Continuous Glucose Monitoring and Insulin Delivery for Managing Diabetes

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➲ Instructions for Use

Table of Contents **Page**

Application 1
Coverage Rationale 1
Medical Records Documentation Used for Reviews 3
Definitions 3
Applicable Codes 3
Description of Services 7
Benefit Considerations 8
Clinical Evidence 9
U.S. Food and Drug Administration 13
References 14
Policy History/Revision Information 16
Instructions for Use 17

Related Commercial/Individual Exchange Policy

- Durable Medical Equipment, Orthotics, Medical Supplies, and Repairs/Replacements

Community Plan Policy

- Continuous Glucose Monitoring and Insulin Delivery for Managing Diabetes

Medicare Advantage Policy

- Durable Medical Equipment (DME), Prosthetics, Orthotics (Non-Foot Orthotics), Nutritional Therapy, and Medical Supplies Grid

Application

UnitedHealthcare Commercial

This Medical Policy applies to UnitedHealthcare Commercial benefit plans.

UnitedHealthcare Individual Exchange

This Medical Policy applies to Individual Exchange benefit plans.

Coverage Rationale

➲ See Benefit Considerations

Insulin Delivery

When used according to U.S. Food and Drug Administration (FDA)–labeled indications, contraindications, warnings, and precautions, external continuous subcutaneous insulin infusion pumps (including Omnipod) are proven and medically necessary in certain circumstances. For medical necessity clinical coverage criteria, refer to the InterQual® CP: Durable Medical Equipment, Continuous Glucose Monitors, Insulin Pumps, and Automated Insulin Delivery Technology.

Click here to view the InterQual® criteria.

External continuous subcutaneous insulin infusion pumps are medically necessary for managing individuals with diabetes due to causes, other than type 1, type 2, or gestational diabetes, that require intensive insulin therapy (insulin treated at least three times a day). Examples include but are not limited to cystic fibrosis–related diabetes, posttransplant diabetes, and diabetes following pancreatic surgery.

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The following devices are unproven and not medically necessary for managing individuals with diabetes due to insufficient evidence of efficacy.
- Implantable insulin pumps
- Nonprogrammable transdermal insulin delivery systems (e.g., V-Go®)

Continuous Glucose Monitoring

Short-Term Continuous Glucose Monitoring (3-14 Days)

Short-term continuous glucose monitoring (CGM) use by a health care provider for diagnostic purposes is proven and medically necessary for managing individuals with diabetes.

Long-Term Continuous Glucose Monitoring (Greater Than 14 Days)

Note: Coverage criteria noted below must be met whether the request comes through the UnitedHealthcare prior authorization process (type 2 or gestational diabetes) or a contracted supplier (type 1 diabetes).

Duration of approved authorization:
- Initial CGM authorization will be for up to 6 months
- Reauthorization will be for up to 12 months

Nonimplantable Continuous Glucose Monitoring

Intensive Insulin Therapy

When used according to FDA-labeled indications, contraindications, warnings, and precautions, initial long-term CGM use is proven and medically necessary in certain circumstances. For medical necessity clinical coverage criteria, refer to the InterQual® CP: Durable Medical Equipment, Continuous Glucose Monitors, Insulin Pumps, and Automated Insulin Delivery Technology.

Click here to view the InterQual® criteria.

For continued long-term use, CGM is proven and medically necessary when all the following criteria are met:
- Device is used according to FDA-labeled indications, contraindications, warnings, and precautions
- Medical necessity clinical coverage criteria are met; refer to the InterQual® CP: Durable Medical Equipment, Continuous Glucose Monitors, Insulin Pumps, and Automated Insulin Delivery Technology
- Individual is assessed by a provider every 6 months for adherence to the prescribed CGM regimen and treatment plan

Click here to view the InterQual® criteria.

Nonintensive Diabetes Therapy

Initial long-term CGM is medically necessary for managing individuals with diabetes on a nonintensive treatment plan (e.g., basal insulin and/or oral medications) who have a history of a level 3 hypoglycemic event or recurrent (more than one) level 2 hypoglycemic events that persist despite multiple (more than one) attempts to adjust medication(s) and/or modify the diabetes treatment plan.

Continued long-term CGM is medically necessary for managing individuals with diabetes on a nonintensive treatment plan (e.g., basal insulin and/or oral medications) when all the following criteria are met:
- Clinical criteria for initial use noted above were met at initiation of CGM
- Individual is assessed by a provider every 6 months for adherence to the prescribed CGM regimen and treatment plan

Long-term CGM is unproven and not medically necessary for managing individuals with diabetes on a nonintensive treatment plan (e.g., basal insulin and/or oral medications) for all other indications.

Implantable Continuous Glucose Monitoring

Initial long-term CGM using an implantable glucose sensor (e.g., Eversense®) is medically necessary for managing individuals with diabetes when all the following criteria are met:
- Device is used according to FDA-labeled indications, contraindications, warnings, and precautions
- Age ≥ 18 years
- One of the following:
  - Individual requires intensive insulin therapy (insulin treated at least three times a day or insulin pump); or

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- Individual has a history of a level 3 hypoglycemic event or recurrent (more than one) level 2 hypoglycemic events that persist despite multiple (more than one) attempts to adjust medication(s) and/or modify the diabetes treatment plan

Continued long-term CGM using an implantable glucose sensor (e.g., Eversense) is medically necessary for managing individuals with diabetes when all the following criteria are met:

- Individual continues to require intensive insulin therapy (insulin treated at least three times a day or insulin pump) or clinical criteria for initial use noted above were met at initiation of CGM for Hypoglycemia
- Individual is assessed by a provider every 6 months for adherence to the prescribed CGM regimen and treatment plan

Noninvasive Continuous Glucose Monitoring Devices

The use of a noninvasive CGM device is unproven and not medically necessary for managing individuals with diabetes due to insufficient evidence of efficacy.

Medical Records Documentation Used for Reviews

Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. Medical records documentation may be required to assess whether the member meets the clinical criteria for coverage but does not guarantee coverage of the service requested; refer to the guidelines titled Medical Records Documentation Used for Reviews.

