



Medicare Advocacy Toolkit

Diabetes Supplies

An Advocate's Guide for Helping Medicare Beneficiaries
Access Supplies for Treating Diabetes

Fall 2020

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About the Medicare Rights Center

Based in New York, the Medicare Rights Center is a national, nonprofit consumer service organization that works to ensure access to affordable health care for older adults and people with disabilities through counseling and advocacy, educational programs, and public policy initiatives. Since 1989, Medicare Rights has helped people with Medicare understand their rights and benefits, navigate the Medicare system, and secure the quality health care they deserve. Medicare Rights is committed to:

1. Serving as a **kind and expert** health insurance counselor, educator, and advocate for those who need it most.
2. Providing **independent, timely, and clear** information on Medicare, Medicaid for dual-eligibles, and related topics to communities nationwide.
3. Fostering **diverse** partnerships and points of view.
4. Finding **lasting** solutions to systemic problems that prevent older adults and people with disabilities from accessing needed health coverage and care.

About the Advocacy Toolkits

With 30 years of counseling and advocacy experience, the Medicare Rights Center possesses specialized knowledge about the barriers people with Medicare face in accessing affordable health care, as well as strategies for overcoming these barriers. This series of Medicare Advocacy Toolkits has been developed for any New York advocate who is helping older adults and people with disabilities navigate health insurance benefits. The goal of this project is to empower New York advocates and those they serve to navigate Medicare coverage so that they can access needed care. While intended for a New York audience, the Medicare Advocacy Toolkits may offer lessons to other states and be useful resources as advocates and policymakers think about ways to improve the federal Medicare program, which today serves 60 million Americans. **Advocates with additional questions can contact Medicare Rights' professional email inbox at professional@medicarerights.org. Consumers with questions can call Medicare Rights' national consumer helpline at 1-800-333-4114.**

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customized assistance, contact Medicare Rights, 1-800-MEDICARE, or a local [State Health Insurance Assistance Program](#) (SHIP).

Introduction: Accessing Durable Medical Equipment

Every year, more than 500 clients reach out to the Medicare Rights Center's national helpline with issues related to accessing durable medical equipment (DME). Medicare's coverage for DME is vital, since the category includes common medically necessary items, such as oxygen supplies, mobility aids, and adaptive medical equipment like commode chairs, patient lifts, and hospital beds.¹ Unfortunately, many individuals find it difficult to access these essential items through Medicare.

This Medicare Advocacy Toolkit serves as a step-by-step resource to help advocates and people eligible for Medicare navigate DME access issues. The toolkit first describes the problem and target audience, then explains strategies for accessing diabetes supplies and offers a case example to demonstrate how to evaluate and use these strategies in a complex scenario. Throughout the guide, content is organized in a way that parallels how our counselors evaluate and troubleshoot actual Medicare issues. In addition, the guide contains a wealth of citations to the relevant rules that form the basis for helping people solve their Medicare problems.

The Problem

An estimated 34 million American adults had diabetes in 2020, while many millions more are likely to become diabetic in the years to come.² Daily access to blood-sugar testing supplies and insulin are vital to ensuring millions of Medicare beneficiaries can stay healthy and safe. Yet, Medicare Rights hears from hundreds of clients annually who face barriers to accessing diabetes supplies they or their loved ones need. These problems vary from coverage denials, affordability, and accessing the correct brand or type of supply. These access problems often have a cascading, negative effect on the lives of Medicare beneficiaries with diabetes. Accessing appropriate diabetes supplies is a key component to maintaining many individuals' health and quality of life. Yet, every year, Medicare Rights hears from people who are rationing their insulin, testing less frequently, or using a brand or type of supply that is not what works best for them."

Target Audience

This Medicare Advocacy Toolkit is designed to help advocates address the needs of New Yorkers who are eligible for Medicare coverage of diabetes supplies. Medicare's coverage rules for these supplies are the same regardless of how someone qualifies for Medicare. Thus, this guide is intended for use with individuals who are eligible for Medicare due to age, disability, or because they have End-Stage Renal Disease (ESRD).

Some diabetes supplies, such as those used for blood sugar testing, are also important for certain individuals without diabetes. Namely, those with impaired fasting glucose, insulin resistance syndrome, carbohydrate intolerance, hypoglycemia disorders (e.g., nesidioblastosis insulinoma), tuberculosis, unexplained chronic or recurrent infections, alcoholism, coronary artery disease, unexplained skin conditions, and individuals with a catabolic or malnutrition

¹ [42 U.S.C. § 1395m](#); Medicare.gov, [Durable medical equipment \(DME\) coverage](#).

² Centers for Disease Control and Prevention, [National Diabetes Statistics Report 2020: Estimates of Diabetes and Its Burden in the United States](#), p. 2.

state.³ Usually, these test are performed by providers rather than at home, are not as common as diabetic uses of these supplies, and they can fall under different Medicare coverage criteria.⁴ For those reasons, this guide focuses specifically on diabetes supplies used to treat diabetes.

Medicare's Coverage of Diabetes Supplies

When troubleshooting diabetes supply issues, Medicare Rights advocates often find it helpful to keep in mind the distinct needs individuals with diabetes have (e.g., to test their blood sugar or to administer insulin) and the various options for addressing those needs (e.g., manual testing versus a continuous glucose monitor). Accordingly, this toolkit organizes diabetes supplies into three categories of needs with various options for meeting those needs underneath:

1. **Blood sugar testing equipment**
 - a. Manual testing
 - b. Continuous glucose monitors
2. **Insulin administration**
 - a. Injection
 - b. Inhalation
 - c. Insulin pumps
 - d. Tubeless, disposable insulin pumps
3. **Diabetic shoes and inserts**

While this organizational system is useful for troubleshooting access issues, diabetes supplies can also be grouped into Part B- and Part D-covered items. This is a crucial distinction because it affects how much an individual will pay in cost-sharing. While using this guide, keep in mind:

Part B covers:⁵

- Testing equipment (including lancets and lancet devices, test strips, glucose control solution, and continuous glucose monitors)
- Insulin pumps and the insulin for them
- Diabetic shoes

Part D covers:⁶

- Injectable insulin and supplies (including syringes, needles, alcohol swabs, and gauze)
- Tubeless, disposable insulin pumps
- Inhalable insulin and supplies

Note: As detailed below, the coverage criteria vary by the type of supply. Yet, Medicare coverage for any diabetes supply requires a diabetes diagnosis. Medicare defines diabetes as “a condition of abnormal glucose metabolism” where the individual has:⁷

³ CMS, National Coverage Determination (NCD) for Blood Glucose Testing [190.20](#).

⁴ Ibid.

⁵ CMS, [Medicare Coverage of Diabetes Supplies, Services, & Prevention Programs](#), pp. 10-14. Although not covered in this guide because they are not supplies, Part B can also cover medical nutrition therapy services, diabetes screenings, diabetes prevention programs, and diabetes self-management training. Ibid at pp. 6-8.

⁶ Ibid., p. 16. Although not covered in this guide because they are not supplies, Part D also covers anti-diabetes drugs.

