

## ACCESS TO DRUGS AND FORMULARIES

This section covers:

- Pharmacy Networks
- Formularies
- Cost-Containment Strategies
- Medication Therapy Management Programs (MTMPs)
- Transition Policies

Each Part D plan has a network of pharmacies from which enrollees routinely can access their Part D drugs. Additionally, each Part D plan covers the prescription drugs that it places on a formulary, or list of covered drugs. Formularies may vary greatly among the plans. Plans also may encourage enrollees to use certain drugs on their formularies in an effort to control costs. All of these factors may affect a beneficiary's access to prescription drugs, and thus are important to consider when selecting a plan.

### PHARMACY NETWORKS

The Part D plans vary in the extent of their pharmacy networks. A pharmacy network is a group of pharmacies under contract with a Part D plan to provide its enrollees access to prescription drugs. In a June 2007 report, the Office of Inspector General for the Department of Health and Human Services (HHS) found that 97 percent of retail pharmacies participate in at least one stand-alone PDP (available online at <http://www.oig.hhs.gov/oei/reports/oei-05-06-00320.pdf>). At the same time, 70 percent of these participating retail pharmacies were members of the pharmacy networks of all the available PDPs in their region.

In addition to network pharmacies, some drug plans also designate preferred pharmacies that offer the lowest prices and out-of-pocket costs among all the plan's network pharmacies. The Plan Finder lists all network pharmacies by name and location and further notes those that are preferred pharmacies. It is important to learn if a beneficiary's pharmacy of choice is in the plan's network, and if it is not, to make sure that convenient alternatives exist. Because the drug plans renew their contracts annually, network pharmacies may change from year to year.

*Note:* Pharmacies in a Part D plan's network charge lower cost-sharing than other non-network pharmacies. For non-routine situations and emergencies, beneficiaries may be allowed to use non-network pharmacies. Each Part D plan has an out-of-network policy for such coverage issues.

A Medicare drug plan may not pay for prescriptions at pharmacies that are not in the plan's network. Exceptions apply, however, in emergencies and some other situations. CMS requires Part D plans to ensure that their enrollees have adequate access to covered drugs at out-of-network pharmacies when someone "cannot be reasonably expected to obtain covered drugs at a network pharmacy, or when such access is not routine." Thus, CMS expects the drug plans to cover prescriptions filled at out-of-network pharmacies when a plan enrollee loses his or her covered drugs or becomes ill, needs a covered drug, and cannot get to a network pharmacy.

Similarly, drug plans should cover prescriptions that a hospital or clinic-based pharmacy fills when someone is an emergency or outpatient surgery patient. Since Medicare Part B covers these types of hospital and clinic visits, Part D covers the prescriptions received during those visits. Many hospital-affiliated pharmacies are not in the network of Part D plans, so this type of coverage would be provided by the plan's out-of-network policy. Since the plan's negotiated price for a drug is often less than the price charged by a hospital pharmacy, beneficiaries should keep in mind that they will have to pay the difference between the two prices.

It is also important to know that the MMA allows pharmacies to waive or reduce the cost-sharing amount (i.e., copayment, coinsurance) for beneficiaries who are otherwise unable to afford their prescription drugs. Pharmacies, however, cannot do this on a routine basis. The amount the pharmacy pays counts toward the beneficiary's true out-of-pocket costs (TrOOP).

**EXAMPLE** *For the past 20 years, Charlie has been going to the ABC Pharmacy, which is exactly 2 miles from his house. He will be turning 65 in one month, and consequently will lose his retiree coverage. He takes three prescription drugs and has decided to enroll in a Part D plan. He is currently deciding between two PDPs. Both plans cover all three of his prescriptions; however, only one plan lists the ABC Pharmacy as a preferred pharmacy in its pharmacy network. Because Charlie wants to get the lowest price at his favorite pharmacy, he decides to enroll in that plan.*

## FORMULARIES

Medicare drug plans use formularies – that is, comprehensive lists of the drugs they cover – to define their drug benefits. The MMA allows each drug plan to develop its own formulary within certain limits. CMS reviews formularies to make sure that they comply with federal law. It evaluates the formularies to ensure adequate access to medically necessary drugs and to make sure that no formulary excludes drugs in such a way as to discourage particular groups from joining a plan. For example, CMS would not approve a formulary if it did not include insulin and oral anti-glycemic agents, as such a formulary would discriminate against people with diabetes.