Definitions

Adjunctive Continuous Glucose Monitor: An Adjunctive Continuous Glucose Monitor (CGM) requires the user to verify their glucose levels or trends displayed on a CGM with a blood glucose monitor prior to making treatment decisions [Centers for Medicare and Medicaid Services; American Diabetes Association (ADA), 2026].

Hypoglycemia:

- Level 2: Glucose of < 54 mg/dL (3.0 mmol/L). This level of Hypoglycemia is associated with increased risk for cognitive dysfunction and mortality.
- Level 3: A severe event characterized by an altered mental and/or physical state requiring third-party assistance for treatment. This level of Hypoglycemia is life-threatening and requires emergent treatment.

(ADA, 2026; McCall et al., 2023; Blonde et al., 2022)

Intermittently Scanned (Flash) Continuous Glucose Monitor: Devices with two components: a combined glucose sensor/transmitter and a separate reader. These devices measure glucose levels continuously but require scanning for visualization and storage of glucose values. They are available with and without alarms (ADA website and ADA, 2026).

Nonadjunctive Continuous Glucose Monitor: A Nonadjunctive CGM can be used to make treatment decisions without the need for a stand-alone blood glucose monitor to confirm testing results (Centers for Medicare and Medicaid Services; ADA, 2026).

Professional Continuous Glucose Monitor: Devices that are placed in a health care professional's office (or with remote instruction) and worn for a discrete period of time (generally 7-14 days). Data may be blinded or visible to the person wearing the device. The data are used to assess glycemic patterns and trends. Unlike Real-Time CGM and Intermittently Scanned (Flash) CGM devices, these devices are clinic based and not owned by the user (ADA, 2026).

Real-Time Continuous Glucose Monitor: Devices with three components: a sensor (small wire catheter that is inserted under the skin), transmitter that attaches to the sensor and sends information, and handheld receiver and/or smartphone that displays glucose readings in real time. These devices measure and display glucose levels continuously and have audible alerts when glucose levels are out of range. Some systems require calibration by the user (ADA website and ADA, 2026).

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan document and

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applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other policies and guidelines may apply.

CPT Code	Description
0446T	Creation of subcutaneous pocket with insertion of implantable interstitial glucose sensor, including system activation and patient training
0448T	Removal of implantable interstitial glucose sensor with creation of subcutaneous pocket at different anatomic site and insertion of new implantable sensor, including system activation
95249	Ambulatory continuous glucose monitoring of interstitial tissue fluid via a subcutaneous sensor for a minimum of 72 hours; patient-provided equipment, sensor placement, hook-up, calibration of monitor, patient training, and printout of recording
95250	Ambulatory continuous glucose monitoring of interstitial tissue fluid via a subcutaneous sensor for a minimum of 72 hours; physician or other qualified health care professional (office) provided equipment, sensor placement, hook-up, calibration of monitor, patient training, removal of sensor, and printout of recording
95251	Ambulatory continuous glucose monitoring of interstitial tissue fluid via a subcutaneous sensor for a minimum of 72 hours; analysis, interpretation and report

CPT® is a registered trademark of the American Medical Association

HCPCS Code	Description
A4226	Supplies for maintenance of insulin infusion pump with dosage rate adjustment using therapeutic continuous glucose sensing, per week
A4238	Supply allowance for adjunctive, nonimplanted continuous glucose monitor (CGM), includes all supplies and accessories, 1 month supply = 1 unit of service
A4239	Supply allowance for nonadjunctive, nonimplanted continuous glucose monitor (CGM), includes all supplies and accessories, 1 month supply = 1 unit of service
A9274	External ambulatory insulin delivery system, disposable, each, includes all supplies and accessories
A9276	Sensor; invasive (e.g., subcutaneous), disposable, for use with nondurable medical equipment interstitial continuous glucose monitoring system (CGM), one unit = 1 day supply
A9277	Transmitter; external, for use with nondurable medical equipment interstitial continuous glucose monitoring system (CGM)
A9278	Receiver (monitor); external, for use with nondurable medical equipment interstitial continuous glucose monitoring system (CGM)
E0784	External ambulatory infusion pump, insulin
E0787	External ambulatory infusion pump, insulin, dosage rate adjustment using therapeutic continuous glucose sensing
E2102	Adjunctive, nonimplanted continuous glucose monitor (CGM) or receiver
E2103	Nonadjunctive, nonimplanted continuous glucose monitor (CGM) or receiver
S1030	Continuous noninvasive glucose monitoring device, purchase (For physician interpretation of data, use CPT code)
S1031	Continuous noninvasive glucose monitoring device, rental, including sensor, sensor replacement, and download to monitor (For physician interpretation of data, use CPT code)
S1034	Artificial pancreas device system (e.g., low glucose suspend [LGS] feature) including continuous glucose monitor, blood glucose device, insulin pump and computer algorithm that communicates with all of the devices
S1035	Sensor; invasive (e.g., subcutaneous), disposable, for use with artificial pancreas device system
S1036	Transmitter; external, for use with artificial pancreas device system
S1037	Receiver (monitor); external, for use with artificial pancreas device system

Diagnosis Code	Description
E11.00	Type 2 diabetes mellitus with hyperosmolarity without nonketotic hyperglycemic-hyperosmolar coma (NKHHC)
E11.01	Type 2 diabetes mellitus with hyperosmolarity with coma

