopted a policy that legally requires all citizens to obtain health insurance. A number of African countries have implemented variations on this policy and medicines coverage, with different degrees of success.

Donor financing

In many LMICs, international donors pay to improve public health services and procure medicines, including multilateral agencies (Global Fund and UNITAID), bilateral agencies (US Agency for International Development), and global initiatives (Gavi, StopTB, and Roll Back Malaria). Financing for the start-up, expansion, or reform of an MBP, including developing the structure and management system or implementing an automated information system, may be available through one of these donors or through loans or debt relief from international development banks. Direct donor financing for ongoing MBP operations is not a sustainable source of revenue for most LMICs, but in many low-income countries, covering poor and marginalized populations would be impossible without it. The case for such donor support was recently made by Averill and Marriot.[11]

» See chapter on Financing and Sustainability in MDS-3.

Cost sharing and user fees

The primary purpose of cost sharing within an MBP is to control spending,

although it also generates some additional revenue for MBPs that provide prescription services through in-house pharmacies. Cost sharing is one of the most contentious issues in LMICs; however, it needs to be considered in the context of high levels of out-of-pocket spending, which is the norm in many LMICs that have dysfunctional public sector pharmaceutical supply systems. Although cost sharing may seem unpalatable, depending on the context, it may actually increase the UHC goals of equity and affordability.

Types of cost sharing

The two major forms of consumer cost sharing are 1) co-insurance, where the beneficiary either pays a fixed percentage of the cost of the service or is subject to paying a fixed deductible amount before insurance coverage picks up the balance of the charge, and 2) co-payments, where the beneficiary pays either a fixed or a "tiered" amount for each visit or each prescription, regardless of the total charge for the prescription or service provided. Co-payments differ from co-insurance in that the co-payment is a fixed amount that is not calculated as a percentage of the cost of service or medicine, is paid every time, and is not capped by a deductible amount.

For fixed co-payments, the amount paid may be the same for all patients and all medicines, or it may vary by the type of health condition and medicine or the level of health facility. For tiered co-payments, the amount paid is usually based on the type of medicine prescribed. For example, generic medicines or those in the MBP formulary would require lower co-pays than branded or nonformulary products. A variation is to base the co-pay on the medicine's medical necessity, with higher co-pay amounts for medicines with less perceived medical benefit—sometimes referred to as value-based insurance design.[17]

Both co-insurance and co-payments can also have sliding scales where the amount is tied to income, geography, patient category, or level of health facility. This is a form of an exemption policy—most consumer cost-sharing programs have some form of exemption, where certain consumers are fully or partially exempt from paying cost-sharing fees. This is also known as means testing. In these cases, the costs are usually subsidized by government funds in one form or another.

TAKING STEPS TOWARD SUSTAINABILITY

Very few LMICs are in a position to fully fund the start-up of a large-scale MBP without substantial external development assistance.[12] Particularly during the early phases of evolution, donor funding can support critically needed investments in health system infrastructure and improve public financial management and taxation systems so that MBPs can move toward self-sufficiency.[13] Data from 2012 shows that external funding comprises between 10 and 60% of total health expenditures for low-income countries—funding that, while crucial in the short and medium terms, will need to be generated in-country for MBPs to be sustainable in the long term.[14]

Fiscal sustainability is a primary consideration in the planning and implementation of programs to expand access to medicines. Even countries further along the path to providing universal access to essential medicines, such as Ghana, Mexico, and Turkey, continue to grapple with the issue. In Ghana, now in its tenth year working toward UHC, the national health insurance scheme is funded through diverse streams of tax revenue, individual premiums, social security earmarks, and investment returns.[15] Despite this progressive approach to health financing, the scheme is not yet solvent, and the country is exploring how to create greater system efficiencies, including improving revenue collection, streamlining claims processing, and incentivizing rational medicine use.[16]

As noted earlier, de facto cost sharing occurs when patients need to purchase their own medicines out-of-pocket from private retail outlets because they cannot get what they need from the public sector facility.

Impact of cost sharing

Cost sharing has a two-pronged impact: on the positive side, in addition to generating revenue and controlling costs, consumers are discouraged from unnecessarily using the program's services and medicines (offsetting moral hazard); but on the negative side, low-income segments of the population may be unable or unwilling to pay for truly necessary services and medicines. Adequately managing the costs of the program, the equity and fairness of exemptions, and the potential abuse by service providers all add complexity to an MBP.

Consumer cost sharing is a standard feature of medicine benefit plans in OECD countries, but in LMICs, it has had mixed results. According to Carapinha, et al. a majority of insurance programs in five African countries had some form of cost sharing as of 2008, but there is still considerable international sentiment to abolish user fees to increase access to UHC.[18] Many advocates and analysts, including Oxfam, now argue that any level of user fee renders services and medicines inaccessible to the poor in LMICs.[19] In countries where cost sharing is the official policy, exemption policies can be so broad or loosely enforced that only a small percentage of patients actually pay the prescribed amount.

The pendulum has swung in recent years from advocating for mandatory cost sharing in public health systems (with active donor encouragement) to removing cost sharing from some national health insurance and social health insurance programs in the name of UHC (again, with active donor encouragement). Each benefit program needs to evaluate the suitability and feasibility of consumer cost sharing in its particular context; however, abolishing cost sharing completely may make financial sustainability difficult if other revenue is not available. It may also lead to indiscriminate overuse of services and medicines.

If the MBP includes cost sharing, the nature and amount of the user charge must be carefully calculated to ensure a balance between expanding access to medicines and promoting financial sustainability. The program must consider how user fees may provide unwanted incentives; for example, a co-payment for each prescription may induce prescribers who also dispense to overprescribe. And as mentioned, poorer patients may not access needed medicines if the fees are set too high.

Further discussion of the arguments surrounding user fee programs is available in MDS-3.

» See chapter on Revolving Drug Funds and User Fees in MDS-3.

Pharmaceutical Distribution Channels

As mentioned, some health insurance plans provide medical services, medicines, and other health technologies exclusively through in-house facilities (hospitals, clinics, and pharmacies). This is sometimes called a closed model. With an open model, health services and medicines are provided through contracts with a variety of service providers, including public and private hospitals and health centers; physicians and physician groups; private retail pharmacies, pharmacy chains, and other licensed retail outlets; mail order or courier pharmacies (where available); and NGO outlets.

If the insurance plan covers both outpatient and inpatient medicines, each could have its own separate MBP structure. For example, a social insurance

fund may operate its own hospitals and provide inpatient medicines directly to beneficiaries, but it could contract for outpatient medicines either directly with pharmacies or through a PBM. And if the primary MBP does not cover specific, high-cost "specialty medicines," such as cancer treatment, or other "innovative" health technologies, a separate or supplemental MBP could be established for that coverage, an approach taken in the UK and Thailand. Supplemental benefit programs are controversial, however, because patients with diseases for which specialty drugs are needed, but advocacy is less, may be disadvantaged and because disease-specific benefits can be costly, but benefit only a few patients; those resources can reduce the overall budget needed to cover medicines for the majority of patients.

The design challenge is determining how to provide all intended beneficiaries with reasonable geographic access to reliably available and affordable medicines. Very few insurance plans or MBPs in LMICs or even in OECD countries can finance and manage national access to medicines through in-house facilities. Furthermore, low-income and rural segments of the population more often suffer from lack of reliable and affordable access in closed models.

Even if a national health insurance or social health insurance plan hopes to implement a closed model by using in-house staff and facilities to distribute medicines, a hybrid model, with some in-house facilities and some contracted services, will likely be needed to provide access to all of the intended beneficiaries.

In designing MBPs, planners need to determine which geographical limits will define reasonable access. For example, some high-income country health plans with medicines benefits define ready access as a designated pharmacy provider available within 10 kilometers of the beneficiary. That distance is not feasible in many rural areas, so medicines are provided through mail order or courier services or through contracts with community health centers.

Whether the MBP plans to use a primarily closed or open model for distributing medicines, the plan designers will need to map the geographical location of all intended beneficiaries. Then they need to map the catchment areas of any in-house facilities and potential contract providers to determine what mix can provide the best access. Note that in the open model, both public and private facilities may provide contract services to the MBP.

Identifying and contracting with pharmacy service providers is discussed in depth in Section III.D.

EXTENDING THE REACH OF A MEDICINES BENEFIT PROGRAM THROUGH PRIVATE DRUG SELLERS

In Tanzania, the Food and Drugs Authority, the Ministry of Health and Social Welfare, and MSH developed a pilot project to establish a regulated network of licensed retail drug outlets, known as accredited drug dispensing outlets (ADDOs). Through the accreditation process, shop premises were upgraded, dispensers were trained in good management and dispensing practices, and essential medicines at each shop were standardized and expanded to include select antibiotics. After a successful pilot, the program was scaled up nationwide, and ADDOs now effectively expand the reach of the health system, often acting as the first point of contact for patients or caregivers seeking treatment. In addition, Tanzania's national health insurance fund allows its beneficiaries to access medicines at specially designated ADDOs, which expands access—particularly to those living in rural and peri-urban areas.[20]

II.C. SCOPE OF THE BENEFIT PROGRAM COVERAGE

A major question in designing a MBP is determining the scope of the coverage—who will be covered and for what types of services and medicines? Considerations include—

- Coverage mapping
- Population coverage
- Disease coverage
- Coverage of different classes of medicines
- Inpatient and outpatient coverage
- Targeting to reach underserved populations
- Costing the benefit program and adjusting the scope
- Identification of professionals with prescription-writing and dispensing authority

Coverage Mapping

To develop or revise a medicines benefit plan, policy makers need to determine which types of medicines coverage currently exist in the country and which geographic areas and population subgroups are covered by each benefit package? Where are the gaps and what options are potentially viable to close any gaps in coverage?

Scheil-Adlung proposes a model for developing a national coverage plan that includes the following steps[23]—

- Compile an inventory of existing benefit programs and financing mechanisms for health care products and services.
- Determine how much total financing is available to support medicines benefits from all current sources and identify any potentially untapped sources.
- Develop a national coverage map of existing programs and map the locations of all populations needing access to medicines.
- Identify the gaps in access to these programs for all target populations in the country.
- Map available channels for medicine distribution (public, NGO, or commercial sector) and identify potential options for increasing access to underserved populations.
- Develop a national coverage plan that identifies potential linkages between existing plans. Linkages may involve subsidies, employer mandates, requirements for mandatory services from private health care providers, co-contracting, combining or sharing management functions, facilitating reinsurance, or guaranteeing financing.
- Identify the best options to mobilize financing and add distribution channels to fill the remaining gaps in access.

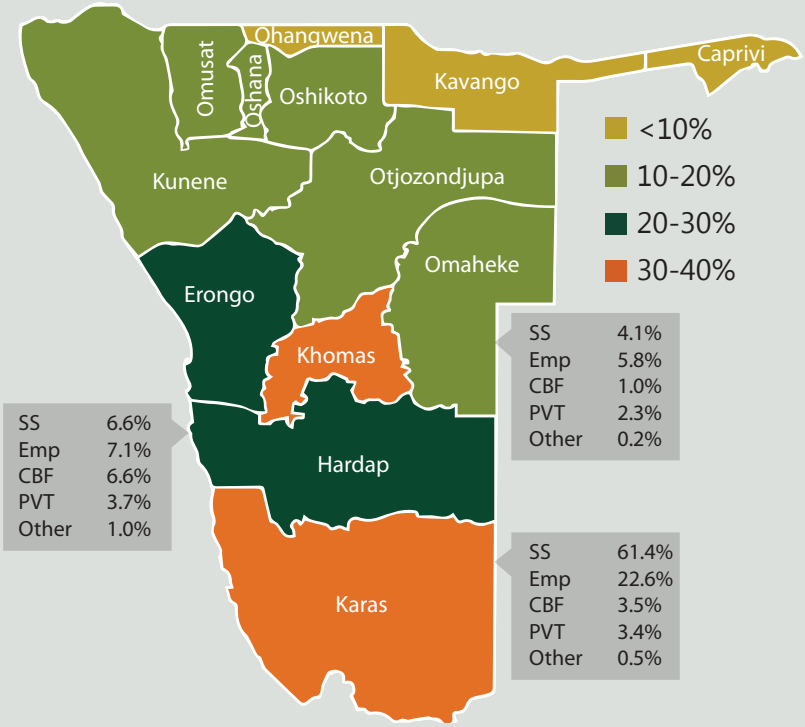
Other steps may include defining coverage based on the country's epidemiology, standard treatment guidelines (STGs), and available levels of health care.

When developing a coverage map of existing MBPs, the following information should be compiled for each program—

- Mission of the MBP
- Administrative structure
- Financing sources
- Pharmaceutical distribution channels
- Expenditures on medicines (actual or projected)
- Cost sharing and user fees
- Geographic coverage
- Population coverage—which subgroups are covered and how many beneficiaries

COVERAGE MAP

A ***coverage map*** defines the areas, populations, or groups that are covered by a health and MBP and often guides efforts to achieve UHC by illustrating progress toward program targets.[21] The example at right shows a coverage map from Namibia showing the percentage of women with health insurance and examples of the types of insurance coverage in select regions[22]



Percentage of Women Covered by Health Insurance in Namibia: 2006–2007
SS: social security
Emp: employer-based
CBF: community-based fund
PVT: privately purchased

- Disease coverage and conditions excluded
- Types of medicines covered or excluded
- Coverage for specialty medicines and health technologies
- Inpatient and outpatient medicines coverage
- Targeting of benefits or exemptions for underserved populations
- Linkages and coordination with other benefit programs
- Costing the benefit program and adjusting the program scope to available funding

A summary of the intended scope of coverage by 42 UHC schemes in 16 LMICs as of 2012 is found in Faden et al.[24] and for 5 sub-Saharan African countries in Carapinha et al.[25] The following discussion focuses on the basic coverage options that might be considered in designing an MBP.

Determining Scope of Coverage

All of these design considerations link to both access and cost—each decision about the scope of coverage has a major impact on the total cost of the program. These decisions must be informed by probable cost of the proposed scope against the plan's financial capacity. In many LMIC situations, the financial capacity of the benefit plan's sponsor (i.e., government or other entity) will not be enough to fully cover medicines for all diseases or conditions. The most equitable solution is to define and cost a minimum benefit package for all targeted beneficiaries with the financing available and expand the package as additional financing is secured. Some plans do define different minimum packages for different categories of beneficiaries, but the concept of equity should be a strong consideration in these decisions.

Population coverage

As mentioned, each type of major financing mechanism, other than comprehensive mandatory national health insurance, is typically designed to serve a certain segment of the national population. Each MBP must define that primary target population and the eligibility criteria for coverage. Plans aimed at a specific population must determine whether benefits extend to family members and, if so, which ones. Finally, in plans that are limited to specific populations, decisions must be made about whether to cover additional populations that would not otherwise be able to participate by providing government or other revenue sources. This is discussed further in the section on targeting benefits below.

To properly design the MBP and stay within its financial capacity, it is necessary to accurately estimate the number of potential beneficiaries in each population to be served and adjust either the population target or services and medicines that will be covered.

Coverage of diseases

Before all else, the scope of coverage must consider whether all diseases encountered will be treated in the eligible population. Some benefit plans aim at only specific health problems, such as prenatal care for pregnant women.[27] Others cover a broad range of, but not necessarily all, health problems. Some benefit plans limit or exclude coverage of chronic diseases, particularly those requiring expensive long-term treatment, such as cancer. The question of coverage for chronic, noncommunicable diseases and high-cost health conditions, such as cancer, is becoming more urgent as UHC becomes a higher priority in the global health community. As with the scope of population coverage, the broader the plan's coverage of health problems, the higher the medicine costs incurred, so the MPB will need to adjust coverage based on financial capacity or find additional resources to extend coverage. One approach to dealing with high-cost health problems is a "carve out" plan—a separate benefit plan with a separate financing mechanism and administrative structure that cover these health conditions and the high-cost medicines used

SCALING UP COVERAGE IN GHANA

Ghana has undergone several health reforms since gaining independence in 1957. Initially, health care was administered through tax-based contributions, but during the 1980s, user fees were introduced to counter mounting economic pressure and shrinking government revenues. The system of user fees, known as "cash and carry," improved cost recovery, but acted as a financial barrier for much of the population and ultimately decreased access to health services and medicines. As the gap in access became more pronounced, a growing network of community-based health insurance schemes began providing services through risk pooling, although overall coverage remained low (<1% of the population).

In 2003, building on the risk-pooling principle, the Government of Ghana introduced the National Health Insurance Scheme (NHIS) with the aim of providing access to basic health care services to all residents of Ghana. Initially covering a defined set of basic services and essential medicines, the NHIS implemented several improvements and expansions in the following years, including free maternal health services, establishment of an accreditation system for service providers, and expedited claims processing, which increased system efficiencies and improved access to quality services. Since its establishment, NHIS has grown from covering 1.3 million residents in 2005 to 12 million in 2012 (about 35% of the total population at that time).[26]

to treat them. These specialty plans may have different mixes and levels of co-insurance or co-payment than the standard MBP. Specialty benefit plans are not common in LMICs, but may become more of an option in the future; some countries already allocate a separate budget line for specialty medicines.

Coverage of specific medicines and health technologies

Payment for different classes of medicines and health technologies is closely linked with disease coverage. For example, if cancer is not covered by the insurance plan, medicines to treat cancer will not be covered under the medicines benefit.

When deciding which types of medicines the MBP will pay for, several options might be considered—

- **Open formulary:** any medicine registered in the country (broadest coverage and highest overall cost).
- **Restricted formulary:** benefit may cover all medicines that are both registered and listed on the national essential medicines list (or equivalent), but not cover medicines that are not on the national list. Coverage may be further restricted to a subset of medicines on the essential medicines list that correlates with the intended disease coverage. With any form of restricted formulary, exceptions may be allowed for specific patients.
- **Hybrid formulary:** includes options such as a tiered formulary, which has lower or no user fees for medicines on the preferred list, but higher fees for nonpreferred medicines. Certain medicines might require prior approval for coverage.

Benefit plans will usually need to accommodate case-by-case exemptions where the standard policy is not applied (e.g., the beneficiary is exempted from a cost-share fee). These exceptions are often grouped into a prior approval provision; before the medicine is dispensed or administered, the provider must contact the benefit manager and obtain approval. If approval is not obtained, the MBP will not reimburse the provider or beneficiary; however, a one-time only exemption may be part of the policy. Exemptions can be linked to the cost-sharing policy, where the beneficiary is exempted from cost sharing or pays a reduced fee or percentage of cost only with prior approval.

An exclusion is a product or service that is not covered at all under the plan. Typical exclusions include expensive specialty medicines such as cancer treatment, lifestyle medicines (e.g., for sexual dysfunction, smoking cessation, baldness), and nonprescription medicines. In countries where products such as insulin or contraceptives are nonprescription items, the MBP may wish to include them. On the health technology side, breast implants might be covered for cancer reconstruction, but not for cosmetic purposes. Coverage for some medicines can be explicitly limited to specific health conditions, unless approved. Again, the

EXAMPLES OF HEALTH TECHNOLOGIES

Diagnostics
- Test kits
- X-rays
- MRI
- Microscopy supplies and assays
- Ultrasound

Implants and devices
- Orthopedic implants
- Pacemakers
- Cardiac stents
- Intrauterine devices

Miscellaneous
- Condoms
- Eyeglasses
- Prosthetics
- Blood glucose test strips

larger the number of medicines covered by the plan, and the more expansive the formulary policy, the higher the total cost of medicines will be to the MBP. However, unduly restricting coverage reduces access and harms the beneficiaries most in need and may actually lead to higher health expenses, if, for example, denying access to a medicine results in hospitalization.

Formulary management, which is the selection of medicines the plan will cover, is one of the most critical elements of MBP management and it is discussed separately in Section III.E.

Inpatient and outpatient coverage

Some insurance mechanisms and MBPs in both LMICs and OECD countries provide only inpatient (in-hospital) coverage, but many plans cover both inpatients and outpatients, although those primarily aimed at inpatient coverage may have very limited outpatient coverage and vice versa. Because medicine costs are a major out-of-pocket cost for outpatients, MBPs targeting universal access will need to cover those patients.

For those plans that do offer inpatient coverage for medicines, an important question is whether the medicine charges are bundled into the basic fee for the inpatient stay with other services or unbundled or carved out and charged separately. The pros and cons will be covered in the section on contracting with providers, but the basic principle is that bundled charging will likely cost the MBP less, while separate charging for medicines facilitates medicines utilization review and assurance of the quality of the pharmaceutical therapy that patients receive.

MBPs may define networks of authorized prescribers (e.g., physicians) that can prescribe medicines for their beneficiaries. Limited prescriber networks are often used for certain high-cost medications or conditions where medications are combined with specialized treatments. In most cases, MBPs allow any prescriber authorized by the country's regulatory or accreditation body to prescribe medicines for their beneficiaries. In some cases, physicians can both prescribe and dispense, but from an MBP perspective, they would then be included in both the prescriber and provider network definitions.

As with the other aspects of coverage, each MBP must assess clinical, financial, and managerial capacity to support the intended scope of inpatient and outpatient options and adjust the scope accordingly.

Targeting benefits

Targeting benefits implies choosing which segments of the population will get special preferences or subsidies in the insurance plan or MBP. With the goal of UHC, social targeting should assure that disadvantaged populations benefit. Targeting mechanisms may include direct financial subsidies to beneficiaries or providers, full or partial exemptions from standard premium payments, exemptions from beneficiary contributions to the plan, or exemption from payment of co-insurance or user fees.

Countries that rely heavily on private insurance to provide universal coverage may find it necessary to establish a risk equalization mechanism to ensure that higher risk patients are not priced out of coverage. In these mechanisms, a risk equalization fund subsidizes insurers to help cover high-risk populations. The fund is accompanied by regulations to prevent discrimination against high-risk patients by private insurers. Government agencies in Belgium, Germany, Indonesia, the Netherlands, the Philippines, and Switzerland manage these types of funds, and in the United States, it is incorporated into the Affordable Care Act, which requires that state or federal agencies establish an effective risk equalization mechanism.

Political targeting may occur if politicians or political parties reward their most important constituents with social benefits, including health insurance and medicines benefits.[28] When subsidized benefits are directed to preferred political parties, preferred regions of the country, or preferred ethnic groups, the programs will not likely be able to provide equitable access to the entire population.

Pfleiderer[29] suggests that the quality of a social targeting method should be evaluated using three criteria—

- **Targeting effectiveness**: are all theoretically eligible individuals and households identified and included? Are any inappropriately excluded (exclusion errors)?
- **Leakage or abuse**: are any theoretically non-eligible individuals or households included in the preference (inclusion errors)?
- **Targeting costs**: what are the management requirements and costs to administer the targeting program? Are they feasible and cost effective?

Pfleiderer identifies the following social targeting methods and some of their advantages and disadvantages.

Categorical targeting

In categorical targeting, specified categories of individuals are given the subsidy or preference, without necessarily requiring means testing (or determining if someone qualifies for assistance). Demographic categories may include some or all groups such as children, the elderly, disabled, or pregnant. Disease-based categories might afford preferences to patients with specific diseases, such as tuberculosis or HIV and AIDS. Other categories might be based on occupation, such as military personnel, teachers, or other government employees. Categorical preferences could also be extended to the defined immediate family of the eligible individual, or those who have access to other benefits may be excluded (e.g., a family member on another insurance plan).

Categorical targeting methods are the most straightforward and least expensive to administer, although they do not ensure access to the poorest segments of the population. Inclusion and exclusion errors are potentially high, and disease-based categories may bring stigma along with the benefit.

Direct means testing or income-based targeting

This method gives subsidies and preferences to poorer populations based on verifiable income and assets. When properly applied and managed, this method minimizes errors of inclusion and exclusion. It also allows for sliding scale subsidies or exemptions based on income. However, it is significantly more complex and costly to administer than categorical methods, because data must be collected directly from the individual participants and analyzed. Individuals have an incentive to falsify their information to get the subsidy, which requires intensive efforts to validate data and monitor eligibility records. Without trained administrative staff and computerized information systems, direct means testing would be difficult to implement and maintain. Therefore, the opportunity costs may outweigh the benefits of direct means testing.

Proxy means testing

Proxy means testing also bases the eligibility for subsidy or preference on income and assets, but it uses proxy indicators, such as location and quality of beneficiary's home, number of children, visible assets, occupation, or educational levels, rather than directly collecting the information from individuals. Proxy means-test indicators may be based on statistical analysis of national data such as household surveys or established at the community level with input from the communities. It is less effective in targeting the poor than is direct means testing,

but more selective than categorical and geographic methods. Validity depends on the quality of the proxy indicators, and people may have incentive to change their personal situation to meet the proxy criteria by bringing in more children, selling assets, and so forth. Administratively, proxy means testing is less complex and costly than direct means testing, but it still requires more staff and more effective management information systems than the categorical methods.

Geographic targeting

The preference goes to individuals living in a specific geographical area, such as urban slums or rural areas with little formal economy or access to care. This method can be combined with some form of means testing to better target the poor in those areas. It is relatively inexpensive to administer without means testing, but more expensive if means testing is incorporated. From the UHC perspective, however, exclusion errors are high because only certain areas of the country are covered. In addition, if the poor of different regions do not receive equal benefits, political and ethnic conflicts may result, along with potential migration from nontargeted to targeted regions.