⁷ CMS, MLN Matters, [Medicare Coverage of Blood Glucose Monitors and Testing Supplies](#) (SE1008); Medicare Benefit Policy Manual, [Ch. 15](#), §300.1.

- A fasting blood glucose at or above 126 mg/dL on two different occasions;
- A two-hour post-glucose challenge at or above 200 mg/dL on two different occasions; or
- A random glucose test over 200 mg/dL for a person with symptoms of uncontrolled diabetes.

Individuals should ensure their doctor includes this testing information in their medical record.⁸ It is required for all diabetes supplies.⁹

Differences for Individuals in Medicare Advantage Plans

Coverage rules for diabetes supplies may change depending on whether the individual receives their Medicare benefits through the federal government (Original Medicare) or through a private health insurance plan (Medicare Advantage). For supplies covered under Part B, there can be small differences in coverage, as noted throughout this guide. This is because Medicare Advantage (MA) Plans have to cover diabetes supplies whenever Medicare would,¹⁰ and the majority of plans follow the same documentation and supplier requirements that Medicare imposes.¹¹ However, it is important for any individual in an MA Plan to make sure they follow any specific rules that their plan has imposed for accessing DME. Individuals can find these rules in the plan's Explanation of Coverage (EOC) or by calling member services at the plan.

Blood Sugar Testing Equipment

Manual Testing

Most individuals self-test their blood sugar level using a glucose monitor, lancets, and test strips. An individual uses a lancet (which may be part of a spring-loaded or laser-lancing device) to collect blood to put on a test strip.¹² A glucose monitor then reads the test strip to determine an individual's blood sugar level.¹³ To ensure accuracy, the glucose monitor is periodically calibrated using a glucose control solution.¹⁴

Suppliers of this equipment (including pharmacies) should not automatically send these supplies to their regular customers because Medicare pays only for refills specifically requested by the patient.¹⁵ Suppliers should not evade this requirement by keeping an open-ended authorization on hand; instead, they are required to get patient permission for each order.¹⁶ Every year, individuals also need a new prescription that includes:¹⁷

- Whether they have diabetes;

⁸ CMS, Medicare Benefit Policy Manual, [Ch. 15](#), §300.1.

⁹ Ibid.

¹⁰ [42 C.F.R. § 422.101](#); CMS, Medicare Managed Care Manual, [Ch. 4](#), §10.12.

¹¹ See, e.g., UnitedHealthcare, Coverage Summary, [Diabetes Management, Equipment and Supplies](#); Aetna, Clinical Policy Bulletin Number: 0161, [Infusion Pumps](#): "Aetna's medical necessity criteria for external infusion pumps for diabetes have been adapted from Medicare national policy..."

¹² CMS, LCA [A52464](#), Coding Guidelines.

¹³ CMS, [NCD 40.2](#).

¹⁴ CMS, LCD [L33822](#), Coverage Indications, Limitations, and/or Medical Necessity, Home Blood Glucose Monitors (BGM).

¹⁵ CMS, [Medicare Coverage of Diabetes Supplies, Services, & Prevention Programs](#), p. 11.

¹⁶ CMS, LCD [L33822](#), Coverage Indications, Limitations, and/or Medical Necessity, Refill Requirements.

¹⁷ CMS, [Medicare Coverage of Diabetes Supplies, Services, & Prevention Programs](#), p. 11.

- What type of glucose monitor they need and why they need it (and, if the individual needs a special type of monitor because of vision or dexterity issues, then an explanation for that as well);
- Whether they use insulin;
- How often they test their blood sugar; and
- How many test strips and lancets they need for one month.

Advocacy Tips: Requesting Refills at the Right Time

CMS is concerned about buying unneeded testing supplies, so there are several limitations built into the ordering process that can create barriers to access. When ordering new testing supplies, individuals should note:

- Suppliers cannot automatically refill orders, even with the individual’s written permission.¹⁸
- Within 14 days of providing a refill, suppliers must confirm with the individual that they need additional supplies and have nearly exhausted their current inventory.¹⁹
- Suppliers can only provide up to three months’ worth of supplies at a time.²⁰

Medicare covers testing supplies that are designed for, and actually used in, the home.

Many diabetes supplies are considered to be durable medical equipment (DME), and Medicare only covers DME (and supplies) that are appropriate for use in the home.²¹ This requirement creates issues with some blood sugar testing supplies (e.g., certain reflectance colorimeter devices), which Medicare considers designed for professional clinical use rather than at-home self-testing.²² Problems are rare since so many diabetes supplies are intended for home use, but can still arise for individuals seeking professional testing equipment.²³

Medicare coverage also requires documentation showing individuals can actually use the supplies in their home, without professional help.²⁴ Individuals must show they can use the testing equipment on their own, or have a “responsible individual” (e.g., a caregiver) who can perform the testing instead.²⁵ In either case, a physician should document the individual’s (or responsible party’s) capacity.²⁶ The medical record should, consequently, describe the individual’s treatment regimen and education around using the supplies.²⁷

Note: There is a special provision for individuals who cannot use standard blood sugar testing equipment in their home due to visual or dexterity impairments, but who could use specialized equipment (e.g., blood sugar monitors with voice synthesizers, timers, and more accessible

¹⁸ CMS, LCD [L33822](#), Coverage Indications, Limitations, and/or Medical Necessity, Refill Requirements.

¹⁹ CMS, LCD [L33822](#), Coverage Indications, Limitations, and/or Medical Necessity, Refill Requirements.

²⁰ Ibid.

²¹ CMS, Medicare Benefit Policy Manual, [Ch. 15](#), §110 and 110.1(D).

²² CMS, MLN Matters, [Medicare Coverage of Blood Glucose Monitors and Testing Supplies](#) (SE1008), p. 4.

²³ Ibid., p. 4.

²⁴ Ibid., p. 5.

²⁵ Ibid., p. 5.

²⁶ Ibid., p. 5.

²⁷ Ibid., p. 7.

parts and arrangements).²⁸ Medicare will cover this specialized equipment if the physician has documented an impairment severe enough to require use of the more expensive supplies.²⁹

Advocacy Tips: Getting the Right Brand of Testing Equipment

Many individuals have strong preferences for the test strips and glucose monitors they use. This is often for good reason, since there are measurable differences in various brands of testing equipment. In order to ensure they are getting the supplies they need, individuals should ask their doctors to write their preferred brand in the prescription.

Picking an MA Plan That Covers the Right Brands

In almost all cases, MA Plans only cover test strips and other supplies from a limited number of brands (the covered types are usually called “preferred brands”).³⁰ Plans will usually only cover non-preferred brands if a doctor contacts the plan and explains that the alternative brand is medically necessary for the individual.³¹

Getting the Right Quantity of Supplies

Often, Medicare Rights hears from clients who are not getting as many testing supplies as they need. Generally, Medicare covers 100 lancets and 100 test strips per month for individuals being treated with insulin injections (and 100 every three months for those who are not being treated with insulin injections).³² Individuals who need more should provide evidence justifying the greater frequency of their testing and showing they are actually using all of the supplies.³³ There are two parts to this documentation. The individual must:

1. Keep a log of how often they are testing themselves, including the date, time, and results of their testing.³⁴
2. Meet with their doctor in-person no more than six months before ordering additional supplies. The doctor must document in the individual’s medical record (and recertify every six months):³⁵
 - Names, dosages, and timings of diabetic medications being taken;
 - Frequency and severity of hyperglycemic and hypoglycemic symptoms;
 - Review of the individual’s blood sugar testing log;
 - Changes in the treatment regimen as a result of reviewing the testing log;
 - Adjustments to dosage the individual should make based on the testing log;

²⁸ CMS, LCD [L33822](#), Coverage Indications, Limitations, and/or Medical Necessity, Home Blood Glucose Monitors (BGM).