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Diagnosis Code	Description
E11.10	Type 2 diabetes mellitus with ketoacidosis without coma
E11.11	Type 2 diabetes mellitus with ketoacidosis with coma
E11.21	Type 2 diabetes mellitus with diabetic nephropathy
E11.22	Type 2 diabetes mellitus with diabetic chronic kidney disease
E11.29	Type 2 diabetes mellitus with other diabetic kidney complication
E11.311	Type 2 diabetes mellitus with unspecified diabetic retinopathy with macular edema
E11.319	Type 2 diabetes mellitus with unspecified diabetic retinopathy without macular edema
E11.3211	Type 2 diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, right eye
E11.3212	Type 2 diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, left eye
E11.3213	Type 2 diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, bilateral
E11.3219	Type 2 diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, unspecified eye
E11.3291	Type 2 diabetes mellitus with mild nonproliferative diabetic retinopathy without macular edema, right eye
E11.3292	Type 2 diabetes mellitus with mild nonproliferative diabetic retinopathy without macular edema, left eye
E11.3293	Type 2 diabetes mellitus with mild nonproliferative diabetic retinopathy without macular edema, bilateral
E11.3299	Type 2 diabetes mellitus with mild nonproliferative diabetic retinopathy without macular edema, unspecified eye
E11.3311	Type 2 diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, right eye
E11.3312	Type 2 diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, left eye
E11.3313	Type 2 diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, bilateral
E11.3319	Type 2 diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, unspecified eye
E11.3391	Type 2 diabetes mellitus with moderate nonproliferative diabetic retinopathy without macular edema, right eye
E11.3392	Type 2 diabetes mellitus with moderate nonproliferative diabetic retinopathy without macular edema, left eye
E11.3393	Type 2 diabetes mellitus with moderate nonproliferative diabetic retinopathy without macular edema, bilateral
E11.3399	Type 2 diabetes mellitus with moderate nonproliferative diabetic retinopathy without macular edema, unspecified eye
E11.3411	Type 2 diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, right eye
E11.3412	Type 2 diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, left eye
E11.3413	Type 2 diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, bilateral
E11.3419	Type 2 diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, unspecified eye
E11.3491	Type 2 diabetes mellitus with severe nonproliferative diabetic retinopathy without macular edema, right eye
E11.3492	Type 2 diabetes mellitus with severe nonproliferative diabetic retinopathy without macular edema, left eye

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Diagnosis Code	Description
E11.3493	Type 2 diabetes mellitus with severe nonproliferative diabetic retinopathy without macular edema, bilateral
E11.3499	Type 2 diabetes mellitus with severe nonproliferative diabetic retinopathy without macular edema, unspecified eye
E11.3511	Type 2 diabetes mellitus with proliferative diabetic retinopathy with macular edema, right eye
E11.3512	Type 2 diabetes mellitus with proliferative diabetic retinopathy with macular edema, left eye
E11.3513	Type 2 diabetes mellitus with proliferative diabetic retinopathy with macular edema, bilateral
E11.3519	Type 2 diabetes mellitus with proliferative diabetic retinopathy with macular edema, unspecified eye
E11.3521	Type 2 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment involving the macula, right eye
E11.3522	Type 2 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment involving the macula, left eye
E11.3523	Type 2 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment involving the macula, bilateral
E11.3529	Type 2 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment involving the macula, unspecified eye
E11.3531	Type 2 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment not involving the macula, right eye
E11.3532	Type 2 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment not involving the macula, left eye
E11.3533	Type 2 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment not involving the macula, bilateral
E11.3539	Type 2 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment not involving the macula, unspecified eye
E11.3541	Type 2 diabetes mellitus with proliferative diabetic retinopathy with combined traction retinal detachment and rhegmatogenous retinal detachment, right eye
E11.3542	Type 2 diabetes mellitus with proliferative diabetic retinopathy with combined traction retinal detachment and rhegmatogenous retinal detachment, left eye
E11.3543	Type 2 diabetes mellitus with proliferative diabetic retinopathy with combined traction retinal detachment and rhegmatogenous retinal detachment, bilateral
E11.3549	Type 2 diabetes mellitus with proliferative diabetic retinopathy with combined traction retinal detachment and rhegmatogenous retinal detachment, unspecified eye
E11.3551	Type 2 diabetes mellitus with stable proliferative diabetic retinopathy, right eye
E11.3552	Type 2 diabetes mellitus with stable proliferative diabetic retinopathy, left eye
E11.3553	Type 2 diabetes mellitus with stable proliferative diabetic retinopathy, bilateral
E11.3559	Type 2 diabetes mellitus with stable proliferative diabetic retinopathy, unspecified eye
E11.3591	Type 2 diabetes mellitus with proliferative diabetic retinopathy without macular edema, right eye
E11.3592	Type 2 diabetes mellitus with proliferative diabetic retinopathy without macular edema, left eye
E11.3593	Type 2 diabetes mellitus with proliferative diabetic retinopathy without macular edema, bilateral
E11.3599	Type 2 diabetes mellitus with proliferative diabetic retinopathy without macular edema, unspecified eye
E11.36	Type 2 diabetes mellitus with diabetic cataract
E11.37X1	Type 2 diabetes mellitus with diabetic macular edema, resolved following treatment, right eye
E11.37X2	Type 2 diabetes mellitus with diabetic macular edema, resolved following treatment, left eye
E11.37X3	Type 2 diabetes mellitus with diabetic macular edema, resolved following treatment, bilateral
E11.37X9	Type 2 diabetes mellitus with diabetic macular edema, resolved following treatment, unspecified eye
E11.39	Type 2 diabetes mellitus with other diabetic ophthalmic complication
E11.40	Type 2 diabetes mellitus with diabetic neuropathy, unspecified
E11.41	Type 2 diabetes mellitus with diabetic mononeuropathy