Costing the Medicines Benefit Program and Adjusting the Scope

As discussed, it necessary to conduct an economic and clinical needs assessment and identify gaps in existing MBPs, while keeping in mind the concept of providing a minimum benefit package. Hsiao and Shaw pointed out that the initial scope and scale of a new or expanded MBP should be determined through a cycle involving[30]—

- Proposing a package of benefits
- Estimating total costs of the benefit
- Comparing the benefits with financial capacity
- Obtaining political input or guidance
- Adjusting the proposed package of benefits
- Re-estimating total costs against financial resources
- Comparing revised benefits against financial resources
- Obtaining political input or guidance

Failure to go through this cycle before announcing the benefit program can produce difficult situations for both politicians and managers of MBPs. For example, one African country passed legislation (reportedly with minimum consultation with technical staff) that mandated an MBP to cover the whole national population for all their needed medicines. The potential cost of this level of coverage was not actuarially calculated before the policy was announced, leaving the designated MBP managers in a very difficult spot—politicians had promised coverage that would not be financially feasible. When projecting the costs of the MBP, two complementary methods can be used: actuarial projections of benefit costs based on household utilization and quantification methods to project utilization and costs of medicines used by beneficiaries.

Actuarial projections

To project future health care use, actuaries combine demographic information from the target population (age, sex, employment, income, health status) with available data on past or current use of health services. The actuary applies standardized probability-based mathematical modeling techniques to estimate service usage and costs and to determine the optimal mix of revenue and cost-sharing policies that will sustain the plan, and that participants will accept.

Elements to consider in the mathematical modeling include—

- Number of potential beneficiaries or participants
- Services and medicines covered by the plan
- Demographics of the target population, including its burden of disease
- Geographic area
- Occupation or industry (where applicable)
- Health status and potential demand for services by demographic cohort
- Claims history or service utilization history for a new program
- Ability to pay
- Other insurance coverage
- Extent of uncertainty (or risk) in each of the key input parameters

In addition, predicting the utilization and costs of services and medicines, the calculation needs to include the requirements for capital reserves and potentially for reinsurance, to protect against risk of ruin. Capital reserves are readily available funds that the insurance plan retains to pay for unforeseen requirements and future liabilities that are higher than available operating funds. Reinsurance is a policy that the MBP purchases to protect the plan or beneficiaries from catastrophic costs that exceed a specified value and that could consume both operating funds and any capital reserves. Reinsurance can be classified as aggregate, which covers excess costs of a group of beneficiaries, or individual, which covers costs for individual policy holders or households. Many countries' laws and regulations stipulate the requirements for capital reserves and reinsurance, but because LMICs are just beginning to implement large-scale health insurance programs, these laws and regulations may not be in place or up-to-date. Professional actuaries should help the MBP model demand/utilization and the requirements for revenue and capital reserves to remain solvent. This should be a standard practice in designing the benefit program, whether or not capital reserve standards are required by national policy or law. An actuary should also provide advice on options related to reinsurance to offset risks and help design cost-sharing programs.

Professional actuaries may be scarce in some LMIC ministries or health planning units, but these services are available through national or international consultants, depending on the country. A resource on managed health care describes how actuaries do their underwriting calculations and projections.[31]

Quantification methods

Quantifying the future demand for medicines in a benefit program can complement actuarial projections. The four main quantification methods are consumption, morbidity, proxy consumption, and service-level projections. These methods are most applicable in programs that provide medicines through in-house pharmacies and health facilities, but they can be useful in modeling medicine costs in systems that plan to contract prescription services.

The **consumption method** uses data on past utilization of medicines and their actual costs in the current health system, and adjusts the projection for potential changes in services provided, demographics, or pricing trends.

Morbidity-based methods combine assumptions on standard prescribing patterns for target diseases with actual or estimated incidence of those diseases to quantify demand and then use actual or estimated prices to project total cost.

Proxy consumption uses information from a comparable health system on known utilization of medicines and costs and then adapts that information based on differences between the two systems and expected changes in the target

health system, such as future utilization or medicine prices. This method is most useful when the nation's health system lacks sufficient data to calculate the estimate.

Projection is similar to proxy consumption, but it uses overall medicine cost data from a comparator health system rather than demand for individual medicines to estimate future costs in the target health system. This method is used to determine a budget number.

These methods are fully explained in the quantification chapter in MDS-3. Although standard tools, such as Quantimed, are available to conduct quantifications, an expert consultant should support a large-scale medicines quantification exercise.

Access to data is a critical requirement for both actuarial projections and quantification of demand for medicines, but reliable data on utilization of health services and medicines may be hard to come by in LMIC settings, particularly during the MBP design and start-up phases. Therefore, employing consultants who have strong experience in working around data limitations is critical when calculating projections of future medicine utilization and cost.

» See chapter on Quantifying Pharmaceutical Requirements in MDS-3.

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III MANAGING THE BENEFIT PROGRAM

This section covers the primary issues to address when establishing the governance and management structure for the MBP, including decisions regarding the "nuts and bolts" of the MBP's day-to-day operations. Topics range from claims processing and beneficiary services to controlling costs and educational programs.

III.A. MODELS FOR INCORPORATING MEDICINES COVERAGE INTO A HEALTH INSURANCE PLAN

Where medicine benefits are covered as part of the health insurance plan, the benefits may be carved in, which means they are provided, paid for, and managed as a unified program. However, an increasing number of insurance plans in the United States have opted for a carved-out model, in which the medicines benefit is contracted out to a PBM, which may manage medicines benefits for multiple insurance plans and health systems. Note that the medicines carve-out and the main health benefits should function together, and in some cases, the PBM may actually be a private insurance company that sells this service in addition to marketing its own health insurance products.

Although this PBM model is mainly used in the United States, Namibia and South Africa have also rolled it out. As large-scale medicine benefits programs spread in other countries, PBM contractors may offer these services more widely. The reason PBMs have grown in their current limited markets is because they have been able to manage benefit programs more cost effectively and efficiently compared to in-house programs managed directly by insurance plans.

In-House Management of the Medicines Benefit

Social health insurance systems in LMICs that offer medicines benefits usually use the carved-in model. In many of these unified systems, both the health care

services and medicines are provided in-house by health facilities and pharmacies operated by government staff or by staff employed by the social insurance plan. Health maintenance organizations in the United States have also used this model. In most OECD countries, the major social insurance schemes have moved away from exclusive reliance on in-house delivery of medicines benefits and instead contract for all prescription services or use a mix of in-house and contracts with private health and pharmacy providers. The in-house management model may involve direct management by a government ministry or establishment of a semi-autonomous nonprofit organization to manage the benefit program.

In some countries, states or provinces manage separate plans and administrative structures rather than rely on a single national administration. In theory, decentralized management should respond better to local needs and more flexibly adjust to local requirements. However, the total cost of operations will normally be higher due to the duplication of management functions, and it may be more difficult to ensure that decentralized plans adhere to national goals and policies.

Some theoretical benefits of in-house management of the medicines benefit include the following—

- The plan has direct control over the program finances, implementation of program policies, and provision of benefits.
- If the plan does not have outside contracts, it avoids the need for negotiation and management, plus the benefit plan can adjust plan policies and benefits without having to renegotiate contracts.
- The plan's direct control of benefits could yield better capacity to monitor quality and costs of services and compliance with plan provisions.
- A unified benefits administration structure and claims processing system for both health services and medicines benefits could allow for less complicated management structures, less duplication of effort, and potentially fewer administrative costs.
- With a unified program, plan administrators should be better able to directly compare utilization of health services and medicines and identify mismatches between medicine use and health problem prevalence.

Insurance plans can only achieve these theoretical benefits if it has the in-house capacity and management systems to administer the program efficiently, control costs, and monitor access to medicines and services; however, many plans lack this capacity. Moreover, the level of effort and associated capital and operating costs of developing and sustaining an effective unified in-house management system may not be feasible or as cost-effective as contracting.

Contracting with a Third-Party PBM to Manage the Medicines Benefits

In a program where the benefit plan for medicines is contracted to a third party, plans may gain several efficiencies—

- Specialized PBM contractors may support the design or revision of a benefit plan, including performing actuarial calculations, modeling the impact of various design choices, carrying out pharmacoeconomic analysis of formulary alternatives, and so forth. This expertise may not be readily available with unified benefit plans managed in-house.
- These companies may have management systems and information technology that is more modern and efficient than those

of the insurance program itself. This benefit would improve claims processing, facilitate monitoring of utilization of services and medicines, and help detect potential fraud and abuse.

- The specialized benefit manager will have established relationships and experience in contracting with potential providers of prescription services along with the ability to manage those contracts to ensure that providers and beneficiaries comply with program policies.
- PBM companies invest in their human resources, who are highly qualified and experienced.
- These specialized companies can process high volumes of claims for a number of clients. Potential clients will therefore benefit from their economies of scale.
- With an effective and efficient contract benefit manager, the cost of managing the benefit program may actually be lower than the cost of managing the program in-house.

However, the most important challenge to a carve-out model is the identification and selection of potential contract service providers and vendors of PBM services; if there are multiple contract vendors in the country, competition may force vendors to offer high-quality services at affordable prices. If the country has no vendors, the use of a contract benefit manager may not be possible at all. And if the country or region has few contracting options, those vendors may not have the competitive incentive to offer low-cost and high-quality services.

Although the operational management burden is less than it is with an in-house structure, there are still significant management requirements and costs to ensure compliance with contract terms for payment, monitor contractor performance, and enforce contract provisions. Managing through contract requires a different set of skills than does managing within an organizational unit.

Assuming that the country's legal framework allows contracting, each health plan should compare the in-house capacity to effectively manage the benefit plan with options for contracting outside management and select the option that offers the best mix of access to quality services and lowest cost of operation.

Whether the insurance plan manages the medicines benefit in-house or contracts with a PBM, the insurance plan is responsible for ensuring that the MBP is effectively managed and that beneficiaries receive the benefits they are entitled to under the plan. Throughout the guide, we discuss the activities that the MBP needs to manage to accomplish these goals, but as noted in the following section about a typical PBM contract, the PBM may actually carry out many of these activities once such a contract is in force.

The services offered by a comprehensive PBM firm may include—

- Consultation concerning benefit design
- Complete administration and management of the MBP
- Claims processing and adjudication
- Business intelligence, including management, operational, and executive reports
- Management of exemptions and prior approval processes
- Management of appeals if service is denied
- Development and performance management of the contract provider network
- Quality management
- Managing claims expenditure
- Mail order prescription delivery (currently in the United States)
- Payment to service providers (although some PBMs will not accept

this fiduciary responsibility, instead passing the claim on to the MBP for payment)

- Billing beneficiaries and collecting co-payments
- Negotiation of pricing and rebate contracts with manufacturers and distributors and management of those contracts
- Development and management of formularies
- Management of generic and therapeutic substitution programs
- Management of health technology coverage
- Management of prospective and retrospective drug use review programs
- Management of programs to address inappropriate utilization by beneficiaries and providers
- Clinical services, such as medication therapy management and disease management programs
- Benefit-related clinical advice
- What-if studies and impact analysis
- Management of communications with beneficiaries and providers, including contact centers
- Educational programs for beneficiaries and providers
- Development of a comprehensive medicine product data base for the country

The MBP can normally pick and choose which services to contract, ranging from the entire benefit management program to just claims processing and adjudication. Therefore, a PBM must be able to accommodate the different requirements. Payment terms for the PBM's services will depend on the nature of the services and the willingness of the PBM and the MBP to consider risk-sharing arrangements. Potential options include the following—

- Fee-for-service variations, where the MBP pays a specified amount for each claim processed, each prescription provided, each payment processed, and so forth.
- Payment of a specified amount for overall management services plus a fee for each specific service provided. If the PBM is paying the providers directly, the contract with the MBP will be based on reimbursing the costs of those payments, plus a fee. Contracts should specify that the PBMs pass on the benefit of any rebates or discounts from manufacturers.
- Capitation, where a fixed payment is made based on a negotiated per member per month amount.
- Shared risk arrangements based on a target total cost, as discussed in the section on outpatient pharmacy services.
- Performance-based contracts, where the PBM's fee may be increased or reduced based on achievement of specified objectives.

If a PBM is prepared to consider capitation or risk-sharing contracts, it will probably demand control of formulary management and generic or therapeutic substitution processes to restrain costs.

Selection of a PBM should be competitive, if the market has competition. A competitive process typically involves a request for proposal specifying the scope of services required and the format for technical and cost response or a request for information based on specific questions. A list of such questions to select a PBM is provided in *Evaluating and Selecting a Pharmacy Benefit Manager*.[32]

After evaluating the proposal or information submitted, the plan will usually have face-to-face interviews at the PBM's service locations, onsite evaluations, and reference checks with clients. Annex 2 includes selection criteria and contract terms. Most of the considerations

described earlier for contracts with outpatient pharmacy providers also apply when contracting with a PBM.

If the MBP does not have experience in developing and negotiating PBM contracts, it should use an experienced consultant, at least in the first round of contracting, to make sure the contract meets its needs.

See chapter on Contracting for Pharmaceuticals and Services in MDS-3.

III.B. MBP MANAGEMENT AND GOVERNANCE STRUCTURE

The benefit plan sponsor, whether it is the government, a social security institute, or a nongovernmental entity such as a private employer or association, is responsible for ensuring that the management and governance structure ensures operational and financial integrity and that the program provides the promised benefits to eligible beneficiaries. The government (either national or provincial) is usually the sponsor of national health insurance programs. In social security programs, the sponsor will be the social security administration or equivalent. In employer-provided insurance, the sponsor is the employer.

The sponsor will typically need to establish an entity to oversee plan management and ensure that contractors who are hired to manage all or part of the benefit program comply with contractual requirements.

As noted by Wang et al.,[33] good governance practices are essential whether management of the MBP is done in-house or contracted out. They identify five important components—

- **Decision making structure**—empowerment and accountability with clear lines of authority.
- **Stakeholder involvement**—involvement of stakeholders in setting policies and overseeing performance.
- **Transparency**—reliable information on status and performance available to policy makers, managers, and stakeholders.
- **Supervision and regulation**—decision makers, managers, providers, and beneficiaries held accountable for poor performance or deviation from policies and procedures.
- **Consistency and stability**—consistent adherence to the basic plan design and guiding principles and maintenance of financial capacity to avoid abrupt changes in the program.

To ensure that these principles are followed, the plan's management structure should have the following components: a governing body, senior management team, operations management, and specific advisory committees. If the program is carved out, contracts must detail the operation of these functions and be explicit as to how to assess if they have been met and the potential consequences if they are not met.

The more complex a MBP's management and administrative structure, the more expensive it will be to operate. Plan designers should cost out alternatives and ensure that the proposed structure can be supported financially, while still providing coverage to intended beneficiaries. Large plans with sufficient funding may have separate units handling each of the management components described; however, when starting up a small benefit plan, many of the operational and support functions can be combined.

Board of Directors or Governing Board

Most medicines benefit plans will be governed by a board of directors, although some programs may not require a separate board. National or state laws or regulations may mandate the board's specific authority and composition. An MBP governing board may be a sub-committee of a health plan's larger board, with separate management bylaws. Board membership will depend on the type of insurance mechanism—if it is government-financed national health insurance, the government will have the primary voice in determining board composition. In autonomous or semi-autonomous plans, the government may still demand at least some representation on or control of the board. An MBP should have representatives of medical and pharmacy groups or associations on the board, as well as at least one representative of a consumer group or a plan member.

The board's bylaws should spell out its composition, specific roles, authorities, responsibilities, and liabilities. Bylaws should specify that board members must carry out their duties to benefit the plan and avoid real or perceived conflicts of interest. Board members should be covered by insurance that protects them against liability, providing they act in accordance with the bylaws. It is considered a best practice to have staggered term limits for board members, which assures that the plan evolves as new members come to the board, and to help keep the board from becoming entrenched by special interests.

Depending on the size and defined responsibilities of the governing board, the bylaws may prescribe a number of board committees. An executive committee may be appointed for situations requiring rapid decisions. A compensation committee may determine compensation guidelines for plan employees, including the chief executive officer (CEO). A finance or audit committee may be responsible for reviewing financial performance and audit results. A compliance committee may be responsible for ensuring that the benefit plan complies with applicable laws and regulations. A membership committee may propose nominees to replace board positions as terms expire.

Human Resources

MBPs that are directly managed by insurance plans must be able to recruit, train, and retain a professional staff that operates in different geographic regions and that can deliver the level of service demanded by their sponsors, providers, and beneficiaries. In turn, the organization must meet compensation, organizational development, safety, wellness, and benefits demands of their specialized workforce. While staffing requirements vary widely, MBPs may have staff members who work in the following areas—

- Operations management
- Account management
- Accounting/finance
- Client relations
- Administration
- Beneficiary eligibility
- Information technology (varies greatly by model)
- Clinical oversight
- Government relations

Human resource systems allow the MBP to manage their employee resources, including salaries and benefits, and the systems should be tightly integrated with other financial systems, including accounts payable, to operate seamlessly.

Typical management requirements for any MBP include the following positions, which may require a separate management unit depending on the

MBP's size and complexity. In all of these functional units, the size of the staff will depend on its scope of responsibility, associated workload, and the availability and integration of modern information technology.

The following positions would typically comprise the senior management team.

Executive director or chief executive officer (CEO)

The CEO is ultimately accountable for overall management operations and performance of the benefit plan. In government-financed plans, this person may be appointed by the government, and in other plans, by the board. In all cases, the CEO should have the training and executive leadership skills to manage a large and complex health care organization. Although the CEO may be a member of the board in some settings, the CEO should be accountable to the board, which should have the authority to change the CEO if he or she is not performing.

Chief financial officer (CFO)

The CFO manages the financial operations according to the business plan, including operating budgets and accounts payable and receivable. This position oversees investments, management of operating cash, and maintenance of reserve funds. The CFO is responsible for internal audits, financial risk management, preventing, detecting, and resolving fraud and abuse, and managing compliance with external audits and audit requirements.

Chief information officer (CIO)

This position is responsible for defining, developing, and managing information systems needed to operate the MBP. The CIO's responsibilities are important no matter where the MBP stands in terms of automated versus paper-based systems, because MBP systems need to evolve along with technology access. The CIO should oversee both information technology governance and service management. Governance responsibilities include facilitating strategic decisions as the information technology system evolves; service management should focus on achieving operational excellence in the current system and the effective and efficient internal supply of information technology services and products.

The staffing required to support the CIO and the information technology office will vary with the type of information system in use. In addition, elements of service and support can be contracted to an external provider. As noted below, the CIO function may be assigned to the head of operations in smaller MBPs, but it really should be a separate position, given the specific skills needed.

Medical director

The medical director is responsible for managing utilization of medical services and quality assurance programs and maintaining medical policies. He or she typically chairs any advisory committees made up of physicians and may chair the Pharmacy and Therapeutics Committee (PTC). The medical director may also manage the authorization process for medical or pharmacy claims. The medical director in some government-sponsored plans may be the same person as the chief medical officer in the ministry of health. In other plans, the medical director may be a prominent physician in the community. Depending on the size and the needs of the benefit plan, this may be a full-time position with one or more deputy medical officers, or it may be a part-time position.

Pharmacy director

Most MBPs will have a chief pharmacist function, which either serves as chair or secretary for the PTC, which is the MBP's most critical advisory committee. He or

she may chair any advisory committees involving pharmacy providers. As with the medical director, in government-financed benefit plans, the MBP pharmacy director may be the ministry of health's chief pharmacist or be that person's appointee. In some settings, the MBP pharmacy director and staff may manage the authorization process for pharmacy claims. This unit may be primarily responsible for the medicines utilization review process.

Operations Management

In larger, more complex benefit plans, this unit may require a full time operations director, or it could be a function of the pharmacy or medical director in smaller plans. The operations unit manages beneficiary and provider enrollment and verification, claims management and adjudication, member services, office management, and facility management. This office may also oversee the information technology function, particularly if the information system is not fully computerized, but usually, a dedicated information technology office with director is recommended.

This unit is the foundation of the benefit plan and is typically the most difficult to manage. The labor requirements for the operations function are directly related to the complexity of the information management system (as discussed in the section on information technology).

In countries where medicines benefit plans vary greatly in size and complexity, private third-party administrators may be contracted to manage the plan's operations functions, or a pharmacy benefit management company may manage most functions of the MBP. PBM companies will be discussed in Section III. D.

Authorization management

As discussed later in this section, a process is needed to manage the formal authorization of payment or reimbursement for non-standard claims. This process may be managed by the medical director's office, the pharmacy director's office, or the operations office, but for most benefit plans of any size, a designated unit and manager will need to process these requests and claims.

Network relations management

This unit manages relationships with prescribers and dispensers who provide services to beneficiaries, whether the providers are directly employed by the insurance plan or MBP or are independent contractors.

Client relations management

This unit develops appropriate materials for beneficiaries and markets the plan to potential beneficiaries and to organizations that might contract with the MBP.

Compliance office

In countries where the MBP is subject to specific laws and regulations governing operations, someone must ensure that the plan complies with regulations and resolves noncompliance issues quickly. This function may also be responsible for maintaining patient privacy and verifying authority to release information. Larger plans and plans operating in heavily regulated environments will likely need a separate compliance unit and director; in other settings, it might be managed through the CFO's unit.

Advisory Committees

Not every MBP will require all of the advisory committees listed below, but they can be useful in building stakeholder involvement in the benefit plan and assuring that the plan continues to extend access to high-quality and affordable services and medicines.

Pharmacy and therapeutics committee

Probably the single most important advisory committee for an MBP, the PTC comprises physicians and pharmacists (and in some cases mid-level providers and nurses) who select products for the MBP's formulary or preferred drug list. It may be chaired by the medical director or the pharmacy director, but the pharmacy director will normally manage committee operations. In an in-house plan, most committee members may be staff physicians and pharmacists, whereas in open model or mixed plans, at least some members should come from the contract provider community. As with any committee, the PTC should have a written policy to prevent conflict of interest, including requiring disclosure of any potential conflict.

The most effective PTCs draw on the local or national academic community for expertise in clinical pharmacy and pharmacoeconomics to help the committee select products for the formulary that are medically necessary and cost-effective. Medical specialists should evaluate medicines most relevant to their specialty. Section III. E discusses the functions of the PTC and the process for selecting medicines for the formulary.

Similar to a PTC, some plans may have a health technology advisory committee with physicians, laboratory specialists, and other experts who can provide direction regarding coverage of different health technologies.

Drug utilization review committee

This committee manages the standards and procedures for retrospective, concurrent, and if applicable, prospective drug utilization reviews (DURs). The committee reviews utilization data that the MBP compiles, identifies outliers and potential problems, and recommends interventions to correct problems. In an MBP, this committee may be a subset of the PTC or quality management committee, or may replace the quality management committee or peer review committee (described below).

Credentialing committee

This committee sets standards for service provider credentials and may help the MBP evaluate the credentials of potential new service providers or periodically re-credential existing providers. Typically, members come from medical and pharmacy academic institutions, professional associations, and agencies that license physicians, pharmacists, and drug sellers, such as the boards of pharmacy and medical examiners.

Quality management committee

This committee oversees quality assurance activities, including setting quality standards, reviewing performance data, providing feedback to providers, and approving sanctions when necessary. The quality improvement function is discussed in Section IV.

Peer-review committees

This committee reviews complaints about provider performance and recommends actions to MBP management—a representative committee of physicians would review complaints about physicians and a committee of pharmacists would review complaints against pharmacy providers. This could be a subset of the quality management committee and may only need to be mobilized when complaints are received.

Denial of coverage appeal committee

As part of the process of evaluating requests for policy exceptions or for service coverage that requires authorization, an appeals process is needed when members or providers are denied their request.

The medical director may manage this process with advice from a committee comprised of specialty physicians and at least some participation by non-voting member advocates. It is typically assembled ad hoc when an appeal is submitted.

Provider and member advisory committees

These committees can help build stakeholder involvement in and acceptance of the MBP. In general, provider and member advisory committees do not have any authority beyond making recommendations, although they may have voting authority in some types of plans. They primarily ensure that the plan is informed about issues affecting stakeholders and serve as a sounding board for changes in plan policies and procedures. One committee can be a mixture of service providers and plan members, or there could be separate committees for medical service providers, pharmacy service providers, and members.

III.C. CLAIMS PROCESSING

This section applies primarily to fee-for-service payment systems, whereby the service provider (or the beneficiary) submits a claim each time a prescription is dispensed.

The requirement to process individual claims is very common in MBPs around the world, particularly in outpatient benefit programs, and it deserves special attention because it is unrealistic in most LMIC settings without access to real-time electronic submission. The volume of claims often outstrips human resource capacity to manage them, leading to major delays in submitting, processing, and adjudicating claims. Such delays lead to the dissatisfaction of both providers and beneficiaries and financial hardship when beneficiaries are forced to pay out-of-pocket and be reimbursed.

In some settings, different payment systems are used, such as bundled payments, where medicines are included in the overall bill for a treatment episode in a hospital or other facility. Other forms of capitation models include the provider receiving a contractually determined sum that covers all services and medicines provided to a beneficiary during the time period covered by the contract. Some of these alternative payment models are covered in Section III.F.

The challenge for MBPs that need to process individual claims is to make the system as efficient as possible, given the financial and technology constraints and to find ways to make the system more responsive to the needs of providers and beneficiaries, while maintaining the financial integrity and sustainability of the MBP.

