Oscar Clinical Guideline: Diabetes Equipment and Supplies (CG028, Ver. 9)

Diabetes Equipment and Supplies

Disclaimer

Clinical guidelines are developed and adopted to establish evidence-based clinical criteria for utilization management decisions. Clinical guidelines are applicable according to policy and plan type. The Plan may delegate utilization management decisions of certain services to third parties who may develop and adopt their own clinical criteria.

Coverage of services is subject to the terms, conditions, and limitations of a member's policy, as well as applicable state and federal law. Clinical guidelines are also subject to in-force criteria such as the Centers for Medicare & Medicaid Services (CMS) national coverage determination (NCD) or local coverage determination (LCD) for Medicare Advantage plans. Please refer to the member's policy documents (e.g., Certificate/Evidence of Coverage, Schedule of Benefits, Plan Formulary) or contact the Plan to confirm coverage.

Summary

Diabetes mellitus (commonly referred to as diabetes) is a chronic (long-term) medical condition characterized by high blood glucose (sugar). This may be because the pancreas (an organ in the belly) does not make enough insulin (a hormone), or because the body is not responding to insulin the way it should. Insulin helps glucose get into cells in the body, giving it energy. With diabetes, sugar builds up in the blood because the body stops responding to insulin, or because there is not enough of it. Diabetes is broadly grouped into two types:

- Type 1 diabetes - the pancreas make no insulin, or a very small amount
- Type 2 diabetes - cells in the body do not respond to insulin the way they should; sometimes, the pancreas also does not make enough insulin

Diabetes requires regular monitoring and treatment. Treatment of Type 1 and Type 2 DM includes a combination of lifestyle changes, self-care measures, and often medications to control blood glucose levels and minimize further risk of diabetes-related complications. Plan members who have been diagnosed with Type 1 or 2 DM, and meet certain medical necessity criteria and standards of care developed by the American Diabetes Association (ADA), may be eligible for specific supplies and

equipment subject to plan benefits, such as those used to monitor blood sugar and inject insulin. Members with more advanced disease or those requiring more frequent insulin may qualify for continuous glucose monitoring and specialized insulin delivery systems.

- For information on medical necessity criteria of medical nutrition counseling, please refer to the Plan Clinical Guideline: Medical Nutrition Therapy (CG010).
- For information on clinical criteria of continuous glucose monitoring, implantable continuous glucose monitoring, and insulin infusion pumps, please refer to the Plan Clinical Guideline: Insulin Delivery Systems and Continuous Glucose Monitoring (CG029).
- The Plan also covers home glucose monitors and products for self-monitoring of blood sugar as an alternative to CGMs. Please contact CVS/Caremark, the Plan's Prescription Benefit Manager, to obtain a standard blood glucose meter from the preferred brand.

Definitions

"Blood Glucose" is the main sugar found in the blood and the body's main source of energy. It is also called glucose or blood sugar. The blood level of glucose is noted in milligrams per deciliter (mg/dL). When blood sugar is too high for long periods of time, complications can occur as a result of blood vessel damage.

"Blood Glucose Monitors" are small, portable machines used to check blood glucose levels in the ambulatory setting. A member will prick his/her fingertip and place a small sample of blood into the device for a glucose reading. There are a number of different types of blood glucose monitors, including but not limited to the following:

- **Standard home blood glucose monitors**: these are defined as standard blood glucose monitors, where the patient uses a separate lancing device to prick the skin and places the blood on a test strip, which is then placed onto or into the glucose monitor for a reading of the blood sugar.
- **Blood glucose monitor with integrated lancing device:** similar to the standard monitor except that the lancing device is integrated into the monitor
- **Hypoglycemia alarm based monitors**: these devices are typically non-invasive, meaning they do not require blood, and do not monitor glucose but measure other bodily functions to alert the patient to possible hypoglycemia.
- **Blood glucose monitor with integrated voice synthesizer**: similar to standard monitor except that the blood sugar reading is verbally read out by the monitor for patients with visual impairments.

- **Personal digital assistant-based blood glucose monitors:** These are similar to home blood glucose monitors except the data is stored and transmitted or linked to a personal computer for further monitoring and tracking of blood sugars and lifestyle modifications.

"Gestational Diabetes Mellitus (GDM)" is a type of diabetes mellitus that develops only during pregnancy and may disappear upon delivery. GDM increases the risk that the mother will develop diabetes later. GDM is managed with meal planning, activity, oral agents, or insulin.