²⁹ CMS, MLN Matters, [Medicare Coverage of Blood Glucose Monitors and Testing Supplies](#) (SE1008), p. 5.

³⁰ See, e.g., Aetna, [Aetna Medicare Elite Plan \(HMO\) 2020 Summary of Benefits](#), p. 10; UnitedHealthcare, [AARP Medicare Advantage Choice \(PPO\) Summary of Benefits 2020](#), p. 9.

³¹ See, e.g., UnitedHealthcare, [2020 Evidence of Coverage for AARP® Medicare Advantage Plan 1 \(HMO\)](#), pp. 4-13.

³² CMS, LCD [L33822](#), Coverage Indications, Limitations, and/or Medical Necessity, Home Blood Glucose Monitors (BGM).

³³ CMS, MLN Matters, [Medicare Coverage of Blood Glucose Monitors and Testing Supplies](#) (SE1008), pp. 3, 7; MLN Matters, [An Overview of Medicare Covered Diabetes Supplies and Services](#) (SE0738), p. 2.

³⁴ CMS, [Medicare Coverage of Diabetes Supplies, Services, & Prevention Programs](#), p. 10; CMS, MLN Matters, [Medicare Coverage of Blood Glucose Monitors and Testing Supplies](#) (SE1008), p. 7.

³⁵ CMS, LCD [L33822](#), Coverage Indications, Limitations, and/or Medical Necessity, Home Blood Glucose Monitors (BGM); MLN Matters, [Medicare Coverage of Blood Glucose Monitors and Testing Supplies](#) (SE1008), p. 7. Additional general requirements can be found in CMS, Medicare Program Integrity Manual, [Ch. 5](#), §5.2.2.

- Lab tests indicating the level of glycemic control; and
- Any other therapeutic interventions and the results of those interventions.

Advocacy Tips: Insufficient Documentation of a Need for Additional Supplies

Realistically, not every individual is going to have a doctor providing documentation for every element listed above. In the end, what impacts the coverage decision is whether there is “enough information in the patient’s medical record to support the medical necessity for the quantity of item(s) ordered and dispensed.”³⁶ In other words, it is a judgement call about whether the doctor has provided sufficient evidence that the individual needs, and will use, extra supplies. Often, this decision is made by the suppliers, since Medicare requires them to “...have documentation to support the medical necessity of changes in the... supply utilization requirements [of DME].”³⁷ In Medicare Rights’ experience, individuals and advocates should:

- Make sure individuals keep a careful log of their testing, since that part of the documentation is completely under their control.
- Consider sharing Medicare’s provider/supplier educational materials on testing supplies, which explain the required documentation,³⁸ as well as the DME Medicare Administrative Contractor’s materials³⁹ and contact information for the company that provides the diabetes supplies.
 - The DME MAC, Noridian Healthcare Solutions, is the entity to which suppliers submit claims and that decides whether Medicare will pay for a specific claim.
- Experienced suppliers can often advise on the adequacy of a provider’s documentation.

Accessing Additional Supplies in an MA Plan

The standard quantity of diabetic testing supplies provided may change depending on which MA Plan an individual is enrolled in. In most cases, plans use the same quantities (up to 100 lancets and test strips per month) as Original Medicare.⁴⁰ MA Plan members can request more from their plan, usually through their doctor or supplier making the request directly with the plan. MA Plans may also have specific rules for how members can access supplies (e.g., requesting prior authorization before ordering quantities of testing supplies above the standard amount).⁴¹ It is crucial for MA Plan members to understand and follow any mandatory procedures. Individuals can find these rules in the plan’s Evidence of Coverage (EOC) or by calling member services at the plan.

³⁶ CMS, MLN Matters, [Medicare Coverage of Blood Glucose Monitors and Testing Supplies](#) (SE1008), p. 7.

³⁷ CMS, Medicare Program Integrity Manual, [Ch. 5](#), §5.9.

³⁸ CMS, MLN Matters, [Medicare Coverage of Blood Glucose Monitors and Testing Supplies](#) (SE1008).

³⁹ Noridian Healthcare Solutions, [Glucose Monitors](#).

⁴⁰ See, e.g., Aetna, [Aetna Medicare Elite Plan \(HMO\) 2020 Summary of Benefits](#), p. 10; UnitedHealthcare, [AARP Medicare Advantage Choice \(PPO\) Summary of Benefits 2020](#), p. 9.

⁴¹ See, e.g., Aetna, [2020 Evidence of Coverage for Aetna Medicare Elite Plan \(HMO\)](#), p. 61.

Continuous Glucose Monitors

Recently, Medicare began covering certain types of glucose monitors that can replace manual testing: continuous glucose monitors (CGMs).⁴² CGMs are regularly prescribed to people with diabetes who need to test their blood sugar more frequently than manual testing reasonably allows. Currently, Medicare only covers “therapeutic” CGMs, those that have been FDA approved to replace (rather than simply supplement) manual testing.⁴³ Most CGMs on the market are non-therapeutic and, therefore, not covered by Medicare. However, there are, as of this writing, three models covered by Medicare because they have been approved by the FDA as therapeutic CGMs.⁴⁴

In order for an individual to show Medicare that a CGM is medically necessary, they must meet in person with their doctor within the six months prior to ordering the device.⁴⁵ At that time, the doctor must document in the medical record (and recertify in-person every six months) that the individual:⁴⁶

- Has diabetes;
- Has been testing with a blood glucose monitor four or more times a day;
- Is treated with three or more daily injections of insulin (or with a Medicare-covered insulin infusion pump); and
- Requires frequent adjustment of their insulin treatment regimen on the basis of their testing.

CGMs generally come in three parts: a glucose sensor, a transmitter, and a receiver (or monitor).⁴⁷ The sensors and transmitter are disposable and last anywhere from a few days or weeks to three months.⁴⁸ As a result, when Medicare covers a CGM for an individual, it will also cover regular shipments of supplies (namely replacement sensors, transmitters, batteries, and calibration supplies).⁴⁹ Since the CGM and related supplies replace a blood glucose monitor, lancets, and test strips, any claims submitted for these three supplies should be denied when Medicare is already paying for a CGM (unless they are used and billed as calibration supplies).⁵⁰

Advocacy Tips: Using a CGM with a Smartphone

Medicare will only cover a CGM if one of the components is a durable receiver and the individual actually uses that receiver to display their blood sugar test results.⁵¹ However, many individuals would prefer to receive these results using their smartphone rather than having to pay cost-sharing for, carry around, and maintain the receiver packaged with their CGM. This is an issue for Medicare coverage because of several restrictions around smartphone use:

⁴² CMS, Ruling # [CMS-1682-R](#) (Jan. 12, 2017).