The MMA requires all Part D drug plans to provide access to medically necessary medications including generic and brand-name drugs. Plans' formularies must include at least two drugs in each treatment category and class that a drug plan sponsor designates, although CMS may require plans to include more than two drugs for some categories and classes. Medicare rules require the plans to cover "all or substantially all" drugs in six categories. CMS refers to these classes as "classes of clinical concern."

- Anti-neoplastics (anti-cancer drugs)
- Anti-convulsants
- Antidepressants
- Antipsychotics
- Immunosuppressants
- Anti-retrovirals

**Note:** Many plans cover more than two drugs in each class, though most plans do not have open formularies that cover all Medicare Part D allowable drugs.

CMS established the "all or substantially all" requirement for plans to cover all drugs and dosage forms within these six classes with only limited exceptions. Those exceptions include:

- Multi-source brands of the identical molecular structure
- Extended release products when the immediate-release product is included
- Products that have the same active ingredient or moiety
- Dosage forms that do not provide a unique route of administration (e.g., tablets and capsules versus tablets and transdermals)



More information about this "all or substantially all" rule can be found in CMS's *Medicare Prescription Drug Benefit Manual*, Chapter 6, Section 30.2.5, available online at <http://www.cms.hhs.gov/Transmittals/Downloads/R2PDB.pdf>.

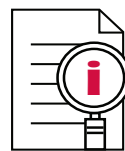
## Drugs Excluded from Part D Coverage

Aside from requiring coverage for drugs in certain categories, the MMA specifically excludes some drugs from Part D coverage. Part D plans do not cover prescription drugs when they are covered by Medicare Part A or Part B, including some chemotherapy drugs. Other drugs that the law generally excludes from Part D coverage are:

- Drugs prescribed for anorexia, weight loss, or weight gain (except drugs used to treat AIDS wasting and cachexia due to chronic disease)
- Drugs prescribed to relieve the symptoms of coughs and colds. This exclusion does not include medications used to treat a cough that results from a medical condition that is not a cold or cough.
- Prescription vitamins and minerals, with the exception of prenatal vitamins and fluoride. Vitamin D analogs such as calcitriol, doxercalciferol, paricalcitol and dihydrotachysterol are not considered prescription vitamins. Also, prescription niacin products, such as Niaspan and Niacor are Part D drugs and are not considered vitamins.

- Over-the-counter drugs, with the exception of insulin
- Prescription drugs to promote hair growth
- Fertility drugs
- Cosmetic drugs. Drugs taken to treat psoriasis, acne, rosacea, or vitiligo are not considered cosmetic.
- Drugs that must be monitored by testing services that only the manufacturer provides, such as certain anti-psychotic medications
- Barbiturates (drugs used to control seizures or used for sedation or anesthesia such as Phenobarbital or Nembutal)
- Benzodiazepines, often referred to as minor tranquilizers, used to treat anxiety or insomnia (such as Xanax, Valium, and Ativan)
- Sexual or erectile dysfunction (ED) drugs, when prescribed for the treatment of sexual or erectile dysfunction

**Note:** For Contract Year (CY) 2006 Erectile Dysfunction (ED) drugs met the definition of a Part D drug and were available on Plan Sponsor formularies. On October 26, 2005, Section 1860D-2(e)(2)(A) of the Social Security Act was amended to exclude ED drugs when prescribed for the treatment of sexual or erectile dysfunction for CY 2007 and beyond. Please see the CMS Q&A on ED drugs for more information available online at [http://www.cms.hhs.gov/PrescriptionDrugCovContra/downloads/QAEDDrugs\\_07.06.06.pdf](http://www.cms.hhs.gov/PrescriptionDrugCovContra/downloads/QAEDDrugs_07.06.06.pdf).



The state Medicaid program may cover some Part D excluded drugs for full dual-eligible beneficiaries. For more information, see Help for Low-Income Beneficiaries on page 37.

## Formulary Changes

Part D plans can change their formularies within certain limits. Medicare drug plans may only change the therapeutic categories and classes in their formularies once each year. These changes must occur between plan years. That is, a 2010 plan can change the categories and classes on its formulary for the 2011 plan year, but the change cannot be effective prior to January 1, 2011.

Medicare drug plans typically may not remove drugs from their formularies at any time during the plan year. A few exceptions to this general rule exist. First, Part D drugs may be removed from formularies when the Food and Drug Administration (FDA) pronounces a Part D drug unsafe. Plans may also remove drugs from formularies if the manufacturer removes the Part D drug from the market.

Medicare drug plans also may not make any change in cost-sharing status of formulary drugs from the start of the Annual Enrollment Period to 60 days after the beginning of the plan year. Plans also must provide a 60-day notice to affected beneficiaries including those who are currently taking a drug that is removed from the formulary or whose costs are changing because of a shift in a drug's tier placement. If the plan does not provide prior notice, it must authorize a 60-day fill of the drug and provide notice at the point of sale.