Many of the specific examples this section describes come from approaches used by commercial PBMs, but the basic steps in the claims submission and adjudication processes are required whether the MBP has fully automated information processing systems or relies on a paper-based system. We try to suggest options to manage the processing systems if access to state-of-the-art technology is unavailable.

The Basic Claims Process

When providers in a fee-for-service model dispense medicines to an eligible beneficiary, the provider (or the beneficiary) will submit a claim to the MBP, which is a request for payment for products and services. Upon receipt, the MBP will adjudicate the claim, which is the official determination of a claim's status. The MBP

will first check to see if the member is currently enrolled and eligible for covered services, then compare the claim's submitted values to the beneficiary's plan benefit definition. If the claim meets all benefit plan criteria, it is approved, and the total payable amount and any beneficiary cost-share contribution is subtracted. If the claim does not meet benefit plan criteria, it is rejected. In most cases, the MBP's information systems can approve or reject the claim and make pricing calculations without any manual intervention.

After the completion of the adjudication process, the adjudicated results are returned to the provider. If the claim is approved, the MBP will reimburse the provider in the next payment cycle. If the claim is rejected, the provider is not reimbursed, but may modify the claim and resubmit it.

Claim Submission Types

The claim submission process significantly affects the overall efficiency of medicine delivery. The timing between claim submission and the return of the adjudicated response to the provider can range from seconds to weeks, depending on the technological infrastructure available. Any delays between dispensing a medication and the payment to the provider can cause cash-flow problems in the provider network, which can put a program at risk of failure. Claim submission technology can be classified into the following four categories: real-time, batch, paper/provider, and paper/patient.

Real-time submission of claims

In a real-time system, a provider's pharmacy system, mobile device, or web portal is used to submit the claim directly to the MBP, where the claim is adjudicated and the results are quickly communicated to the provider. This ensures that all systems align with the final status of the claim (i.e., MBP and provider). This type of claim submission method is also called point-of-sale because the claims originate at the point of dispensing or sale.

The submission of claims in a real-time environment requires the most comprehensive infrastructure. The provider must have some level of information technology infrastructure, including external communication capability, or they must have access to a specialized web or mobile application that support claims submission.

Because the claim adjudication response can arrive within seconds, the real-time submission method offers the best opportunity to implement complex benefit designs and return clinical messages to providers prior to the beneficiary receiving the prescription. This method also helps providers manage financial and clinical risks because all parties know the cost structure, who is responsible for what payment, and whether certain medicines are safe, based on age or contraindications. Because of the delayed turn-around time in the other three claim submission methods, the provider typically dispenses the medication prior to receiving the adjudicated results, which minimizes the opportunity for claim response-initiated interventions.

Batch submission of claims

The provider's system collects claim transactions during a defined period (e.g., one week) and then securely transmits a group of claims electronically to the MBP for adjudication. The adjudicated results are returned to the provider in a few days via mail, email, or as part of the MBP's regular payment cycle. Having providers submit claims in a batch eliminates the manual keying of claims into the MBP's system, but the claim is not adjudicated until days after the beneficiary has left the pharmacy with medication. This method can work

well for providers who have a computerized dispensing application, but do not have reliable Internet connectivity. The risk, however, is that some co-payments may not be collected, which requires a post-event collection process. In addition, the provider may not be aware of unauthorized dispensing or medical care or certain clinical interventions until adjudication takes place.

Paper-based claims from providers and patients

LMICs may need to use a paper-based claims system for the initial phase of MBP rollout; however, because of variations in the technology infrastructure between urban and rural areas, urban providers may be early adopters of real-time claims submission. Most developing countries will use a hybrid model of claims submission, and the MBP can vary the benefit design rules by the claim submission method until the operating infrastructure evolves.

Large MBPs with paper-based systems require a large staff to review every claim prior to payment, and even if the MBP's management unit is fully staffed with skilled employees, delays in processing and payment are inevitable. One option to avoid the backlog is a sampling process in which a defined percentage of claims are checked for fraud and abuse, with greater priority given to claims from providers or beneficiaries who are high-volume consumers of services or those suspected of abusing the system. Unchecked claims would be paid as submitted. This sort of system would probably result in financial losses due to fraud and abuse, but the losses may outweigh the program sinking under the weight of unprocessed claims.

Another option is a system in which a percentage of each claim is paid before adjudication and then the rest paid once the claim is fully approved. If the claim is ultimately rejected, the amount already paid could be deducted from future claims from that provider or beneficiary. This type of system is vulnerable to fraud and abuse unless the sampling process is well managed and a strong mechanism is in place to control the partial payments made on a rejected claim.

Paper-based claims from providers

The provider prints paper claims and then sends the claims to the MBP in bulk for adjudication. MBP staff members will manually key the printed claims into the MBP's system. The adjudicated results are returned to the provider as part of the MBP's regular payment cycle. The MBP could adjudicate these paper-based claims either manually or electronically; however, manual processes will lead to inconsistency and delayed turn-around times.

The use of provider-submitted paper claims requires minimal technological infrastructure on the provider's side, because the claim is printed or handwritten by the provider and mailed or delivered to the MBP. Paper submission allows for centralized pricing and payment of prescription claims, and it also facilitates the collection of prescription utilization data that can be analyzed for trends (discussed in a later section). The main disadvantages of the paper claims submission method include the inability to provide clinical messaging back to the provider and the unavoidable delay in reimbursing the provider.

Paper-based claims from patients

The patient pays 100% of the prescription cost and then submits a paper claim to the MBP requesting reimbursement. MBP staff members will manually key the claim into the MBP's system where it will be adjudicated. The adjudicated results, including payment, are returned to the member within a few weeks of submission. Beneficiary-submitted paper claims require a similar turnaround time to provider-submitted paper claims, but with

the added disadvantage that the beneficiary would pay 100% of the drug cost prior to submitting the claim. Paying the entire cost of the medication could put a financial burden on the beneficiary, and the MBP pricing and cost-share contribution rules may restrict the reimbursement amount to well below the amount that the beneficiary paid. This method should only be used when the beneficiary had to go out-of-network because of geographical challenges or inventory shortages.

Claim Adjudication

The process of adjudicating a prescription claim follows a path where benefit rules are applied in sequence to determine if all of the submitted data elements meet the benefit plan definition. Although claim adjudication systems vary in design, the outline below illustrates a comprehensive adjudication sequence for an automated MBP.

1. Receive claim
A prescription claim is received via real-time submission from the provider, keyed via a mobile device or web portal, submitted via a batch transmission, or manually keyed from a paper claim. Submitted claim data is reformatted into an internal transaction format that is useable by the MBP's claim adjudication system.

2. Claim validation
A technical validation ensures that all required fields contain data and that information is in the right format. Other validations include ensuring that the date is valid (e.g., not in the future) and that the claim itself is valid; for example, a reversal or resubmission cannot be submitted if an original claim never existed. A duplicate check ensures that this is the only valid claim.

3. Validate patient eligibility
The submitted cardholder identification (ID)/patient ID, date of birth, patient gender, and patient name are used to determine if the submitted values match a beneficiary in the MBP's eligibility system. If a beneficiary is found who is eligible for prescription benefits on the date of service, the appropriate benefit plan design is identified. If the beneficiary could not be found or was not eligible for benefits on the date of service, the claim is rejected and returned to the submitter.

4. Validate provider eligibility
The submitted provider ID is used to validate that the provider is in the benefit plan's network and thus is authorized to dispense medicines to the beneficiary. If the provider is not valid or the network excludes the submitted provider ID, the claim is rejected and returned to the submitter.

5. Validate prescriber eligibility
The submitted prescriber ID is used to validate that the prescriber is authorized to write prescriptions for the beneficiary's benefit plan. If the prescriber is not valid or the benefit plan excludes the submitted prescriber ID, the claim is rejected and returned to the submitter.

6. Validate medicine
First, the claim is validated to ensure the medicine is valid (i.e., the product is registered in the country, a valid code is used, and the product is still available and not discontinued). Second, if the benefit plan is an open formulary, a check determines if the submitted product ID (medicine) is excluded from the benefit plan design. The validation usually occurs at both the specific product ID level as well as at a higher level of classification (e.g., weight-loss medications, nonprescription medicines). If the benefit plan is a closed formulary, a check validates that the submitted product ID is explicitly included in the benefit plan.

7. Address generic substitution policy
If the submitted product ID is a branded product and generic alternatives are available, a decision is made to reject

the claim (mandatory generic substitution), to reimburse at the generic rate, or to direct the beneficiary to pay the difference between the brand and the generic cost. If the submitted medicine is not covered by the plan or the benefit plan excludes branded products when a generic alternative is available, the claim is rejected and returned to the submitter.

8. Validate prior authorization

Some products require that the physician obtain approval from the MBP prior to prescribing specific medications. Without preapproval, the adjudication of any claim for the specified products will not be accepted. Unlike the step therapy validation, prior authorization criteria usually involve information beyond what is available in the beneficiary's claims history. Although the prior authorization review is normally a manual or semi-manual process, once the prior authorization has been approved, a claim can be processed without manual intervention.

9. Validate treatment or clinical information

The submitted product ID is used to validate other benefit plan restrictions including—

- **Age**: minimum/maximum restrictions on patient age
- **Gender**: male/female restrictions
- **Quantity**: minimum/maximum restrictions on quantity that can be dispensed per fill/refill
- **Days' supply**: minimum/maximum restrictions on the length of therapy per fill/refill
- **Daily dosing**: minimum/maximum limits on the number of doses per day for the prescribed medicine
- **Quantity/time**: restrictions on the quantity of a specific medicine that can be dispensed during any specific time period

Note that restrictions that depend on patient age, diagnoses, prior therapies, etc., require the ability to link enrollment and historical prescribing data, for example. Although this is a goal for advanced information technology systems, it is a challenge in many computerized systems and is particularly difficult in paper-based and mixed processing systems.

Examples of quantity and days' supply limit

- Albuterol nebulization (0.63 mg/3 mL, 1.25 mg/3 mL, and 2.5 mg/3 mL) has a maximum quantity of 375 mL every 30 days
- Axert (almotriptan) 6.25 mg and 12.5 mg tablets has a minimum age of 12 and has a maximum of 6 tablets every 30 days
- Baclofen intrathecal (Gablofen intrathecal; Lioresal intrathecal) solution for injection has a minimum age of 4 and a maximum days' supply of 120 days

10. Validate step therapy

A review of the beneficiary's claim history determines if any prerequisite product(s) have been tried before the submitted medicine is approved. Benefit rules can also preclude the return to an earlier prerequisite drug once the beneficiary has moved to another step.

Example of migraine step therapy

- **Step 1.** Use sumatriptan, naratriptan, or rizatriptan
- **Step 2.** Requires the prior use of at least one Step 1 product, then frova or imitrex

11. Determine refill timing

Additional validation determines if a specified percentage of a previous prescription for the same product has been used before a refill of that medicine is

allowed. This type of validation is often called early refill. The percentage specified may be a specific number or may be tiered based upon the submitted days' supply.

Example of early refill plan parameters

Days' Supply	Refill Percentage
1 – 5	50%
6 – 15	70%
16 – 30	80%
31 – 90	85%

12. Validate prior authorization

Some products require that the physician obtain approval from the MBP prior to prescribing specific medications. Without preapproval, the adjudication of any claim for the specified products will not be approved. Unlike the step therapy validation, prior authorization criteria usually involve information beyond what is available in the beneficiary's claims history. Although the prior authorization review is normally a manual or semi-manual process, once the prior authorization has been approved, a claim can be processed without manual intervention.

Example of prior authorization approval criteria for sitagliptin (Januvia®)[34]

Clinical criteria:

The treatment must be in combination with metformin;
OR
The treatment must be in combination with a sulfonylurea,

AND

Patient must have, or have had, a HbA1c measurement greater than 7% despite treatment with either metformin or a sulfonylurea;
OR
(where HbA1c measurement is clinically inappropriate) blood glucose levels greater than 10 mmol/L in more than 20% of tests over a 2-week period despite treatment with either metformin or a sulfonylurea).

Prior authorizations can also be used to override benefit plan restrictions that would cause a claim to be rejected. These are often used on a one-time basis to allow approval of a claim that falls slightly outside of the standard benefits. Negative authorization (i.e., refusal to reauthorize) can exclude a normally covered product from being approved for an individual. Negative authorization is often used in cases of inappropriate medicine use or abuse.

13. Perform prospective drug utilization review

Before final approval, prospective DUR algorithms review the submitted prescription's ingredient(s), strength, and dosing for appropriateness and for possible interactions or conflicts with other medications the beneficiary is taking. If a serious issue is detected, such as a life-threatening drug interaction, the claim may be rejected and require additional follow-up by the provider or the MBP. Additional information is available in Section III.B.

14. Calculate claim pricing

If a submitted claim moves through all steps successfully, the submitted quantity is multiplied by the appropriate unit cost plus any dispensing fees to determine the total amount payable for the prescription. The unit cost may be a rate established by regulatory bodies or it could be an amount negotiated between the MBP and the provider or other stakeholders. If taxes or professional service fees are due, those payments are calculated and included in the total payment.

15. Determine patient cost-share contribution

Many benefit plan designs require the beneficiary share in the cost of the medication. Often, the beneficiary will pay a percentage of the cost (e.g., 20%) or a fixed monetary amount (e.g., $3). The beneficiary may be asked to pay a larger percentage for a branded or specialty medication's cost than for a generic medicine.

16. Return claim

All information gathered during the adjudication process, including approved or denied status, payable amounts, and custom messaging, is combined and formatted into the appropriate response layout. The combined response is returned to the requester.

III.D. MANAGING THE INFORMATION TECHNOLOGY SYSTEM

Managing an efficient and reliable information system is perhaps the most difficult challenge for any MBP, particularly in an LMIC setting, but information management is at the core of every MBP. As noted in other sections, an MBP's structure and operations (and therefore the information system requirements and capacity) will vary depending on the beneficiary population, plan design, and the country's technology infrastructure. In settings where full automation is feasible and electronic connectivity with service providers and beneficiaries is reliable, the tasks of managing claims, monitoring services and utilization, and measuring performance are simplified.

As noted, a major limitation with paper-based information systems is the potential for delay at each stage of the claims process, which makes it difficult to keep providers motivated to stay in the program and allow beneficiaries to access needed services. In addition, the lack of electronic systems makes it hard to conduct DURs, monitor adherence to plan policies, and detect problems with overutilization and outright fraud. These are essential functions, however, that must still be incorporated, even in a purely paper-based environment. Paper-based systems can still be serviceable if properly managed and staffed, and they may be required in the early stages of a program where either cost or lack of infrastructure make a fully automated information system impractical. In fact, not many years ago, MBPs in developed economies operated with primarily paper-based systems by using telephones for communications. The processes were slower and less efficient than those with fully automated systems, but benefit programs functioned.

The following sections outline the information technology systems and operating components.

Data Requirements

The necessity and complexity of each information system component will differ, depending on the type of program being managed. Each of the following major MBP functions has specific data management requirements—

- Processing claims/requests for payment from providers
- Managing beneficiary relations
- Managing relationships with medicine providers
- Managing relationships and interactions with prescribers/health facilities
- Managing the formulary
- Managing procurements and pricing for medicines

Other MBP components, such as financial systems, accounting systems, and human resource management, would have their own set of information system requirements.

In systems where individual claims are submitted to the MBP, regardless of the claim submission method, the consistent definition and exchange of claim data elements is fundamental to the successful rollout of any fee-for-service model. In the United States, the American National Standards Institute standard for prescription claims is the NCPDP D.0 transaction layout (www.ncpdp.org). The standard file definition supports a significant number of data elements that can be transmitted between the provider and MBP, but only a limited number of those data elements would support claims adjudication in an LMIC (see example on the next page). Consistent claim validation and processing requires standard

CLAIM DATA ELEMENTS AND STANDARD FILE DEFINITIONS IN A FEE-FOR-SERVICE CLAIM

Claim Routing Information is used for real-time routing of claims to the MBP

- **BIN Number** (1Ø1-A1)
- **Processor Control Number** (1Ø1-A4)
- **Group ID** (1Ø1-A1)

Service Provider ID (201-B1) is the dispensing pharmacy that is submitting the claim for adjudication

Prescriber ID (411-DB) is the prescriber that wrote the beneficiary's prescription

Date of Service (401-D1) is the date that the prescription is filled and is used to determine if the beneficiary is eligible for service on a specific date

Cardholder ID/Patient ID (302-C2/332-CY) is the identifier that is used by the MBP for identification of the beneficiary

Patient Name is matched to the MBP's eligibility information to insure that the proper person is receiving benefits

- **Patient First Name** (31Ø-CA)
- **Patient Last Name** (311-CB)

Date of Birth (304-C4) is matched to the MBP's eligibility information to insure that the proper person is receiving benefits

Patient Gender (305-C5) is matched to the MBP's eligibility information to insure that the proper person is receiving medication

- **Product ID** (407-D7) is the unique identifier assigned to a specific medication
- **Quantity Dispensed** (442-E7) is the quantity of the medication that was dispensed (ex. 30)

Days' Supply (405-D5) is the length of time in days that a medication should last before it is exhausted (ex. 10 days' supply with a quantity of 30 would be 3/day).

Claim Data Elements and Standard File Definitions

{ Note – Bold values are the American National Standards Institute D.0 field name and the values in parentheses are the associated field identifiers.

coding mechanisms, such as National Pharmaceutical Product Index codes for products, Board of Healthcare Funder numbers for providers, and International Classification of Diseases codes for conditions. Some countries may have to start at a rudimentary level of developing or enforcing standards for prescription claims within their health systems. The Private Healthcare Information Standards Committee supports LMICs in setting up clinical standards and pharmaceutical coding standards (www.PHISC.org.za).

Beneficiary eligibility

Fundamental to all MBPs is the creation and maintenance of data about the beneficiaries. In most cases, the sponsor organization regularly provides beneficiary eligibility information to the MBP to keep the data updated. Eligibility data is used to determine benefit eligibility, bill premiums, determine drug appropriateness (e.g., age, gender), and carry out clinical initiatives.

Eligibility information can be provided via secured electronic file transmission (batch), entered via the MBP's web portal, or accessed through a real-time interface with the plan sponsor's system. In some circumstances, a paper-based system can be used to transfer eligibility updates from the sponsor to the MBP's system, where it can be keyed into the beneficiary enrollment system. The box on the next page lists examples of data required for beneficiary accounts.

DATA ELEMENTS FOR BENEFICIARY ACCOUNT RECORDS

- Demographics of primary beneficiary and any eligible family members
  - Full names
  - Ages/dates of birth
  - Gender
  - Social security number, national ID number, if applicable in the country
  - Driver's license number (if applicable in the country)
  - Passport number (might be used in lieu of social security number or national ID)
- Personal contact information
  - Residence address
  - Phone numbers (land line and mobile)
  - Email address (if applicable)
- Employer/work address and contact information
- Benefit eligibility
  - Medicine benefits to be provided to the primary beneficiary
  - Benefits to be provided to family members
  - If user cost sharing is required, provisions that apply to the primary beneficiary and family members
  - Exemptions to cost sharing
- Premium/contribution rates (if applicable) for primary beneficiary and family members
- Pre-existing health conditions (if applicable in the plan design)
- Primary service providers (medical services and prescriptions), if applicable
- Other insurance coverage held by either primary beneficiary or family members that includes medicines
- Effective date of coverage under the MBP

Providers (dispensing facilities)

MBPs should try to get a list of eligible dispensing facilities from a regulatory entity, so they can begin building their provider network based on beneficiary geography and plan objectives. Provider files should be updated regularly to maintain accuracy (see box at right). These files should have a process for receiving updates on changes in license status for prescribers and providers.

Prescribers

MBPs should have a list of physicians or other health care professionals who are eligible to prescribe medicines within the country or coverage area.

Medicine and price

MBPs must maintain an up-to-date master list of any prescription, nonprescription, or specialty medications and other health technologies that can be dispensed or provided to their beneficiaries. Each medication must be assigned a unique identifier that references a product's manufacturer, ingredient, and strength. Providers will use the identifier when they submit claims to the MBP. In addition, each medication in the master list must include product reimbursement information and one or more pricing reference points. The master list should also include clinical information that can support any MBP clinical initiatives. In many countries, the drug registration authority maintains a master list of all registered medicines with the information required for most of these data fields.

MBPs may decide to build and maintain their medicine and price database by collecting data directly from manufacturers, wholesalers, and distributors. If the country has a large number of products available, using an outside vendor to collect and maintain this information may be advantageous. The vendor can regularly provide the consolidated list to the MBP

DATA ELEMENTS FOR CONTRACTED PROVIDERS

- Provider identifier (must be unique)
- Business name
- Business owner
- License number
- Facility type (ex. hospital, clinic, retail, in-house)
- Contracted effective date/termination date
- Preferred payment method indicator (ex. check, electronic payment)
- Facility address
- Payment address
- Banking information
- Phone number
- Email address

DATA ELEMENTS FOR PRESCRIBERS

- Prescriber identifier (must be unique)
- License number
- Prescriber name (family name, given name)
- Facility address
- Phone number
- Email address

DATA ELEMENTS FOR MEDICINE AND PRICE INFORMATION

- Medicine identifier (must be unique)
- Manufacturer
- Ingredient and strength
- Dosage form
- Generic/branded generic/originator status
- Units
- Units dispensed
- Category or therapeutic class (e.g., ATC)
- Type (e.g., prescription, non-prescription)
- Price information (date sensitive)
- Optional: defined daily dose (DDD) for use in DUR

in an electronic form. Many vendors provide this kind of support in South Africa; for example, Medi-Span (www.medispan.com) maintains the master list of products for South Africa, and MediKredit maintains a system of unique medicine identifiers called the NAPPI codes.

Online Portal Applications

An online or web portal is the website "entrance" where users go to access data. The ability for providers, prescribers, beneficiaries, and sponsors to interact directly with MBP systems can make a plan's operations more efficient. Many portal applications could include the following.

Provider portals can be used by pharmacies or drug dispensing outlets to review beneficiary clinical history, including adherence and real-time claim submission; request prior authorizations; determine payment status; and access the latest clinical or benefit plan information. For providers without a dispensing application, the provider portal could be a substitute if the portal could support provider dispensing operations. For some developing countries, augmenting the portal to better support the computing needs of providers can eliminate the need for provider systems and promote the earlier adoption of real-time claim submission.

Beneficiary portal applications provide beneficiaries with the ability to review their medicine histories, access benefit plan information, instant message with MBP personnel, send online requests for information, register for voice or SMS (short message system—texting) refill or adherence reminders, and request refills if a centralized dispensing benefit is available.

Prescriber portals allow reviews of beneficiary clinical history, including adherence, requests for prior authorizations, and access to latest clinical or benefit plan information.

Sponsor/board portal applications allow program sponsors or advisory boards to determine if program goals are being met. It also allows monitoring of program expenses and forecast future funding needs or benefit changes.

Call Center and Interactive Voice Response

MBPs must be able to effectively develop, staff, and operate a call center that can support provider, prescriber, and beneficiary communication with response standards and indicators. The call center is an integral feature of a fully automated claims management system, but it is perhaps even more critical if providers and beneficiaries are not electronically connected to the MBP. In situations where claims are submitted manually or in batch form, providers and beneficiaries need to be able to call the MBP to request approvals and inquire about claim status.

Where fully automated information systems are used, the call center will require significant technology infrastructure including—

- Desktop or laptop computers
- Headsets
- Local area network and servers
- Call/issue tracking application
- Internet connectivity
- Trunk lines
- PBX (private branch exchange)/ automatic call distributor
- Voice over Internet protocol technology
- Interactive voice response system
- At least two-factor authentication procedures/systems

In most developing countries, the call center will have to be located in an urban area that has reliable electricity

and communications infrastructure. In addition, call center staff will need the necessary computer and language skills (including local languages).

All inbound calls should be routed inside the MBP by caller type (i.e., provider, prescriber, or beneficiary) to specific customer service representatives who are trained to handle caller-specific inquiries. This can be accomplished through separate phone numbers for each caller type or through an automated interactive voice response script that can request the caller type. If multiple languages are supported in the call center, beneficiary calls may need an additional check to determine the caller's language.

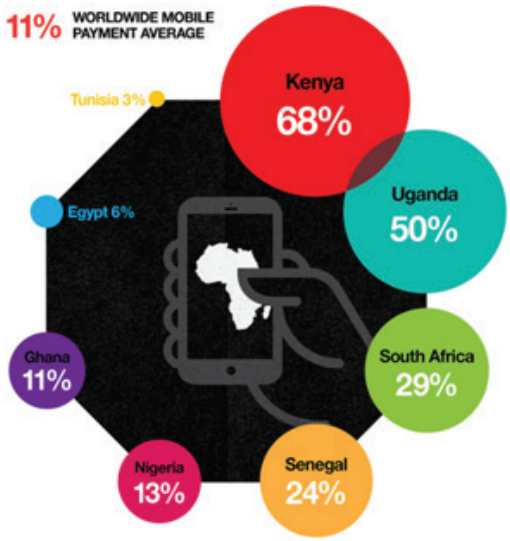
The MBP may find that some routine inquiries (e.g., check claim status or initiate refill request) can be fully automated through the interactive voice response application.

Mobile Applications to Increase Efficiency

Increased availability of general packet radio service or wireless mobile devices offers significant advantages to MBPs in their interactions with providers, prescribers, and beneficiaries. Mobile applications can enable—

- Providers to transmit claim transactions and receive payment information.
- Providers or prescribers to request prior authorizations.
- Providers or prescribers to review a beneficiary's medication history including adherence.
- MBP managers or providers to target outbound communications with beneficiaries including adherence information, refill reminders, and disease management information.