⁴³ Ibid.

⁴⁴ Dexcom’s G5 and G6 and Abbott’s FreeStyle Libre.

⁴⁵ CMS, LCD [L33822](#), Coverage Indications, Limitations, and/or Medical Necessity, Continuous Glucose Monitor (CGM).

⁴⁶ Ibid. In addition, the provider must complete a five element order, a dispensing order, and a detailed written order as explained in Noridian Healthcare Solutions, [Clinician Checklist Continuous Glucose Monitors](#).

⁴⁷ CMS, Ruling # [CMS-1682-R](#) (Jan. 12, 2017).

⁴⁸ Ibid.

⁴⁹ CMS, LCA [A52464](#), Non-Medical Necessity Coverage and Payment Rules; Noridian Healthcare Solutions, [Dear Clinician Letter: Continuous Glucose Monitors](#), (Sept. 2018).

⁵⁰ CMS, LCD [L33822](#), Coverage Indications, Limitations, and/or Medical Necessity, Continuous Glucose Monitor (CGM).

⁵¹ CMS, Ruling # [CMS-1682-R](#) (Jan. 12, 2017).

- Medicare will not cover a smartphone, even for use in conjunction with the sensors and transmitter of a CGM, because smartphones are “not primarily medical in nature and are useful in the absence of illness.”⁵²
- Medicare will not cover a CGM without the receiver because the receiver is the only “durable” component (the sensors and transmitter need to be regularly replaced after weeks or months of use, while the receiver is designed to last for over three years). Without a receiver, the CGM as a whole does not meet Medicare’s definition of DME.⁵³ Consequently, Medicare will only cover the sensors and transmitter components of a CGM if it is also covering the receiver.⁵⁴ Unintuitively, this means that if an individual prefers to use their smartphone rather than the CGM’s receiver to display their testing results, they will not be able to get Medicare to pay for their CGM unless it also pays for the unwanted receiver component.
- Furthermore, Medicare will not cover a CGM if the individual plans on only using it with their smartphone rather than with the packaged receiver.⁵⁵ In short: “If a beneficiary never uses a DME receiver for a therapeutic CGM, the supply allowance is not covered by Medicare.”⁵⁶

Accordingly, individuals should understand Medicare coverage for CGMs depends on their record showing they will use.⁵⁷

- Only the CGM receiver to display their testing results;
- Their CGM receiver “on some days” and a smartphone on other days; or
- The CGM receiver themselves, but have a caregiver use a smartphone to track their testing results.

Medicare does not mandate a specific process for documenting this information. In some cases, individuals have been asked to sign a document reflecting a promise not to solely use their smartphone with their CGM. Medicare Rights advises individuals to follow the directions provided by their supplier and the manufacturer.

Differences for Individuals in an MA Plan

As mentioned previously, coverage rules for diabetes supplies can differ for individuals enrolled in MA Plans. This is particularly true with CGM coverage, since some MA Plans provided coverage before Original Medicare did. Other MA Plans may cover non-therapeutic CGMs and CGMs that work solely with smart phones.⁵⁸ Despite some differences, MA Plans have to cover diabetes supplies whenever Original Medicare would,⁵⁹ and the majority of plans follow the same documentation and supplier

⁵² Ibid.

⁵³ Ibid.

⁵⁴ Ibid.

⁵⁵ CMS, LCA [A52464](#), Non-Medical Necessity Coverage and Payment Rules.

⁵⁶ Ibid.

⁵⁷ Ibid.

⁵⁸ See, e.g., Cigna, [Diabetes Equipment and Self-Management](#), (Coverage Policy Number 0106).

⁵⁹ [42 C.F.R. § 422.101](#); CMS, Medicare Managed Care Manual, [Ch. 4](#), §10.12.

requirements that Medicare imposes.⁶⁰ It is important for any individual in an MA Plan to make sure they know what their plan covers and follow any specific rules that their plan has imposed for accessing DME. For example, in some MA Plans, the preferred glucose monitor brands do not offer a CGM, and in order to get coverage, plan members must submit a medical exception (usually with the assistance of their provider).⁶¹ Others cover CGMs regardless of the brand.⁶² Individuals can find these rules in the plan's Evidence of Coverage (EOC) or by calling member services at the plan.

Insulin Administration

Most people who are diabetic require regular insulin treatment to make sure their body metabolizes glucose. There are four common ways that people take their insulin, all of which are covered differently by Medicare.

Advocacy Tips: Getting the Right Brand of Insulin

Many individuals have strong preferences for the insulin they use and how it is administered. In order to ensure they are getting the type of insulin and equipment they want, individuals should ask their doctor to specifically prescribe the brand they would like. If the prescribing doctor includes a brand name in the prescription, then the supplier has to provide that brand or contact the doctor for a new prescription with a different brand name.

Picking an MA Plan That Covers the Right Brands

In almost all cases, MA Plans only cover specific types or brands of insulin.⁶³ Often, plans will only cover non-preferred brands if a doctor shows that the alternative brand is medically necessary for the individual.⁶⁴ For that reason, it is vital for individuals with diabetes to choose a plan that covers what they need. If they are currently in an MA Plan that does not cover their preferred brand, they can also consider switching plans either during Fall Open Enrollment or by using a Special Enrollment Period.⁶⁵ Individuals can find these rules in the plan's Evidence of Coverage (EOC) or by calling member services at the plan.

Injection

Most commonly, people with diabetes manually inject insulin. For this group, their insulin and the supplies used to inject it (i.e., syringes, needles, alcohol swabs, and gauze) are covered

⁶⁰ See, e.g., UnitedHealthcare, Coverage Summary, [Diabetes Management, Equipment and Supplies](#); Aetna, Clinical Policy Bulletin Number: 0161, [Infusion Pumps](#): "Aetna's medical necessity criteria for external infusion pumps for diabetes have been adapted from Medicare national policy..."

⁶¹ See, e.g., Aetna, [2020 Evidence of Coverage for Aetna Medicare Elite Plan \(HMO\)](#), p. 61.

⁶² See, e.g., UnitedHealthcare, [2020 Evidence of Coverage for AARP® Medicare Advantage Plan 1 \(HMO\)](#), pp. 4-13.

⁶³ See, e.g., Aetna, [Aetna Medicare Elite Plan \(HMO\) 2020 Summary of Benefits](#), p. 10; UnitedHealthcare, [AARP Medicare Advantage Choice \(PPO\) Summary of Benefits 2020](#), p. 9.

⁶⁴ See, e.g., UnitedHealthcare, [2020 Evidence of Coverage for AARP® Medicare Advantage Plan 1 \(HMO\)](#), pp. 4-13.

