



Module 6: MEDICARE PRESCRIPTION DRUG COVERAGE (PART D)

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MODULE 6 LEARNING OBJECTIVES

- 1. Explain the Part D benefit and the costs a client can expect with Part D.
- 2. Assist clients in choosing and enrolling in a Part D plan.
- 3. Troubleshoot Part D issues with clients, such as appeals or medication affordability.

PART D BASICS AND ELIGIBILITY

Medicare's prescription drug benefit, called Part D, is the part of Medicare that provides outpatient drug coverage. Part D is provided only through private insurance companies that have contracts with the federal government—it is never provided directly by the government, unlike Original Medicare.

To enroll in Medicare Part D, an individual must:

- Be enrolled in Medicare Part A and/or Part B. In other words, someone must be enrolled in at least one part of Medicare to enroll in Part D.
- Live within a Part D plan's service area. People are not eligible for Part D if they live outside the U.S. or are incarcerated.

If a beneficiary wants Part D coverage, they can choose one of the following options:

- Private Medicare prescription drug plan, also called a "stand-alone" PDP, which offers only drug coverage.
- Medicare Advantage Plan with drug coverage, which covers all Medicare benefits, including prescription drug coverage, through a managed care plan.





Part D enrollment is optional, though recommended to avoid future penalties or gaps in coverage. Beneficiaries can only enroll in Part D coverage during approved enrollment periods. Typically, people should sign up for Part D when they first become eligible to enroll in Medicare.

Whether a beneficiary should sign up for a Medicare Part D plan depends on their circumstances. If a Medicare beneficiary does not have other creditable drug coverage, they should enroll in a Part D plan. This is true even if they do not currently take any prescription drugs. If they delay Part D enrollment and later find that they need drug coverage, they will likely owe a premium penalty.

On the other hand, a client may have creditable drug coverage from employer or retiree insurance. If so, they don't need to enroll in a PDP until they lose this coverage. Also, some people already enrolled in certain low-income assistance programs may be automatically enrolled in a Medicare drug plan and receive additional financial assistance paying for their medicines.

Like other insurance, Part D plans usually charge a monthly premium, an annual deductible, and a share of the cost of prescriptions. Costs to beneficiaries vary depending on the individual plan. All drug plans must provide at least a standard level of coverage, which Medicare sets. Some plans offer more coverage but may charge a higher monthly premium.

Because drug plans vary in terms of which prescription drugs are covered, how much a beneficiary pays, and which pharmacies a beneficiary can use, it is important for people to choose a plan that best meets their needs.

PART D COSTS

Coverage phases

There are four different phases—or periods—of Part D coverage. A Part D plan should keep track of how much money a beneficiary has spent out of pocket for covered drugs and the beneficiary's progression through coverage periods. This information should appear in a beneficiary's monthly statements.

Deductible period: Until meeting the Part D deductible, a beneficiary will pay the full negotiated price for their covered prescription drugs. Once they have met the deductible, the plan will begin to cover the cost of their drugs. While deductibles can vary from plan to plan, no plan's deductible can be higher than \$545 in 2024, and some plans have no deductible.

Initial coverage period: After a beneficiary meets the deductible, the plan will help pay for covered prescription drugs. The plan will pay some of the cost, and the beneficiary will pay a copayment or coinsurance. How long a beneficiary stays in the initial coverage period depends on their drug costs and the plan's benefit structure. For most plans in 2024, the initial coverage period ends after a beneficiary has accumulated \$5,030 in total drug costs. Total drug costs include amounts the beneficiary, their plan,





and certain other payors, including State Pharmaceutical Assistance Programs (such as EPIC, see HIICAP Notebook Module 11), have paid for covered drugs.

Coverage gap: After a beneficiary's total drug costs reach a certain amount (\$5,030 for most plans in 2024), they enter the coverage gap, also known as the donut hole. During this phase, a beneficiary is responsible for 25% of the cost of their drugs. Beneficiaries may see a difference in cost between the initial coverage period and the donut hole. For example, if a drug's total cost is \$100 and a beneficiary pays their plan's \$20 copay during the initial coverage period, they will be responsible for paying \$25 (25% of \$100) during the coverage gap. Note: Beneficiaries enrolled in Extra Help do not have a coverage gap (see HIICAP Notebook Module 10).

Catastrophic coverage: In all Part D plans, a beneficiary enters catastrophic coverage after reaching \$8,000 in out-of-pocket costs for covered drugs in 2024. This amount, also called the true out-of-pocket costs (TrOOP), is made up of what a beneficiary pays for covered drugs and some costs that others pay. During this period, a beneficiary owes no cost-sharing for covered drugs.

True out-of-pocket (TrOOP)

Troop costs are the expenses that count toward the threshold that determines the start of catastrophic coverage. The out-of-pocket costs that help someone reach catastrophic coverage include:

- The deductible
- What the beneficiary paid during the initial coverage period
- Almost the full cost of brand-name drugs (including the manufacturer's discount) purchased during the coverage gap
- Amounts paid by others, including family members, most charities, and other persons on the beneficiary's behalf
- Amounts paid by State Pharmaceutical Assistance Programs (SPAPs, such as EPIC in New York State), AIDS Drug Assistance Programs, and the Indian Health Service

Not all drug costs count, though. Costs that do not help reach catastrophic coverage include monthly premiums, what the plan pays toward drug costs, the cost of non-covered drugs, the cost of covered drugs from pharmacies outside the plan's network, payments reimbursed by a third party (such as a supplemental insurance plan sponsored by a former employer), and the 75% generic discount.

Part D premium: IRMAA

The Medicare Income-Related Monthly Adjustment Amount (IRMAA) is an amount a beneficiary may have to pay in addition to their Part B or Part D premium if their income is above a certain level. The Social Security Administration (SSA) sets income brackets that determine a beneficiary's IRMAA. SSA determines if a beneficiary owes an IRMAA based on the income the individual reported on their IRS tax return two years prior, meaning two years before the year in which the individual is paying IRMAA. The income that





counts is the adjusted gross income reported plus other forms of tax-exempt income. The IRMAA is collected by SSA, not by the Part D plan, and is paid in the same way as the Part B premium. For most beneficiaries, this means the IRMAA is deducted directly from their Social Security check.