Percentage of mobile phone users who regularly make or receive payments on their phones.



Source: Pew Research Center, 2013.
Graphic by: Ivan Colic, Afrographique

The MOTECH pilot project in Ghana used mobile devices for communications with health care professionals and patients (pregnant women and new mothers).[35] A number of lessons from that pilot project are applicable to MBP interactions with providers, prescribers, and beneficiaries including—

Patients

- Phones are often loaned or borrowed among family and friends.
- Even low SMS costs may be too expensive for the poorest populations.
- Illiteracy is prevalent among some target populations, so voice support in the local language is needed.
- If able to read SMS messages, the level of understanding of written messages was rudimentary.

Health care professionals

- General packet radio service for data transmission was more cost effective than SMS message fees.
- Use of Java-enabled devices was more suitable in areas that had

poor network coverage because transactions could be stored on the device until connectivity was available (see earlier batch claim submission method).

- The use of a standardized mobile device improved training and troubleshooting.

III.E. MANAGING BENEFICIARY SERVICES

This section discusses the critical processes in managing beneficiary qualification, enrollment, and participation in the MBP. We cover the intricacies around important management issues such as exemptions and authorization systems, which are used to manage exceptions to standard program provisions.

Note that in most programs, the enrollment process refers to enrollment in the insurance program that offers medicine benefits as part of the program. Separate enrollment in an MBP is normally not required.

Beneficiary Enrollment

The enrollment process is the first contact between beneficiaries and the insurance plan, so enrollment must be managed effectively. All processes must be carefully designed and tested before announcing that the plan is open to enrollment. Failure to do so may result in financial losses if the plan and its MBP mistakenly accept enrollees who are not eligible, not to mention damaging the program's reputation.

Applications for enrollment

Applications for enrollment may come from individual members or be submitted on their behalf by government agencies, employers, unions, or associations. Depending on the type of management information system available to the MBP, applications may be on paper forms or submitted electronically. If the management information system is a mixed system—paper and electronic—it might involve submitting both types of applications, with paper forms scanned into the system. As is the case with other management processes, a paper-based element will require more effort to capture and verify the required information than an automated system. It will also add time from application to certification. But automated systems also require more capital to implement and more training for the employees who manage enrollment. The MBP must make the process as quick and efficient as possible in manual, mixed, or fully automated systems.

Verifying eligibility

A critical step in most benefit programs is verification of eligibility at the time of enrollment and during confirmation of continued eligibility. This may not be a major concern in some national health insurance schemes where all citizens are eligible, but even in those cases, it may be necessary to verify citizenship and residency, determine eligibility for specific services, or approve exemption from cost sharing.

The level of effort and costs involved in managing verification of eligibility for plan participation will vary by the type of plan and the country context. If the employer pays for the member's coverage, the MBP may choose to accept the employer's assurance of a participant's eligibility (unless further medical history or testing is required to enter the plan). When individuals submit applications, the MBP should verify the accuracy of

the information. This is particularly true for individuals who claim eligibility in a category targeted for special benefits or exemptions from cost sharing. A physical visit to the applicant's residence or workplace may be necessary or verification via phone or email with references provided, if appropriate. Some LMICs may not have a good dwelling address system for verification, therefore, innovative options such as finger biometric identifiers linked to national databases can be considered.

Managing the enrollment and verification process, whether automated or manual, requires significant numbers of staff, and although computerization can reduce the number of clerical staff need to process manual submission, it will require a more skilled and higher paid workforce to manage the computerized system.

Identification Card and Other Materials

Once the plan has confirmed eligibility for benefits, the MBP needs to provide each member with ID cards certifying the member's eligibility for benefits. This ID card will typically contain—

- Members name—if family members are covered, each person may have a card with their own name, or the member's card may specify names of eligible family members, and each gets a duplicate of the member's card
- Employer's name and group number, if applicable
- Member's account number or policy number
- Cost-sharing status including required amount of co-pays, co-insurance, or deductibles
- Eligibility for preferences or exemptions from cost sharing
- Contact information for the MBP and PBM, if applicable

This member ID may be in the form of a standard paper or plastic card; a "smart card," which could allow the provider to access the member's information electronically; or potentially be included as part of a mobile phone application. The choice will be based on the technology available and the costs to implement and manage the process.

In addition to the ID card or equivalent, the MBP needs to provide each primary member with materials related to the plan. These typically will include—

- Certificate of coverage stipulating the dates of effective coverage and which beneficiaries are covered.
- Summary of member's coverage, including the specific medicine benefits available, cost-sharing requirements, and eligibility for preferences or exemptions from cost sharing.
- Member handbook that explains the features, benefits, and limitations of the MBP and spells out—
  - Services and medicines covered and any exclusions from coverage.
  - A list of providers who are authorized to provide services and medicines; specifies if member is limited to specific providers as their primary source of services.
  - Expectations for member's responsibilities and penalties for non-compliance with program policies (and incentives for compliance, if any).
  - Program policies and procedures for accessing services and for payments and reimbursements.
  - The process for obtaining out-of-network coverage and accessing alternative providers (if applicable) including any differences in cost share policy that may apply.
  - The process for authorizing services and requesting exceptions to plan policies.

- Any additional member services available such as educational materials, disease management initiatives, wellness programs, etc.

- Primary pharmacy services provider (individual or network), as applicable.
- Pharmacy benefits management, if applicable.
- Primary medical services provider, if applicable.

The plan can make these materials available online, via email or smartphone applications, or through paper copies, which may be the most realistic option where Internet access is not universal. In some countries, the benefit plan is required to provide paper materials, even if the materials are available electronically.

Status Review and Re-Enrollment

The insurance plan should define the period for reviewing each member's eligibility to participate. In most situations, where the members or employers are paying for participation, the review occurs annually, but given the level of effort and associated costs required to conduct the review and recertification process, lengthening the period to two years or more may be necessary. Long intervals between reviews or failure to review eligibility will waste money as the program pays for services and medicines for people who are no longer eligible for coverage. However, national insurance or social security insurance plans may have longer eligibility periods, in some cases for a lifetime.

The re-enrollment process is similar to the enrollment process, except that the emphasis is on verifying that the member and any family members enrolled are still eligible for the program, that personal information in the record is still correct, and that members have been compliant with program policies and procedures and have met financial obligations.

Managing Confidentiality of Patient Information

Many countries have explicit laws and regulations that govern confidentiality of beneficiary information and their medical treatment records. Even if the country has no official restrictions, the MBP should still develop and enforce its own policies to protect patient privacy and ensure contracted service providers follow the same policies. Components of this privacy program would include—

- Safeguards that protect the information from unauthorized access.
- Limitations on disclosure of the information without express consent of the beneficiary.
- Policies and procedures that limit who can view and access information.
- Training programs to make sure program staff and contractors are familiar with the policy and procedures (and regulations that may apply); the MBP must ensure that all internal systems comply with privacy regulations and that contracted outside service providers also comply with the same restrictions.
- Monitoring programs to assure that policies and procedures are being followed both internally and by contractors.
- Penalties for unauthorized disclosure.

Managing Exemptions

As discussed in Section II, cost sharing is a feature of most benefit plans in developed economies, but is viewed as problematic in some LMICs. In LMIC programs that do have cost sharing, it is customary to have targeted exemption policies that lower or eliminate cost sharing for targeted segments of the population. However, unless these exemption programs are managed

effectively and transparently, abuse may become widespread with exemptions granted based on political clout or social or familial contacts or on outright corruption, with the sale of exemptions. If not managed effectively, beneficiaries who should get exemptions fall through the cracks and are denied access to quality services and medicines.

Designing exemptions for the plan

Determining which beneficiaries should receive exemptions begins in the design process, in conjunction with determining targeting policies and procedures. If exemptions are based on targeting categories of people, the plan's enrollment process needs to verify that beneficiaries and family members claiming exemptions are part of a target category. If exemptions are based on either direct or proxy means testing, the plan will need extra staff to investigate the beneficiary's financial situation. In some administrative structures, a separate unit may process exemptions, in which case a specific form requesting the exemption may be submitted as part of the enrollment process, and routed to the responsible unit.

Verifying exemption requests

In settings with computerized information systems, the exemption request, review, and verification process will be largely automated and based on electronically submitted forms or scanned manual forms. The forms are compiled and reviewed by the computer software, which flags gaps or conflicting information that a staff person must physically verify.

In most LMICs, computerized record systems are not widely used, particularly in public sector benefit programs, and the exemption verification process may be a paper-based submission and review, combined with physical visits by program staff to verify statements made on the beneficiary's application. Whether the requests for exemptions are managed electronically or manually, an MBP official eventually must certify the eligibility of the beneficiary for exemption. In some community-based plans, a committee from the community may determine the exemption eligibility.

Most exemptions should be granted for a specific period, such as a year or two, before recertification. As with the re-enrollment process, the focus is to make sure that nothing has changed to invalidate the exemption. This is, of course, not required for categories such as "senior" (65 years or older).

The benefit plan can consider adding an appeal process, whereby a beneficiary can appeal the exemption denial to a higher level of benefit plan management.

Reviewing exemption processes and policies

Considerable pressure to subvert the verification process can exist, both during the first-level review and in an appeal, if allowed. The MBP will need a process to review the work of those involved in granting exemptions to assure that the program's policies and procedures are implemented fairly. This will require additional staff and may require a dedicated unit.

MBPs that have cost-sharing programs with exemptions should periodically review the impact of the policies on access for targeted populations and on program operating costs, to assure that the program is not costing more than it is worth or restricting access for target populations. An exemption review could also include an update of program policies when the exception becomes the rule.

Managing Service Authorizations and Exclusions

The MBP design needs to define which services and medicines are automatically

covered and which are excluded (as discussed in Section II). Some services and medicines may be subject to formal authorization by the MBP on a case-by-case basis.

Most benefit plans allow some exceptions, such as allowing payment or reimbursement for a medicine or a procedure that is normally excluded from plan coverage, but only for specific patients in certain circumstances, on a case-by-case basis, and with formal authorization. Authorization may also be required for the numbers of prescriptions dispensed per visit or the quantity of medicine dispensed, if they are limited in the benefit plan. Some US plans require authorization to cover medicines for "off-label" uses.

Currently, in most MBPs in LMICs, prior authorization processes relate to high-cost medicines that require verification of clinical conditions, not standard medicines on the national essential medicines list.

Authorization categories

Kovacs et. al. describe basic authorization categories as[36] —

- Prospective or prior authorization or approval
- Concurrent authorization
- Retrospective authorization
- Sub-authorization

Prior authorization

Prior approval (or prior authorization) is the most common model used to manage exceptions. In this model, the provider notifies the designated unit at the MBP or the pharmacy benefit management company that a beneficiary is presenting with a prescription or request for services that requires prior approval. The medicines or services are not dispensed or provided until approval is received. Once approval is received, the patient is only responsible for any cost share requirement. In some plans and for some medicines, the pharmacy may be authorized to dispense a limited quantity of the medicine (usually a one to two day supply) to cover the patient's needs during the time required to process the approval request.

Concurrent authorization

This request is generated while the treatment that would require authorization is already under way. The MBP will typically grant at least conditional approval, but it may instead redirect treatment options.

Retrospective authorization

This authorization request occurs after the beneficiary has received the service or medicine. This model is a potential option when the benefit plan's design requires beneficiaries to pay out-of-pocket for the full cost of services and medicines and then get reimbursed by the benefit plan. Requiring beneficiaries to pay out-of-pocket is not a viable model for socially focused benefit plans, because patients who cannot afford to pay will be denied access, and those who can pay run the risk of having their reimbursement denied.

A retrospective authorization system may be considered in situations where the providers and MBP have no real-time communications capacity, and the provider is willing to risk providing medicines to beneficiaries and then submit a claim subject to retrospective authorization. Even plans using prior authorization, however, will have some requests for retrospective authorization from some providers, due to a breakdown of communication systems or other problems that prevent a connection with the MBP to obtain prior authorization.

If all such requests are denied and the claims are not paid, the providers will stop providing the services, which will alienate providers and beneficiaries. Therefore, in some cases when the services were urgently needed, but the MBP is unable to respond quickly, it may need to grant retrospective approval for

payment. Both providers and beneficiaries who repeatedly request retrospective authorization when the standard policy is prior authorization, should receive educational interventions, and if those fail, be denied future claims.

Appeal process

The MBP needs a defined process by which providers or beneficiaries can appeal denials of requests for prior authorization. The process may be managed by a dedicated review committee or by the medical director (or equivalent). In some plans, the governing board could be directly involved.

Sub-authorization

In this model, the authorization of exceptions is linked, meaning if one product or service is approved, then another service that would normally require approval is automatically authorized. This is most applicable in hospital settings; once hospitalization is approved, authorization flows down to the associated services. For an MBP, that could apply to coverage for a specific medicine, which means that ancillary treatment is also authorized. For example, if insulin is authorized, then other diabetic supplies, such as syringes and test strips, would also be authorized.

Processing authorizations

In paper-based systems, requests are submitted by paper or by phone. Once plan staff receives requests, they classify them into three batches: pending review, approvable without further information, and denial, although partial approval may allow partial payment. The pending classification could result from needed information, approval could be in full or with a co-payment, and denial means the request is denied in its totality with no reimbursement.

In fully automated settings, with real-time adjudication, the provider submits the authorization request electronically, and in some cases, it may be approved electronically or by the MBP or PBM, while the patient waits at the point of service. The provider may need to speak directly with an MBP official to get approval.

With telephone requests, the provider or the beneficiary will speak with an MBP manager who will approve, deny, or refer the request for further review, which allows for immediate intervention at the time of the authorization request. The provider or patient may be required to sign and fax a form attesting to the information submitted. In paper-based systems, the provider will mail or fax the request to the MBP, then wait for the MBP to determine whether to approve payment. This will obviously be the slowest processing option.

Approving authorizations

The MBP must identify who is authorized to approve requests. The officials at the MBP or PBM company who are responsible for the primary review of an authorization request should have the clinical education needed to make the appropriate judgments and communicate with providers. For an MBP, that person would typically be a pharmacist, although a physician or nurse is an alternative. Requests classified as needing further review may be referred to a medical director or chief pharmacist.

In benefit plans where the prior authorization process is fully or mostly automated, one review official can handle many requests in a day—most of the requests are handled by the computer software and only require quick review and sign-off. In paper-based systems, the authorization review process may require staff members to manage the workload and minimize the turnaround time for ruling on requests and managing the appeal process.

As with exemptions, there should be a process allowing patients or providers to appeal claims that are denied

initially. The claims might be referred to the medical director or to an appeals review committee made up of pharmacists, physicians, and patient advocates, or the plan could have a contract with a separate organization that specializes in reviewing and ruling on denial appeals.

III.F. MANAGING DISTRIBUTION OF MEDICINES TO BENEFICIARIES

As discussed in Section II, the delivery of medicines to MBP beneficiaries can be through in-house facilities that are staffed by plan employees (the closed model); through contracts with outside medical and pharmacy facilities, which could be public, private, or NGO entities (the open model); or a mixture of both. Although the term "pharmacy" is used to designate the contracted dispensing provider in this section, in some countries, the service provider may be a licensed drug shop, public or private health clinic, or dispensing prescriber. A variety of providers may be needed to provide access to all target beneficiaries because of the inadequate distribution of pharmacies in the country (i.e., urban locations).

Managing the delivery of medicines to members using in-house facilities and staff is well beyond the scope of this guide, but it is covered in detail in MDS-3.

When evaluating systems for delivering medicines through any type of contracted provider, several criteria are important[37]—

- The provider payment system should provide positive incentives for the dispenser to improve quality of care by reaching out to the prescriber or beneficiary when he or she detects potential problems with the treatment. For example, the plan could pay a negotiated fee each time the pharmacist intervenes or increase the dispensing fee for pharmacies who review medication regimens for beneficiaries.
- The management system and the provider contracts should have mechanisms to monitor services and ensure that beneficiaries receive required services and that the claims are submitted as the contract mandates.
- The system should provide incentives for prescribers, dispensers, and beneficiaries to choose the most cost-effective medicines to treat health problems. Incentives could involve a higher dispensing fee when a generically equivalent product is substituted for a brand name product, or where markups on the cost of the medicine are allowed, the markup could be higher for lower-cost products that are generically or therapeutically equivalent to higher-cost products.
- The system should encourage prescribers and dispensers to participate in the benefit program and serve covered beneficiaries.
- The administrative systems should be consistent with available technology and existing claims-processing capacity and manageable for beneficiaries, service providers, and claims administrators.
- The service delivery and payment systems should promote equitable access for all covered beneficiaries.

» See Part II Pharmaceutical Management in MDS-3.

Separation of Prescribing and Dispensing

One issue for the MBP is determining which service providers should deliver medicines to members. Inpatient medicines and many specialty medicines, particularly injectables, are routinely administered by the medical provider and may be bundled in the overall charge for patient services.

If prescribers of outpatient medicines are also reimbursed for dispensing those medicines to the patient, the prescriber benefits financially as the number of prescriptions goes up, thereby increasing the risk of overprescribing. On the other hand, if generic medicine policies and payment and reimbursement policies are not harmonized with the prescribing or dispensing policy, the prescriber who does not dispense may have little incentive to prescribe lower-priced medicines. Prescribing or dispensing restrictions could lower the total number of prescriptions issued, but could also increase average prescription costs and MBP expenditures on medicines.[38]

In some countries, national or state laws or regulations mandate the separation of prescribing and dispensing. If the prescriber is legally barred from dispensing, he or she can try to evade the ban by owning a pharmacy and steering patients to that pharmacy. This can lead to another round of regulation, such as banning physicians from having any financial interest in a pharmacy. If the dispensing prescriber is not legally banned, the MBP will need to develop its own policies. If all plan members have reliable access to licensed dispensing outlets, it makes sense to limit or ban MBP reimbursement for medicines dispensed by prescribers, while tying reimbursement for their medical services to compliance with the plan's formulary, generic drug policies, and clinical practice guidelines.

However, some places may have limited access to licensed dispensing outlets, so although the MBP separates the functions, it may need to make some exceptions to allow prescriber dispensing to ensure full access to the entire target population, if the exceptions are legal. Generally, MBP's attempts to change existing laws regarding prescribing and dispensing authority will be met with strong opposition from whichever professional groups feel their roles are being undermined. The critical point is that the MBP's policy on dispensing prescribers needs to link to its policies on generics and on reimbursement to providers to limit perverse incentives for overprescribing while providing positive incentives for cost-effective treatment and compliance with clinical practice guidelines.

Choosing Providers

An important MBP decision is how much freedom to give beneficiaries in choosing medical and pharmacy service providers.[39] From the MBP's point of view, monitoring service quality and compliance with program policies and guidelines is easier with a limited set of providers; in addition, administration of the contracts is less burdensome and expensive.

Open access and network

Open access means that members can receive medicines from any outlet licensed to provide prescription medicines to consumers, without any contractual relationship between the provider and the MBP. To the MBP, this is the least desirable way of providing medicines to beneficiaries because the plan has limited or no leverage over dispensing practices, choice of products, or pricing and markups. This may sound good from the provider's perspective, but because the MBP has no contractual obligations regarding payment time or guarantees, the provider and members may find this option to be undesirable in practice.

Open network means that a beneficiary can receive services and medicines from any licensed provider who is willing to accept the MBP's terms and conditions (known as "any willing provider"). An open network still requires that the provider sign a contract with the benefit plan to get claims paid, but the option must be open to any willing provider who meets the criteria. In some country settings, laws and regulations may mandate that any willing provider must be allowed to provide pharmacy benefit services to members.

The open network model potentially provides benefit plan members with access to the largest selection of potential service providers. Again, the open network model may appear preferable to providers and members, but the provider will receive a relatively uneven volume of medicine benefit payments, and patient visits to the outlet will be more erratic. The MBP will find it harder to standardize and manage the claims adjudication and authorization process, which may slow payment turnaround. The MBP will also find it more difficult to assure quality and review utilization; in addition, it may have less leverage to negotiate discounts on fees or medicine prices. As the MBP or PBM company introduces or expands electronic information systems that require automation on both provider and plan sides, an open model will make that process more complex.

Closed network and preferred providers

In a closed network, the MBP selects a group of preferred service providers to provide medicines to members. The preferred providers may include individual outlets (community pharmacies, selected pharmacy chains, health centers and hospitals, NGOs, or mail order outlets). In some plans, members may go to any provider in the preferred network, but other plans may assign members to a certain provider that the member must use unless an exception is authorized. The latter is standard in the case of mail-order prescription services.

In a closed network, the preferred providers benefit from higher volumes of patients, prescriptions, and sales. Assuming competition exists for preferred provider status, the MBP may be able to negotiate discounts on dispensing fees and markups on medicine prices. A closed network model makes it easier for the MBP or PBM to establish efficient mechanisms for submitting and adjudicating claims, manage authorization processes, communicate with providers, and monitor service utilization and quality, such as through customer satisfaction surveys. Those efficiencies may then allow the MBP to reduce turnaround times for claim payment and be more responsive to provider and member issues. As discussed below, with a closed model, the MBP will need to deal with out-of-network coverage when members are unable to access a preferred provider.

Choosing a network type

As mentioned, each MBP will need to review the potential providers and geographic distribution of beneficiaries and providers to determine whether an open or closed model is most appropriate for the situation. Another consideration is the extent to which political factors could affect the choice of providers in a closed model. If the closed model is used to steer beneficiaries to politically connected providers or favored providers, it may adversely affect both access to and costs of medicines.

Benefit plans that use an open access or open network model may want to analyze the potential benefits of moving to the opposite model. Changing the model may or may not be politically feasible, even if it reduces costs, enhances access and service quality, or increases managerial effectiveness. Mapping stakeholders and analyzing political feasibility would be a

prerequisite to attempting to change the model for existing plans.

Out-of-network coverage

Designers of an MBP need to decide whether and how to provide coverage for medicine benefits when beneficiaries are traveling or otherwise unable to obtain prescriptions from an accredited network provider. One option is for the beneficiary to pay out-of-pocket and then submit a claim to the MBP for reimbursement. This method clearly limits access for beneficiaries who cannot afford the out-of-pocket payment. Another option is for the provider or beneficiary to contact the MBP online or by phone, explain the circumstances, and obtain approval before dispensing the medicine. Assuming approval is granted, the beneficiary would only pay the standard co-payment or co-insurance, and the provider would bill the MBP for the remainder of the charge. In some plans, the standard co-payment or percentage may be higher for out-of-network prescriptions, but if this is an option, the increase should not be enough to reduce access for poorer beneficiaries.

Mail-order prescriptions (where feasible) may be the preferred choice for beneficiaries who are unable to access a local network provider. Although it may be the most cost-effective option for the MBP and the beneficiary, issues may arise with the delivery time, if therapy must be started immediately or if interruption of chronic therapy would be harmful.

Identifying and Contracting with Pharmacy Providers

As part of an MBP's certification and contracting process with authorized medicine providers, it confirms that each provider meets specific quality standards and that the provider agrees to accept an approved rate schedule (if supported by current regulations). In addition, MBPs can define a restricted network that requires the providers to accept stringent criteria on information technology capabilities, formulary adherence, clinical interventions, or reimbursement rates, but such demands may cause logistical obstacles for beneficiaries and could complicate their timely access to medications. With a very large provider network, the MBP has less influence on its providers, which may weaken its strategic initiatives to reduce costs or provide timely clinical interventions.

The MBP needs to develop standards for evaluating the credentials of potential service providers and their capacity and willingness to provide access to quality services and medicines. In addition, each contract provider must sign an agreement to comply with all contract terms. (Annex 1 has more details on credentialing and contract terms.) Identifying all potentially eligible pharmacy service providers is required in both open and closed network models, although in the open model, the basic premise is that any willing provider with the proper credentials is eligible to sign a contract; however, the MBP or PBM company will still need to verify that the provider meets the standards before approving the contract.

Potential providers across the country may be identified through lists of licensed outlets from the national licensing agencies, such as the board of pharmacy or board of medical examiners, and from the respective professional associations. Requests for expressions of interest in participation can be published in newspapers and online, depending on the context. Or requests can be mailed, emailed, or delivered by phone to eligible providers. The MBP's credentialing unit may do the due diligence on a provider's fitness for a contract or a national agency such as the board of pharmacy, ministry of health, or a contracted professional association may manage it. If a PBM is

providing services to the MBP, it will usually identify providers and manage the credentialing and contracting process. Additionally, monitoring of contracted pharmacies must be continual to ensure consistent service delivery.

Mail order and online service providers

Prescription and nonprescription medicines are available by mail order in much of the world, often through orders placed online through pharmacy websites. In highly developed economies, insurance programs and MBPs contract with dedicated mail order pharmacies to deliver medicines to beneficiaries. These contracts may supplement contracts with local pharmacies or pharmacy chains, but at least in the United States, many benefit programs use mail order as the primary supplier of prescription medicines, particularly for chronic care medicines. Mail order may also be used to provide medicines to beneficiaries who are traveling or otherwise unable to access the network provider.

Currently, few LMICs have mail-order pharmacies, but the following example from South Africa illustrates an alternate approach—courier service delivery to designated pick-up points. The issues discussed regarding mail-order pharmacy services in this section are also applicable to courier pharmacy services.