⁶⁵ Medicare Rights Center, [Special Enrollment Periods for Medicare Advantage Plans and Medicare Part D Drug Plans](#).

under Part D of Medicare.⁶⁶ While every Part D plan has to cover insulin and the supplies to inject it, they do not have to cover every brand. Instead, different plans can have different preferred brands as well as different cost-sharing for different brands. For this reason, it is extremely important for individuals who have a preferred type of insulin that they select a Part D plan who has that type of insulin on its formulary (or list of covered drugs).

Advocacy Tips: Making Insulin Affordable

Medicare Rights regularly hears from individuals struggling to afford the insulin they need to stay healthy. As a result of high insulin costs, some people are forced to choose between sacrificing other needs or rationing their insulin and facing the potentially fatal health consequences. To get assistance, individuals can:⁶⁷

- Apply for Extra Help⁶⁸ or their State Pharmaceutical Assistance Program.⁶⁹
- Contact insulin manufacturers⁷⁰ or charity programs.⁷¹
- Speak to their doctor about other brands or types of insulin.
- Ensure they are in a Part D plan that covers their preferred insulin.⁷² Consider requesting a mail-order option or a tiering exception⁷³ to reduce the cost-sharing.
- Speak to their pharmacy about discount programs, rebates, or other ways to save money.

Inhalation

While relatively rare, some people with diabetes take insulin through an inhaler. Currently, Afrezza appears to be the only brand of insulin designed for inhalation.⁷⁴ Both the insulin powder and inhaler are covered under Part D.⁷⁵

Insulin Pumps

Other individuals with diabetes use insulin pumps. Insulin pumps act as an artificial pancreas by infusing an individual's blood with the insulin they need to metabolize glucose. Insulin pumps are considered DME and are therefore covered under Medicare Part B.⁷⁶ Likewise, the insulin used in insulin pumps is also covered under Part B (because it is a supply used with DME). Even though this insulin can be identical to the insulin someone uses to manually inject with a syringe, insulin in a pump is covered under Part B, while insulin used for manual injection is covered under Part D.⁷⁷

⁶⁶ CMS, MLN Matters, [An Overview of Medicare Covered Diabetes Supplies and Services](#) (SE0738), p. 5.

⁶⁷ Medicare Interactive, [Options for those who are having trouble affording drug costs.](#)

⁶⁸ Medicare Interactive, [The Extra Help/Low-Income Subsidy \(LIS\) program.](#)

⁶⁹ Medicare Interactive, [EPIC: The New York Elderly Pharmaceutical Insurance Coverage program.](#) For other states, see Medicare Interactive, [State Pharmaceutical Assistance Programs.](#)

⁷⁰ diatribe Learn, [Paying for Insulin.](#)

⁷¹ Medicare Interactive, [Charity programs that help pay for prescriptions.](#)

⁷² Medicare Interactive, [Questions to ask when comparing Part D plans.](#)

⁷³ Medicare Interactive, [Requesting a tiering exception.](#)

⁷⁴ Afrezza, [Take control with Afrezza.](#)

⁷⁵ CMS, MLN Matters, [An Overview of Medicare Covered Diabetes Supplies and Services](#) (SE0738), p. 5.

⁷⁶ Medicare.gov, [Insulin.](#)

⁷⁷ CMS, MLN Matters, [An Overview of Medicare Covered Diabetes Supplies and Services](#) (SE0738), p. 5.

Medicare has strict coverage requirements for insulin infusion pumps that go beyond what is required for coverage of other ways to take insulin. In order to be covered, the individual must meet certain testing requirements, understand how to manage their diabetes, and meet quarterly with their doctor— all of which are explained to providers by the DME MACs.⁷⁸

Advocacy Tips: Accessing Insulin for an Insulin Pump

Medicare Rights often sees individuals having difficulty accessing insulin for their insulin pump. Here are the three most common problems, with troubleshooting suggestions:

- A pharmacy does not want to fill an individual's insulin prescription because the reimbursement rate is too low.
 - Go to a different pharmacy (e.g., Medicare Rights' clients have had some success accessing insulin for insulin pumps at larger chain pharmacies where the volume of business lessens the impact of low reimbursement rates).
 - Speak with the pharmacy to find a type or brand of insulin that works for both the pharmacy and the individual's health.
- A pharmacy is confused as to whether the insulin should be billed to Part B or Part D of Medicare. For example, one client's pharmacy incorrectly billed the individual's Part D plan for their insulin used in a pump for over five years. Such incorrect billing can lead to denials or incorrect cost-sharing.
 - Speak with the pharmacy about the correct way to bill, or provide them with education materials, such as CMS' MLN Matters [Current Medicare Coverage of Diabetes Supplies](#) (SE18011).
 - Have the prescribing doctor indicate in the order that the request is for "insulin for insulin pump."⁷⁹
- An individual cannot afford the cost-sharing for their insulin.
 - Talk to the individual's provider about whether there is a less expensive type or brand of insulin that will work for the individual.
 - Consider any supplemental insurance options to help with cost-sharing for the individual, such as a Medigap or Medicaid, or a protection from cost-sharing, like the QMB level of the Medicare Savings Program.⁸⁰
 - Research whether there are MA Plans in the individual's area that provide better cost-sharing for the brand and type of insulin the individual needs.⁸¹

Tubeless, Disposable Insulin Pumps (Omnipod)

In recent years, tubeless, disposable insulin pumps have become more popular. (At this time, it seems that Omnipod is the only device of this type on the market.) Since they are disposable, CMS has ruled that these alternative insulin pumps do not fall under the definition of DME and, therefore, will not be covered by Medicare Part B.⁸² However, in 2018, CMS released a new

⁷⁸ CMS, LCD [L33794](#), Coverage Indications, Limitations, and/or Medical Necessity.

⁷⁹ CMS, MLN Matters, [Current Medicare Coverage of Diabetes Supplies](#) (SE18011), p. 4.

⁸⁰ Medicare Interactive, [Medicare Savings Program Basics](#).

⁸¹ When trying to predict cost-sharing at different plans, it is important to consider whether the individual's insulin would be covered under Part B or Part D, since that can affect cost-sharing even at MA Plans.

⁸² CMS, [LCA A52507](#), Non-Medical Necessity Coverage and Payment Rules.

policy that says insulin injection devices (like the Omnipod) can be covered by Part D plans.⁸³ This does not change Part B coverage and it does not require Part D plans to cover devices like the Omnipod, but it does allow Part D plans to provide coverage if they want to.