If a beneficiary believes they should not owe IRMAA, their circumstances have changed, or their IRMAA was miscalculated, they have the right to request that SSA lower or eliminate their premium increase. The beneficiary will have to submit evidence if they are appealing SSA's original determination or requesting a new determination.

The chart below shows the IRMAA a beneficiary may owe depending on their income. Note that an IRMAA is always calculated using the national base beneficiary premium. A beneficiary's IRMAA will not decrease if they enroll in a Part D plan with a lower premium.

2024 Part D IRMAA				
Income		Amount owed in		
Individual	idividual Couple	Married, filing	addition to regular	
iliuiviuuai		separately	Part D premium	
\$103,000 or below	\$206,000 or below	\$103,000 or less	\$0	
\$103,001 - \$129,000	\$206,001 - \$258,000	N/A	\$12.90	
\$129,001 - \$161,000	\$258,001 - \$322,000	N/A	\$33.30	
\$161,001 - \$193,000	\$322,001 - \$386,000	N/A	\$53.80	
\$193,001 -\$499,999	\$386,001 - \$749,999	Above \$103,000 and	\$74.50	
\$133,001 -\$433,333	7360,001 - 7749,999	less than \$397,000		
\$500,000 and above	\$750,000 and above	\$397,000 and above	\$81	

Late enrollment penalty

Even if a person with Medicare does not take many (or any) prescription drugs, they still should consider enrolling in a Part D plan or seeking creditable coverage from another source. Those who do not enroll in a plan when first eligible will have to pay a Part D late enrollment penalty (LEP), unless they:

- Have creditable drug coverage (such as insurance through a former employer or union, the Veterans Administration, TRICARE for Life, or the Indian Health Service)
- Qualify for the Extra Help program (see HIICAP Notebook Chapter 10)
- Prove that they received inadequate information about whether their drug coverage was creditable

In most cases, an individual will have to pay that penalty every month for as long as they have Medicare. If they are enrolled in Medicare because of a disability and currently pay a premium penalty, once they turn 65 they will no longer have to pay the penalty.





The LEP is equivalent to 1% of the national base beneficiary premium per full month that the person with Medicare was not enrolled in a Medicare prescription drug plan (and did not meet any of the exceptions listed above). In 2024, the national base beneficiary premium is \$34.70, so the penalty would be \$34.70 x 1%, or approximately \$0.35 (\$0.3470) per month. You should count from the month following the end of the seven-month Initial Enrollment Period for Part D to determine the number of months without creditable drug coverage to calculate the Part D LEP. If the Medicare beneficiary has had creditable coverage with a gap of no more than 63 days from when that coverage ended and Medicare Part D begins, they will not be subject to the penalty.

PART D COVERAGE

Each Part D plan has a list of covered drugs, called its formulary. Plans must obtain Centers for Medicare & Medicaid Services (CMS) approval of their formularies and must make their formularies publicly available. You can find plan formularies on the individual plan websites. If a client's drug is not on the formulary, they may have to request an exception, pay out of pocket, or file an appeal.

A drug category is a group of drugs that treat the same symptoms or have similar effects on the body. All Part D plans must include at least two drugs from most categories and must cover all drugs available in the following categories:

- HIV/AIDS treatments
- Antidepressants
- Antipsychotic medications
- Anticonvulsive treatments for seizure disorders
- Immunosuppressant drugs
- Anticancer drugs (unless covered by Part B)

Vaccines

If a client's provider recommends that they get a vaccine, in most cases it will be covered by Part D. Part D plans must include most commercially available vaccines on their formularies, including the vaccine for shingles (herpes zoster). The only exceptions are flu, pneumonia, hepatitis B, and COVID-19 vaccinations, which are covered by Part B.

As of January 2023, Medicare-covered vaccines are free under Part D. This means beneficiaries should not owe any cost-sharing, such as a copayment, coinsurance, or deductible, for their covered vaccines. This applies to the vaccines, including the shingles vaccine, recommended by the Advisory Committee on Immunization Practices (ACIP) for adults.

To avoid billing issues, it is usually best to make sure that a health care provider or pharmacy administering the vaccine will bill the Part D plan. When a beneficiary gets a vaccine at their doctor's





office, they should ask the provider to call their Part D plan first to find out if the provider can bill the Part D plan directly.

Compounded drugs

Sometimes a pharmacist or physician will combine, mix or alter ingredients of a drug to create a medication tailored to the needs of an individual patient. This type of medication is called a compounded drug. Part D will only cover compounded drugs that contain at least one ingredient that is a Part D drug, and that do not contain any Part B ingredients.

Insulin

Part D may cover insulin and related medical supplies used to inject insulin (syringes, gauze, and alcohol swabs) if the beneficiary has a prescription from their doctor. Part D should cover medications and supplies needed to treat diabetes at home if they are on the plan's formulary. As of January 2023, Part D-covered insulin copays are capped at \$35 per month, with no deductible.

Medical supplies used to inject insulin (syringes, fillable pens, non-durable patch pumps like the Omnipod, gauzes, and alcohol swabs) can be covered by Part D with a prescription, as long as they are on the plan's formulary. This equipment is not subject to the \$35 per month cap and a deductible may apply. The \$35 cap applies to the insulin that is used with these supplies.

If a beneficiary uses an insulin pump, the insulin and the pump may be covered under Part B as DME (see HIICAP Notebook Module 4).