Where the service is viable, centralized mail-order or courier pharmacies may offer lower prices than community pharmacies because they can obtain volume discounts from manufacturers. They may also offer discounted dispensing fees through economies of scale and automation of the dispensing process. Mail-order prescription services can also reduce the MBP's administrative burden because only one provider serves beneficiaries in a large geographic area, which simplifies claims processing and adjudication. Mail-order pharmacies that contract with benefits programs will typically have call centers to manage issues raised by beneficiaries and providers. These call centers may also contact providers to suggest changes in the prescription based on the formulary or the therapeutic substitution policies of the MBP. Many beneficiaries may appreciate the convenience of home delivery or pick-up at a local facility, particularly if they are older, disabled, or have difficulty traveling to a network pharmacy. However, the lack of personal contact with a pharmacist limits the opportunity for patient counseling.

One potential constraint to an MBP's use of mail order or courier prescription services is opposition from community pharmacies or pharmacy chains and their professional associations. MBPs should anticipate and handle this opposition, if possible. Analyzing the political situation and managing the political issues may be just as important as negotiating a good contract and analyzing the potential impact on access and program finances.

COURIER PHARMACIES

In countries where pharmacies are only in urban areas, the postal service is poor, and there is no other type of drug outlet, such as licensed chemical sellers, a courier pharmacy may be an option. A courier pharmacy delivers chronic care medications to clients on a monthly basis. The Western Cape Province of South Africa has contracted with a third-party courier pharmacy company, UTI, to deliver HIV and AIDS, hypertension, and other chronic care medications to over one million South Africans living in rural areas. The Western Cape Province's Central Chronic Dispensing Unit receives paper prescriptions from visiting physicians after patient visits. The medications are dispensed at a central point by a team of pharmacists and shipped by the courier company to the church or farm closest to the beneficiary, where he or she can pick them up.

Another potential constraint to mail order is the lack of reliable home addresses for beneficiaries in many LMICs. Without consistent use of addresses or access to postal boxes, assuring delivery is difficult. The benefit of the courier service alternative is that medicines are shipped to a public, NGO, or commercial facility where beneficiaries pick them up.

When negotiating a contract with a mail-order or courier pharmacy service to provide medicines benefits, the following considerations apply[40]—

- License and accreditation status
- Status and capacity of the physical facility where prescriptions will be filled
- Advanced technology to support the dispensing processes
- Qualifications of professional and support personnel for dispensing and managing interactions with prescribers
- Capacity to support formulary management and drug utilization review processes
- Capacity to manage generic or therapeutic substitution policies and generic substitution rates achieved for other clients
- Shipping (including labeling and packaging) methods to beneficiaries and delivery capacity to geographic target areas
- Average price to be charged for ingredient costs of commonly used medicines compared with community pharmacy prices
- Dispensing fees compared with community pharmacy fees
- Capacity and willingness to offer discounts on medicine prices and dispensing fees
- Promised versus demonstrated service level and turnaround time for delivering prescriptions
- Capacity to manage claims submission process in line with MBP requirements
- Capacity to manage cost-share process
- Error rates and error prevention procedures
- Error correction process
- Billing accuracy rates
- Performance standards on managing exceptions, denials, and appeals

Contracting for specialty medicine services

The following criteria are used to define specialty medicines[41]—

- Chronic disease target
- High medicine cost
- Special handling requirements
- Need for close clinical support and customized dosing
- Typically a small patient population

Examples of disease conditions where specialty medicines are used include cancer, hemophilia, kidney failure, intractable arthritis, and multiple sclerosis.

Specialty medicines may be administered in clinics, physician offices, or hospitals and may be covered by the inpatient medical benefit. However, some countries now have specialty pharmacies that prepare and distribute these products. The pharmacies typically store the specialty medicines, prepare the product for administration, and deliver them to a clinic or physician's office. Delivery may be on a just-in-time basis for a patient appointment or even to a patient's home, depending on the medicine and the therapeutic requirements. In some situations, the specialty pharmacy may directly administer the medication to the patient. In the United States, many specialty pharmacies have been acquired recently by large commercial PBM companies.

Payment for specialty pharmacy services and the cost of medicines may be either based on a negotiated charge for each medicine and professional service or on a fixed charge covering bundled services and medicines discussed previously for inpatient services.

MBPs that plan to cover specialty medicines or innovative health technologies may need to adjust their cost-sharing policy because these products and services are usually much more expensive than standard therapies. If the beneficiary cost share is based on a percentage of the medicine's cost, many patients would not be able to pay or experience severe financial hardship—essentially denying them access. Even flat co-payments may lead to inequity if they are significantly higher. Therefore, funding for targeted exemptions will be required to assure equity where cost sharing is in effect.

The evaluation criteria for prospective specialty pharmacy providers and the contracting considerations are essentially the same as those applied to outpatient and mail-order providers, as discussed earlier.

» See chapter on Contracting for Pharmaceuticals and Services in MDS-3.

Determining Reimbursement Terms for Providers

In open and hybrid models, a key design decision is how providers will be paid and how much. Most socially focused benefit plans will want a system where the beneficiary pays only a cost share or nothing and the contract service provider submits the claim to the benefit plan. This system can limit the choice of service providers, because some may be unwilling to take the risk of waiting for payment from the benefit plan, but it avoids subjecting beneficiaries to out-of-pocket costs they cannot or will not pay; however, assuming the claims process is fair and reasonably prompt, the providers benefit from higher volume of patients and prescriptions because more eligible members can access the benefit. The discussions of payment and claims management in this section focus on that model, and payment terms generally follow the fee-for-service model, although we also include other options, such as bundled pricing and capitation.

In many countries, medicine pricing is regulated by a government agency that is separate from the insurance system (see the discussion of managed market entry and reference pricing below). Where reimbursement rates are not governed by one of these mechanisms, the reimbursement rate for medicine costs (also known as ingredient costs) is usually the most complex payment parameter for the MBP to establish. Some benefit plans have a policy stating that pharmacies will be reimbursed based on "usual and customary charges" or the cash price charged for a medicine for a patient without insurance. This will typically be the most expensive of the available options, and it gives the MBP limited leverage over prices charged for medicines—making it unlikely to be financially sustainable. However, usual and customary prices language can ensure that the plan is not charged more than that price in situations where the pharmacy is deeply discounting prices for certain medicines to other customers. If a contract includes such a provision, the MBP will need a way to audit the usual and customary prices paid by the community. In some countries, a government agency or advocacy organization regularly surveys medicine price information from private pharmacies. The MBP may want to do its own price surveys, for example by using "mystery shoppers" that go to the outlets with prescriptions to determine what prices are being charged.

Components of payment terms

As discussed in Section II, the basic models for determining allowable sales prices for medicines can be based on markup or set for each medicine with variations based on reference pricing. Some plans receive a rebate from the manufacturer or from a contract PBM for part of the medicine price.

The basic components of payment terms for pharmacy services are as follows—

- Cost of the medicine (ingredient cost) in cost-based reimbursement or the established sales price in reference pricing and similar systems
- Dispensing fee
- Fee for additional professional services, such as medication therapy management or disease management programs
- Sales tax or value added tax, if applicable

If the MBP is being designed and implemented in a country with government-mandated price regulations, then its policy on reimbursement to providers will need to comply with those regulations. If there are no government regulations, the MBP will need to develop its own policies. This is discussed in the section on contracting with service providers.

Reimbursement under managed market entry and reference pricing systems

In many high-income countries, managed market entry, often combined with reference pricing, sets the official price for reimbursement for ingredient costs. Australia, Canada, and most of Europe manage the entry of new medicines into reimbursement programs. Annex 5 summarizes a useful review of the various managed market entry programs in Europe.[42]

Reference pricing

A review found that many high- and middle-income countries had adopted reference pricing for medicines in one form or another, including Australia, Germany, the Netherlands, New Zealand, South Africa, Spain, Taiwan, and regionally in Canada.[43] Others found that only a few low-income countries' medicines benefit plans used generic reference pricing, but they cited Kyrgyzstan as a successful example.[44]

The two overall categories of reference pricing are internal reference pricing, based on the range of prices in the national market and external reference pricing, which may be based on average international prices from different references.[45] Some countries may be able to access information from programs such as the WHO/Health Action International Project on Medicine Prices and Availability, which compiles pricing data from multiple countries. MSH publishes the *International Drug Price Indicator Guide* each year, which can help the MBP determine how local market prices from manufacturers and wholesalers compare with prices available internationally; however, that source would be unsuitable for setting the cost basis for payment in a particular country.

There are also two approaches to applying reference prices—generic and therapeutic—and some programs use both. With generic reference pricing, the reference price pertains only to generically equivalent products. In therapeutic reference pricing, the reference price pertains to all products in a specific therapeutic class, whether generic or branded (e.g., proton pump inhibitors, histamine 2 antagonists, statins).

Reference pricing and its variations establish a set reimbursement or sales price for a medicine based on market price information on all versions of that product that are available. The reference price may be based on prices that are available in the local market or on a

basket of prices for the same product in comparable countries. The reference price is usually set below the highest priced product in the markets being considered, but may not be set at the lowest price. For example, in some European countries, the reference price is set at a level just above the lowest third of market prices for the targeted group of products. Once a government or an MBP establishes a generic reference price system, the payer pays the pharmacy provider only the reference price for that generic medicine, no matter which brand of the generic product is dispensed. In the therapeutic reference price system, only the reference price for that therapeutic category of products is paid, no matter which generic or branded medicine in that category is dispensed. This provides an incentive to prescribers and patients to choose a low-cost generic medicine or one in the therapeutic category that is priced at or below the reference price; in many cases, this therapeutic reference pricing means switching the treatment regimen from one chemical entity to another.

Single-exit pricing

South Africa has implemented a variation called the single exit pricing system. In this system, the government establishes the allowable price for each level of the supply chain using a method similar to reference pricing. The manufacturer's single exit price is the same for all providers and all purchasers. Wholesalers and distributors are eligible to negotiate for logistics fees, and dispensers are allowed to add a dispensing fee up to a maximum that applies to all providers.

Maximum allowable cost

In the absence of a government-mandated reference pricing system, the MBP may wish to set its own standard reimbursement prices by determining average medicine prices in the national market, at least for high-volume products. An approach that some US benefit plans use for paying ingredient costs for generically equivalent products is maximum allowable cost, which bases the payment rate on either the lowest-priced generic product available for a particular medicine or on an average price of all generic equivalents in the market (with maximum allowable cost pricing in benefit plans usually based on government-established limits). This approach is closely akin to reference pricing.

When a government or MBP adopts either a maximum allowable cost or reference pricing, there is no question about paying for ingredient costs for products covered by the mandate. The pharmacy provider will be paid for ingredient costs at the maximum allowable cost level or the reference price for that generic medicine or the reference price for that therapeutic category.

Cost-based reimbursement

These systems are based on the acquisition cost to the dispensing provider. That cost can be difficult for the pharmacy to calculate if they purchase from different sources and in different package sizes.

In some settings, an estimated average ingredient cost (with or without standard percentage discounts or markups) will be used as the cost basis for reimbursement; for example, in the United States, the published average wholesale price has long been used as a standard cost basis for medicines, even though it is an artificial price that no pharmacy actually pays. Newer variations in the United States include average sale price, based on information submitted by suppliers to the federal government, and average manufacturer price, based on all manufacturers' list prices for medicines as reported to the government. Again, few pharmacies actually pay any of these prices because of discounts and rebates offered by manufacturers and wholesalers, negotiated discounts, and rebates in cost-based reimbursement.

In the absence of maximum allowable cost, reference pricing, or

government-mandated pricing such as the single exit price, once the cost basis for payment of ingredient costs is established, the question is whether any discounts or markups can and should be incorporated into the contract terms. When pricing is based on an artificial price, such as the average wholesale price, the contract terms will usually state "average wholesale price less x%," because pharmacies rarely if ever pay that much to suppliers. For other types of averaged prices or government-established prices, the contract may stipulate payment of the average or government list price plus a fee, and in some situations, a percentage markup may be allowed on the actual or estimated cost. This markup can be important in environments where inflation in the pharmaceutical market is significant, so that the pharmacy can continually replenish stock. The problem with percentage-based markups is that the dispenser has an incentive to sell higher-cost products. In some plans, a higher percentage markup is allowed for low-cost generic medicines than for higher-priced medicines.

The MBP may be in a strong position to negotiate discounts if many providers are competing for access to a restricted provider network. The MBP may also be able to negotiate discounts on both medicine prices and fees. This is less likely to work in the open network model, but discounts could be possible if the MBP has the political power to make them a standard term in all contracts.

Manufacturer rebates

In the United States, manufacturer rebates are widely applied to reduce net medicine costs. Rebates, which are partial refunds from the manufacturer, may go directly to the benefit plan or to the PBM. A PBM contract should require that it shares the rebate with the benefit plan. Rebate levels may be regulated for government-funded programs, such as Medicaid and Medicare in the United States, or through direct negotiation with suppliers, which commercial pharmacy benefits companies now usually manage. The main concern with rebate systems is transparency—whether suppliers accurately report the average actual prices on which rebates are based and the utilization and the benefit plan itself receives the advantage of the rebates.

Dispensing fees

Prices for standard pharmacist services, such as dispensing fees, may be established through government laws and regulations or through negotiation between payers such as insurance plans and service providers. The dispensing fee is usually a standard amount for all prescriptions, or it may be tiered, for example, adjusted higher for lower-cost generic medicines. The plan may negotiate with the national pharmacy association or with individual pharmacies or pharmacy chains for the fee. In cases where the government does not establish a statutory fee level, large payers such as benefit plans may negotiate a discount on those fees in exchange for the business. As is the case with discounts on ingredient costs, such negotiations are most likely to produce results in a closed rather than open provider network.

Fees for additional professional services

Where benefit plans have been operating for many years, some reimburse pharmacists for additional services. One such service is called medication therapy management, where the pharmacist intervenes with patients or prescribers to address a problem identified through drug regimen review or DUR. Other examples might be administering vaccinations or managing the patient's chronic drug regimen. If laws permit and pharmacists have the training, capacity, and willingness to provide these services, the MBP could negotiate a fee, perhaps based on advice from the applicable professional associations.

Taxes

The last component of the fee-for-service payment is reimbursement for taxes.

Many countries have eliminated sales or value added taxes on medicines, but if taxes do apply in the country, they will need to be reimbursed to the provider as part of the payment terms. WHO has recommended that countries remove taxes on essential medicines to promote equitable access to medicines, but not all countries have taken this step.

World Health Organization recommendations

WHO's 2013 guidelines on pharmaceutical pricing policies make recommendations that will likely influence country-level policies and regulations. In summary, the basic WHO findings and recommendations include the following—

- Regulating markups can control excessive prices and promote use of cost-effective medicines, if the regulations fit the country context and if compliance is reliably monitored and enforced. But lack of transparency and other unintended consequences are concerns.
- Cost-plus price regulation is not generally recommended due to the difficulty in obtaining accurate and reliable cost data and the potential for suppliers to manipulate the system.
- Countries should consider exempting essential medicines from taxes and assuring that savings are passed to patients or purchasers.
- Countries should consider external reference pricing in combination with other methods for setting allowable prices, making sure to use appropriate comparator data. (Note that the international pharmaceutical industry contends that this strategy adversely affects tiered pricing strategies.)
- Promoting the uptake and use of high-quality, low-priced generics is a critical price control strategy, which may require changes to laws and regulations.
- Countries should move toward health technology assessment, which is a formal process to evaluate the properties, effects, and impact of health technologies including medicines, to help decide which new medicines to include on essential medicines lists and reimbursement lists for benefit programs.
- More research is needed on several issues, including the role of rebates in price control.

See chapter on Pharmaceutical Pricing Policy in MDS-3.

Capitation and case-bundled payment for outpatient pharmacy services

Capitation and bundled payments are alternatives to the fee-for-service approach.

Case-bundled payments are best known in the form of diagnostic-related group reimbursements, whereby a provider receives a fixed amount for each episode of a certain disease or medical condition that he or she treats, no matter which treatments and medicines are provided. It is most common in the hospital setting and is discussed later in that section.

Capitation involves risk sharing between the MBP, which makes the payments, and the PBM or medical/pharmacy provider. Instead of paying ingredient costs plus fee for each prescription dispensed, the plan negotiates a fixed fee to be paid to the pharmacy that covers all products and services provided to plan members who use the pharmacy, hospital, or clinic. One version is a contract that provides a fee paid in advance based on a per-member per-month amount. This is coupled with a requirement that members use a designated pharmacy provider. These average out over the months when the assigned members use few or inexpensive medicines, with the months when utilization is heavy

or more expensive medicines are prescribed. Under capitation, the pharmacist or other provider has an incentive to dispense the least-expensive products, which can be good or bad, and also to limit or deny needed medicines if they exceed capitation budgets. Therefore, it is critically important that the MBP is able to capture and analyze utilization data to assure that beneficiaries are receiving the level of services and the medicines they need.

The capitation model has fallen out of favor for outpatient medicine benefits in the United States, primarily because plan sponsors did not find significant decreases in overall costs, and changes in Medicare made it less attractive for PBMs; however, some newer and more complicated risk-sharing models have emerged. One example is a contract between a PBM and a benefit plan based on an annual cost per member for ingredient costs. If at the end of the year the total medicine costs per member are lower than the target, the PBM and the MBP share the savings, but if the annual per member costs are higher than the target, the PBM must pay half of the difference. A monitoring system needs to ensure that member access and service quality are not compromised by the PBM's efforts to stay under the target.

In many LMICs that have limited availability of data on utilization and morbidity patterns, it may be difficult for either the MBP or the contract provider to accurately project demand for medicines over a capitated population, and providers may also be unwilling to take the risks involved with capitation. Moreover, the limited availability of utilization data makes it hard to ensure that beneficiaries receive optimal care. While fee-for-service models incentivize overuse of medicines, capitation has the opposite effect—incentivizing providers to underuse medicines—both of which result in suboptimal care.

Reimbursements for inpatient medicines

As mentioned, the main consideration in paying for inpatient medicines is whether the medicine charges are included in the total patient bill for the hospital stay (bundled billing) or whether they are listed as separate line items with a charge for each dose administered (unbundled billing).

Bundled charges for medicines are the most common when inpatient medicines are covered under the medical benefit rather than the pharmacy benefit, and

THE UNIVERSAL COVERAGE SCHEME IN THAILAND

Some LMIC benefit programs are working with alternatives to fee-for-service models in their medicines benefit plans. One example is the universal coverage scheme in Thailand, which implements outpatient capitation contracts with a closed network of registered providers and assigns beneficiaries to a designated provider.[46] The scheme reported a significant decrease in per capita expenditures compare to the civil service medical benefit scheme, which continued using a fee-for-service model; in 2011, the expenditures per capita were 3.8 times those of the UHC scheme. However, the UHC scheme underprovided some necessary but costly services under capitation, and subsequently, some of those services and medicines were removed from capitation and paid on a fee-for-service basis.

Other countries in Southeast Asia are supposedly exploring capitation and related models in government-sponsored MBPs. It will be instructive to see how well these programs can capture utilization data to monitor levels and quality of services and how sustainable these models prove to be over time.[47]

when the basis for inpatient reimbursement is a single fixed payment for a patient's hospital stay. This payment may be based on diagnostic-related groups, fixed-rate per diem payments (a form of capitation), fixed rates established by a government for specific diseases or conditions, or disease-based reference pricing.

Of course, when the patient needs expensive medicines, hospitals may want to charge for them separately or insist on separate charges or higher bundled rates. When the hospital reimbursement rate is based on individual charges for each procedure, medicines are billed separately. Generally, bundled billing will lower inpatient medicine costs; bundling gives the hospital the incentive to administer the most cost-effective medicines to treat the patient's particular health problem. Likewise, the incentive to minimize the use of medicines could lead to the patient not receiving more effective, but higher-cost therapy or not receiving the needed medication at all.

Hospitals usually prefer to charge for medicines based on cost plus a markup, with a minimum fixed price set for doses of inexpensive medicines. Whenever a markup is allowed, the incentive is to prescribe and administer more and higher-cost medicines. If the MBP has leverage, it may be able to insist on no markup over cost or use a form of reference pricing to set the payment rate for different medicines (see discussion of pricing options for outpatient medicines). But some incentive for over-prescribing will remain.

Bundled billing does make it more difficult for the MBP to access the data on which medicines are being prescribed and administered, therefore limiting its capacity to monitor the utilization of inpatient medicines and confirm that patients are receiving appropriate therapy.

III.G. MEDICINE SELECTION: FORMULARIES, TREATMENT GUIDELINES, AND SUBSTITUTIONS

The MBP's formulary includes the medicines that it approves for prescribing and dispensing to beneficiaries and for payment or reimbursement. The American Academy of Managed Care Pharmacy defines the formulary list as follows:[48]

"A drug formulary or preferred drug list is a continually updated list of medications and related products supported by current evidence-based medicine and the judgment of physicians, pharmacists and other experts in the diagnosis and treatment of disease and preservation of health. The primary purpose of the formulary is to encourage the use of safe, effective and most affordable medications."

Designing a Formulary System

One of the critical aspects of the MBP benefit design and management system is determining which medicines the plan will pay for (called a positive list). Most MBPs also have a list of medicines and therapeutic medicine categories that are excluded from eligibility for payment by the MBP (negative list). Many plans provide exceptions for specific patients, requiring specific authorization from the MBP.

Typical categories of medicines that are excluded from the medicines benefit include—

- Most over-the-counter (non-prescription) medicines

- Medicines to treat sexual dysfunction and hair loss
- Infertility treatment
- Medicines to promote weight loss or gain
- Anti-smoking medicines
- Medicines to treat alcoholism or drug addiction
- Soaps, shampoos, and sunscreen or tanning preparations
- Dietary supplements
- Herbal medicines and other traditional medicines

Formulary lists are either open or closed. The basic open formulary options for an MBP are an unlimited open formulary list and a tiered open formulary list (or preferred medicine list). The unlimited open formulary list can include any medicine registered in the country for some level of payment coverage, unless the medicine or the category of medicines is expressly excluded in the plan design. As new medicines are registered, they automatically become eligible for coverage unless they are in an excluded therapeutic category. On a tiered open formulary list, any non-excluded medicine is still eligible for payment, but the amount reimbursed may be lower or the cost-share higher than for preferred medicines in the same therapeutic category. Some plans may require prior approval for nonpreferred medicines before they are eligible for payment. Tiered formularies are discussed further in the next section.

A closed formulary list is a specific list of medicines that are eligible for payment by the MBP. Many LMIC benefit plans use a national essential medicines list as the basis for a closed formulary list, although they may add supplemental medicines. MDS-3 describes approaches for developing and maintaining essential medicine lists and formularies.

An MBP's closed formulary list may limit the number of different medicines listed in most therapeutic categories, or it may be unlimited, with no explicit restrictions on therapeutic duplication. Criteria for adding new medicines to the closed formulary list may be strict and may require that if a new medicine is added when other therapeutic alternatives exist, an older medicine must be taken off the list. For unlimited closed lists, the primary criterion for adding a new medicine is whether it adds clinical value or offers a cost-effective alternative to other drugs in the category. In some closed formulary plans, medicines not on the list are not eligible for payment under any condition; some plans allow coverage of unlisted medicines with prior approval, although they may be subject to higher cost share.

Open unlimited formularies are popular with pharmaceutical companies, physicians, and beneficiaries, but they are generally much more expensive for the MBP. Advocates of open formularies argue that closed formularies deny access to optimal individualized treatment and unnecessarily restrict choices available to prescribers and beneficiaries. Some studies (often sponsored by the pharmaceutical industry) have suggested that some patients suffer adversely and that other expenditures, such as hospitalizations, increase when closed limited formularies are too restrictive.

Closed formulary lists can significantly reduce overall medicine costs for the health system or benefit plan without reducing the quality of patient care and therapeutic effectiveness. This is only true, however, when clinically qualified staff and committees carefully select and regularly review the medicines on the closed list and that exceptions are allowed when an individual patient really needs a medicine that is not on the list. An MBP should consider changing from an open to a closed formulary list if it is struggling financially.

Closed limited formularies help reduce MBP medicine costs in several ways—

- Many manufacturers will offer significant pricing discounts or more aggressive rebates to place their medicine on the formulary list.
- If the formulary is effectively managed and enforced, beneficiaries should have access to the most cost-effective medicines in the various therapeutic categories.
- If the MBP is dispensing medicines through in-house pharmacies, procurement expenditures decrease because manufacturers compete for formulary status, and inventory holding costs come down because the pharmacies do not need to stock as many medicines.

An MBP that pays for medicines with an open unlimited formulary list may find it instructive to analyze the costs of medicine in high use and high-expenditure therapeutic categories and determine its savings if only the most cost-effective alternatives in those categories were prescribed and dispensed. An example of how to conduct this therapeutic category analysis is available.[50]

» See chapter on Managing Medicine Selection in MDS-3.

A 2005 study from the Kaiser Family Foundation[49] reports that the US Veterans Administration was able to save $100 million over two years by closing selected therapeutic categories. When a class of drugs was closed, 85–97% of prescriptions dispensed went to the on-formulary medicine, compared to 23% of the preferred drug in another class of drugs that was not closed.

Selecting Medicines for the Formulary List

As discussed in the earlier section on administration and management, MBPs that maintain a formulary list should have a pharmacy and therapeutics committee to select medicines for the list, review new medicines and new therapeutic guidelines, and update the list accordingly.