Advocacy Tips: Finding a Plan That Covers the Omnipod

Not every Part C and D plan covers Omnipods, a potentially significant issue, especially for people who are new to Medicare and previously had health coverage that did pay for their Omnipod use. In order to ensure continuation of their care, these individuals should select a Part D or MA Plan that would cover the Omnipod for them, but this is often quite difficult to do. Unlike most prescription drugs, individuals cannot use Medicare's Plan Finder to see which Part D plans covers the Omnipod (at least as of June 2020). However, individuals can:

- Look up prospective plans' online formularies or call them.⁸⁴
- Request a formulary exception (i.e., asking the individual's current MA or Part D plan to cover the device even though it is not on the plan's formulary).⁸⁵
- Contact the manufacturer to ask which Part D and MA Plans in their area provide coverage.⁸⁶

Therapeutic Shoes and Inserts

Individuals with diabetes live with a greater risk of health complications in their feet, some of which can be lessened with therapeutic shoes and inserts.⁸⁷ The Medicare law itself excludes coverage for routine foot care and orthotics, so, like dental services, many individuals with Medicare may have to pay out-of-pocket for medical services related to their feet.⁸⁸ In 1993, however, Congress amended the Medicare law to add a new benefit category: therapeutic shoes and inserts for individuals with diabetes.⁸⁹ Although they are covered and accessed in much the same way as DME, therapeutic shoes and inserts are a separate and distinct category with its own specific coverage criteria.⁹⁰

Medicare covers therapeutic shoes and inserts under Part B only when a doctor certifies that an individual has met three conditions:⁹¹

1. They have diabetes.
2. They have at least one of these conditions:
 - a. Foot amputation (partial or complete)
 - b. Past foot ulcers
 - c. Calluses that could lead to foot ulcers
 - d. Nerve damage, related to diabetes, with signs of problems with calluses

⁸³ CMS, [Medical Supplies Associated with the Injection of Insulin](#) (Jan. 5, 2018).

⁸⁴ E.g., Independent Health, [Independent Health's Medicare Advantage 2020 Individual Part D Formulary](#); CDPHP, [2020 Enhanced Drug Formulary](#); MVP Health Care, [2020 Medicare Part D Formulary](#).

⁸⁵ Medicare Rights, [Medicare prescription drug plan appeals](#).

⁸⁶ Omnipod Insulin Management System, [You Can Finally Choose the Omnipod System Through Medicare Part D](#).

⁸⁷ American Diabetes Association, [Foot Complications](#).

⁸⁸ [42 U.S.C. §1395y\(a\)\(8\)](#) and (13).

⁸⁹ [42 U.S.C. §1395x\(s\)\(12\)](#).

⁹⁰ CMS, Medicare Benefit Policy Manual, [Ch. 15](#), § 140.

⁹¹ CMS, [Medicare Coverage of Diabetes Supplies, Services, & Prevention Programs](#), p. 12.

- e. Poor circulation
 - f. A deformed foot
3. They are being treated under a comprehensive diabetes care plan and need therapeutic shoes or inserts (or both) because of diabetes.

Advocacy Tips: Replacements and Back-Ups

Medicare will only cover one pair of therapeutic shoes per year.⁹² If an individual already received a pair of therapeutic shoes within the last year, it is vital that the provider and supplier document why a new pair is needed. If they do not, Medicare will deny the second device as not reasonable and medically necessary because it is duplicative of a device the person already owns.⁹³ A new order is not required for the replacement of an insert or modification within one year of the order on file, though the supplier should document the reason for the replacement.⁹⁴ On the other hand, a new order is required for the replacement of any shoe.⁹⁵

Under Medicare, therapeutic shoes come in two types:⁹⁶

1. Extra-depth shoes that are made extra deep to accommodate custom inserts.⁹⁷ One pair of shoes with inserts and two additional pairs of inserts are covered each year.⁹⁸
2. Custom-molded shoes constructed over a model of the individual's foot with removable inserts.⁹⁹ One pair of shoes with inserts and three additional pairs of inserts are covered each year.¹⁰⁰ These shoes are only covered when the individual has "a foot deformity that cannot be accommodated by a depth shoe," which is documented in the supplier's records.¹⁰¹ In addition, individuals can also substitute Medicare coverage of their inserts for Medicare coverage of modifications to their shoes, such as rigid rocker or roller bottoms, metatarsal bars, wedges, offset or flared heels, velcro closures, and inserts for missing toes.¹⁰² The important caveat is that the Medicare payment for the modifications cannot exceed what the payment for the inserts would be.¹⁰³

Note: Medicare will also cover inserts on their own if the supplier can document that the patient has "appropriate footwear into which the insert can be placed."¹⁰⁴ In other words, if an individual already has custom-molded or extra-depth shoes that Medicare did not pay for, Medicare will still cover inserts for those shoes.

⁹² Ibid., p. 13.

⁹³ CMS, LCA [A52501](#), Policy Specific Documentation Requirements.

⁹⁴ Ibid.

⁹⁵ Ibid.

⁹⁶ Ibid., Non-Medical Necessity Coverage and Payment Rules and Coding Guidelines.

⁹⁷ CMS, Medicare Benefit Policy Manual, [Ch. 15](#), § 140(A)(2).

⁹⁸ Medicare.gov, [Therapeutic shoes & inserts](#); CMS, Medicare Benefit Policy Manual, [Ch. 15](#), § 140(B)(1).

⁹⁹ CMS, Medicare Benefit Policy Manual, [Ch. 15](#), § 140(A)(1).

¹⁰⁰ Medicare.gov, [Therapeutic shoes & inserts](#); CMS, Medicare Benefit Policy Manual, [Ch. 15](#), § 140(B)(1).

¹⁰¹ CMS, LCD [L33369](#), Coverage Indications, Limitations, and/or Medical Necessity.

¹⁰² CMS, Medicare Benefit Policy Manual, [Ch. 15](#), § 140(B)(3). For descriptions of these modifications, see CMS, LCA [A52501](#), Coding Guidelines.

¹⁰³ CMS, Medicare Benefit Policy Manual, [Ch. 15](#), § 140(B)(3).

¹⁰⁴ CMS, Medicare Benefit Policy Manual, [Ch. 15](#), § 140(B)(4); LCD [L33369](#), Coverage Indications, Limitations, and/or Medical Necessity.

Steps to Securing Coverage of Therapeutic Shoes

There are several steps to securing coverage.¹⁰⁵ First, a doctor who is not a podiatrist¹⁰⁶ must certify that an individual needs diabetic shoes by documenting that: the individual has diabetes, is being treated under a comprehensive plan of care, needs diabetic shoes, and meets the coverage criteria (i.e., has one of the conditions listed previously).¹⁰⁷ This documentation must be provided after an in-person visit within six months prior to the delivery of the shoes.¹⁰⁸

Advocacy Tips: Timing is Important

While going through the process of securing the required documentation for shoes, it is important to ensure all of the deadlines are met. For example, the certifying doctor needs to have the in-person visit within six months of the delivery of the shoes and sign the certification after the date of the visit and within three months prior to the delivery of the shoes.¹⁰⁹

Second, “a podiatrist or other qualified physician who is knowledgeable in the fitting of diabetic shoes and inserts” must write a prescription, called a Standard Written Order (and formerly called a Detailed Written Order).¹¹⁰ The provider writing the prescription can “be a podiatrist, M.D., D.O., physician assistant, nurse practitioner, or clinical nurse specialist... .” This provider may be the supplier who actually provides the shoes.¹¹¹ The Standard Written Order must be based on an in-person evaluation prior to actually selecting the specific shoes and inserts.¹¹² Once it is communicated to the supplier, the Standard Written Order is called a Written Order Prior to Delivery,¹¹³ which, as the name suggests, is required to be given to the supplier before the supplier provides the shoes.¹¹⁴

Finally, the shoes and inserts must be delivered in person so that they can be fitted and provided by a podiatrist, pedorthist, orthotist, prosthetist, or “other qualified individual.”¹¹⁵ The physician who certified that the individual needs diabetic shoes should not also furnish the diabetic shoes, unless they are the only qualified individual in the area as determined by the Medicare Administrative Contractor (this would usually only happen in very rural areas).¹¹⁶

¹⁰⁵ Noridian Healthcare Solutions, [Documentation Checklist Therapeutic Shoes](#) and [Clinicians! Are You Ordering Diabetic Shoes for Your Patients? - Revised](#).