"Hemoglobin A1c (HbA1c)" is a test that measures a person's average blood glucose level over the past 2 to 3 months. It is also known as "A1C" or "glycosylated hemoglobin". A1C should be measured at least twice annually for stable glycemic control and at least quarterly for unstable glycemic control. A1C test results may be affected by age, certain conditions, ethnicity, genetic traits, and pregnancy; the ADA recommends that treating providers review for discrepancies between A1c results and blood glucose results.

"Hyperglycemia" is excessive blood glucose. Fasting hyperglycemia is blood glucose above a desirable level after a person has fasted for at least 8 hours. Postprandial hyperglycemia is blood glucose above a desirable level 1 to 2 hours after a person has eaten.

"Hypoglycemia" is a condition that occurs when one's blood glucose is lower than normal, usually less than 70 mg/dL. Signs include hunger, nervousness, shakiness, perspiration, dizziness or lightheadedness, sleepiness, and confusion. If left untreated, hypoglycemia may lead to unconsciousness. Hypoglycemia is treated by consuming a carbohydrate-rich food such as a glucose tablet or juice. It may also be treated with an injection of glucagon if the person is unconscious or unable to swallow.

"Hypoglycemia Unawareness" is a state in which a person does not feel or recognize the symptoms of hypoglycemia. People who have frequent episodes of hypoglycemia may no longer experience the warning signs of it.

"Insulin" is a hormone made by the beta cells of the pancreas. Insulin allows glucose to enter the cells in the body for use in energy production, and when it is inadequate, the sugar remains in the blood leading to diabetes. There are a variety of oral and parenteral medications that can increase insulin production, increase the body's sensitivity to existing insulin and reduce blood sugar. Insulin can also be injected or infused when lifestyle changes and non-insulin medications are inadequate.

"Type 1 Diabetes" is an autoimmune condition that occurs when the beta cells of the pancreas are unable to produce enough insulin and therefore blood glucose cannot enter cells to be used for energy. Type 1 diabetes is often referred to as "insulin-dependent" because these patients require insulin daily to maintain their blood glucose at acceptable levels.

"Type 2 Diabetes" is a condition that occurs when either the pancreas doesn't produce enough insulin or the body cells become resistant to insulin. Type 2 diabetes is much more common than Type 1, and is often treated with combinations of lifestyle changes and non-insulin medications, although insulin can be required later in the disease course. Many individuals with Type 2 Diabetes are "insulin-requiring".

Medical Necessity Criteria for Authorization

General Criteria

The Plan considers **diabetes equipment and supplies** medically necessary when **ALL** of the following criteria are met:

1. The member has a diagnosis of diabetes mellitus; ***AND***
2. Recent clinical documentation[⇅] (within the last 12 months) is provided showing ALL of the following:
    a. A prescription for the requested product with **ALL** of the following:
        i. Product to be dispensed; ***and***
        ii. Quantity to be dispensed (or frequency of testing); ***and***
        iii. Prescriber's signature and date; ***and***
    b. Hemoglobin A1c test results; ***and***
    c. Medical necessity statement (i.e., documentation) from the treating provider confirming the need for the requested product.

    NOTE: [⇅]All of the above documentation must be updated every 12 months to show compliance with treatment options. If any of the required documentation is more than 12 months old, it must be updated as soon as possible before any renewal request for coverage.
3. Additional criteria, as outlined below, must also be met depending on the specific equipment and supplies requested:

Blood Glucose Monitors

Standard Home Blood Glucose Monitors

The Plan considers **standard home blood glucose monitors** **once annually** when ALL of the following criteria are met:

A. The **"**General Criteria" for diabetes equipment and supplies above are met; ***AND***
B. The member or member's guardian is capable of being trained to use the particular device in an appropriate manner; ***AND***
C. The blood glucose monitor is designed for home use, and not the clinical office setting.
   NOTE: Disposable blood glucose monitors are an acceptable alternative to a standard home blood glucose monitor when all criteria are met.

Specialized Home Blood Glucose Monitors

The Plan considers **specialized home blood glucose monitors** medically necessary for the visually impaired once annually when **ALL** of the following general criteria are met:

1. The criteria (A-C) for ***Standard Home Blood Glucose Monitors*** above are met; ***AND***
2. The member's physician certifies that the member's visual impairment is of a severity that requires specific supplies, which include, but are not limited to:
   a. Voice synthesizers***; or***
   b. Automatic timers***; or***
   c. Specially designed supplies to promote self-management***; or***
   d. Integrated lancet/monitoring devices.