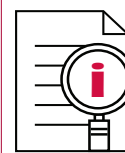
Part D plans usually must follow these general rules about mid-year formulary changes:

- Plans may remove or place in a higher tier brand-name drugs when generic or multi-source brand name equivalents enter the market.
- Plans may remove non-Part D drugs included on their formularies by mistake.
- Plans may add utilization management tools based on new FDA warnings.
- Plans may remove drugs based on new FDA market withdrawal notice.
- Plans may remove or place in a higher tier drugs based on new clinical guidelines or recommendations. An example is following CDC’s recommendation against using older antivirals for treatment and prevention of the flu.
- Plans may add utilization management tools in the following cases:
  - To respond to other approved formulary changes. One example is adding prior authorization to a brand name drug when a generic version is on the market.
  - To help determine B vs. D coverage
  - To promote the safe utilization of a Part D drug based upon new clinical guidelines or information

## Medically Accepted Indications and Off-Label Use

Part D plans must ensure that physicians and other health providers prescribe Part D covered drugs for medically accepted indications. In some cases, providers prescribe drugs for a purpose other than the one originally approved by the FDA. This is called an “off-label use” of the drug. Sometimes physicians prescribe a drug to treat a medically accepted indication that is an off-label use. CMS does not require Part D plans to approve off-label use, but does expect them to refer to common medical practice in determining that a prescribed drug effectively deals with a medically accepted indication.

Because plans can differ in their decisions about medically accepted indications, it is important to check with a plan about its policies for approving off-label use. One plan, for example, may consider peer-reviewed literature in deciding on an acceptable use, while another may limit its consideration to the uses described in a CMS-approved drug compendium. Plans may deny coverage for off-label drug use for lack of medical necessity. If the client’s physician is willing to help make the case that an off-label use is within common medical practice, SHIPs can assist their clients to appeal these coverage denials.



For more information on coverage determinations, see Coverage Determinations and Appeals on page 67.

## COST-CONTAINMENT STRATEGIES

The Part D program relies on competition among drug plans and limits on the use of some covered drugs, often called utilization management tools, to help contain costs and control government spending on the prescription drug program.

### Price Competition

The federal government does not regulate the drug prices that plan sponsors charge in the Medicare Part D program. Part D plan sponsors individually negotiate prices with drug manufacturers. Thus, drug prices vary from plan to plan. The plans' negotiated drug costs affect the length of time it takes enrollees to reach the initial coverage limit, as well as the full prices they pay for drugs once in the doughnut hole.

### Utilization Management Tools

Along with price competition, the MMA allows drug plans to control costs through drug utilization management systems that may have an impact on a beneficiary's ability to access prescribed medications. The common elements in these utilization management systems are:

- Cost tiers
- Prior authorization
- Step therapy
- Quantity limits

As a SHIP counselor, keep in mind that even though a drug plan lists a client's medication as a covered drug on its formulary, a utilization management tool may restrict access to that drug. It may be necessary to ask the prescribing physician to make the case to the plan that your client's medical condition creates a medical need for the drug. When a Part D plan uses a utilization management tool to deny coverage for a formulary drug that your client needs, SHIPs can play an important role in assisting through the exceptions or redetermination appeals processes.



It is a good idea for beneficiaries to fill all of their medications at the same pharmacy to better predict their drug spending as well as to benefit from the pharmacist's expertise about avoiding drug interactions.



For more information about exceptions, see Coverage Determinations and Appeals on page 67.

### Cost Tiers

Many plan sponsors assign the covered drugs on a plan's formulary to different cost-sharing tiers. The MMA allows plan sponsors to design plans with as many as six tiers, though plans more commonly have three or four. Plans usually assign generic drugs to a low cost-sharing tier. For example, a plan's copayments for generic furosemide and brand-name Lasix might be \$5 and \$40, respectively. The smaller copayment in the lower tier works as an incentive for beneficiaries to select less costly drugs instead of the more expensive alternatives placed in higher tiers.

**EXAMPLE** Bernard was enrolled a PDP plan, while his neighbor, Kyle was enrolled in a different PDP plan. Both take diabetic medication and use the same local pharmacy. Bernard takes the brand-name drug Avandia, and Kyle takes the generic form metformin. Bernard's medication is on the fourth tier, and his copayment is \$120 for a month's supply. Kyle's medication is on the second tier as a generic drug, and costs only \$22 per month.

