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., 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 MBP 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.
Management of Medicines Benefit Programs in Low- and Middle-Income Settings

(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—

- 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
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 through 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 Marriott.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. 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. 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. 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.

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. 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.
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.

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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
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 steps23—

- 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
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. and for 5 sub-Saharan African countries in Carapinha et al. The following discussion focuses on the basic coverage options that might be considered in designing an MBP.
**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. 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).
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**

<table>
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<tr>
<th>Diagnostics</th>
<th>Implants and devices</th>
<th>Miscellaneous</th>
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<tbody>
<tr>
<td>Test kits</td>
<td>Orthopedic implants</td>
<td>Condoms</td>
</tr>
<tr>
<td>X-rays</td>
<td>Pacemakers</td>
<td>Eyeglasses</td>
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<tr>
<td>MRI</td>
<td>Cardiac stents</td>
<td>Prosthetics</td>
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<td>Microscopy supplies</td>
<td>Intrauterine devices</td>
<td>Blood glucose test strips</td>
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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. 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 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—

- 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.

**REFERENCES**


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