Excluded drugs

There are certain kinds of drugs that are excluded from Medicare coverage by law. Medicare does not cover:

- Drugs used to treat anorexia, weight loss, or weight gain (Note that Part D may cover drugs used to treat physical wasting caused by AIDS, cancer, or other diseases)
- Fertility drugs
- Drugs used for cosmetic purposes or hair growth (Note that drugs used for the treatment of psoriasis, acne, rosacea, or vitiligo and other dermatologic diseases or conditions are not considered cosmetic drugs and may be covered under Part D)
- Drugs that are prescribed only for the relief of cold or cough symptoms
- Drugs used to treat erectile dysfunction
- Prescription vitamins and minerals (except prenatal vitamins and fluoride preparations)
- Non-prescription drugs (over-the-counter drugs)

Prescription drugs used for the above conditions may be covered if they are being prescribed to treat other conditions. For example, a medicine for the relief of cold symptoms may be covered by Part D if





prescribed to treat something other than a cold—such as shortness of breath from severe asthma—as long as it is approved by the U.S. Food and Drug Administration (FDA) for such treatment.

If a doctor prescribes a non-cancer medication on a beneficiary's plan's formulary for a reason other than the use approved by the FDA, the drug will probably not be covered unless the use is listed in one of three Medicare-approved drug compendia (medical encyclopedias of drug uses). For fighting cancer, a drug plan will draw from these and additional compendia and peer-reviewed medical literature when deciding whether to cover a drug.

A beneficiary may also receive a denial from their Part D plan stating that a drug does not meet the FDA's Drug Efficacy Study Implementation (DESI) standards. DESI evaluates the effectiveness of drugs that had been previously approved on safety grounds alone. Drugs that are found to be less than effective by DESI evaluation are excluded from coverage by Part D.

Enhanced Part D plans may include certain excluded drugs as part of their enhanced plan benefit, but the cost of Part D-excluded drugs cannot be counted toward TrOOP.

Provider preclusion list

The Provider Preclusion List, effective January 1, 2019, is a list of providers and prescribers who are precluded from receiving payment for Medicare Advantage items and services or Part D drugs furnished or prescribed to Medicare beneficiaries. The Preclusion List is a list of prescribers and individuals or entities who fall within any one of the following categories:

- Are currently revoked from Medicare, are under an active reenrollment bar, and CMS has determined that the underlying conduct that led to the revocation is detrimental to the best interests of the Medicare program.
- Have engaged in behavior for which CMS could have revoked the prescriber, individual or entity to
 the extent applicable if they had been enrolled in Medicare, and CMS determines that the
 underlying conduct that would have led to the revocation is detrimental to the best interests of
 the Medicare program
- Have been convicted of a felony under federal or state law within the previous 10 years that CMS
 deems detrimental to the best interests of the Medicare program. Such conduct includes, but is
 not limited to, felony convictions and Office of Inspector General (OIG) exclusions.

Part D sponsors are required to reject a pharmacy claim (or deny a beneficiary request for reimbursement) for a Part D drug that is prescribed by an individual on the Preclusion List. CMS has additional information on the Preclusion List.





Part A vs. Part B vs. Part D

While Medicare Part D covers prescription drugs in most cases, there are circumstances where drugs are covered under either Part A or Part B.

- Part A covers the drugs needed during a Medicare-covered inpatient stay in a hospital or skilled nursing facility (SNF). Additionally, most drugs administered to hospice patients are covered under Part A. However, drugs unrelated to the terminal illness can be covered under Part D. Part D plans may impose prior authorization requirements on certain categories of drugs for beneficiaries who have elected hospice to determine whether the drugs are coverable under Part D.
 - Note: If a beneficiary is getting SNF care that is not covered by Part A, their drugs may be covered by Part D. These drugs can also be covered under Part B if the person does not have Part A coverage, Part A coverage of the hospital or SNF stay has run out, or if a stay is not covered.
- Part B covers most drugs administered by a provider or at a dialysis facility, but the provider or facility must buy and supply the drugs. Part B also covers some outpatient prescription drugs, mainly certain oral cancer drugs (chemotherapy). Outpatient drugs previously paid for by Part B will continue to be paid for by Part B. Part D cannot pay for any drugs that are covered by Part B.
- Part D covers most outpatient prescription drugs (drugs filled at a pharmacy). Check a plan's formulary to find out whether it covers the drugs needed.

There are a few drugs that can be covered by either Part B or Part D depending on the circumstances. Generally, Part B coverage is usually—but not always—limited to medications that are infused or injected in a doctor's office or hospital outpatient setting. See this chart, Medicare Drug Coverage: Part B vs. Part
D, from the Medicare Rights Center for more information.

Utilization management techniques

In an effort to control costs, many Part D plans employ "utilization management" tools, the most common of which are prior authorization, step therapy, and quantity limits. Additionally, plans use tiers to further control costs.

- **Prior authorization** means that the person's doctor must request permission ahead of time from the plan to get the drug covered, and the beneficiary may have to meet specific criteria before the plan will approve the request.
- **Step therapy** is a type of prior authorization where a Part D plan will require a beneficiary to try less expensive drugs for the same condition before they will pay for a more expensive or brand name medication. Beneficiaries who have already tried the less expensive drugs should speak to their doctor about contacting the plan to request an exception (explained below).
- Quantity limits limit the quantity of drugs that a plan covers over a certain period of time for safety and cost reasons. For instance, a plan may only cover up to a 30-day supply of a drug at a time. However, regardless of the quantity the plan approves, the same copayment applies. For formulary drugs that are provided on an extended supply basis (longer than 30 days), the plan may





choose to impose a 30-day limit on the initial fill. CMS is allowing this change to limit drug waste when a new therapy is not working for the patient or has adverse effects.

• **Tiers** are a system used to price prescription drugs. Most Part D plans divide their formulary into tiers and encourage the use of drugs covered under the lowest tiers, by assigning different copayments or coinsurance for each tier. Generic drugs are generally on the first, least expensive tier (Tier 1), followed by brand-name drugs (Tier 2), and then specialty drugs (Tiers 3 and above), with each higher tier generally requiring higher out-of-pocket costs or percentages.

Note: Prior authorization, step therapy, quantity limits, and tiers are all indicated on the <u>Medicare Plan</u> <u>Finder</u> when searching for specific drugs covered under a Part D plan.