¹⁰⁶ CMS, LCA [A52501](#), Non-Medical Necessity Coverage and Payment Rules: “The certifying physician may not be a podiatrist, physician assistant, nurse practitioner, or clinical nurse specialist.”

¹⁰⁷ CMS, Medicare Benefit Policy Manual, [Ch. 15](#), § 140(C); Noridian Healthcare Solutions, [Therapeutic Shoes for Persons with Diabetes](#) and [Therapeutic Shoes for Diabetics – Physician Documentation Requirements](#). See CMS’ [Statement of Certifying Physician for Therapeutic Shoes](#) and [Therapeutic Shoes for Persons with Diabetes Statement of Certifying Physician Template Guidance](#).

¹⁰⁸ CMS, LCA [A52501](#), Non-Medical Necessity Coverage and Payment Rules.

¹⁰⁹ Ibid.

¹¹⁰ CMS, Medicare Benefit Policy Manual, [Ch. 15](#), § 140(D); Noridian Healthcare Solutions, [Documentation Checklist Therapeutic Shoes](#).

¹¹¹ CMS, LCA [A52501](#), Non-Medical Necessity Coverage and Payment Rules.

¹¹² Ibid.

¹¹³ Ibid., Requirements for Specific DMEPOS Items Pursuant to Final Rule 1713 (84 Fed. Reg Vol 217).

¹¹⁴ Noridian Healthcare Solutions, [Standard Written Order](#).

¹¹⁵ CMS, Medicare Benefit Policy Manual, [Ch. 15](#), § 140(E); LCA [A52501](#), Non-Medical Necessity Coverage and Payment Rules. For details on the in-person evaluation, see the section “Policy Specific Documentation Requirements.”

¹¹⁶ CMS, Medicare Benefit Policy Manual, [Ch. 15](#), § 140(E); LCA [A52501](#), Non-Medical Necessity Coverage and Payment Rules.

Advocacy Tips: Common Reasons for Denials

Most frequently, Medicare Rights hears about therapeutic shoe denials because the quantity of shoes or inserts that Medicare allows in a year is surpassed. It is important to remember that Medicare takes this requirement quite literally, 364 days is still too soon.

Secondly, Medicare Rights also see problems when the documentation has not been correctly kept, filed, or attested to by the provider and supplier. These steps are statutory requirements (since therapeutic shoes had to be added to the Medicare law), so the shoes and inserts in such cases are denied as noncovered, instead of simply being not reasonable or medically necessary. Consequently, beneficiaries are liable for the payment even though they are not in control of the documentation. This is one powerful reason why it is so important for individuals to pick the right provider and supplier. Other common mistakes that lead to a non-coverage decision, include billing for compression molding inserts, inserts used in shoes other than custom-mold or extra-depth shoes, or “deluxe” add-on features for shoes.¹¹⁷

Accessing Diabetes Supplies

Working with a Provider

The first step for any individual looking to access Medicare-covered diabetes supplies is to see their doctor, often a primary care physician or endocrinologist, to secure medical documentation and an order for the equipment.¹¹⁸

Advocacy Tips: When the Provider Needs Help

Some providers have difficulty putting together the correct medical documentation or understanding the requirements. Fortunately, there are several resources to assist providers.

- **Supplier:** Suppliers are trained by Medicare to understand the coverage criteria and make assessments to determine when someone qualifies for diabetes supplies.¹¹⁹ Providers can reach out to the supplier for help in understanding what documentation they need to supply and how to complete it correctly.
- **Centers for Medicare & Medicaid Service (CMS) materials:** CMS has created educational materials for providers,¹²⁰ and extensively laid out the coverage criteria and documentation requirements for diabetes supplies.¹²¹
- **DME Medicare Administrative Contractor (MAC):** The DME MACs process Original Medicare claims for diabetes supplies and publishes the coverage criteria.

¹¹⁷ CMS, LCA [A52501](#), Non-Medical Necessity Coverage and Payment Rules.

¹¹⁸ Noridian Healthcare Solutions, [Medical Records](#).

¹¹⁹ Noridian Healthcare Solutions, [Durable Medical Equipment, Prosthetics, Orthotics and Supplies \(DMEPOS\)](#).

¹²⁰ CMS, MLN Matters, [Medicare Coverage of Blood Glucose Monitors and Testing Supplies](#) (SE1008); MLN Matters, [An Overview of Medicare Covered Diabetes Supplies and Services](#) (SE0738).

¹²¹ CMS, [NCD 40.2](#) and [190.20](#); LCD [L33822](#), [L33369](#), and [L33794](#); LCA [A52464](#), [A52507](#), and [A52501](#).

Providers can reach out to the DME MACs directly¹²² or use their online training materials.¹²³

- **Medicare Advantage Plan:** MA Plans process claims for diabetes supplies for their plan members. Providers can reach out to the plan to discuss coverage criteria, documentation requirements, and any other coverage-related questions. In addition, providers, suppliers, and plan members can all request pre-service organization determinations from the plan.¹²⁴ An organization determination is the plan's decision about whether it will cover the diabetes supplies.¹²⁵ An individual or their provider can appeal an unfavorable organization determination.¹²⁶

Finding a Supplier

To ensure their diabetes supplies are covered and to protect themselves from higher costs, individuals should carefully choose their supplier (including pharmacies). How to find an appropriate supplier depends on whether the individual receives their Medicare benefits through Original Medicare or an MA Plan.

Those with Original Medicare should use a Medicare-approved supplier that takes assignment. Individuals can call 1-800-MEDICARE or visit www.medicare.gov/supplier to find DME suppliers who take assignment.

- **If the supplier takes assignment for diabetes supplies:**¹²⁷ Once an individual meets their Part B deductible, Original Medicare normally pays 80% of the Medicare-approved amount for the supplies, leaving individuals (or their secondary insurance) responsible for 20% of the Medicare-approved amount. The supplier must accept Medicare's approved amount as payment in full.
- **If the supplier does not take assignment for diabetes supplies:**¹²⁸ The supplier may charge the individual more than Medicare's approved amount for the supplies. Medicare may still pay the same 80% of the Medicare-approved amount, which leaves the individual responsible for the additional costs. There is no limiting charge for DME as there is with most health care services, meaning a supplier who does not accept assignment can charge any amount over the Medicare-approved cost for a service or item.

¹²² In New York, this is [Noridian Healthcare Solutions](#), which providers can reach online at the [Noridian Medicare Portal](#) or by calling (866) 419-9458.