The MBP's medical director or chief pharmacist usually chairs the PTC, and members should include qualified physicians and pharmacists from the academic community as well as some who are full-time practitioners. Ideally the committee should have members with expertise in pharmacoeconomics or access to consultants to assess the merits and costs of formulary medicines objectively.

The PTC's role will not usually require full-time effort, but the committee must meet regularly to carry out its responsibilities. Specialists should be invited to comment on medicines relevant to their specialty if they are not formal committee members. PRC members should be free from conflict of interest, and in cases where there might appear to be a potential conflict, such as a physician who is participating in a clinical trial of a new medicine proposed for the formulary list, the potential conflict of interest should be declared and managed (e.g., recusal from discussions and decisions where the conflict of interest applies).

The PTC should develop formal written criteria for selecting medicines for the formulary list. General questions include—

- Is the medicine clearly indicated to treat diseases that are within the MBP's scope?
- Is the medicine safe when used as directed and effective to treat the target diseases or health indications for which it is intended?
- What are the side effects, interactions, and dangers with the medicine? How frequently do they occur?
- Are other medicines equally or more safe and effective for the target

indications? What therapeutic value does this medicine add compared with other medicines in the same therapeutic category?

- Is the medicine included or under consideration for inclusion in relevant STGs?
- Is the medicine cost-effective for the target indications? How does the cost per treatment course compare with alternative medicines in the therapeutic category?
- What are the short- and long-term costs of listing the medicine? Will changes in STGs and education for providers and beneficiaries be required? What will be the impact on the MBP's total medicine expenditure if the new medicine replaces an older medicine in standard use, both in terms of medicine costs and the costs of informing providers and introducing the new medicine into practice?

As noted, a country's national essential medicines list or equivalent would be a logical starting point for the MBP's formulary list, with additional medicines added to treat health problems beyond the scope of the essential medicines list but within the MBP's scope.

Although cost-effectiveness and cost impact are strong considerations when deciding which medicines to include on the formulary list, controlling costs should not be the only goal. Instead, the PTC should work to assure that beneficiaries receive the most appropriate medicines that are safe and effective to treat their health needs, while maintaining the MBP's financial health.

Proposals for adding a new medicine to the formulary list may come from members of the committee itself, from medical or pharmacy providers who serve beneficiaries, or directly from manufacturers. Formulary decisions will be much easier if the information on medicines proposed for inclusion are presented in a standard format. In some PTCs, the chief pharmacist prepares the data for review; in others, the manufacturer presents the required information. The Academy of Managed Care Pharmacy has developed a standard format for submitting data for the PTC to review, which can be downloaded from their website.[51] A good review of the role and function of the PTC in an MBP is found in Navarro et al.[52] In addition, MDS-3 has practical guidelines for developing STGs and formularies and managing the medicine selection process.

See chapter on Selection in MDS-3.

The Role of Standard Treatment Guidelines

Some MBPs around the world use STGs to guide to medical practitioners on the recommended approach to treating specific diseases and health conditions. At a basic level, the STGs may designate first-line and second-line therapies. In other settings, the guidelines may advocate a stepped therapy algorithm, starting with one or two potential medicine regimens that will most cost-effectively treat most patients and that have the most favorable efficacy profile versus side effects and toxicity. If the first regimen fails, the provider moves to a second, and if that fails, to a third regimen, and so on.

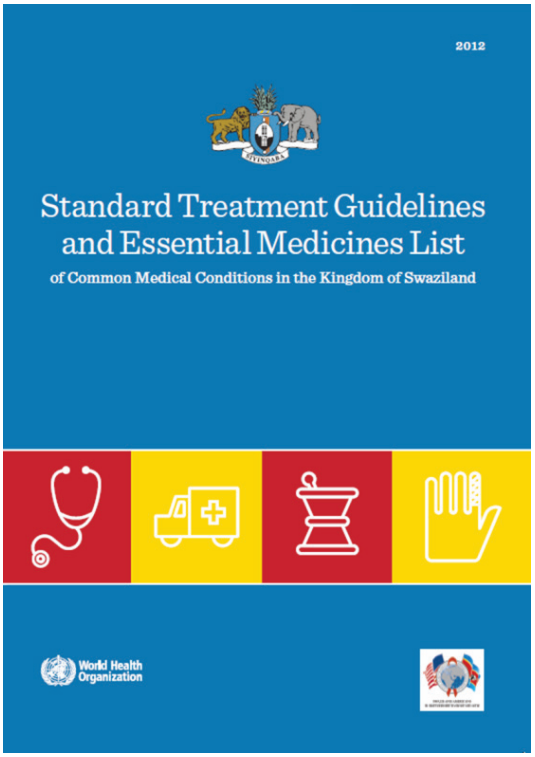
As is the case for formulary lists, the STGs serve a dual purpose: 1) to standardize treatment of common diseases to ensure that beneficiaries receive optimal therapy based on the most current state of medical knowledge, and 2) to control medicine costs by encouraging prescribers to focus on the most cost-effective regimens. When appropriately developed, updated, and enforced, STGs can improve health outcomes while reducing total medicine costs.

Although beyond the reach of MBPs in most LMIC settings, the MBP can

develop its own STGs based on international guidelines, such as those from WHO, or on national guidelines developed by professional organizations in coordination with the ministry of health. Or the MBP can develop them in-house, in consultation with the PTC or special committees of qualified medical academics and practitioners. If the MBP does develop in-house STGs, they should be harmonized with international and national guidelines.[53]

The different types of in-house STGs include—

- Individual STGs for health problems such as malaria, HIV/AIDS, or hypertension.
- Packaged guidelines that cover a set of common diseases affecting certain groups, such as maternal and child health, which might include pre- and postnatal care, immunization, diarrheal disease, acute respiratory illness, and malaria.
- Comprehensive guidelines that might cover 50–100 commonly encountered health problems.



Clearly the more health problems the STGs cover, the higher the potential impact on rationalizing treatment and reducing medicine costs—assuming use of the STGs is encouraged and monitored. But as the number of guidelines grows, so does the effort and cost required to regularly review and update them. In benefit plans that have both formulary lists and STGs, medicines recommended in the STGs must align with the formulary lists, and STGs should be updated to reflect changes in the formulary list.

Linking STGs directly to MBP coverage and reimbursement has inherent challenges. For instance, if the MBP obtains services from private as well as public sector providers, then private sector providers need to be involved in the development of the STGs to ensure their buy-in and acceptance of the guidelines. In addition, many health systems link STGs to the minimum benefit package and emphasize using only the most cost-effective medicines. Private providers' commitment to the MBP will probably be higher if avenues to access more expensive alternatives are available. In Ghana, for example, the national health insurance formulary list, which was based on the STGs, was expanded to address private sector interests and increase participation by providers and potential plan participants. As discussed, if a formulary list is more extensive, mechanisms such as tiered co-payments and prior approval can encourage use of the most cost-effective products. The goal should be to avoid the perception or reality of having separate standards of care for wealthy and poor beneficiaries.

When considering a change in plan STGs, there are several questions to consider—

- Is the new medicine regimen readily available to in-house and provider pharmacies? This must be confirmed before revising the STGs and formulary list.
- For in-house pharmacies, what is the

impact on inventories of medicines that are being replaced in the STGs?

- What is the impact on medicine costs for the MBP? Is the revised regimen affordable to treat all beneficiaries who need it?
- What is the impact on affordability for patients? Will cost share be affected?
- How will prescribers react? Will there be an immediate change in prescribing or will adaptation be slower? Will there be significant resistance? How will that affect the market?
- How will beneficiaries react? Will there be significant differences in medicine form or their treatment experience?
- What communications and educational activities will be required to transition to the revised STGs? Those activities and materials need to be developed and rolled out before a final change is made effective.

See chapter on Treatment Guidelines and Formulary Manuals in MDS-3.

Generic Substitution Policies

Along with effective formulary management, generic substitution policies can have a major impact on MBP medicine costs. Generic medicines are products that have been certified by the national drug regulatory authority as being equivalent to a brand-name medicine in safety, purity, strength, and effectiveness. In most markets, once generic equivalent medicines are approved, they are much less expensive than the branded product. However, "branded generics," which are generic medicines marketed with a company's brand name, may be marketed beside the generics with the International Nonproprietary Name (INN). Branded generics are typically more expensive than those marketed under the INN, unless a national law or regulation, such as South Africa's single-exit pricing policy, limits the price for all versions of the generic medicine.

Assuming it is legal under national or state laws and regulations, MBP generic substitution policies can mandate that the pharmacist or dispenser substitute a generically equivalent product for a prescribed brand name product whenever it is available. Policies may further require dispensing the lowest priced generic available. However, this sort of policy needs to consider the challenges of guaranteeing product quality in the market; reimbursing only the lowest-priced generic product may lead to dispensing inferior quality products in countries where the regulatory authorities cannot control the quality of all medicines that are marketed.

In some MBPs, if the branded product is prescribed, the patient must be offered the choice of a lower priced generic, and if the patient insists on the branded product, he or she is responsible for the cost difference. In many settings, the prescriber may specify "dispense as written" on the prescription for a brand name, which prevents automatic generic substitution, but the MBP can require that the dispenser contact the physician and explain the price difference, requesting authority to substitute. The MBP may also require prior approval before a brand name product is dispensed when a generic equivalent is available.

The MBP's PTC should determine whether some medicines should not be subject to mandatory generic substitution. These exceptions might include some medicines with a narrow therapeutic window that have known potential for lack of bioequivalence, such as some medicines for epilepsy, some medicines that are manufactured as modified release formulations, or some medicines that have multiple medicines in the same tablet or capsule.

As noted, some LMICs may not have the capacity to ensure that all generic

products in the market meet safety, purity, strength, and effectiveness standards. Similarly, there may be questions as to whether all medicine manufacturers and distributors in the country adhere to international standards for Good Manufacturing Practices and Good Distribution Practices, which involves proper storage and shipping as well as tracking the product's chain of custody from manufacturer to end user. Falsified medicines may also circulate in the market.

In a country where substandard and falsified medicines are perceived as a significant problem, prescribers and beneficiaries will be more resistant to mandatory generic substitution policies. The MBP can take some measures to promote confidence in generic medicines, such as specifying in contracts with manufacturers, distributors, and pharmacy providers that all medicines sold to the MBP and dispensed to beneficiaries must meet specified quality standards. It may be feasible in some settings to specify that medicines must come from manufacturing plants that are WHO prequalified or certified by a stringent regulatory authority. Although specifying quality standards is necessary, it may not be sufficient. The MBP should also encourage active prescriber and dispenser participation in national pharmacovigilance and problem-product reporting programs.

Because generic medicines are so important to controlling costs, and some national regulatory authorities lack the capacity to effectively control the quality of medicines in their markets, large MBPs may consider developing parallel pharmacovigilance and quality testing programs in collaboration with the regulatory authorities and national or regional testing laboratories. Some of the larger social insurance programs, particularly in Latin America, have in-house laboratories to test medicines and other health products. Some LMICs have implemented medicine product screening programs by using thin-layer chromatography, which is a quick way to detect fake or substandard medicines.[54] An MBP could explore the use of this technology where medicine quality is suspect.

Therapeutic Substitution Policies

Where therapeutic substitution is allowed by law and mandated by MBP policy, the pharmacist or dispenser will be authorized or directed to substitute a preferred medicine on the formulary list that provides equivalent therapeutic benefits. For example, if the MBP, PTC, or STG names captopril as the most cost-effective angiotensin-converting-enzyme (ACE) inhibitor for hypertension, a beneficiary's new prescription for a different ACE inhibitor, such as enalapril, would prompt the pharmacy provider to contact the physician and advocate a switch to captopril. In some plans, the pharmacist would make the switch without contacting the prescriber, unless the physician has included "dispense as written" on the prescription. Even then, the pharmacy provider would be required to contact the prescriber and promote a switch.

As discussed, therapeutic substitution policies will usually be more unpopular with prescribers and beneficiaries than generic substitution will be, but this policy is a standard complement to closed restricted formulary lists, because it ensures that the most cost-effective medicines are prescribed for MBP beneficiaries. The policy will be easier to implement in MBPs that provide medicines through in-house staff model facilities, but with proper incentives, they can use it with contract service providers.

Financial Incentives to Promote Adherence to Formulary and STG Policies

Tiered formulary lists and stepped care policies are two approaches that tie payment or reimbursement and cost share to generic dispensing and adherence to formulary medicines and STGs.

Tiered formularies

Tiered formularies are common in the United States, but not yet the norm elsewhere. They offer potential economic benefits, but without automated information systems, would be difficult to manage. As technology evolves, they may become more common in LMIC settings.

In a typical three-tiered formulary list, cost share amount differs depending on the tier: Tier one is for generic medicines, and the cost share is the smallest amount or percentage; the cost share is increased (often doubled) for tier two medicines, which are brand name medicines, which may be generically equivalent to a tier one medicine, or they may not be preferred choices, even if they are included on the formulary list. The third tier, with the highest cost share, is for medicines (usually brand name) that are either not on the formulary list or the preferred medicine list. Coverage for this tier often requires MBP authorization in addition to the highest cost share. In some plans with a fourth tier, the beneficiary must pay the entire cost for medicines, although the MBP may have negotiated a discount price from the manufacturer to offset the cost.

Some plans have only two tiers, one for generic medicines and one for brand-name medicines that have generic alternatives. In one variation, the plan has two tiers for generic medicines, with the lowest co-pay reserved for the lowest-price generic alternative and a second tier with a higher co-pay for higher-cost generic equivalents. The third tier is the branded medicine, with a significant increase in cost share, and the fourth tier is non-formulary medicines. Other MBPs have other four- or five-tiered designs, where the highest tiers might include lifestyle or specialty medicines, if they are covered at all.

When a prescriber writes a prescription for a tier two or three medicine, the MBP can require that the pharmacist inform the beneficiary when a generic equivalent with lower cost-share is available and let the beneficiary make the decision or require that the dispenser contact the prescriber and attempt to get the prescription changed to a lower tier alternative.

Higher tiered cost-sharing will normally reduce overall costs in the MBP because most beneficiaries will opt for the lower cost share choice. Some argue that equity suffers in this plan because poorer beneficiaries are forced to accept low-cost medicines that may not be the best choice for them; opponents may also argue that it prevents some beneficiaries from accessing needed treatment or reduces patient adherence. But tiered formularies that incentivize high use of generics with lower co-payments have been shown to increase adherence.[55]

A related option to tiering is differential fees and markups. As discussed in the section on payment for medicines to providers, the MBP may allow a higher markup percentage or a higher dispensing fee for generic medicines than for branded medicines. In this model, the dispenser has the incentive to dispense the lower-cost medicine whenever feasible. Generic and therapeutic reference pricing and related strategies will also provide incentives for dispensing lower-cost generic medicines.

Stepped care

Developed country MBPs use stepped care policies to encourage adherence to STGs. In this model, prescribers are required to start the beneficiary with the first recommended medicine from an STG to obtain payment for the service or

medicine. The MBP verifies that the patient has tried step one before authorizing payment for medicines from a second level of the STG. MBPs in the United States primarily apply this model to high-cost specialty and injectable medicines that must be administered by a medical provider, but the policy could be applied to any STG. Similar to tiered formularies, this concept is not widely applied in LMICs, but that may change as MBPs evolve.

MBPs may apply financial incentives to stepped care policies by tying cost share percentages, allowable markups, and service fees to STG adherence, with lower cost share for step one medicines compared to second or third step medicines that are prescribed first. Any such incentives must be carefully structured and monitored to insure that some beneficiaries do not lose access to needed medicines.

Other interventions

MBPs can also use a variety of behavior change and educational interventions to influence the selection of medicines by prescribers, dispensers, and beneficiaries. These are discussed in Section III.I of this manual.

III.H. MEDICINE PURCHASING STRATEGIES

Large social insurance programs that have long-standing pharmaceutical procurement systems use a combination of competitive tenders and direct negotiation to reduce the prices of medicines. Many of these programs have traditionally used in-house (staff model) facilities to provide services and medicines to their beneficiaries. Procurement management for these systems is beyond the scope of this manual, but is addressed by the procurement and tendering chapters of MDS-3.

Medicine benefit program that distribute medicines to beneficiaries through contracted service providers can negotiate payment terms for medicines purchased from those contract providers, as discussed in section III.F.

The MBP may have additional options for reducing the overall cost of medicines—by negotiating with manufacturers and suppliers of medicines for discounted pricing or rebates or by tapping into existing pooled procurement mechanisms for certain medicines. However, in many countries, only the government has the authority to negotiate prices.

» See chapter on Procurement in MDS-3.

Negotiated Pricing and Manufacturer Rebates

Pricing discounts and rebates are two different ways to reduce medicine costs through negotiation with manufacturers. Manufacturers apply discounts at the time a medicine is purchased, and provide rebates retroactively, based on use of the specific medicines covered by the rebate. Discounts are usually a specified percentage off either list price or an average price, such as wholesale acquisition cost or other standard average price that is commonly used in the country.

Pricing discounts are generally only available when the MBP or health facility takes possession of the medicines and dispenses them in-house. Rebates from manufacturers can be available to insurance programs and MBPs that provide medicines through contracts with private prescribers and dispensers. The rebate is generally a flat percentage off of the list or average price of the medicine that is refunded to the MBP based on documented use. MBPs can negotiate rebate agreements with manufacturers—in many cases a commercial PBM will have experience in both negotiating and managing rebate

contracts and may have existing rebate agreements with multiple manufacturers.

In countries where large MBPs are well established, these entities may negotiate discount pricing from manufacturers below even standard government pricing or negotiate higher rebates than those that law or regulation mandate. A recent study reported on discounts and rebates achieved in the hospital setting in five European countries.[56] A 2011 study of health insurance programs in LMICs, however, found that relatively few were trying to negotiate for discount pricing or rebates.[57] Every MBP, at a minimum, should negotiate to reduce medicine costs.

The negotiation of discount prices and rebates is closely tied to the formulary management process. Manufacturers will be more eager to offer deep discounts and significant rebates when they are competing to list their products on a closed restricted formulary, but many will still offer discounted pricing or rebates to get preferred status on an open formulary list.

The manufacturer may wish to tie the rebate percentage to market share or the percentage of prescriptions for their product compared to competing medicines in the same therapeutic category by offering higher rebate percentages with increasing market share. In some cases, the MBP and the manufacturer may enter into a volume purchasing agreement where the MBP is eligible for rebates, if certain market goals are reached.

Assuming that medicines dispensed are itemized on claims, MBPs can periodically analyze claim data (e.g., quarterly) to support market share agreements with the manufacturer. Amounts owed can be recorded in the MBP's accounts receivable system and serve as another source of revenue to offset the overall cost of medicines.

The following information is often included in manufacturer contract reporting to benefit programs in OECD countries—

Invoice information

- Manufacturer identifier (must be unique)
- MBP identifier (must be unique)
- Reporting period (e.g., October 1, 2013–December 31, 2013)

Detail information (multiple occurrences)

- Therapeutic classification
- Medicine identifier (must be unique)
- Total prescriptions filled
- Total quantity filled
- Total medicine cost

In most LMIC programs, the manufacturers/suppliers do not typically report sales information to benefit programs. However, they know the quantities and value of government procurements and sales to pharmacies and depend on market surveys to determine their relative market share.

If the MBP wants to negotiate direct rebates with manufacturers, it will need to have staff or consultants with the necessary expertise to manage the negotiating and contracting process. Some countries may have a commercial PBM firm available to manage the negotiations on behalf of the MBP on a short-term consulting contract, although as discussed, this is rare in LMICs. If the MBP does contract with a PBM to manage all or part of the program, part of that contract should address the negotiation of rebates and discounts and ensure that the MBP receives the benefits from the rebates. It is not uncommon for rebates to be shared between the PBM managing the contract and the MBP sponsor; the contract should state the percentage split, along with a requirement of transparency for disclosing all rebates received.

Navarro et al. provides a thorough description of the process for negotiating discount and rebate contracts.[58]

Pooled Procurement

Pooled procurement, also known as group purchasing, is a mechanism whereby member institutions pool their procurement volumes and negotiate tenders on behalf of all members, thereby reducing medicine prices for all. Like negotiated discounts, this mechanism primarily is available to MBPs that purchase, store, prescribe, and dispense medicines through in-house facilities and staff.

A number of global pooled procurement mechanisms negotiate for discounted prices and purchase medicines for LMIC health systems. Most of these mechanisms would not be accessible to MBPs directly; however, a socially focused MBP might be eligible, for example, if it were designated as a Principal Recipient or a Sub-recipient on a Global Fund grant. In some countries, forming a pooled procurement system with the public sector or with other individual MBPs may be feasible. Pooled procurement and the requirements to manage it successfully are discussed in MDS-3's procurement chapter.

For MBPs that provide medicines through provider contracts, two or more independent MBPs should be able to negotiate rebates that apply to the whole group. If a PBM company is administering the medicine benefit for multiple MBP sponsors, this pooled negotiation would definitely be feasible, assuming the various MBPs harmonize their formulary policies.

The Affordable Medicines Facility for malaria, hosted by the Global Fund, is not exactly a pooled procurement scheme, but rather a buyer co-payment mechanism. In this model, the Global Fund pays the manufacturer for most of the costs of artemisinin-based combination therapy medicines, which are then distributed at deeply discounted prices to public and private sector outlets in selected LMICs, under the assumption that the discounted prices will be passed to consumers. MBPs in participating countries could require that contract pharmacy providers access this program and pass the discounted prices along to the MBP. The first countries to use this mechanism were Cambodia, Ghana, Kenya, Madagascar, Niger, Nigeria, Tanzania/Zanzibar, and Uganda. Criticism suggests that the segments of the population that most need access to the discounted medicines do not necessarily receive them. Exploring a buyer-co-payment mechanism for other categories of medicine may be possible in the future.

» See chapter on Procurement in MDS-3.

Purchasing Options for Expensive Specialty Products and Innovative Health Technologies

Access to most specialty products (i.e., high-cost medicines requiring special handling or with limited therapeutic indications or expensive diagnostic imaging) in LMICs has mainly been limited to the wealthy. High prices and lack of financing have restricted access to specialty medicines and health technologies. International initiatives have significantly expanded access to treatment for HIV and AIDS, both through measures that reduce prices in LMICs and through major donor-supported funding for procurement and distribution. Funding for access to other categories of specialty medicines, however, has not kept pace.

Clearly, it is more difficult to achieve significant discounts or rebates for innovative single-source medicines that are therapeutically superior to alternatives, but some options exist. For select specialty products, for example, the manufacturer may provide substantial discounts or even donate products for select patient groups. In MBPs that would normally require large

co-payments for a specialty medicine or product, the manufacturer may pay the beneficiary co-payment through rebates. This helps the beneficiary, but not the MBP, who must still pay a high price.

In countries with specialty pharmacies or PBMs, these companies may be able to negotiate discounts for some specialty medicines, and contracting with one of these firms for specialty medicine services may be beneficial, assuming the discounts are passed on to the MBP.

As discussed in Section IIIF, managed market entry agreements are common in Europe and other developed economies and are becoming more prevalent in LMICs. Expensive specialty medicines are frequently a target for price negotiations before reimbursement approval under an MBP. These negotiations are often contentious and can result in litigation. The process is obviously more applicable in countries where intellectual property (i.e., patent) rights are enforced.

Several innovative risk-sharing approaches have been negotiated for specialty products. These include agreements based on conditionally reducing prices for an MBP, for example through[59]—

- Per patient caps on expenditures (UK)
- Overall annual expenditure for the medicine (France)
- Conditional treatment continuation—providing a deep discount for a set period until the short-term treatment goal is either met or not met, and then continuing treatment at a higher price (Italy)
- Reference-based pricing—an innovative drug is priced at the level of the existing medicine until a comparative trial proves the superiority of the innovative medicine
- Cost sharing—cost of initial course of therapy is discounted (Italy)

Another risk-sharing example includes reimbursement to the benefit plan if treatment fails to demonstrate specific benefits (Australia, Canada, France, Italy, and UK).[60]

An emerging option for reducing the cost of some specialty biological medicines is the advent of "biosimilars." A manufacturer designs a biosimilar to have active properties that produce the same or similar therapeutic effect to a biological product that has previously been licensed by another manufacturer, but different enough that the new product is not technically a generic equivalent. Typically, biosimilars are priced lower than the original licensed product. In some countries in Europe and Latin America, biosimilars are eligible for accelerated approval by regulatory authorities (and then for reimbursement by MBPs). Acceptance of biosimilars by MBPs, providers, and patients is tied to the level of cost savings the product offers—the deeper the discount, the more likely the biosimilar product's acceptance.

Lyles recently reviewed these issues affecting acceptability of biosimilars and commented on a study from three countries Latin America.[61]

The current reality is, however, that despite the available pricing options, the cost puts many innovative specialty medicines beyond the reach of most LMIC medicines benefit programs. As the movement toward UHC gains momentum, and as international attention focuses on managing chronic as well as acute disease, financing and targeted initiatives for specialty medicines will be needed. International discussion about tiered pricing for some specialty medicines is ongoing (e.g., most recently for hepatitis C), but whether that mechanism will benefit LMIC benefit plans in the near future is unclear. Similar to the mechanism for artemisinin-based combination therapy for malaria, donors and agencies could potentially establish a "facility" for purchasing or subsidizing discount pricing for selected specialty medicines.