COORDINATION WITH OTHER DRUG COVERAGE

Job-based insurance

Some job-based insurance plans offer creditable drug coverage. This drug coverage could be from a current employer, union, former employer (retiree coverage), or even COBRA. Creditable coverage is determined to be at least as good as the standard Medicare prescription drug coverage under an actuarial analysis. If a beneficiary is eligible for Medicare and enrolled in creditable drug coverage, they can delay Part D enrollment without incurring a late enrollment penalty. When they decide to enroll in Part D, they will have a two-month Special Enrollment Period (SEP).

Even if a client's drug coverage is not creditable, they may want to keep it as a form of secondary insurance and enroll in a Part D plan as primary insurance. Having secondary insurance may help lower the cost of Part D-covered drugs when an individual is in the coverage gap (donut hole). A client should contact their plan to learn whether it coordinates with Part D coverage. A client should also consider whether the cost of their monthly premium for the plan is offset by the coverage it provides, or whether they are better off disenrolling and only keeping Part D.

In some job-based plans, a beneficiary cannot drop drug coverage without losing their health benefits or vice versa. Also keep in mind that a client's spouse or dependents are not eligible to use the client's Medicare coverage and may need other insurance if they drop their job-based insurance. A client should contact their benefits administrator to learn more about their job-based insurance before making Part D enrollment decisions.

If a client's job-based drug coverage is not creditable, they can still delay enrollment into Part D. They will have the previously mentioned two-month SEP to enroll in a Part D plan. However, this SEP does not eliminate the Part D LEP. To avoid the LEP, the client needs to enroll in Part D when first eligible.





Medicaid

If a beneficiary has Medicare and Medicaid (meaning they are dually eligible), their drugs are generally covered by Part D and Extra Help. In many states, Medicaid covers some of the drugs that are excluded from Medicare coverage. Each state has its own Medicaid formulary. New York State Medicaid drug coverage for dually eligible individuals includes certain over-the-counter (or non-prescription) drugs and prescription vitamins and minerals. Beneficiaries will only pay a small copayment for prescriptions that are covered by Medicaid in their state.

Veterans Affairs (VA)

VA benefits offer creditable drug coverage. This means that if a client is enrolled in VA drug coverage, they can delay Part D enrollment without incurring an LEP. The beneficiary should be sure to compare the costs and benefits of Part D and their VA drug coverage to decide which best suits their needs. Typically, VA drug coverage has no premiums and no or limited copayments for prescriptions—but beneficiaries must use VA pharmacies and facilities. A client may want Part D coverage if they:

- Live far from a VA pharmacy or facility, or do not want to use a VA provider to get prescriptions
- Want the flexibility of filling prescriptions at retail pharmacies
- Find the VA formulary too restrictive
- Reside in a non-VA nursing home and want to get prescriptions from the long-term care pharmacy that works with their nursing home
- Qualify for Extra Help, which has lower copays than VA coverage

If a client is considering enrolling in VA drug coverage and Part D, they should remember that the two do not work together. VA benefits will only pay at VA pharmacies and facilities, and Part D will only pay at pharmacies in the plan's network. For more information about VA benefits and coverage, visit the Department of Veterans Affairs website or call at 1-800-827-1000.

TRICARE For Life (TFL)

TFL offers a pharmacy program that provides creditable drug coverage. This means that if a client is enrolled in the TFL pharmacy program, they can delay Part D enrollment without incurring a late enrollment penalty. They should be sure to compare the costs and benefits of Part D and the TFL pharmacy program to decide which best suits their needs.

If the client is eligible for Extra Help, they may want to consider enrolling in Part D. The drug copayments for individuals who have Part D and Extra Help are typically lower than copays in the TFL pharmacy program. However, TFL's formulary may be broader than the formularies of Part D plans offered in a beneficiary's area. A client may also want to keep TFL's pharmacy program if the plan covers their drugs with no or fewer coverage restrictions than available Part D plans. The TFL pharmacy program may also cover medically necessary drugs not on its formulary for a higher copay. If a client enrolls in both Part D and TFL's pharmacy program, Part D is the primary payer for their prescription drugs.





Indian Health Services (IHS)

IHS beneficiaries have creditable drug coverage. This means they can delay enrollment in Part D without an LEP. People should consider their costs and access under both programs to decide if declining Part D coverage is the right choice for them.

Medigap

Medigap plans stopped offering prescription drug coverage in 2006. However, there may be some beneficiaries who were enrolled in Medigap plans H, I, or J with prescription drug coverage prior to 2006 who are still enrolled in the same Medigap plan today. (Plans H, I and J no longer exist in the current standardized Medigap plans. They were eliminated in June 2010.) These plans were never considered to be creditable drug coverage. If a beneficiary kept their existing Medigap plan H, I, or J with drug coverage and later decide to enroll in a Part D plan, they will be subject to a late enrollment penalty.

ADAP (AIDS Drug Assistance Program)

ADAP, administered through the NYS Department of Health, provides free medications for the treatment of HIV/AIDS and opportunistic infections. There is an income test for ADAP (500% of the Federal Poverty Level). ADAP does not have a citizenship/immigration status requirement but does require enrollees be NYS residents.

For beneficiaries who have both ADAP and Part D, Part D will generally be the primary payer for HIV-related medications. ADAP can help with Part D copayments and deductibles and will pick up the cost of HIV-related medications during the Part D coverage gap. ADAP expenditures count toward TrOOP.

Additionally, ADAP can be billed as primary payer in order to meet a Medicaid spenddown obligation (i.e., if the person needs Medicaid or Extra Help coverage). For more information about how ADAP and Part D work together, see Frequently Asked Questions from NYS Department of Health.

CHOOSING A PART D PLAN

For many beneficiaries, one of the most challenging aspects of Part D is choosing a plan. Fortunately, Medicare's Plan Finder tool makes that process considerably easier. The website has comprehensive information about Part D plans, how well they are rated, what drugs they cover, the cost sharing involved, utilization management requirements (i.e., any special restrictions on covered drugs, such as a prior authorization requirement, quantity limits, and step-therapy) and contact information for the plans. The website has a search function that allows the user to find plans that cover specific drugs and then view a detailed comparison of each plan's coverage.