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Diagnosis Code	Description
E11.42	Type 2 diabetes mellitus with diabetic polyneuropathy
E11.43	Type 2 diabetes mellitus with diabetic autonomic (poly)neuropathy
E11.44	Type 2 diabetes mellitus with diabetic amyotrophy
E11.49	Type 2 diabetes mellitus with other diabetic neurological complication
E11.51	Type 2 diabetes mellitus with diabetic peripheral angiopathy without gangrene
E11.52	Type 2 diabetes mellitus with diabetic peripheral angiopathy with gangrene
E11.59	Type 2 diabetes mellitus with other circulatory complications
E11.610	Type 2 diabetes mellitus with diabetic neuropathic arthropathy
E11.618	Type 2 diabetes mellitus with other diabetic arthropathy
E11.620	Type 2 diabetes mellitus with diabetic dermatitis
E11.621	Type 2 diabetes mellitus with foot ulcer
E11.622	Type 2 diabetes mellitus with other skin ulcer
E11.628	Type 2 diabetes mellitus with other skin complications
E11.630	Type 2 diabetes mellitus with periodontal disease
E11.638	Type 2 diabetes mellitus with other oral complications
E11.641	Type 2 diabetes mellitus with hypoglycemia with coma
E11.649	Type 2 diabetes mellitus with hypoglycemia without coma
E11.65	Type 2 diabetes mellitus with hyperglycemia
E11.69	Type 2 diabetes mellitus with other specified complication
E11.8	Type 2 diabetes mellitus with unspecified complications
E11.9	Type 2 diabetes mellitus without complications
O24.111	Pre-existing type 2 diabetes mellitus, in pregnancy, first trimester
O24.112	Pre-existing type 2 diabetes mellitus, in pregnancy, second trimester
O24.113	Pre-existing type 2 diabetes mellitus, in pregnancy, third trimester
O24.119	Pre-existing type 2 diabetes mellitus, in pregnancy, unspecified trimester
O24.12	Pre-existing type 2 diabetes mellitus, in childbirth
O24.13	Pre-existing type 2 diabetes mellitus, in the puerperium
O24.410	Gestational diabetes mellitus in pregnancy, diet controlled
O24.414	Gestational diabetes mellitus in pregnancy, insulin controlled
O24.415	Gestational diabetes mellitus in pregnancy, controlled by oral hypoglycemic drugs
O24.419	Gestational diabetes mellitus in pregnancy, unspecified control
O24.420	Gestational diabetes mellitus in childbirth, diet controlled
O24.424	Gestational diabetes mellitus in childbirth, insulin controlled
O24.425	Gestational diabetes mellitus in childbirth, controlled by oral hypoglycemic drugs
O24.429	Gestational diabetes mellitus in childbirth, unspecified control
O24.430	Gestational diabetes mellitus in the puerperium, diet controlled
O24.434	Gestational diabetes mellitus in the puerperium, insulin controlled
O24.435	Gestational diabetes mellitus in puerperium, controlled by oral hypoglycemic drugs
O24.439	Gestational diabetes mellitus in the puerperium, unspecified control

Description of Services

Diabetes mellitus can be classified into the following general categories [American Diabetes Association (ADA), 2026]:

- Type 1 diabetes (due to autoimmune β-cell destruction, usually leading to absolute insulin deficiency, including latent autoimmune diabetes in adults). Latent autoimmune diabetes in adults can be classified as a more slowly progressing variation of type 1 diabetes, yet it is often misdiagnosed as type 2.

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- Type 2 diabetes (due to a nonautoimmune progressive loss of adequate β-cell insulin secretion, frequently on the background of insulin resistance).
- Gestational diabetes mellitus (GD; diabetes diagnosed in the second or third trimester of pregnancy that was not clearly overt diabetes prior to gestation or other types of diabetes occurring throughout pregnancy, such as type 1 diabetes). GD resembles type 2 diabetes and usually disappears after childbirth.
- Specific types of diabetes due to other causes, e.g., monogenic diabetes syndromes (such as neonatal diabetes and maturity-onset diabetes of the young), diseases of the exocrine pancreas (such as cystic fibrosis and pancreatitis), and drug- or chemical-induced diabetes (such as with glucocorticoid use, in the treatment of HIV, or after organ transplant).

If poorly controlled, diabetes can lead to complications such as heart disease, stroke, peripheral vascular disease, retinal damage, kidney disease, nerve damage, and erectile dysfunction. In GD, fetal and maternal health can be compromised.

Improved glycemic control has been shown to slow the onset or progression of major complications. Management of diabetes involves efforts to maintain blood glucose levels near the normal range. Glycemic status can be assessed by blood glucose monitoring, continuous glucose monitoring (CGM), and laboratory testing of hemoglobin A_{1c} (ADA, 2026).

Insulin Delivery

Standard external insulin pumps connect to flexible plastic tubing that ends with a needle inserted just under the skin. Another type of insulin pump (Omnipod) combines an insulin reservoir placed on the skin with a wireless device to manage dosing and perform blood glucose monitoring. Both types of devices can be programmed to release small doses of insulin continuously (basal) or a bolus dose close to mealtime to control the rise in blood glucose after a meal. Newer patch devices (e.g., V-Go) deliver preset basal and on-demand bolus dosages of insulin transdermally and lack programmability. Implantable insulin pumps are placed inside the body to deliver insulin in response to remote-control commands from the user (ADA Common Terms website).

Continuous Glucose Monitors

CGM devices continuously monitor and record interstitial glucose levels and have three components: a sensor, transmitter, and receiver. Some CGM systems are designed for short-term diagnostic or professional use. These devices store retrospective information for review at a later time. Other CGM systems, such as Real-Time CGMs and Intermittently Scanned (Flash) CGMs, are designed for long-term personal use and allow the individual to take action based on the data displayed (ADA, 2026; American Medical Association, 2009). Available sensors are either disposable or implantable. Implantable sensors include a smart transmitter and mobile application and are based on fluorescence sensing technology. The sensor is designed to be inserted subcutaneously and communicate with the smart transmitter to wirelessly transmit glucose levels to a mobile device. These long-term devices are available with or without an integrated external insulin pump. A review by Messer et al. (2019) highlighted clinically relevant aspects of newer, advanced diabetes devices. Refer to the Definitions section for more details on the different types of CGM devices.

Benefit Considerations

Most benefit plans include coverage for proven and medically necessary continuous glucose monitoring (CGM) and insulin delivery for managing diabetes under the durable medical equipment benefit. Coverage limitations and exclusions may apply. Refer to the member specific benefit plan document for details.

Certain plans exclude coverage for over-the-counter CGMs. Refer to the member specific benefit plan document for details.