## Prior Authorization

Prior authorization requires an added step in filling a prescription. Plans typically use prior authorization requirements to control the use of higher cost medications. The MMA gives plan sponsors considerable latitude to design their prior authorization systems. The plans can use different forms, and may ask physicians to provide more or less documentation to establish the need for a drug. Thus, it may be easier for prescribing physicians to secure prior authorization in one plan as opposed to another. SHIP counselors may be in a position to help clients with information about the exceptions and appeals process following an unsuccessful request from the plan for prior authorization.

**EXAMPLE** Bernard's physician has prescribed a brand-name blood pressure drug, Zestril. The plan covers the generic form of the drug, lisinopril, but requires prior authorization for Zestril. Bernard's doctor contacted the plan and provided documentation, through notes in his medical record, that Bernard had tried the generic form in the past and that it caused him to feel dizzy. He also provided information from clinical trials to tie Bernard's reaction to a proven side effect. The drug plan approved the physician's request for coverage. This approval by the plan applies only to Bernard; it does not change its policy about covering Zestril for other enrollees who cannot take the generic form.

## Step Therapy

Step therapy is a cost-control method that requires beneficiaries to use a less expensive medication, long-established as effective in treating a condition, before moving on to the next "step" in the process, involving a higher cost or newer, brand-name drug. Drug plans that require step therapy for a particular drug will not pay for the more expensive drugs, in the second and third steps, until the beneficiary tries the less expensive first step, and it proves to be ineffective or harmful. When beneficiaries have already tried the less expensive drug unsuccessfully, the doctor should contact the drug plan to request an exception.


**EXAMPLE** Carmen's doctor prescribed Prevacid to treat symptoms of acid reflux disease. The cost for a 30-day supply of the 15mg tablets is \$135. Carmen's drug plan required her to first try Omeprazol at \$25 per month. The pharmacist contacted her doctor to ask if she could take Omeprazol instead of Prevacid. Because Carmen had a history of negative reactions to the less expensive drug, her doctor contacted the plan to ask it to cover the brand-name drug. The plan would not pay for the Prevacid until the doctor described in writing the poor results Carmen had with Omeprazole.

## Quantity Limits

Plans may limit the amount of medication that they pay for over a certain period of time. The Kaiser Family Foundation reported that quantity limits are the most common utilization management tool that national PDPs use with ten frequently prescribed brand-name drugs (<http://www.kff.org/medicare/upload/7749.pdf>). It is not unusual to find plans only paying for a limited supply of a brand-name medication, even though a physician prescribes more.

**EXAMPLE** *Ethel takes Imitrex, a medication for migraine headache. She has done well on this drug. Her doctor wrote a prescription for 15 doses, but her drug plan will only cover a supply of 10, under a quantity limit restriction. To overcome the restriction, Ethel will need to request an exception to the 10-dose quantity limit.*

The MMA allows Part D plans to use any of these cost-containment strategies. SHIP counselors can expect that their clients will encounter one or more of them as potential road-blocks to access their prescribed drugs. Thus, it is important for clients to understand their rights, and know how to exercise them, when a drug plan's cost-control requirements impede needed care.



Our health is unpredictable; therefore, it is impossible to predict the “best” plan for the unforeseeable future. It’s usually best to encourage beneficiaries to choose a plan that meets their needs at that point in time.

## MEDICATION THERAPY MANAGEMENT PROGRAMS (MTMPs)

All Part D plans (including MA-PD plans) must offer a Medication Therapy Management Program (MTMP) to eligible enrollees. MTM programs are intended to reduce the risk of adverse medication events and improve medication use by participants.

Beginning in 2010, CMS has established new rules for MTMPs. CMS has defined certain criteria for these programs. Plans must:

- Enroll beneficiaries using an opt-out method
- Target enrollment at least quarterly during the plan year
- Enroll beneficiaries who
  - Have multiple chronic conditions
    - Programs cannot require more than three chronic diseases as a minimum, and they must target at least four of the following chronic conditions:
      - Hypertension
      - Heart Failure
      - Diabetes
      - Dyslipidemia
      - Respiratory Disease

- Bone Disease-Arthritis
  - Mental Health
- Are taking multiple Part D drugs
  - Programs cannot require a minimum of more than eight drugs
- Are likely to spend at least \$3,000 annually out-of-pocket for covered drugs
- Offer the following services
  - Interventions for beneficiaries and prescribers
  - An annual comprehensive medication review, including review of drugs, consultation, and a written summary
- Report extensive details on the activities of the program

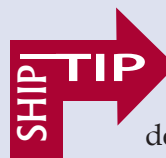
## TRANSITION POLICIES

All Part D drug plans have transition policies through which enrollees sometimes can obtain a temporary fill of their prescription drugs. Transition policies cover new Medicare beneficiaries' enrollment in Part D plans, a switch from one Part D plan to another, level of care changes affecting long-term care facility residents, and formulary changes from one contract year to the next affecting current plan enrollees.