In addition to accessing this tool online, beneficiaries can call 1-800-MEDICARE (1-800-633-4227) for detailed information on Part D options. TTY users should call 1-877-486-2048. Callers can speak with a customer service representative at 1-800-MEDICARE 24 hours a day, including weekends.





Before a client begins looking for plans, they should know:

- The prescriptions they take, including their dosages and usual costs (they may want to ask their doctor for help creating a list)
- The pharmacies they regularly use

When a client is choosing between multiple Part D plans here are some questions they should be asking:

- Drug coverage: Are my prescriptions on the plan's formulary? Does the plan impose any coverage restrictions, such as prior authorization or step therapy? If the plan does not cover a medication I take, does it cover one that will work for me? (Ask doctor.)
- Costs: How much will I pay at the pharmacy (copayments or coinsurance) for each drug I need? How much will I pay for monthly premiums and the annual deductible? How much will I have to pay for brand-name drugs? How much for generic drugs? What will I pay for my drugs during the coverage gap? If a drug I take has a very high coinsurance, is there a drug I can take that will cost less? (Ask doctor.)
- Pharmacy network: What is the service area for the plan? Can I fill my prescriptions at the pharmacies I use regularly? Can I fill my prescriptions when I travel? What will my coverage options and costs be if I visit out-of-network pharmacies? Can I get prescriptions by mail order?
- Coordination with other insurance: Will Part D work with other coverage I have to lower my costs? Do I need to enroll in Part D if I have other creditable coverage? Do I need to enroll in Part D if I have job-based drug coverage?

Annual Notice of Change (ANOC)

It is important for Part D beneficiaries to compare their current coverage with other options each year, to find the best coverage for their individual circumstances and maximize savings. This is because from year to year, Part D plans can change their costs, benefits, and rules in ways that might make them less attractive or less affordable for beneficiaries.

All Medicare Part D plan members should receive a combined Annual Notice of Change (ANOC)/Evidence of Coverage (EOC) notice from their plan each year by September 30. The ANOC details all changes for the following year including premiums, costs, restrictions, and formularies. The ANOC is not specific to the plan member, so beneficiaries should read it carefully to identify which changes may apply to them.

ENROLLMENT

An individual can usually enroll in a Medicare Advantage or stand-alone Part D plan through Medicare's website. (There are a few exceptions; someone cannot enroll online into a special needs plan or a low performing plan—one with a consistently low-quality rating.) Beneficiaries can also enroll in a Part D plan by calling 1-800-MEDICARE or by contacting the plan directly.





Initial Enrollment Period (IEP)

The Part D Initial Enrollment Period (IEP) is when a beneficiary is first eligible to enroll in a Part D plan. Remember that an individual must have at least Part A or Part B to be eligible for Part D.

Beneficiaries who are new to Medicare may enroll in a Part D plan in the same 7-month IEP that they have for Part B, including the month of their eligibility, the three months prior, and the three months after.

If a client is not eligible for Part D during their Part B IEP (meaning they do not have Part A or B), they have a Part D IEP that is the three months before becoming eligible for Part D, the month of Part D eligibility, and the three months after. Those who were eligible for Medicare before turning 65 have another Part D IEP upon reaching age 65.

Fall Open Enrollment Period

Beneficiaries can also enroll, drop, or change plans during the Fall Open Enrollment Period, sometimes also called the Annual Election Period (AEP). This period is the same for both PDP and Medicare Advantage enrollment. Fall Open Enrollment is October 15 – December 7, with the change becoming effective January 1.

Special Enrollment Periods (SEPs)

In general, beneficiaries can change plans only once each year, during Fall Open Enrollment. However, there are also limited exceptions where a beneficiary would be granted a Special Enrollment Period (SEP) to enroll in, disenroll, or switch plans outside of the Fall Open Enrollment Period. A beneficiary may be eligible for an SEP if they:

- Lose creditable coverage through no fault of their own.
- Make a change to their job-based drug coverage.
- Move out of their Part D plan's service area.
- Disenroll from their Medicare Advantage Plan and enroll in Original Medicare, assuming they joined the MA Plan when they first qualified for Medicare based on age and want to disenroll within the first year.
- Want to join a five-star plan available in their service area.
- Have or lose Extra Help.
- Are admitted into or reside in a qualifying institution.
- Receive inadequate information about whether their existing prescription drug coverage is creditable.
- Are in a Part D plan that stops offering coverage, fails to provide benefits on a timely basis, or misled them about what benefits they would get.
- Enroll or fail to enroll in a Part D plan because of a federal employee's error.
- Enroll in an All-inclusive Care for the Elderly (PACE) program.





• Become eligible for a Special Needs Plan (SNP).

For a full list of SEPs and requirements, please see the <u>Part D Special Enrollment Period Chart</u> from the Medicare Rights Center.

Tips on switching or disenrolling from plans

When switching Part D plans, it is not necessary to contact the current plan to disenroll. Simply enroll in the new Part D plan. This will automatically disenroll the beneficiary from their current plan because they cannot be enrolled in two Part D plans at the same time. The beneficiary will be disenrolled on the last day of the month before the new enrollment takes effect. No additional contact with the previous plan is needed. CMS recommends that people change plans early in the month to avoid delays at the pharmacy counter. Remember that beneficiaries can enroll online, by calling 1-800-MEDICARE, or by calling the plan directly.

Part D enrollment for those with Medicaid

Medicaid recipients newly enrolled into Medicare will have their Part D enrollment become effective the first of the month in which Medicare Part A or Part B starts.

Medicare recipients who are not already enrolled in Part D, and who gain Medicaid coverage, will gain Part D coverage effective the first day of the month of Medicaid eligibility.