For details regarding repair and replacement coverage, refer to the Medical Policy titled Durable Medical Equipment, Orthotics, Medical Supplies, and Repairs/Replacements.

Some products may only be provided under the pharmacy benefit. Refer to the member specific benefit plan document for details.

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Clinical Evidence

Insulin Delivery

Insulin Pumps for Diabetes Due to Other Causes

Specific types of diabetes due to causes other than type 1, type 2, or gestational diabetes may require intensive insulin management. Examples include cystic fibrosis–related diabetes, posttransplant diabetes, and diabetes following pancreatic surgery. Although the evidence is limited, professional societies state that insulin pumps may be considered in these populations with insulin deficiency that requires multiple daily injections (American Diabetes Association, 2026; McCall et al., 2023).

Implantable Insulin Pumps

At this time, implantable insulin pumps are only available in a clinical trial setting.

Nonprogrammable Transdermal Insulin Delivery

There is insufficient evidence in the clinical literature demonstrating the safety and efficacy of nonprogrammable, wearable, disposable insulin delivery devices in the management of individuals with diabetes. Larger, well-designed studies, with long-term follow-up and comparative effectiveness data, are needed.

Grunberger et al. (2020) conducted a prospective, observational, open-label, multicenter study that evaluated glycemic control, insulin dosing, and hypoglycemia risk in participants using a V-Go device in a real-world setting. The primary objective was to compare change in mean hemoglobin A_{1c} (HbA_{1c}) from baseline to the end of use. Overall, 188 participants with type 2 diabetes and suboptimal glycemic control ($HbA_{1c} \geq 7\%$) were enrolled in the study. At 12 months, 112 participants (60%) remained in the study, among whom 66 were on V-Go and 46 were using therapies other than V-Go. Use of V-Go resulted in significantly improved glycemic control across the participant population and did so with significantly less insulin among most participants with prior insulin use. In total, 22 participants (12%) reported hypoglycemic events (≤ 70 mg/dL), with an event rate of 1.51 events per participant per year. Study limitations include the lack of a control group and high attrition rates.

Several retrospective chart reviews suggest that V-Go therapy is associated with improved glycemic control; however, these studies are limited by a retrospective design, small sample size, and/or short-term follow-up. Further well-designed, prospective studies are needed to establish the safety and efficacy of this device in managing individuals with diabetes (Hundal et al., 2020; Zeidan et al., 2020; Everitt et al., 2019; Raval et al., 2019; Sutton et al., 2018; Lajara et al., 2016; Lajara et al., 2015; Rosenfeld et al., 2012).

Continuous Glucose Monitoring

Implantable Glucose Sensor

A review of the clinical evidence concluded that the Eversense implantable glucose sensor is an acceptable alternative to standard continuous glucose monitors (CGMs). Comparative studies suggest that the clinical validity of Eversense is comparable to that of other CGM devices.

Summary of Clinical Trials

- PROMISE: The prospective, multicenter, unblinded, nonrandomized study evaluated the accuracy and safety of the next-generation implantable Eversense CGM system for up to 180 days in 181 participants with type 1 or type 2 diabetes (Garg et al., 2022).
- PRECISION: The prospective multicenter study evaluated the accuracy and safety of Eversense in 35 adults with type 1 or type 2 diabetes through 90 days (Christiansen et al., 2019).
- PRECISE II: The prospective multicenter study evaluated the accuracy and safety of the Eversense CGM system in 90 adult participants with type 1 or type 2 diabetes (Christiansen et al., 2018).
- PRECISE : The prospective, multicenter pivotal trial evaluated the accuracy and longevity of the Eversense implantable CGM sensor in 71 participants, aged 18 years or older, who had type 1 or type 2 diabetes (Kropff et al., 2017).

Bailey et al. (2025) published results from the ENHANCE prospective, multicenter, nonrandomized study that evaluated the safety and accuracy of a 365-day CGM through 1 year in adults with diabetes. The study data were used to support the U.S. Food and Drug Administration submission for the Eversense 365 CGM system. A total of 110 participants received the Eversense 365 CGM system. The study used primarily one calibration per week. The overall mean absolute relative difference (MARD) was 8.8%, with 96.6% and 97.9% confirmed alert detection rates at 70 mg/dL and 180 mg/dL,

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respectively. Overall, 90% of the sensors survived 365 days. There were no serious adverse events related to the device or insertion/removal procedures.

A Hayes Health Technology Assessment (2022; updated 2025) concluded that a low-quality body of evidence suggests that the Eversense CGM system is moderately accurate in measuring glucose levels compared with venous blood glucose or self-monitoring of blood glucose (SMBG) as reference standards. However, substantial uncertainty remains pertaining to the accuracy of the device across a range of glucose values. Additionally, the body of evidence is limited by an evidence base of fair- to very poor-quality studies, small numbers of individuals, limited data assessing the accuracy of CGM across different glucose parameters, and inconsistencies in results between studies. Assessments of clinical utility were of low quality due to a small number of studies available that evaluated health outcomes. One randomized controlled trial (RCT) reported no difference in HbA_{1c} levels between a group of individuals with an activated Eversense device compared with a group of individuals with a blinded Eversense device (who used intermittent CGM or SMBG); however, individuals with type 1 diabetes spent a significantly lower amount of time in hypoglycemia ranges than baseline use of SMBG. Overall, the evidence from the single-arm cohort studies suggests that the Eversense CGM system statistically significantly reduces HbA_{1c} values by approximately 0.5%, which is of unclear clinical relevance. In addition, only a single study was available that compared health outcomes in individuals who used the Eversense CGM system vs intermittent CGM or SMBG, which limits the conclusions that may be drawn regarding clinical utility.