III.I. INFORMATION AND EDUCATIONAL PROGRAMS

This section covers the basic requirements for information that the MBP should make available, including print materials, text/email messaging, and online portals. In addition, the MBP can use educational programs to increase the buy-in of beneficiaries and service providers, while improving their adherence to MBP policies and ultimately the benefit program's health impact.

Basic Informational Requirements

The MBP should provide print and online materials that fully describe MBP coverage and all of the policies and procedures that apply to providers and beneficiaries. Materials should complement outreach programs that target providers and consumers and explain the rationale for MBP policies and procedures, the benefits of formularies, STGs, and generic medicines, and the principles of appropriate medicine use.

Prescribers, pharmacy providers, and beneficiaries must be informed about which medicines are on formularies and preferred drug lists and the cost-share status for each medicine (if cost share varies). The lists must be updated as the master formulary list changes. If feasible, the list can include information on medicine cost, although this will require more frequent reviews and updates. Lists can be printed, online, or distributed through mobile applications, but it is the MBP's responsibility to ensure that all who need it have the information. In addition, STGs must explain the basic treatment algorithms and steps to follow; the MBP may choose to add information on the therapeutic rationale and expert sources for the recommendations, cost per course of treatment, or literature references.

Large MBPs may be justified in using the resources to develop complex formulary manuals with summary information on pharmacology, indications, contraindications, and side effects. Ready access to this information may increase the likelihood that prescribers will select the formulary medicines and use them more appropriately.

Responsibility for developing the information for stakeholders on formulary medicines and STGs may rest with the MBP's PTC if it has the capacity, or it could be contracted out to university schools of medicine or pharmacy or relevant professional associations.

Where providers and beneficiaries have Internet access, the MBP should establish and maintain a website that provides access to plan information, updated materials for providers and beneficiaries, and a mechanism for direct communication. Section III.D describes the basic contents of a typical MBP portal.

Educational Programs

In LMICs, MBPs must commit to providing a high-level of service to their sponsors and beneficiaries, but also to help advance pharmacy practice in their countries. In that role, the MBP can deliver objective clinical material to their provider and prescriber networks on the latest treatment information for diseases as well as medicine adherence information. This is particularly critical in countries where providers and prescribers have limited opportunities to stay current on industry best practices and evolving drug therapies. MBPs can use their claims experience, clinical knowledge, and communication infrastructure to deliver unbiased content to help remote providers and prescribers advance their professional development. This outreach can take a number of forms—

Rx FOR CHANGE

The Canadian Agency for Drug and Technologies in Health has a web-based database that includes reviews and analyses of interventions to improving performance of health care providers and patients (https://www.cadth.ca/rx-change). This is an excellent resource for MBP managers charged with developing and improving behavior change programs and educational initiatives for providers and beneficiaries.

- Clinical material included with claim reporting and payment information
- Webcasts to support continuing education programs (distance learning)
- Regional instructor-led training programs
- Continuing education conference calls
- Clinical or education material on the web portal
- Outreach and continuing education on STGs for prescribers

Educational outreach is an added expense, but it should be considered as a long-term investment. Effective educational outreach programs may be able to increase the use of generics and adherence to formulary lists and STGs and also boost provider and beneficiary satisfaction. The MBP's medical director should oversee educational outreach programs by ensuring that the format and content is appropriate for its audiences and that all providers and beneficiaries can access the programs.

» See chapter on Medicines and Therapeutics Information in MDS-3.

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IV MONITORING UTILIZATION AND PERFORMANCE

Perhaps the most important way for an MBP to support its financial health and sustainability is to monitor beneficiaries and providers' use and costs of services and medicines against targets and standards.

Monitoring utilization and performance is obviously much easier when automated information systems are in place. However, MBPs need to start from their existing systems and use whatever data is available to assess the effectiveness of plan designs, provider networks, and formulary adherence in delivering cost-effective and clinically relevant medicines to beneficiaries. The ability and the commitment to collect and analyze available data and take specific corrective actions based upon that analysis is crucial to an MBP's sustainability.

Equally important, MBP sponsors and program managers must monitor the MBP's own performance against targets for financial operations and for providing beneficiaries' access to services and medicines.

An article by Wagner, Quick, and Ross-Degnan proposed examples of indicators to monitor the impact of medicines policies and programs in UHC systems.[62] They include indicators in four areas—

- Availability of quality generic and innovative medicines
- Equitable access
- Appropriate use
- Affordable costs

In addition, MDS-3 describes proven indicator-based approaches for monitoring and evaluating the use of medicines that can be readily applied even in paper-based systems.

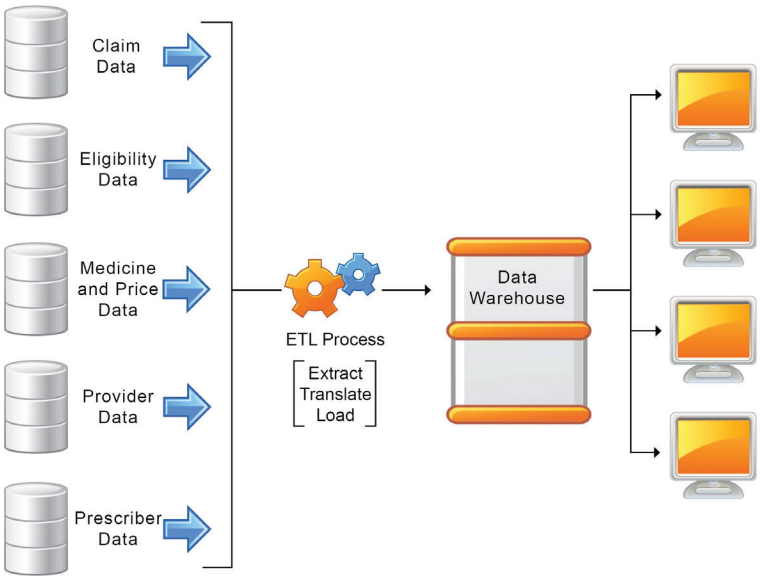
Annex 3 offers examples of monitoring and evaluation indicators and the potential source of data for the indicators.

» See chapter on Investigating Medicine Use in MDS-3.

IV.A. EXTRACTING DATA FROM CLAIMS AND DISPENSING RECORDS

When claims processing and adjudication systems are fully automated, claims data can be extracted and stored in a data warehouse to generate reports, assuming standard coding systems exist and are used by all providers submitting claims and that medicines are itemized in claims (see also Section III.B).

When the processing systems are partially or completely based on submitting and processing paper claims, more time and staff will be needed to compile data for performance reports. Claims can be scanned and converted into standard database files (again assuming standard coding is enforced and the relevant technology is accessible). Or the information from claims can be manually entered into computer programs to facilitate analysis. Although an MBP in technologically advanced countries can develop or purchase custom database programs to manage retrospective drug utilization reviews, it is possible to use a spreadsheet to carry out most of the essential analyses, such as therapeutic class analyses or ABC analyses sorted by prescriber, dispenser, beneficiary, and medicine. The spreadsheet approach is presented in detail in MDS-3.



Even if entering individual claims into a computer program for analysis is logistically or financially unmanageable, the MBP can still monitor payments to individual providers and then target high-use, high-cost providers for field audits (discussed in the next section on fraud). MBPs that have claims data available or that provide medicines through in-house facilities can also conduct DURs in the field to follow up on potential problems detected in the prospective or retrospective review of claims.

These DUR visits can be coupled with on-site education for prescribers and dispensers, so that providers do not see them only as "police" activities. This is not the ideal method for carrying out large-scale DURs, and it can be expensive given the need for clinically qualified on-site reviewers, but wealthy countries have used the method for many years, and it was the primary DUR method before systems were automated. In situations where compiling claims data for analysis is not realistic, it may be the most feasible option for a DUR.

MBPs with advanced electronic information systems can extract data from their claim adjudication data sources, reformat the data into a reporting-friendly data structure, and file it in their data warehouse. When the data is available, management, operations, and clinical personnel can assess it for decision making. This process is illustrated in the diagram at left.

MBP Data Processing

By extracting data from the claims adjudication system and storing it in a separate data warehouse, MBPs eliminate performance conflicts between the adjudication and reporting systems. In addition, the

database design of a data warehouse is often optimized for ad hoc queries and standard reporting, while the database design for the adjudication system is optimized for claims processing.

An MBP without a fully automated system must still monitor utilization of medicines and services by providers and beneficiaries and take all possible measures to detect and correct instances of inappropriate utilization and potential or actual fraud.

See chapter on Analyzing and Controlling Pharmaceutical Expenditures in MDS-3.

IV.B. STANDARD MEASUREMENTS AND REPORTS OF PERFORMANCE

Each MBP should establish indicators to help management monitor plan performance and identify areas for corrective action. Annex 3 includes a list of sample indicators with their associated data sources. MBPs normally have a package of standard reports that they source from data uploaded to the data warehouse. These reports quantify basic claim entities and data elements that show an overall picture of use that can be distributed regularly to account managers, operational staff, and business sponsors. Standard reporting packages can be developed with a variety of reporting tools.

Examples of a simple standard reporting package include—

- Average plan cost per beneficiary (by eligible beneficiaries, by utilizing beneficiaries) Top 200 products (by value and by volume of claims)
- Top 20 therapeutic classes (by value, by claims)
- Top 100 utilizing beneficiaries (by value, by claims)
- Top 100 providers (by value, by claims)
- Top 100 prescribers (by value, by claims)

A simple standard report example that identifies top products by number of prescriptions is illustrated below. These reports can focus administrative and clinical actions on areas most likely to yield the greatest benefit. Over time, trends as well as cross-sectional analyses become crucial management tools.

Ad Hoc Analysis and Reporting

Operations managers and clinical experts can use ad hoc query tools to access the MBP's data warehouse and review claims data. Graphical query tools allow staff to develop, execute, and refine complicated

TOP PRODUCTS BY NUMBER OF CLAIMS

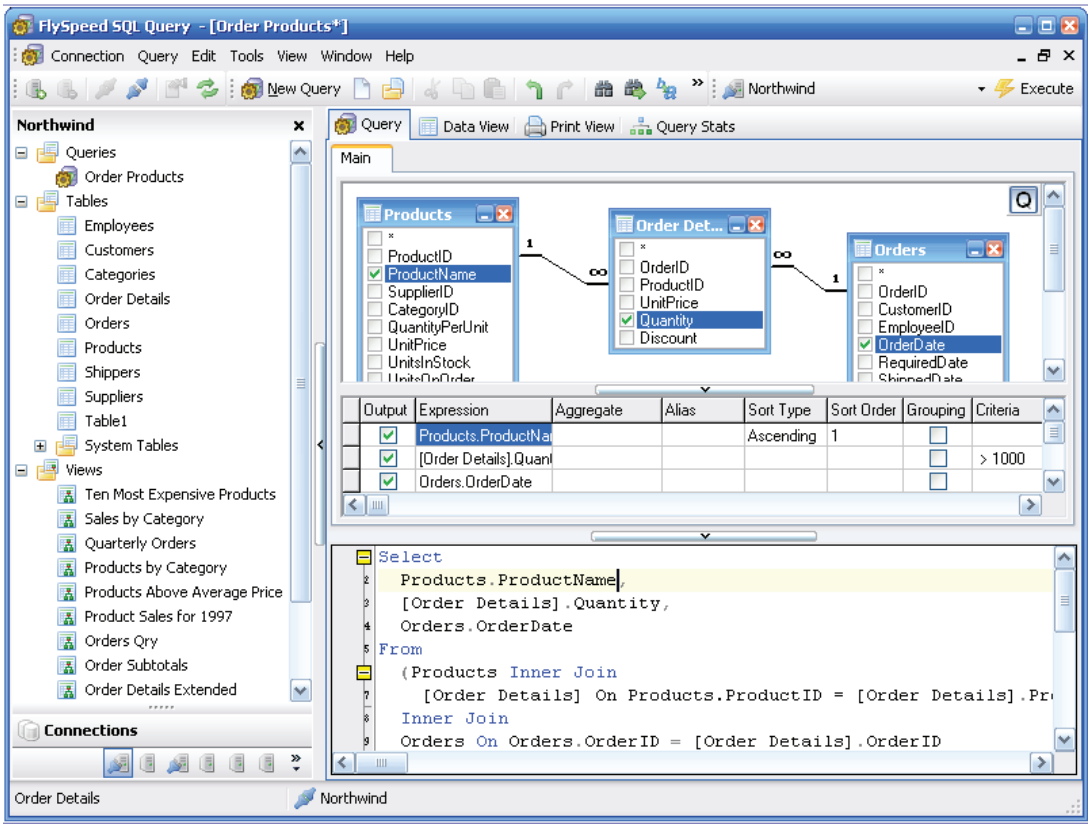
Product Name	Product ID	Claims	Plan Cost	Cost Share	Total Cost
Amoxicillin cap 250 mg	11-111111-111111	219	657.00	131.40	788.40
Lopermide 2 mg	44-444444-444444	164	738.00	147.60	885.60
Diovan tab 320 mg	22-222222-222222	139	3711.30	742.26	4453.56
Naproxen tab 250 mg	33-333333-333333	54	842.40	168.48	1010.88
Zocor tab 10 mg	55-555555-555555	28	840.00	168.00	1008.00

database queries. By using standard drag-and-drop techniques, MBP personnel can develop queries without knowledge of the data warehouse database design or the support of a technical resource person.

Many database query tools are available. The screenshot is from FlySpeed SQL Query from ActiveDBSoft (www.activedbsoft.com). The available data model entities are shown on the left side of the window, and the user drags the desired entities into the query window and applies the search criteria.

See section on Information Management in MDS-3.

Screenshot from FlySpeed SQL Query



IV.C. DRUG UTILIZATION REVIEW

As mentioned, DUR is the analysis of available data to understand, interpret, evaluate, and improve the prescribing and use of medications. DUR is important to avoid problems and detect potential problems with inappropriate medication therapy and to identify patterns of potentially inappropriate use, misuse, and fraud by providers and beneficiaries. The results of DURs are used to promote more efficient use of scarce health care resources and to improve evidence-based pharmacotherapy.

The MBP may manage the utilization review process internally or choose to contract with a PBM (if available), an academic institution, or a professional association to manage DUR programs. As discussed in the section on plan governance, the MBP should have a department or committee that determines DUR requirements and standards and reviews the results and takes action, even if it does not directly manage the DUR activities. DUR responsibility could be assigned

to the PTC or other committee or to a dedicated utilization review committee.

DUR programs do have limitations—many providers and beneficiaries resent any attempt to constrain medicine choices and see these programs as an effort to control costs rather than an effort to improve the overall quality of medicine use. Moreover, data for DUR can be hard to capture and use effectively. Compiling data to analyze is a complex process that requires the evaluation of the data quality and completeness and the validation of the information. This is a bigger challenge in settings with limited automated technology or qualified staff to manage the DUR programs.

Although DUR is costly and difficult to manage, particularly in resource- and technology-limited settings, evidence shows that every MBP should have an effective medicines utilization review program. MBPs that do not rigorously review medicine utilization are almost certainly losing significant resources to wasteful utilization and in too many cases to outright fraud.

The three DUR variations are prospective, concurrent, and retrospective.

Prospective Review

The dispenser reviews the patient's drug regimen and history before dispensing the medicine. The dispenser checks for patient and prescriber eligibility, therapeutic duplications or conflicts, contraindications or potential drug interactions, potentially inappropriate duration, dosage, or medication, and any conflicts with the MBP formulary or STG policies. The dispenser may contact the prescriber to discuss a potential problem and request a change in the prescription or contact the MBP and request an exception prior to dispensing.

Where the technology is available, the prospective DUR process uses point-of-sale technology with electronic links between the provider and the MBP. Prospective DUR can also be done with manual or automated patient profiles that the dispenser maintains, if the medicines all come from the same location or from a networked provider, who then calls the prescriber or MBP to clarify issues before dispensing the medicine.

Concurrent Review

This form of DUR takes place while medical therapy is in process. It is generally applicable in inpatient and long-term care settings, but may be used in other situations involving long-term medical therapy. This is an important component of special purpose medication management and disease management programs. The emphasis again is on reviewing the beneficiary's medication regimen and patient profile and contacting the prescriber or the MBP to correct any potentially harmful problems with policies.

Retrospective Review

This DUR process takes place after medicines have been provided. Although retrospective review can identify potential problems with a specific patient's medication regimen, because this review takes place after the patient has gotten the prescription, it may be useful for that person only to avoid similar issues in the future. The primary aim of retrospective DUR is to compile information from claims or from patient profiles and dispensing records (in the case of in-house dispensing) to monitor and analyze medicine use patterns by beneficiaries, prescribers, and pharmacy providers. Results are then fed into the standard reports described in the section on MBP performance measurement.

Some typical targets of retrospective DUR include—

EVALUATING PRESCRIBING PRACTICES IN LESOTHO FOR BETTER HEALTH OUTCOMES

In Lesotho, four of the five leading causes of death are due to infectious diseases, many of which can be prevented or treated with access to safe and effective medicines. However, irrational prescribing practices—giving a patient too many, too few, or incorrect medicines—often jeopardize patient outcomes, accelerate the occurrence of drug resistance, and limit future treatment options. To assess whether prescribing patterns were in line with national treatment guidelines, the Strengthening Pharmaceutical Systems program, funded by the US Agency for International Development, conducted a DUR by analyzing pharmacy records, health information data, and other quantitative and qualitative indicators at six hospitals in Lesotho.[63] The results indicated that on average, more medicines were prescribed to patients in Lesotho compared to comparable settings (3.8 medicines prescribed per encounter compared to 1.3–2.2 in similar settings), over 20% of medicines prescribed were not on the national essential medicines list, and only 43% of prescriptions aligned with STGs. Results from DURs, like the one conducted in Lesotho, can be used to design interventions, ensure the continued effectiveness of medicines, and improve patient outcomes.

- Monitoring adherence to formulary policy and policies on generic medicines
- Monitoring adherence to STGs and stepped care policies
- Identifying patterns of overutilization or underutilization of medicines
- Identifying instances or patterns of potentially inappropriate therapeutic choices, including incorrect dosage or duration of treatment, drug/disease contraindication, or medicine/medicine harmful interactions
- Identifying instances of potential abuse or misuse of medicines by providers and beneficiaries
- Identifying high use and high medicine cost prescribers, dispensers, and beneficiaries for further review of their utilization patterns

When the DUR identifies potential problems with utilization patterns by particular providers or beneficiaries, the MBP can target interventions to avoid future problems. Some critics of retrospective DUR have tried to show that it does not consistently result in fewer prescribing errors or reduced hospitalization rates, but retrospective review is a vital way to identify opportunities for significant reductions in medicine costs for the MBP.

» See chapter on Promoting Rational Prescribing in MDS-3.

IV.D. DETECTING POTENTIAL FRAUD AND ABUSE

Fraud and abuse are two separate issues: Fraud occurs when someone misrepresents facts related to health care services to receive or increase payments from a health plan or the government; abuse occurs when a provider or beneficiary provides or receives services or medicines that are not medically necessary.[64]

Every MBP should have a dedicated phone line allowing beneficiaries, providers, and concerned members of the public to report suspected fraud or abuse. This hot line should allow anonymous reporting by phone and by Internet/email, where feasible. In addition to active DUR, this is a critical way to detect and control fraud and abuse.

FRAUD DETECTION AND PREVENTION

Each year, approximately 7% of all health care spending is lost to fraud—the equivalent of $415 billion.[65] Health care fraud is found in every country and in every type of health benefit program. Fraudulent claims or activities increase system inefficiencies and costs while diluting the program benefits. Although investigation of possible fraud is critical to any MBP, many groups are looking to prevent fraud by designing and implementing MBPs with fraud prevention mechanisms. Countries such as Ghana, Namibia, and South Africa are moving toward mandatory photo or biometric identification to alleviate instances of identification fraud, while the United States is working to reduce improper payments through the use of electronic claims processing and tracking systems.[66] Addressing fraud before it happens through prevention measures and investigating suspected cases of fraud by conducting audits and post-treatment reviews are imperative to ensure the program's efficiency and long-term sustainability.

When suspected fraud or abuse is identified through DUR programs, the MBP needs to investigate further with an audit. One level of audit comes with prospective review, which is most applicable in point-of-sale systems, where potential fraud or abuse alerts can be built into the automatic system, problems can be detected, and dispensing blocked. However, when fraud or abuse is suspected, the MBP should exercise the contractual right to conduct detailed audits of provider records (and beneficiary records if warranted). A detailed audit includes the desk audit and the field audit.

A desk audit is reviewing all claims or prescription records for a particular provider based on suspicious patterns detected in the general utilization review process. If the desk audit identifies potential instances of fraud or abuse, the next step should be a field or on-site audit whereby an auditor (ideally with clinical qualifications) visits the provider's office or outlet. The auditor reviews prescribing and dispensing records, records documenting receipt of medicines or services by beneficiaries, and where unusually high quantities of medicines have been billed, records of procurement and receipt of medicines from manufacturers and distributors. The auditor may need to contact beneficiaries to verify that they received the services and medicines that were billed. To be most effective, the field audit should not be announced in advance to minimize the opportunity to falsify records. Where the claims data and other records do not allow a detailed desk audit for a provider (or beneficiary), the field audit may be the first step after identifying potential issues.

If fraud or abuse is evident or highly suspected based on audit evidence, the provider can be terminated from the network, or in less clear-cut cases, suspended. Providers or beneficiaries who are identified as having engaged in fraud may be reported to authorities for prosecution or compelled to reimburse the plan for the inappropriate payments.

Annex 4 provides examples of fraud and abuse drawn from the actual experiences of MBPs in the United States and other developed countries; LMICs are equally susceptible to these problems and need to implement effective utilization review programs to prevent them or detect and take action to correct any problems.

IV.E. INTERVENTIONS TO PROMOTE APPROPRIATE USE OF MEDICINES

When inappropriate medicines use by providers or beneficiaries is identified, the MBP needs to intervene to correct the problems and improve future behavior. Programs to improve medicine use by providers and beneficiaries can be grouped into three categories: financial mechanisms, interventions to change behavior, and suspension or termination of eligibility.

The Rx for Change database, mentioned in section III.I as a source of information for evaluating educational alternatives, is also an essential resource for reviewing evidence related to the value of the various interventions mentioned in this section (https://www.cadth.ca/rx-change).

Financial Mechanisms

Financial mechanisms are crucial in promoting appropriate use of medicine, both as incentives and penalties. Incentives or penalties that can be used in plans delivering medicines through contracted service providers have been covered in earlier sections.*

Interventions to Change Provider and Beneficiary Behavior

When inappropriate use is detected during the course of a DUR, educational or behavior change interventions to correct behavior by providers or beneficiaries may be an option, assuming there is no intentional fraud involved.

The educational intervention should include contacting the provider or beneficiary, explaining how their use of medicines deviates from plan policies or preferred practices, the reason the policy or preferred practice is mandated by the plan, and requesting change in future prescribing or use. It can help to compare the wrong behavior against that of peers; for example, if a prescriber is writing far more prescriptions per encounter than his or her peers, the comparison can be offered without naming the peers.

The communication regarding medicine use can be through mail, email, or phone. Some benefit plans have incorporated face-to-face interventions, whereby a clinical pharmacist or other clinically qualified practitioner visits the targeted providers or beneficiaries and combines education on best practices with personal requests to change to conform to MBP policies and guidelines. This approach is also known as counter-detailing. It is clearly more expensive than sending out messages or making calls, but evidence shows that this method is more effective in changing provider practices.[67]

Combined approaches to changing behavior involving education, financial incentives, and feedback on utilization are most likely to be effective. However, when these interventions fail, further action must follow. If policies and guidelines for medicine use are not enforced, then monitoring use is pointless. In benefit plans that deliver medicines to beneficiaries through in-house facilities, staff performance ratings, salary increases, and continued employment can be tied directly to appropriate use of medicines and compliance with MBP policies.

*See Section III.F Managing Distribution of Medicines to Beneficiaries (particularly the subsections on payment to providers) and Section III.G Medicine Selection: Formularies, Treatment Guidelines, and Substitutions).

For contract providers, a contract provision should allow for suspension or termination if the provider fails to comply with MBP policies. In most cases, the next step after an educational intervention fails would be suspension, followed by termination for a repeat offense. Immediate termination might be justifiable as a next step after education for egregious or unrepentant offenders.

As discussed, if fraud is suspected, it would be justifiable to immediately suspend the provider or beneficiary, and if fraud is confirmed, terminate the offender and report them to legal authorities or in the case of providers, to the appropriate regulatory agency.

See chapter on Promoting Rational Prescribing in MDS-3.

Monitoring and Encouraging Adherence to Treatment and Appropriate Medicines Use

WHO has defined patient adherence (formerly known as compliance) as "the extent to which a person's behavior—taking medications, following a diet and/or executing lifestyle changes—corresponds with agreed recommendations from a health care provider."[68] Failure to adhere to prescribed instructions for medicine use is a widespread phenomenon in all health care settings. Some beneficiaries do not fill their prescriptions, some do not take the medicine in the dose and frequency prescribed, and some stop when they feel better.