Medicare beneficiaries new to Medicaid who do not have an existing Part D plan, and Medicaid recipients who are new to Medicare and have not chosen a Part D plan, can obtain Part D drugs through a special program called LI-NET (Limited Income Newly Eligible Transition). LI-NET provides temporary prescription drug coverage at the point of sale (pharmacy) until the person enrolls in, or is auto-assigned to, a Part D plan. Read more about the LI-NET program.

The LI-NET Program also provides retroactive coverage for new dual eligibles. Medicare automatically enrolls these individuals into the LI-NET Program with an effective date retroactive to the start of their dual-eligible status. Enrollment in LI-NET is temporary until Medicare enrolls these individuals in a Part D plan for the future.

Part D enrollment for those with Extra Help

Those with Original Medicare and Extra Help (either through automatic enrollment or through an SSA application) may be automatically enrolled in a benchmark Medicare PDP if they do not choose their own Part D plan. This is sometimes called facilitated enrollment. A benchmark plan is a PDP available at zero premium for beneficiaries who receive Extra Help.

Beneficiaries enrolled in a Medicare Advantage plan without Part D who later receive Extra Help will be facilitated into their own plan company's Medicare Advantage Plan that includes drug coverage.





Beneficiaries in a Private Fee for Service or Medicare Medical Savings Account plan without Part D who receive Extra Help will be facilitated into a random stand-alone Part D plan, similarly to those beneficiaries in Original Medicare.

PROTECTIONS: TRANSITIONS, EXCEPTIONS AND APPEALS

Transition drug refills

A transition refill, also known as a transition fill, is typically a one-time, 30-day supply of a drug that a beneficiary was taking:

- Before switching to a different Part D plan (either stand-alone or through a Medicare Advantage Plan)
- Or, before their current plan changed its coverage at the start of a new calendar year

Transition refills let a beneficiary get temporary coverage for drugs that are not on their plan's formulary or that have certain coverage restrictions (such as prior authorization or step therapy). Transition refills are not for new prescriptions. A beneficiary can only get transition fills for drugs they were already taking before switching plans or before their existing plan changed its coverage.

The following situations describe when an individual can get a transition refill if they do not live in a nursing home (there are different rules for transition refills for those living in nursing homes):

- 1. The current plan is changing how it covers a Medicare-covered drug the beneficiary has been taking.
 - a. A Part D plan's formulary can change from year to year. If the plan is taking a beneficiary's drug off its formulary or adding a coverage restriction for the next calendar year for reasons other than safety, the plan must either:
 - i. Help the individual switch to a similar drug that is on the plan's formulary before
 January 1
 - ii. Or, help the beneficiary file an exception request before January 1
 - iii. Or, give the beneficiary a 30-day transition fill within the first 90 days of the new calendar year along with a notice about the new coverage policy.
- 2. The new plan does not cover a Medicare-covered drug the beneficiary has been taking.
 - a. If a drug the beneficiary has been taking is not on the new plan's formulary, this plan must give the individual a 30-day transition refill within the first 90 days of their enrollment. It must also give the beneficiary a notice explaining that their transition refill is temporary and informing them of their appeal rights.
 - b. If a drug the beneficiary has been taking is on the new plan's formulary but with a coverage restriction, this plan must give a 30-day transition refill free from any restriction within the





first 90 days of the beneficiary's enrollment. It must also give them a notice explaining that the transition refill is temporary and informing the individual of their appeal rights.

c. In both above cases, if a drug the beneficiary has been taking is not on the new plan's formulary, a beneficiary should be sure to see whether there is a similar drug that is covered by the plan (they should check with their doctor about possible alternatives) and, if not, to file an exception request. (If the request is denied, they have the right to appeal.)

If the beneficiary files an exception request and the plan does not process it by the end of the 90-day transition refill period, the plan must provide additional temporary refills until the exception is completed.

Remember: All stand-alone Part D plans and Medicare Advantage Plans that offer drug coverage must provide transition fills in the above cases. When an individual uses their transition fill, the plan must send a written notice within three business days. The notice will explain that the supply was temporary and that the beneficiary should either change to a covered drug or file an exception request with the plan.

Mid-year formulary changes

After the first 60 days of the year, plans can make changes to their formulary. These are known as midyear formulary changes. Plans that remove a drug from their formulary midyear or change its cost sharing are supposed to give 60 days notice in advance to affected members, their prescribing doctors, and pharmacists. Plans should also post midyear formulary changes on their websites.

If a client's drug is removed from the formulary through a midyear change, the plan should continue to cover the drug for them until the end of the calendar year, unless there are safety issues or there is a generic form of the drug.

Part D appeals

If a beneficiary was denied coverage for a prescription drug, they should ask their plan to reconsider its decision by filing an appeal. The appeal process is the same in stand-alone Part D plans and Medicare Advantage Plans with Part D coverage. Below are the steps to follow if a plan denies coverage for a prescription. If a client needs their prescription immediately, they can file a fast (expedited) appeal.

If the appeal is successful at any point outlined below, the plan should cover the drug in question until the end of the current calendar year. A beneficiary should ask the plan if they will cover the drug after the year ends. If they will not, the beneficiary can appeal again next year or consider switching during Fall Open Enrollment to a Part D plan that does cover the drug.

While following the steps below, a beneficiary should make copies of all the documents they send to and receive from the plan, and take detailed notes about who they talk to at the plan, when they spoke to them, and what they said. See the table below for an overview of the appeals process, and the corresponding numbers below for additional details.





Le	vel	Standard Appeal	Expedited Appeal
1	Redetermination by	The plan has up to 7 days to make its	The plan has 72 hours to
	Medicare Part D	decision.	make its decision.
	plan		
2	Reconsideration by	The IRE has up to 7 days to make its	The IRE has 72 hours to
	Independent Review	decision.	make its decision.
	Entity (IRE)		
3	Office of Medicare	The amount in controversy must be at least	OMHA has 10 days to
	Hearings and	\$180 (in 2024). OMHA has 90 days to make	make its decision.
	Appeals (OMHA)	a decision.	
4	Council	The Council has 90 days to make its	The Council has 10 days to
		decision.	make its decision.
5	Federal District	The amount in controversy must be at least	Not applicable.
	Court	\$1,840 (in 2024). There is no timeframe for	
		the Federal District Court to make a	
		decision about an appeal.	