When a transition policy is in effect, a Part D plan must cover an enrollee's prescription drugs even if they are not on the plan's formulary. While CMS has set forth minimum transition policy requirements to address the needs of new and current drug plan enrollees, the agency allows plans to craft their own transition policies. Because the policies may vary from plan to plan, with some exceeding the minimum requirements, it is important for your clients to check with their drug plans to learn how the transition policies might affect them.

### New Enrollees

Under the MMA, Part D plans must offer a transition process for beneficiaries who are either enrolling in a Part D plan for the first time (i.e., new Medicare beneficiaries and beneficiaries who recently lost creditable coverage) or are enrolling in a different plan. This includes beneficiaries who are joining a Part D plan through a Special Enrollment Period (SEP). Under the transition process, plans must provide new enrollees with a temporary, 30-day supply of a non-formulary drug, including a drug dispensed under a utilization management restriction (e.g., prior approval) that they were taking before enrolling in new Part D plans. Plans may choose to extend the 30-day supply for new enrollees, but at a minimum they must provide a 30-day supply. Plans must cover this temporary supply, or transition fill, when beneficiaries go to pharmacies to fill prescribed medications within 90 days of drug coverage becoming effective.



Clients may want to check the plan's transition policy before deciding to enroll in or switch to a plan.

The transition process also is an opportunity for enrollees to work with their physicians to find alternative drugs on the plan's formulary or to file an exception to request coverage for the drug. Medicare rules require plans to give new enrollees a written notice that states that they must either switch to a therapeutically equivalent drug that is on formulary or request an exception from the plan to continue taking the drug for the remainder of the calendar year. Plans work with pharmacies to distribute the notice to enrollees when they receive a transition fill. In the event that a prescription is not filled and such a notice is not distributed, it is best to contact the plan for further information on the plan's reasons for denying coverage and the appropriate next steps. For 2010, CMS has provided plans with a model transition letter, available online at <http://www.cms.hhs.gov/PrescriptionDrugCovContra/PartDMMM/list.asp>. The transition letter should explain the reason that the plan is providing a temporary fill, e.g., that the drug is not on the formulary or that the plan places a utilization management restriction on the drug.

## Current Enrollees

CMS expects Part D plans to have a meaningful transition process in place for current plan enrollees whose drugs are no longer on the plan's formulary in the change from one contract year to the next. CMS expects plans to select one of two options.

1. Plans can provide for current enrollees a transition process that is consistent with the process for new enrollees. Under this option, CMS requires plans to provide enrollees with a temporary supply of the requested prescription drug (where it is not medically contraindicated) and with written notice that states how they must either switch to a drug that is on the plan's formulary or request an exception to continue taking the drug.
2. Alternatively, plans can establish and implement a transition process for current enrollees prior to the start of a new contract year (January 1, in most cases). This option requires plans to prospectively transition current enrollees to a therapeutically equivalent drug on the formulary or complete requests for formulary and cost-sharing exceptions before prior to the start of a new contract year. If a plan does neither, it must provide a temporary fill until the beneficiary has transitioned to a new drug on the formulary or until it has granted an exception.

**EXAMPLE** *Mary joined a Part D plan in February of 2009, and decided to remain in the same PDP for 2010. In 2009, she paid \$25 for a brand-name drug for her arthritis. In November 2009, she learned in the plan's Annual Notice of Change (ANOC) that her share of the cost would increase to \$50 in 2010. Because Mary lives on a fixed income and takes six other prescription drugs, she cannot pay the extra \$25 per month. She checked with her prescribing physician about switching to another drug, but he advised against it. Mary filed an exception to the cost-sharing amount on December 30, but as of January 2 she had*

*not heard from the plan. When she went to fill her prescription on January 2, the pharmacist provided a transition fill. On January 3, she heard from the plan that she had been granted an exception to the higher cost-sharing amount. As a result, she will continue to pay \$25 for her drug in 2010.*

Chapter 6 of the Medicare Prescription Drug Benefit Manual provides details on plan transition requirements as they currently exist, available online at <http://www.cms.hhs.gov/PrescriptionDrugCovContra/downloads/R2PDBv2.pdf>.