Renard et al. (2022) reported the results of two small RCTs in adults treated with insulin. The first trial (cohort 1) included 149 adults with type 1 diabetes or type 2 diabetes and an HbA_{1c} of above 8%. Participants were implanted with the Eversense CGM and then randomized to access or no access to the sensor readings. The study failed to demonstrate a benefit on the primary outcome, which was changes in HbA_{1c} at 6 months after implantation. The second trial (cohort 2) included 90 adults with type 1 diabetes who spent more than 90 minutes per day with glucose values of below 70 mg/dL over the previous 28 days at baseline. This trial demonstrated a significant decrease after 3 to 4 months of Eversense use in time below 54 mg/dL (primary outcome, clinically significant hypoglycemia), with a group difference of approximately 23 minutes. The group differences further increased at 6 months post implantation (secondary outcome).

Boscari et al. (2022) conducted a randomized crossover trial comparing 12 weeks with a first-generation Eversense implantable sensor (n = 8) and 12 weeks with a Dexcom G5 transcutaneous sensor (n = 8). The primary outcome was sensor accuracy, expressed as MARD vs capillary glucose values obtained by SMBG. The secondary outcomes were time of CGM use, efficacy (HbA_{1c}; time in range and time above and below range), and safety. Psychological outcomes were also considered. Overall, Eversense performed better than Dexcom G5 with a MARD vs SMBG of 12.27% ±11.55% (mean ±SD) vs 13.14% ±14.76% ($p < 0.001$). Eversense was more accurate than Dexcom G5 in the normal range, but there were no differences in the hypo- and hyperglycemic ranges.

Boscari et al. (2021) conducted a small study (n = 11) that compared the accuracy of the Dexcom G5 transcutaneous sensor and the first-generation Eversense implantable sensor in adults with insulin-treated type 1 diabetes. The two devices were worn simultaneously and compared with SMBG (over 7 days) or venous blood glucose during a 1-day clinical visit when hypoglycemia was induced to test CGM performances during rapid glycemia changes. Dexcom G5 and Eversense had similar accuracy compared with SMBG readings collected both at home and during the clinic visit. However, compared with venous glucose levels during the clinic visit, Dexcom G5 was more accurate than the Eversense device (absolute relative difference, 7.9% vs 11.4%; $p < 0.001$). When blood glucose decreased, Dexcom also performed better than Eversense (7.3% vs 13.6%; $p < 0.001$).

Fokkert et al. (2020) compared the performance of two CGM devices between a week of normal daily activities and a week of intense physical activity (mountain biking) in 23 adults with type 1 diabetes. The investigators concluded that during “exercise compared with daily life activities, interstitial glucose readings with both the Eversense (fluorescence based) and the Free Style Libre (glucose oxidase based) were less accurate, often with clinically relevant differences, compared with capillary measurements.” However, the performance of the two devices did not seem to be clinically significantly different from one another, although the study did not test differences between the devices. This study suggests challenges in accuracy during intense exercise but no clinically significant difference in performance between the Eversense and FreeStyle Libre devices.

An ECRI (2020) Clinical Evidence Assessment reported that evidence from five multicenter, diagnostic accuracy cohort studies that compared Eversense’s accuracy with that of plasma glucose readings or SMBG values indicates that the device provides relatively accurate data. A European registry study of > 3,000 users found that the system was safe over multiple cycles of use. Implantation was associated with infrequent, nonserious adverse events. However, findings from the three prospective cohort studies that compared sensor readings with plasma glucose levels recorded at predetermined time intervals may not generalize to the broader population of individuals for whom the device is intended. Also, most of the real-world experience data on the Eversense device are derived from its use in Europe and South Africa;

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therefore, they may not be completely generalizable to other health care settings due to differences in health care practices and because the Eversense sensor that was initially approved in Europe had a different design.

Tweden et al. (2020) assessed the performance of the Eversense CGM system in adult patients with diabetes who had gone through at least four sensor cycles. Sensors were replaced every 90 or 180 days, depending on the product used. The Eversense Data Management System was used to evaluate the accuracy of sensor glucose (SG) values against SMBG. Mean SG and associated measures of variability, glucose management indicator, and percentage and time in range were calculated for the 24-hour time period over each cycle. In addition, transmitter wear time was evaluated across each sensor wear cycle. Among the 945 users who were included in the analysis, the MARD, using 152,206, 174,645, 206,024, and 172,587 calibration-matched pairs, against SMBG was 11.9% (3.6%), 11.5% (4.0%), 11.8% (4.7%), and 11.5% (4.1%) during the first four sensor cycles, respectively. Mean values of the CGM metrics over the first sensor cycle were 156.5 mg/dL for SG, 54.7 mg/dL for SD, 0.35 for coefficient of variation, and 7.04% for glucose management indicator. Percent SG at different glycemic ranges was recorded and showed that < 54 mg/dL was 1.1% (16 min), < 70 mg/dL was 4.6% (66 min), ≥ 70 to 180 mg/dL (time in range) was 64.5% (929 min), > 180 to 250 mg/dL was 22.8% (328 min), and > 250 mg/dL was 8.1% (117 min). The median transmitter wear time over the first cycle was 83.2%. CGM metrics and wear time were similar over the subsequent three cycles. This study is limited by its retrospective design.

Irace et al. (2020) conducted a prospective, multicenter, observational study that evaluated the changes in HbA_{1c} and CGM metrics associated with the use of the implantable 180-day Eversense CGM system in 100 adult participants with type 1 diabetes. HbA_{1c} was measured at baseline and at 180 days. Changes in time in range (glucose, 70-180 mg/dL), time above range (glucose, > 180 mg/dL), time below range (glucose, < 70 mg/dL), and glycemic variability were also assessed. Overall, 56% of participants were insulin pump users, and 45% were previous CGM users. HbA_{1c} significantly decreased in participants after 180 days of sensor wear (-0.43% ±0.69%, 5 ±8 mmol/mol; $p < 0.0001$). Improvements were greater in subgroups of participants who were CGM naive regardless of the insulin delivery method. The time in range significantly increased, and the time above range and mean daily SG significantly decreased; the time below range did not change after 180 days of sensor wear. Study limitations include the lack of a comparator group, small participant population, and short-term follow-up.