- 1. If a pharmacist tells a beneficiary that their plan will not pay for their prescription drug, the pharmacist should give the beneficiary a notice titled Medicare Prescription Drug Coverage and Your Rights. First, the beneficiary should call the plan to find out the reason it is not covering the drug. The plan may deny coverage because the drug is not on its formulary, or because a coverage restriction imposes requirements that must be met before the beneficiary can get their drug. Keep in mind that this is not a denial notice from the plan, meaning the beneficiary has not started a formal appeal.
- 2. Once a beneficiary knows why their drug was not covered at the pharmacy, they should speak to their prescribing physician or other provider about their options. For example, a beneficiary may be able to try a comparable drug that is on the formulary. If switching to another drug is not an option, the beneficiary can choose to appeal. Their provider may appeal on their behalf or help with the appeal process but is not required to do so.
- 3. Before starting the appeal process, a beneficiary needs to file an exception request (a formal coverage request) with the plan. Contact a plan to learn how to file an exception request. A beneficiary will need a doctor's letter of support for an exception request. A doctor may file on someone's behalf but is not required to do so. The plan should issue a decision within 72 hours.





- 4. A beneficiary can request a fast (expedited) exception request if they or their doctor feel that their health could be seriously harmed by waiting the standard timeline for a decision. If a doctor supports the decision to file an expedited exception request, the plan must follow the expedited timeline. A beneficiary can request an expedited exception request without their doctor's support, but in this case the plan does not have to follow the expedited timeline. If the plan grants the request to expedite the process, the beneficiary will get a decision within 24 hours of the initial request.
- 5. If the exception request is approved, the drug will be covered. If the exception request is denied, the plan should send a Notice of Denial of Medicare Prescription Drug Coverage. The beneficiary has 60 days from the date listed on this notice to begin the formal appeal process by filing an appeal with the plan. This timeline applies regardless of whether the appeal is under standard or expedited review. The beneficiary should follow the directions on the notice. If a doctor is not appealing on their behalf, the beneficiary may want to ask their doctor to write a letter of support addressing the plan's reasons for not covering the needed drug. The plan should issue a decision within seven days. If it is an expedited appeal, the plan should issue a decision within 72 hours. If the plan approves the appeal, the drug will be covered.
- 6. If the appeal is denied, the beneficiary can choose to move to the next level by appealing to the Independent Review Entity (IRE) within 60 days of the date listed on the appeal denial. The IRE should issue a decision within 7 days. If it is an expedited appeal, the IRE should issue a decision within 72 hours. If the IRE approves the appeal, the drug will be covered.
- 7. If the appeal is denied and the drug is worth at least \$180 in 2024, the beneficiary can choose to appeal to the Office of Medicare Hearings and Appeals (OMHA) level within 60 days of the date on the IRE denial letter. A client may want to contact a lawyer or legal services organization to help with this or later steps of the appeal—but it is not required. MCCAP-funded agencies can provide help with Part D appeals, including representing individual beneficiaries in the appeals process. For a list of MCCAP agencies, go to the HIICAP Quick Reference Guide found under Resource Materials. OMHA should issue a decision within 90 days. If the appeal is expedited, OMHA should issue a decision within 10 days. If the appeal to the OMHA level is successful, the drug will be covered.
- 8. If the appeal is denied and the drug is worth at least \$180 in 2024, the beneficiary can appeal to the Council within 60 days of the date on the OMHA level denial letter. The Council should issue a decision within 90 days. If appeal is expedited, the Council should issue a decision within 10 days. If the appeal to the Council is successful, the drug will be covered.





9. If the appeal is denied and the drug is worth at least \$1,840 in 2024, the beneficiary can appeal to the Federal District Court within 60 days of the date on the Council denial letter. There is no timeframe for the Federal District Court to make a decision about an appeal.

If a Part D plan is not following Medicare rules, and efforts to resolve the problem directly with the plan have failed, a formal complaint can be filed with the CMS regional office. CMS regional office staff will investigate and attempt to resolve the complaint. HIICAP counselors should use the Complaint Tracking Module (CTM) system to file such a complaint.

Requesting a tiering exception

If a Part D plan is covering a drug but the copayment is expensive, it could be that the medication is on a high tier. Part D plans use tiers to categorize prescription drugs. Higher tiers are more expensive and have higher cost-sharing amounts. Each plan sets its own tiers, and plans may change their tiers from year to year. If a client cannot afford their copay, they can ask for a tiering exception by using the Part D appeal process. A tiering exception request is a way to request lower cost-sharing. For tiering exception requests, the beneficiary or their doctor must show that drugs for treatment of their condition that are on lower tiers are ineffective or dangerous for the beneficiary. Follow the steps below when asking for a tiering exception:

- 1. If a beneficiary is charged a high copay at the pharmacy, they should talk to the pharmacist and their plan to find out why. If the copay is high because the prescription is on a higher tier than other similar drugs on the formulary, they can ask for a tiering exception.
 - a. A beneficiary can't make a tiering exception request if the drug is in a specialty tier (often the most expensive drugs). Tier exceptions also cannot be requested to have brand name drugs covered under a generic tier.
- 2. They should next ask the plan how to send a tiering exception request. It is usually helpful to include a letter of support from the prescribing physician. This letter should explain why similar drugs on the plan's formulary at lower tiers are ineffective or harmful for the beneficiary. The plan must give a decision within 72 hours of receiving the request. The beneficiary can request a fast (expedited) appeal if they or their doctor feel that their health could be seriously harmed by waiting the standard timeline for appeal decisions. If the plan grants the request to expedite the process, the beneficiary will get a decision within 24 hours.
 - a. The beneficiary's doctor may fill out a standard Coverage Determination Request Form to support the request. All plans must accept this form, but some plans may have their own forms that they prefer being used.
 - b. The beneficiary may be able to file their request over the phone, but the plan can still require that the doctor submit a written statement of support. The plan may not process the request until the doctor has provided requested information. A beneficiary should keep records of the documents they and their doctor send and when they were sent.