¹²³ E.g., Noridian Healthcare Solutions, [Clinician DME on Demand Tutorials](#).

¹²⁴ CMS, Medicare Managed Care Manual, [Ch. 4](#), § 160; [Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance](#), § 40.6.

¹²⁵ CMS, Medicare Managed Care Manual, [Ch. 4](#), § 160.

¹²⁶ CMS, Medicare Managed Care Manual, [Ch. 4](#), § 160; [Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance](#), § 50.1.

¹²⁷ Medicare.gov, [Lower costs with assignment](#); CGS, [DME Supplier Participation and Assignment Reminders](#).

¹²⁸ Ibid.

Finding a Supplier for Those in an MA Plan

Follow the plan's rules for getting DME, including which providers and suppliers to use. Individuals can find these rules in the plan's Evidence of Coverage (EOC) or by calling member services at the plan. In most MA Plans, it is important to find a supplier that contracts with that plan (an in-network supplier). In most cases, individuals who use an out-of-network supplier will face higher costs and may lose some billing protections. Plans are required to keep up-to-date lists of their in-network suppliers.¹²⁹

Advocacy Tips: Provider-Supplier Miscommunications

Some of the most difficult diabetes supply access cases Medicare Rights encounters are where there is a breakdown in communication between the ordering provider and the supplier. When encountering this situation, individuals can:

- **Advocate:** The individual or their advocate can educate themselves on the coverage criteria and prior authorization process in order to reach out to the provider and suppliers to make specific, actionable requests.
- **Complain:** Suppliers should have grievance processes that individuals can use to try to escalate a problem internally.
- **Escalate:** Individuals in Original Medicare can contact the CMS Regional Office to get assistance from a caseworker.¹³⁰ Both the Regional Office and 1-800-MEDICARE can also forward a complaint to the Medicare Ombudsman or Competitive Acquisition Ombudsman. Individuals in an MA Plan can call member services at the plan, file a grievance with their plan, or file a complaint against their plan with 1-800-MEDICARE.
- **Choose a different provider or supplier:** Sometimes the easiest resolution is simply to find a different prescribing provider (perhaps one more familiar with helping their patients secure diabetes supplies) or supplier (perhaps one that specializes in diabetes supplies or a larger store that sells a large volume of diabetes supplies).

Addressing Problems with a Supplier

Medicare imposes specific requirements on DME suppliers and MA Plans regarding DME coverage, delivery, maintenance, and replacement. Relevant to individuals with diabetes supplies, suppliers must:¹³¹

- Document compliance with medical device safety standards.
- Employ appropriately credentialed personnel to deliver, set-up, and train the patient on how to use the equipment.
- Inform patients about the equipment's use and maintenance in a way that is tailored to the patient's needs and abilities.

¹²⁹ CMS, Medicare Managed Care Manual, [Ch. 4](#), §10.12.1.

¹³⁰ CMS, [New York Regional Office](#).

¹³¹ CMS, [Supplier Quality Standards and Beneficiary Protections](#).

- Ensure patients can use the equipment safely in the setting in which the patient plans to use it.
- Repair and replace equipment.
- “Whenever the beneficiary needs assistance,” answer “all” questions, come out to the home, provide additional equipment, or, otherwise, troubleshoot the issue.

Advocacy Tips: Escalating Supplier Issues for Those in Original Medicare

When suppliers fail to meet these requirements, individuals can escalate the issue in different ways, depending on whether they have Original Medicare or an MA Plan. For those in Original Medicare:

- File a complaint with the supplier, as all suppliers are required to have an internal grievance process.
- Contact the CMS Regional office to request a caseworker.¹³²
- Call 1-800-MEDICARE to file a complaint against the supplier and ask for the complaint to be sent to the Medicare Ombudsman or Competitive Acquisition Ombudsman.

Escalating Supplier Issues for Those in an MA Plan

- File a complaint with the supplier.
- Call member services at the plan asking for help with the in-network supplier.
- If the plan is not helping, file a grievance with the plan for failing to assist with the supplier issue. Forward a copy of the grievance to the CMS Regional Office.¹³³
- If the plan does not resolve the supplier issue, call 1-800-MEDICARE to file a complaint against the plan.

Repairs and Replacement

Medicare or, if available, a manufacturer’s warranty, will pay for repairs and replacement of DME, including diabetic equipment.¹³⁴ This is true, even if an individual has an item of non-Medicare purchased DME when they enroll in Medicare.¹³⁵ Medicare differentiates between repairs (of wear or damage,) which are covered, and maintenance (“[r]outine periodic servicing, such as testing, cleaning, regulating, and checking), which is not covered.¹³⁶ If the equipment is beyond repair, lost, or stolen, the supplier is responsible for replacing it.¹³⁷

¹³² CMS, [New York Regional Office](#).

¹³³ CMS, [New York Regional Office](#).

¹³⁴ CMS, Medicare Benefit Policy Manual, [Ch. 15](#), § 110.2.

¹³⁵ Ibid.

¹³⁶ Ibid. § 110.2(a)-(b).

¹³⁷ Ibid. § 110.2(c).

Case Example

Gavin is enrolled in an employer group health plan, but he plans on retiring in a few months when he will enroll in either Original Medicare or a Medicare Advantage plan. Gavin has diabetes and manages it through manual testing and insulin injections. However, lately, he has experienced sudden, unexpected changes in his blood sugar level, and he has had to test more than four times per day. Consequently, Gavin's doctor, who has helped him managed his diabetes for over 25 years, has been talking with him about whether he should get a CGM. What would you advise Gavin to do as he transitions to Medicare?

- Will Gavin need more than the usual number of supplies?** One thing to consider is that it appears Gavin's manual testing uses up more than the standard number of supplies for someone injecting insulin (100 lancets and 100 test strips a month). If Gavin continues with manual testing while on Medicare, he should start a diary tracking his blood sugar testing. He should also reach out to his doctor to start preparing the documentation to show why Gavin needs additional supplies.
- Does Gavin meet the coverage criteria for a CGM?** While Gavin's doctor seems to think he would benefit from a CGM, Medicare only covers CGM's in specific situations and only covers therapeutic CGMs designed to replace manual blood testing. Gavin should let his doctor know that he is switching to Medicare and ensure his doctor understands the coverage criteria and documentation requirements.
- Should Gavin join Original Medicare and a Part D plan or an MA Plan?** There is quite a bit to consider here. What types and brands of insulin and testing supplies (or, CGMs, if Gavin switches over) will be covered by different plans? What plans would cover the quantity of supplies Gavin needs? Gavin may want to keep his long-time doctor, so it would also be important to make sure that any MA Plan he picked had his doctor in-network. Gavin might consider asking his doctor if he has had good experiences getting diabetes supplies covered through a particular plan. Also, what supplier does Gavin want to use to get his equipment? Would they be in-network or a preferred pharmacy at any of the plans he is looking at? Lastly, what is the cost-sharing for his supplies at different plans? Does Gavin qualify for any low-income benefit programs that might affect his cost-sharing? Is he eligible for supplemental coverage, like a Medigap, to help pay for Part B costs?