Jafri et al. (2020) performed a 6-week home-use study that evaluated the accuracy of the Dexcom G5, Abbott FreeStyle Libre Pro, and Senseonics Eversense CGM devices in 23 individuals with type 1 diabetes who wore all three devices concurrently. The primary outcome was the MARD between CGM readings and plasma glucose values obtained approximately twice daily by the individuals. All three CGM systems produced higher average MARDs than during in-clinic studies. However, since all three CGM systems were worn by the same individuals and used the same meter for comparator glucose measurements, direct comparisons were possible. In the three-way comparison, Eversense achieved the lowest nominal MARD (14.8%), followed by Dexcom G5 (16.3%) and Libre Pro (18.0%). Studies that include longer follow-up and larger populations of individuals are needed to confirm these findings.

Deiss et al. (2020) used the Post-Market Clinical Follow-Up registry to evaluate the long-term safety and performance of the Eversense CGM system over multiple sensor insertion/removal cycles among adults with type 1 or type 2 diabetes. The primary safety end point was the rate of serious adverse events through four sensor insertion/removal cycles. Of 3,023 enrolled individuals, 280 completed four cycles. No related serious adverse events were reported. The most frequently reported adverse events were sensor location site infection, inability to remove the sensor on first attempt, and adhesive patch location site irritation. One nonserious allergic reaction to lidocaine was reported, which resolved with administration of an antihistamine. The full intended sensor life was achieved by 91% of 90-day sensors and 75% of 180-day sensors. This study is limited by its observational nature. Further studies are needed to evaluate the clinical utility of the Eversense system and the impact on health outcomes.

Sanchez et al. (2019) analyzed real-world data from the first U.S. commercial users of the Eversense system. The first 205 individuals who reached a 90-day wear period were included in the analysis. Of the 205 individuals, 129 had type 1 diabetes, 18 had type 2 diabetes, and 58 were unreported.

- Time in range (≥ 70-180 mg/dL) was 62.3%
- > 180 to 250 mg/dL was 21.9%
- > 250 mg/dL was 11.6%
- < 54 mg/dL was 1.2%
- < 70 mg/dL was 4.1%

Nighttime values were similar. The sensor reinsertion rate was 78.5%. The median transmitter wear time was 83.6%. There were no related serious adverse events. The data showed promising glycemic results, sensor accuracy, and safety. Further long-term studies are needed to confirm these results and determine the impact on health outcomes.

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Nonintensive Diabetes Therapy

An ECRI report (2025) assessed CGM compared with blood glucose monitoring for managing individuals with type 2 diabetes on noninsulin therapies. Evidence from one systematic review and meta-analysis of six RCTs (Ferreira et al., 2024) showed that individuals with type 2 diabetes on noninsulin therapies who received CGM had better glycemic control metrics, such as reduction in HbA_{1c}, glucose variability, time above range, and time in severe hypoglycemia and increased time in range and treatment satisfaction, than individuals who performed blood glucose monitoring at up to the 9-month follow-up. Studies included in the analysis were limited by open-label designs, a small sample size, and short-term follow-up, leading to low-confidence conclusions. Additionally, the studies did not report on some key patient-oriented outcomes, such as type 2 diabetes–related hospitalizations and complications. The studies also included different CGM device types and monitoring regimens, which may affect the generalizability of the findings. (Moon et al., 2023, and Wada et al., 2020, previously cited in this policy, were included in the Ferreira et al. systematic review noted above.)

Uhl et al. (2024) conducted a systematic review and meta-analysis of RCTs that assessed the effectiveness of CGMs in the management of adults with type 2 diabetes on glucose control and clinical outcomes. The primary outcomes included HbA_{1c}, time in range, time in hyperglycemia, and time in hypoglycemia. Overall, 14 RCTs were included, with nine (n = 825) using real-time CGM (rt-CGM) and five (n = 822) using flash CGM. Both rt-CGM and flash CGM led to modest but statistically significant declines in HbA_{1c} in individuals with type 2 diabetes, with little heterogeneity in the results. While not statistically significant, improvements in percent time in hypoglycemia and hyperglycemia range were also observed with the use of rt-CGM. No such patterns of improvement for time in range, time in hypoglycemia, or time in hyperglycemia were seen in studies of flash CGM. There was a trend of improvements in other metrics of glucose control that favored rt-CGM over blood glucose monitoring; however, the duration of the included RCTs was relatively short, and few studies reported on important clinical outcomes, such as adverse events, emergency department use, and hospitalization. Longer-term studies are needed to determine if the short-term improvements in glucose control lead to improvements in clinically important outcomes. (Martens et al., 2021, and Wada et al., 2020, previously cited in this policy, are included in this systematic review.)

Jancev et al. (2024) conducted a systematic review and meta-analysis that evaluated the effect of rt-CGM or intermittently scanned CGM (is-CGM) on glycemic control in adults with type 2 diabetes. Overall, 12 RCTs (n = 1,248) were included, with eight investigating rt-CGM and four investigating is-CGM. The sample size ranged from 25 to 224 individuals. Change in HbA_{1c}, time in range, time below range, time above range, and glycemic variability were assessed. The investigators also assessed the effects of CGM on severe hypoglycemia and micro- and macrovascular complications. Compared with blood glucose monitoring, CGM use (rt-CGM or is-CGM) led to an average 3.43-mmol/mol decrease in HbA_{1c}. This effect was comparable in studies that included individuals using insulin with or without oral agents and individuals using oral agents only. Use of rt-CGM showed a trend toward a larger effect than the use of is-CGM. CGM was also associated with a 6.36% increase in time in range, a 0.66% decrease in time below range, a 5.86% decrease in time above range, and a 1.47% decrease in glycemic variability. Three studies reported one or more events of severe hypoglycemia and macrovascular complications. Compared with blood glucose monitoring, CGM use led to a non–statistically significant difference in the incidence of severe hypoglycemia and macrovascular complications. No studies reported data on microvascular complications. The authors concluded that CGM use compared with blood glucose monitoring is associated with improvements in glycemic control in adults with type 2 diabetes. Included study limitations are small sample sizes, short-term follow-up, and an open-label design. (Moon et al., 2023, Martens et al., 2021, Wada et al., 2020, and Vigersky et al., 2012, previously cited in this policy, are included in this systematic review.)