3. If the plan approves the tiering exception request, the drug will be covered at cost-sharing that applies in the lower tier. Normally, an approved exception will be good until the end of the current calendar year. A beneficiary should ask the plan if they will cover the drug after the year ends. If they will not, the beneficiary can appeal again next year or consider switching during the Fall Open Enrollment Period to a Part D plan that does cover the drug. If the plan denies the request, it should send the beneficiary a letter titled Notice of Denial of Medicare Prescription Drug Coverage—and the beneficiary can appeal this decision.

CMS has developed a model form for coverage determinations, which beneficiaries and their physicians can use. Plans often have their own coverage determination request forms, although they cannot require beneficiaries or their physicians to use a specific form. CMS mandates a uniform exceptions and appeals process, meaning that, among other things, there is one standardized form to be used by all plans.

STRATEGIES FOR PRESCRIPTION AFFORDABILITY

First, screen the client for cost-assistance programs like Extra Help and EPIC (New York State's State Pharmaceutical Assistance Program). (See HIICAP Notebook Module 10: Extra Help and HIICAP Notebook Module 11: EPIC.) Whether or not the client is enrolled in or eligible for these programs, there are a few additional strategies that may help lower their drug costs. These programs may be able to assist individuals with no drug coverage at all, people who need help paying for a specific drug (such as an off-label medication), or beneficiaries who have drug coverage but can't afford their cost sharing obligation.

The client can ask their doctor:

- About generics: Generic drugs are often less expensive than brand-name drugs and might be more affordable. A client should check with their doctor to see if a generic drug will work.
- For samples of medication: This is a temporary solution, as a doctor may not be able to provide samples for very long. If a client is using samples, be sure to explore other options for getting these drugs covered.

The client can ask their plan:

- About mail-order prescriptions: If they have Extra Help and their drug plan has a mail-order option, they may be able to get a 90-day supply of the prescription at a lower cost. Keep in mind that with mail order, it may take longer to get the drugs than if they were to go to the pharmacy. A client should plan ahead when filling prescriptions by mail.
- For a tiering exception: If a Part D plan is covering a drug and the copayment is expensive, it could be that the medication is on a high tier. A tiering exception request is a way to request lower cost-sharing. See the section of this module on appeals for more information.

The client can ask their pharmacy or hospital:





- To waive the copay: Pharmacies are not allowed to routinely waive their copays for people without Extra Help, but a pharmacist can waive copays on a case-by-case basis. A client can tell their pharmacist that they cannot afford the copay, and request that it be waived. If a client is looking for a pharmacy that may waive their copay, make sure it is in the plan's network. Some pharmacies routinely waive copays for people with Extra Help. A client can ask their pharmacist if their pharmacy does this.
- About charity care: Hospitals may have a charity care policy that can reduce drug copays if someone cannot afford them. Under such a policy, the final copay is determined by the individual's income (using a sliding scale). To qualify, the prescription must be written by a doctor in the hospital and filled out at the hospital's pharmacy. A client should tell the hospital's pharmacist that they cannot afford the copay and ask if they qualify for prescription assistance. Make sure to confirm that the hospital's pharmacy is in-network.

Other options to lower costs:

- Needy Meds: The Needy Meds website is administered by a national nonprofit organization. It has
 a comprehensive listing of national and state resources to help pay for prescription medications,
 including drug discount cards or coupons for specific medications. You can look up a client's
 medication and also find if the drug manufacturer has a patient assistance program (PAP) that
 offers free or low-cost drugs directly to people with limited incomes.
- Promotional pharmacy price: Check if a pharmacy in the plan's network has a special promotion (limited time offer) to sell a medication that is on the plan's formulary at a lower price. The client will need to tell the pharmacist to refill the medication without using their Medicare drug coverage. It is best to take advantage of such specials only during the deductible or coverage gap because it is only during these times that what a client pays will count toward reaching the plan's catastrophic coverage limit. The client will need to submit receipts to the plan with any other required documentation for this amount to count toward reaching the catastrophic coverage limit.
- Pharmacy discount generic programs: Some retail pharmacies offer year-round discounts on generics. The client can check with in-network pharmacies to see if they sell any of their prescribed generics at a lower price. If the client normally pays a coinsurance, they will pay it based on the lower store price.

Sources of Assistance

NYSOFA HIICAP Hotline

1-800-701-0501

Medicare

1-800-MEDICARE (1-800-633-4227)





Call for questions about Medicare coverage, claims, or how Medicare works with your clients' other insurance.

http://www.medicare.gov

Social Security Administration

Hotline: 1-800-772-1213 Fax: 1-833-914-2016

Call for Medicare eligibility and enrollment information, lost Medicare card replacement and general Social Security issues. Visit www.ssa.gov/locator to find your local SSA office and contact information for

that office.

C2C Innovative Solutions, Inc.

Independent Review Entity (IRE) https://partdappeals.c2cinc.com/ (833) 919-0198

Fax (Standard): (833) 710-0580 Fax (Expedited): (833) 710-0579

Additional Resources

Your Guide to Medicare Prescription Drug Coverage, CMS Publication # 11109 https://www.medicare.gov/publications/11109-Medicare-Drug-Coverage-Guide.pdf

How Medicare Drug Plans Use Pharmacies, Formularies, and Common Coverage Rules, CMS Publication # 11136

https://www.medicare.gov/Pubs/pdf/11136-pharmacies-formularies-coverage-rules.pdf

Drug Coverage under Different Parts of Medicare, CMS Publication #11315-P https://cmsnationaltrainingprogram.cms.gov/sites/default/files/shared/11315-P%20Drug-Coverage-Parts-Medicare.pdf