Poor adherence is not just a health problem for the individual—it can contribute to problems such as antimicrobial resistance and wasted money. There are many reasons for non-adherence; for example, prescribers and dispensers may not explain how to use the medicine in language that the beneficiary understands; the beneficiary may not be able to afford even the cost share and neglect to fill some or all of the prescriptions; the beneficiary may not have easy access to a dispenser. In addition, patients, particularly older and sicker people, may be unable to remember exactly how and when to take medicines, especially with complex regimens comprising multiple medicines that need to be taken at different times. The medicine may have unpleasant side effects, which seem worse than the disease. And the beneficiary may not really understand the need for the medicine, particularly when a disease does not have clear symptoms, such as high blood pressure.

Clearly, educational outreach to improve the beneficiary's understanding of the need to take medicines as prescribed and programs to improve prescriber and dispenser communication are important strategies, but they may not be sufficient.

The MBP needs to develop strategies for monitoring and improving treatment adherence when problems are detected. Monitoring individual patient adherence using methods such as pill counting can be difficult and time-consuming and those relying on patient recall have questionable accuracy. One proxy approach to monitoring adherence to antiretroviral therapy at the health-facility level was developed and validated by the International Network for the Rational Use of Drugs Initiative on Adherence to Antiretrovirals (INRUD-IAA), as the box below describes.[69,70]

Vogenberg[71] suggests potential strategies that MBPs can use to improve beneficiary adherence to treatment—

- Ensuring that all patients have reasonable access to prescribers and to dispensing outlets that have a steady medicine supply.
- Reducing economic burden through reduced or exempted cost-sharing and co-payments.
- Prescribing regimens that are less complex, such as one combination

product rather than two separate medicines or medicines that require only one daily dose as opposed to multiple doses. The MBP must weigh tradeoffs if the medicine that is easier to take is more expensive than alternatives.

- Carefully screening for adverse drug reactions, which discourage adherence.
- Involving family or community members to help patients adhere with therapy.
- Handing out weekly medication containers that remind patients when to take medicines.
- Sending voice mail/email/text messages to remind patients when they need new prescriptions or refills.
- Tying automated tracking systems to billing systems that alert the MBP when beneficiaries fail to pick up prescribed medicines, keep appointments, and request refills.

Many countries have introduced dedicated disease management programs, where medication therapy of individual patients is closely managed because nonadherence or suboptimal therapy could lead to costly or potentially life-threating situations. Examples of those diseases include asthma, chronic obstructive pulmonary disease, coronary artery disease, hepatitis, high blood pressure, and HIV. Because they often involve co-morbidity, some MBPs and international initiatives are moving toward integrating disease management programs, such as tuberculosis and HIV and AIDS.

As reported by Plocher, disease management programs should have the following elements*—

MONITORING AND INCREASING ADHERENCE TO ANTIRETROVIRAL THERAPY IN RESOURCE-LIMITED SETTINGS

INRUD-IAA, in collaboration with national AIDS control programs in Kenya, Rwanda, Tanzania, and Uganda, made major contributions to measuring and understanding antiretroviral adherence and how patient adherence and retention relates to facility-level operations. Specifically, INRUD-IAA—

- Documented inconsistencies in approaches that programs and facilities within a given country and across countries used to measure antiretroviral therapy adherence and retention
- Developed and validated reliable indicators for monitoring adherence that can be measured using routine data available in treatment centers, including indicators based on appointment keeping; the actual indicators are the monthly percentages of patients who attended the clinic—

  (1) on or before the day of their next scheduled appointment
  (2) within three days of their scheduled appointment
- Developed and field-tested a survey manual and software to measure facility-level adherence and retention
- Documented that adherence rates differ substantially between facilities
- Identified facility-level and system-level determinants of adherence
- Conceptualized and tested practical and scalable health system interventions to improve adherence and retention

Successful interventions were implemented and assessed in Kenya, Rwanda, Tanzania, and Uganda, including developing an appointment register to fix negotiated appointments, monitoring appointment keeping, and reaching out in a timely way to patients who missed appointments. The researchers have advocated for using these methods to monitor other patients with chronic conditions.

- Effective measures to identify the target health problem in different population segments
- Evidence-based STGs
- Collaborative approach to treatment and support involving prescribers, dispensers, and other care providers, including community health workers
- Active patient involvement and education to improve self-management of the health problem
- Measurable progress and outcome indicators to monitor and adjust the treatment regimen
- Proactive educational programs for patients and all involved care providers
- Routine communication and reporting involving the patient, physician, other health care providers, and the MBP

Disease management programs may be funded and managed either by the government, donors, NGOs, or directly by the MBP or by a PBM contracting with the MBP. In some places, commercial companies market disease management programs to MBPs and directly to large employers. Some pharmaceutical manufacturers are willing to co-sponsor disease management programs and provide discounted or even free medicines for some patients as well as educational materials for providers and patients.

Disease management programs can incorporate medication therapy management programs provided through pharmacies. In these situations, the pharmacist actively monitors and manages the patient's medication regimen and even makes adjustments to the regimen once the responsible physician has developed the treatment plan.

Caps or Limits on Prescriptions

When DUR reveals that excessive numbers of prescriptions per patient encounter are being prescribed, the MBP or PBM can place limits on the number of prescriptions for one patient visit or the number of prescriptions a beneficiary can receive in a month. For example, the policy might state that the MBP will not reimburse more than five prescriptions per month. Such limits can reduce excessive or unnecessary use of medicines by some providers and beneficiaries, but they can harm sicker beneficiaries who need more than the capped number. Total costs may actually increase if these patients must be hospitalized when they could have been treated as outpatients. If the MBP is going to use these types of limits, it should monitor the impact on beneficiary sub-groups who are at or near the limit to ensure they receive necessary care. Most MBPs allow exceptions through the prior approval process when the provider states that a higher number of prescriptions are needed for a specific beneficiary.

» See chapter on Encouraging Appropriate Medicine Use by Consumers in MDS-3.

*Plocher's chapter provides a thorough discussion of how disease management programs are incorporated into managed care in the United States. Plocher D. Fundamentals and Core Competencies of Disease Management. In: Kongstvedt, P.R. 2013. Essentials of Managed Care, 6th Edition. Burlington, MA: Jones and Bartlett.

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ANNEX 1. PROVIDER CONTRACT CREDENTIALING AND ISSUES

Some credentialing factors that should be considered when evaluating a provider's eligibility for a contract include—

- Willingness to accept and comply with MBP or PBM contract terms and conditions
- Appropriate license for the services required, updated as necessary
- Access for beneficiaries – location and hours of service
- Physical facility – necessary space for dispensing and counseling, cleanliness and neatness, and storage conditions meeting national regulatory standards for medicines (including cold storage)
- Dispensing equipment and practices meeting professional standards
- Physical security, including capacity to secure and effectively control medicines that require special handling, including controlled substances
- Staffing standards – professional staff with required education and license, support staff with appropriate training, quantity of professional and support staff needed to manage the workload associated with serving MBP members
- Procurement standards – sourcing of high-quality medicines meeting standards of the national drug regulatory authority, all with required product registration
- Inventory management capacity, including prior performance reports and extent of past experiences with stock-outs
- Process for managing prescription records and patient profiles
- Internal DUR process and capacity to support MBP utilization review processes
- Patient services provided including counseling
- Quality management and improvement programs
- Accounting and auditing procedures
- Ability to manage the claims process required by the MBP

- Computerized systems, if any, and compatibility with MBP claims process (if MBP uses automated systems)
- Willingness to offer discounts on dispensing fees and markups on medicine cost (if discounts are allowable under national pricing regulations)
- Past performance in other programs or networks

Typical contract terms will cover the following issues*—

- General and specific responsibilities and rights of the service provider
- Credentialing and licensing requirements including those covering physical facilities, patient access, and staffing
- Insurance – provider will maintain liability coverage as required for the profession in the national laws and regulations (or as stipulated by the MBP if no applicable law)
- Professional services and standards and exercise of professional judgment
- Requirements for verification of beneficiary eligibility
- Collection of user fees – co-payments or co-insurance (if required)
- Limitation on collections – no charging to beneficiaries beyond collecting the co-pays or co-insurance stipulated by the MBP for covered services and medicines/health commodities
- Documentation of receipt of medicines by beneficiaries
- Documentation of patient counseling (as required)
- Manual maintenance of patient medication profiles by contract pharmacists and dispensers to facilitate DUR, if automated patient profiles are not available (may be required by MBP)
- Record retention (prescription records, patient profiles, and copies of prescriptions)
- Electronic communication standards (if applicable)
- Compliance with the MBP's drug formulary or preferred drug list
- Compliance with policies on dispensing generic drugs or "lowest cost" alternatives as applicable
- Policies regarding caps on numbers of prescriptions or dispensing quantities (if applicable)
- Authorization process for requests or prescriptions that are non-standard or may violate MBP standards
- Compliance with MBP utilization review procedures, in addition to providing professional review of prescriptions according to national standards for the profession
- Compliance and cooperation with audits as may be required by the MBP or PBM, including providing access to all relevant records
- Non-discrimination – all eligible members will be served equally and be provided medicines and services unless professional judgment dictates

*A sample provider contract from the United States is provided in Appendix 5.1 in Sterler, L. and Stephens, D. Pharmacy Distribution Systems and Network Management, In: Navarro, R. ed. 2009. Managed Care Pharmacy Practice. Sudbury, MA: Jones and Bartlett.

otherwise for a specific patient, in which case the prescriber or the MBP will be notified

- Cooperation and compliance with member complaint procedures stipulated by the MBP
- Compliance with claims submission and adjudication process
- Contract pricing terms for dispensing fees and medicines (ingredient costs), including any tiered or discount terms applying to different medicine categories
- Standard process for payment of claims and terms of payment and timing of payment process
- Payment process, terms and timing for out of network claims
- Payment process, terms and timing for non-standard claims requiring authorization
- Prior authorization process and retrospective authorization process if applicable
- Confidentiality policy concerning information provided by MBP or PBM company
- Confidentiality of patient information
- Intellectual property rights for products, terms, trademarks, and information materials provided by or owned by MBP or PBM company
- Incentives for participation or compliance with specific MBP programs
- Penalties for provider's non-compliance with contract terms
- Financial penalties including requirement for reimbursement for paid claims identified as fraudulent
- Suspension or termination of network participation initiated by MBP
- Termination of network participation, initiated by provider

ANNEX 2. KEY PHARMACY BENEFIT MANAGER SELECTION CRITERIA AND CONTRACT TERMS

Key selection criteria include the following[72]—

- Capacity to provide required medicines and prescription services to target beneficiaries within desired lead times
- Efficiency of claims handling processes and ability to interface with provider and MBP systems
- Capacity to manage communications with beneficiaries and service providers, including educational outreach programs and call centers to respond to provider or beneficiary questions
- Access to technology to support claims management, management reports, utilization review and related audits, and communications/outreach programs
- Capacity to develop and manage the provider network including specialty and mail order services if appropriate for the setting
- Capacity to support effective formulary development and management to assure adherence
- Capacity to manage conflict-of-interest policies
- Capacity to manage and support utilization review programs
- Capacity to negotiate discounts and rebates with pharmaceutical suppliers
- Capacity to respond to queries and complaints from providers and beneficiaries and call centers to support responsiveness
- Capacity to prevent, detect, and correct medication errors
- Capacity to support clinical programs, such as medication therapy management and disease managements
- Capacity to detect potential fraud and abuse and to manage interventions to correct problems that are identified
- Flexibility of system or capacity to support multiple plans with complex rules
- Quality assurance and quality management

- Robust information technology systems
- Comprehensive reporting
- Clinical support
- Plan design consulting
- Pharmacy contracting and performance management
- Development of a comprehensive medicine product database for the country

Once a PBM is selected the contract should specify—

- The roles, authorities and responsibilities of the PBM and the MBP in the medicines benefit plan
- The specific tasks and services to be provided by the PBM
- Payment terms for each of the services to be provided, including any penalties for poor performance
- Performance targets, which might include indicators such as fill rates, turnaround times, generic substitution rates, formulary adherence, rebate levels, average and total prescription costs, beneficiary and provider satisfaction
- Compliance with all MBP policies
- Transparency regarding medicine costs and pricing, rebate arrangements and amounts, and any other fees that are charged to the PBM
- Provisions for auditing provider performance by the PBM
- Provision for auditing the PBM's performance by the MBP, preferably on a rolling basis rather than one massive audit each year. Audits should consider financial compliance with contract terms, service quality, and responsiveness to client needs

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ANNEX 3. MBP SAMPLE MONITORING AND EVALUATION INDICATORS AND DATA SOURCES

Indicators derived from the plan's general information systems

- Total monthly and annual MBP revenues versus expenses
- Monthly and annual expenditure for plan administration and beneficiary services, by department
- Number of beneficiaries served, and new enrollment, per month and annual total
- Patient and provider satisfaction, measured by number of complaints received and results of satisfaction surveys
- Monthly and annual costs for claims processing and adjudication
- Monthly and annual total costs and medicine expenditures per member
- Monthly and annual total cost of medicines procured for in-house dispensing
- Monthly and annual total cost of payments for prescriptions provided to outpatients
- Monthly and annual total cost of payments for inpatient medicines (if they are billed separately from other patient charges)
- Monthly and annual cost of payments for specialty medicines or health technologies
- Monthly and annual value of rebates or discounts from manufacturers
- Average turnover time for claims adjudication and payments
- Number of complaints received and processed, sorted by prescribers, dispensers, and beneficiaries

Indicators derived from compiling and analyzing claims data or dispensing records

- Numbers and average cost of prescription claims per month and annual, sorted by prescribers, pharmacy providers, and beneficiaries.

- Monthly and annual medicines cost per each beneficiary, and ABC-type analysis of "high use/high cost" member utilization
- Monthly and annual expenditure on medicines per each prescriber, and ABC-type analysis of high volume/high cost prescribers.
- Monthly and annual expenditures on medicines per pharmacy provider/dispenser and ABC-type analysis of high volume/high cost dispenser
- Monthly and annual use of specific medicines in specific therapeutic category, with analysis of use by individual prescribers, providers
- Generic prescribing/dispensing rate by prescriber and by dispenser; number of missed substitution opportunities by prescriber and dispenser
- Percentage of formulary adherent prescriptions and number of incidents of non-formulary prescriptions, sorted by prescribers and dispensers
- Exception requests and approval/rejection rates sorted by prescribers and dispensers and beneficiaries; incidents of potential fraud or abuse of medicines, sorted by prescriber, dispenser, and beneficiary
- Drug utilization problem reports by prescriber, dispenser, and beneficiary

Other relevant indicators for identifying potential fraud and abuse

- Excessive numbers of patient encounters reported for specific providers, suggesting potential lack of appropriate care, "prescription churning", or falsified claims
- High number of referrals to specialists
- Evidence of having and using conflict of interest policies
- Consistently poor patient outcomes and hospitalization for beneficiaries treated by certain providers (may suggest lack of treatment or under-treatment)
- Reports or complaints from regulatory agencies, beneficiaries, or providers concerning potential fraud and abuse (including anonymous reports to "complaint hotlines")

Information derived from special purpose studies

- Results of studies of patient adherence to prescription use instructions
- Results of satisfaction surveys, covering prescribers, dispensers, and beneficiaries
- Results of interventions to correct behavior of providers or beneficiaries

ANNEX 4. EXAMPLES OF FRAUD RELATED TO MEDICINES BENEFIT PROGRAMS

Corrupt practices by plan administrators

- Corruption involving staff or managers of the benefit program, whereby providers kick back payments in exchange for approval of fraudulent or abusive claims.
- Approval of exemptions from cost sharing or approval of other plan benefits for people or groups who are not really eligible for the benefit or exemption. This may involve financial corruption (selling exemptions or benefits) or simply bowing to family, clan, or other pressures (including political pressure).

Provider fraud

- Billing for medicines, equipment and services not actually received by an eligible beneficiary
- Billing using the provider ID of another provider
- Falsifying a diagnosis or medical record to justify use of medicines or procedures that are not really needed
- Billing for medicines separately when the provider contract calls for bundled billing
- Splitting claims into multiple submissions to avoid detection of improper billing
- Medicine shorting - billing for more medicines or greater quantities than are actually dispensed
- Prescription splitting – dispensing less than the prescribed quantity, and telling the patient to return for a second visit, thereby billing for two dispensing fees for the same prescription
- Billing for brand name medicines when a generic was actually dispensed
- Upcoding—billing for a more costly service than the one actually provided
- Duplicate billing—billing more than once for a service or medicine provided

- Exempting beneficiaries from cost sharing when they are not eligible for exemption
- Falsification of medical or dispensing records to justify payment
- Billing for services or medicines provided to ineligible beneficiaries or non-existent people (including dead people)
- Receiving payments or kickbacks to induce prescribers or beneficiaries to switch a prescription to a medicine supplied by the firm providing the kickback
- Engaging in fraudulent arrangements with beneficiaries, buying back all or part of a dispensed prescription and reselling it while billing the MBP for the full prescription

Beneficiary fraud

- Identity theft, obtaining services under the name of another beneficiary
- Falsification of eligibility for plan membership
- Misrepresentation on application for coverage
- Filing false claims, when the plan reimburses the beneficiary for covered services
- Forging prescriptions
- Obtaining prescriptions for resale to other beneficiaries or resale to a service provider
- Obtaining prescriptions for use by family members or associates
- Doctor shopping or dispenser shopping to obtain medicines and services that are not medically necessary (may involve narcotics abuse or attempts to receive treatment that is more expensive than required)
- Visits to multiple prescribers to obtain treatment for the same health problem, often coupled with schemes to resell some or all of the medicines received
- Falsely reporting loss of medicines or covered equipment to obtain replacements which are often used for resale (or personally abused as can be the case with narcotics)

Abuse of the benefit

Examples of abuse of the medicines benefit include—

- Overutilization of medicines and prescribing and dispensing medicines which are not medically necessary
- Excessive numbers of prescriptions per patient or excessive quantities prescribed and dispensed
- Unnecessary prescribing or dispensing of medicines that are not on the formulary or consistent with STG even coupled with requesting exception approval for non-covered medicines and services when it is not really medically necessary
- Prescribing and dispensing of expensive medicines when more cost-effective alternatives are available
- Prescribing or dispensing of brand name products rather than generic products when there is no medical justification
- Prescribing or dispensing refills when they are not necessary

- Charging unjustifiably high fees for services not explicitly covered in the provider contract
- Beneficiary doctor shopping to obtain prescriptions when the first prescriber suggests no medicine is needed
- Beneficiaries who see multiple providers and obtain multiple courses of treatment for the same health problem

Adapted from Moon, C. Health Care Fraud and Abuse. In: Kongstvedt, P.R. 2013. Essentials of Managed Care, 6th Edition. Burlington, MA: Jones and Bartlett.

ANNEX 5. MODELS OF MANAGED ENTRY AGREEMENT IN THE EUROPEAN UNION

MODEL NAME AND DESCRIPTION	FEATURES
Belgium	
Budget capping	▪ Budget cap ▪ May be linked to data collection as part of an observational study or risk-sharing
Compensation mechanism	▪ Compensation mechanism ▪ Data collection
Price-volume agreement	
Cyprus	
Price-volume agreement upfront agreement: Price reduction as the number of cases increases (within the same indication)	▪ Registry
Price-volume agreement upfront agreement: Payments according to dose capping due to dosage scheme uncertainty or wastage uncertainty	▪ Patient registry
Price-volume agreement upfront agreement: Discounts or free goods requested in case of uncertain and/or unfavorable efficacy or cost effectiveness data	▪ Patient registry ▪ Usually in line with National Institute for Health and Care Excellence (NICE) decisions ▪ Patient access scheme if available
Discounts for usage extension	▪ Registry
Czech Republic	
Very innovative products (VILP) + AIFA notes: Conditional reimbursement for 12 months for specific indications where the data on efficiency are to be collected	▪ Limited reimbursement (specific patient subgroups, after failure of alternative treatment, limited number of doses) ▪ Data collection

MODEL NAME AND DESCRIPTION	FEATURES
France	
Price/volume agreement: For each drug, different levels of sales are and associated repayments are defined. Repayments are later converted into a price cut	
Agreement on daily cost of treatment: A target of daily cost of treatment is set. If it is exceeded, the company repays the excess	
Study requirement: The company is required to carry on a specific study concerning the real-life use of the drug. The price can be revised on the basis of its results	
Risk-sharing agreement: A price is set on higher basis than the existing evaluation of the product. If, after additional studies, the product gets a better evaluation, the price is maintained. If not, it is decreased and the company pays back the difference	▪ Uncertainty around effectiveness in real life
Italy	
Risk sharing: Discount on price of initial therapy cycle(s) for non- responder patients, identified following clinical evaluation in a pre-set time frame	▪ Discount for non-responders ▪ Conditional treatment continuation (only for patients who positively respond to the drug) ▪ Monitoring registry
Payment by results: Initial cycle(s) fully reimbursed by manufacturer for non-responder patients (fully reimbursed by the National Health Service for responders), identified following clinical evaluation in a pre-set time frame	▪ Full reimbursement for non-responders ▪ Conditional treatment continuation (only for patients who positively respond to the drug) ▪ Monitoring registry
Cost sharing: Discount on price of initial therapy cycle(s) for all eligible patients	▪ Initial discount for all eligible patients ▪ Conditional treatment continuation (only for patients who positively respond to the drug) ▪ Monitoring registry
Monitoring registries: Registries track the eligibility of patients and the complete flow of treatments, which guarantees appropriate use of medicines according to their approved indications	▪ Collection of patient-level data including information on eligibility for treatment, length of treatment, administered doses, epidemiological data, adverse drug reactions
Volume-based agreements: The Italian Medicines Agency negotiates a volume of sales, related to a target population, with the manufacturer. The volume of sales, exceeding the pre-set threshold, will have to be paid back by the manufacturer to the National Health Service	▪ Monitoring databases providing sales and expenditures of pharmaceuticals

MODEL NAME AND DESCRIPTION	FEATURES
AIFA-Notes: reimbursement is limited to specific patient sub-groups. The AIFA Note is reported by the general practitioner on the prescription form, which will allow the patient to get the medicinal product free of charge	
Therapeutic plans: diagnosis and treatment must be reported exclusively by specialized health care centers identified at regional level. This tool guarantees the reimbursement of certain medicines for the authorized therapeutic indications only under close monitoring of the specialists	
Lithuania	
Price volume agreements	▪ The manufacturer has to return a part of the excess expenditure to the NHIF ▪ Collection of information about medicines consumption and expenditure
Pay back agreements	▪ Pay back mechanism is applied to pharmaceuticals, when reimbursed price is too high compared with similar pharmaceuticals ▪ Collection of information about medicines consumption and expenditure
Expenditure cap agreement	▪ Manufacturer returns excess expenditure to the NHIF ▪ For drugs that are already on the market and whose expenditure is more than 1 million and 1% of all expenditure for drug reimbursement. ▪ Collection of information about medicines consumption and expenditure
Malta	
Dose capping	
The Netherlands	
Coverage with evidence development: Coverage is granted under the condition that cost-effectiveness is determined within a four-year period	▪ Submission of a cost-utility analysis to support continued reimbursement after the initial 4-year study period

MODEL NAME AND DESCRIPTION	FEATURES
Portugal	
Price-volume agreement: The manufacturer is required to reimburse the NHS if expenditure has exceeded the agreed budget	▪ Definition of the universe of eligible patients ▪ Establishment of an annual budget limit for NHS ▪ Re-evaluation of therapeutic added-value and cost-effectiveness at the end of the first two-year period ▪ If the re-evaluation is positive, the agreement is extended for another two years (for hospital medicines) and new budget limits are established, based on previous sales data, new maximum prices (if they changed), and forecasted evolution of the medicine and the market ▪ Alternatively, the medicine is included in a global list of reimbursed medicines (without agreement); the manufacturer must submit quarterly data on sales (volume, expenditure, and prices) to Infarmed ▪ Promotional activities are limited to the therapeutic indications approved for the medicine ▪ Some agreements have an additional pay-back scheme to guarantee acceptable prices for NHS, while maintaining list prices; for these agreements, the manufacturer must reimburse the NHS the difference between the approved list price and the discounted price for NHS
Coverage with evidence development: reimbursement extension after the initial two-year period is conditional to the provision of additional data on cost-effectiveness	▪ Re-evaluation of therapeutic added-value and cost-effectiveness at the end of the first two-year period ▪ If the re-evaluation is positive, the agreement is extended for another two years (for hospital medicines) and new budget limits are established, based on previous sales data, new maximum prices (if they changed), and forecasted evolution of the medicine and the market ▪ Alternatively, the medicine is included in a global list of reimbursed medicines (without agreement); the manufacturer must submit quarterly data on sales (volume, expenditure, and prices) to Infarmed ▪ Promotional activities are limited to the therapeutic indications approved for the medicine ▪ Some agreements have an additional pay-back scheme, to guarantee acceptable prices for NHS, while maintaining list prices; for these agreements, the manufacturer must reimburse the NHS the difference between the approved list price and the discounted price for NHS

MODEL NAME AND DESCRIPTION	FEATURES
Sweden	
Coverage with evidence development	▪ Depending on the type of uncertainty the manufacturer is required to submit data on use and/or cost-effectiveness
UK - England and Wales	
Patient access schemes: proposed by a pharmaceutical company and agreed between the company and the Department of Health, with input from NICE, to facilitate patient access to cost-effective innovative medicines	▪ Discount ▪ Initial free doses ▪ Dose capping

Adapted from Ferrario A, Kanavos P. 2013. Managed entry agreements for pharmaceuticals: The European experience. London: The London School of Economics and Political Science.

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