Several retrospective observational studies evaluated the use of CGM in patients with poorly controlled type 2 diabetes who were on less intensive treatment regimens. While these studies showed reductions in HbA_{1c}, further results from larger RCTs are needed to determine the role of CGM in this patient population (Conti et al., 2024; Al Hayek and Al Dawish, 2023; Carlson et al., 2022; Wright et al., 2021).

Noninvasive CGM Devices

There are no U.S. Food and Drug Administration–approved, noninvasive CGMs on the market at this time.

Clinical Practice Guidelines

American Association of Clinical Endocrinology (AACE)

AACE clinical practice guidelines provide evidence-based recommendations for the comprehensive care of patients with diabetes mellitus (Blonde et al., 2022).

AACE clinical practice guidelines provide evidence-based recommendations for the use of advanced technology in the management of patients with diabetes mellitus (Grunberger et al., 2021).

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American Diabetes Association (ADA)

The 2026 ADA *Standards of Care in Diabetes* is a comprehensive resource that outlines key elements of diabetes care, sets treatment goals, and provides tools to assess care quality to improve diabetes care and outcomes across diverse populations. The recommendations include screening, diagnostic, and therapeutic actions that are scientifically proven or known based on expert clinical practice or believed to favorably affect health outcomes. The section on diabetes technology addresses the hardware and software used to assist with diabetes management.

Endocrine Society

An Endocrine Society clinical practice guideline presents several recommendations for managing patients at a high risk for hypoglycemia. Most of the studies reviewed during the development of the recommendations included patients with type 1 or type 2 diabetes who were at risk for hypoglycemia. Although these populations make up the majority of people living with diabetes and are the target population for this guideline, others with diabetes are at risk for hypoglycemia and would benefit from these recommendations. They include those with monogenic forms of diabetes, diabetes in pregnancy, or diseases involving the exocrine pancreas (e.g., cystic fibrosis, hemochromatosis); those with drug-related hyperglycemia (including those taking glucocorticoids); and those with diabetes following pancreatic surgery (McCall et al., 2023).

An Endocrine Society clinical practice guideline on the treatment of diabetes in older adults recommends that patients who are aged 65 years or older and treated with insulin perform frequent finger-stick glucose monitoring and/or CGM (to assess glycemia), in addition to HbA_{1c} (LeRoith et al., 2019).

U.S. Food and Drug Administration (FDA)

This section is to be used for informational purposes only. FDA approval alone is not a basis for coverage.

Insulin Delivery

For information on external insulin pumps, refer to the following website (use product codes LZG or QFG): http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. (Accessed March 10, 2026)

For information on automated insulin delivery systems or hybrid closed-loop insulin pumps, refer to the following website (use product code OZP): https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm. (Accessed March 10, 2026)

No implantable insulin pumps have received FDA approval at this time.

Insulin pump models with or without a CGM component (this is not an exhaustive list):

- Beta Bionics iLet
- Insulet Omnipod 5
- Insulet Omnipod DASH®
- MiniMed™ 630G
- MiniMed 770G
- MiniMed 780G
- Sequel twiist™
- SOOIL Dana Diabecare
- Tandem Mobi
- Tandem t:slim X2 with Control-IQ

Continuous Glucose Monitors

For information on CGMs, refer to the following website (use product codes MDS, QCD, or QHJ): https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm. (Accessed March 10, 2026)

CGM models (this is not an exhaustive list):

- Abbott FreeStyle Libre 2
- Abbott FreeStyle Libre 3
- Abbott FreeStyle Libre 3 Plus
- Abbott FreeStyle Libre 14-Day
- Dexcom G6
- Dexcom G7

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- Medtronic Guardian™ Connect
- Senseonics Eversense E3
- Senseonics Eversense 365

The Eversense 365 CGM system (product code SBA) received FDA clearance through the 510(k) process on September 16, 2024. The device is indicated for continually measuring glucose levels for up to 1 year in individuals (18 years or older) with diabetes. The system is indicated for use to replace finger-stick blood glucose measurements for diabetes treatment decisions and can be used alone or in conjunction with digitally connected medical devices for the purpose of managing diabetes. Additional information is available at: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID=K241335. (Accessed March 10, 2026)

CGM systems that are available over the counter, without a prescription (e.g., Dexcom Stelo, Abbott Lingo, Abbott Libre Rio), are out of scope for this policy. These products are obtained through a local pharmacy and are not supported by mail-order durable medical equipment providers. Also, refer to Benefit Considerations.

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Policy History/Revision Information

Date	Summary of Changes

08/01/2026	**Coverage Rationale**
	Insulin Delivery
	• Added language to clarify:
	  ○ External continuous subcutaneous insulin infusion pumps *(including Omnipod)* are proven and medically necessary in certain circumstances when used according to U.S. Food and Drug Administration (FDA)–labeled indications, contraindications, warnings, and precautions
	  ○ External continuous subcutaneous insulin infusion pumps are medically necessary for managing individuals with diabetes due to causes, *other than type 1, type 2, or gestational diabetes,* that require intensive insulin therapy (insulin-treated at least three times a day)
	Supporting Information
	• Updated *Description of Services*, *Benefit Considerations*, *Clinical Evidence*, *FDA*, and *References* sections to reflect the most current information
	• Archived previous policy version 2026T0347WW

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This Medical Policy may also be applied to Medicare Advantage plans in certain instances. In the absence of a Medicare National Coverage Determination (NCD), Local Coverage Determination (LCD), or other Medicare coverage guidance, CMS allows a Medicare Advantage Organization (MAO) to create its own coverage determinations, using objective evidence-based rationale relying on authoritative evidence (Medicare IOM Pub. No. 100-16, Ch. 4, §90.5).

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