Alternate Site Blood Glucose Monitors

The Plan considers **alternate site blood glucose monitors** medically necessary **once annually** when **ALL** of the following general criteria are met:

1. The criteria (A-C) for ***Standard Home Blood Glucose Monitors*** above are met; ***AND***
2. The member meets **ONE** or more of the following:
   a. Is a child age 12 or younger; ***or***
   b. Have been using a conventional finger-stick blood glucose monitor for at least 30 days and have been non-compliant with testing because of pain or heavily calloused fingertips.

Replacement Blood Glucose Monitors

The Plan considers replacement of a blood glucose monitor medically necessary when **BOTH** of the following criteria are met:

1. Approval for replacement glucometer models will not exceed more than once per calendar year; ***AND***
2. Documentation is provided showing **ONE** of the following:
    a. The current glucometer is unsafe, inaccurate, or no longer applicable to the member's level of monitoring required***; or***
    b. The current glucometer is not functioning properly or has been irreparably damaged, lost, or stolen, requiring replacement.

    NOTE: Replacement is limited to one glucometer per calendar year. Exceptions may be considered with documentation for special populations (e.g., children who may accidentally damage monitors) where monitoring needs cannot be met with the approved replacement limit.

Needle-Free Insulin Injection Systems (e.g., Jet Injectors)

The Plan considers **needle-free insulin injection systems** medically necessary when **ALL** of the following criteria are met:

1. The member meets the **"**General Criteria" above; ***AND***
2. The member meets at least **ONE** of the following:
    a. Member has needle-phobia; ***or***
    b. Member and/or caregiver is unable to use standard syringes.

Diabetic Supply Quantities

When the General Criteria are met, the Plan considers the following quantities medically necessary:

Diabetes Supply	Suggested Quantity Limits * Per 3 Months	Suggested Quantity Limits * Per 1 Year
Blood test strips (glucose, ketone) (A4252, A4253)	100 strips (not on insulin) 400 strips (on insulin)	400 strips (not on insulin) 1600 strips (on insulin)
Automatic and manual lancets (A4259)	100 lancets (not on insulin) 400 lancets (on insulin)	400 lancets (not on insulin) 1600 lancets (on insulin)
Needle-free injectors (Jet-injectors) (A4210)	- Not applicable	2 injectors
Urine test tablets or strips (A4250)	300 tablets/strips (6 boxes)	1200 (24 boxes)

*The *Suggested Quantity Limits* are intended to provide guidance and are subject to review of the medical record and prescription. Requests that exceed the suggested quantity must be submitted with clinical documentation of medical necessity. Exceptions to the *Suggested Quantity Limits* may be authorized on a case-by-case basis for high-utilization members when ALL of the following criteria are met:

1. All "**General Criteria**" above for diabetic supplies and/or equipment are met; ***AND***
2. The member's physician has evaluated the member within the past six (6) months and has documented the medical necessity for quantities exceeding the utilization guidelines; ***AND***
3. There must be documentation of how often the member is testing their blood sugar or administering insulin that corresponds with the request; ***AND***
4. The member meets *at least* ***ONE*** of the following:
    a. Member is 12 years of age or younger; ***or***
    b. Member has newly diagnosed diabetes or gestational diabetes; ***or***
    c. Member is on an insulin pump; ***or***
    d. Member is on an insulin regimen such that blood glucose testing greater than (>) three (3) times per day is indicated.

Experimental or Investigational / Not Medically Necessary

The following products, supplies, or indications are considered experimental, investigational, or convenience features and are therefore **NOT** considered medically necessary:

1. Devices to measure glycated serum proteins (fructosamine assay) (e.g., Duet™ Glucose Control System by LXN Corporation) [82985]
    a. *Rationale:* The literature has not demonstrated the clinical benefit of GSP measuring devices. Goldstein et al (2004) concluded, "GSP is not equivalent to A1C and has not been shown to be related to the risk of development or progression of chronic complications of diabetes." The American Diabetes Association (ADA) consensus guidelines reflect this view. Lindsey et al (2004) and Petitti et al (2001) are two randomized trials demonstrating lack of efficacy for GSP. The Lindsey study compared weekly fructosamine + daily glucose tests vs. daily glucose tests alone. They found that quality of life and the meeting of A1C goals were similar in both groups. At the 1 year time point, blood glucose alone was superior to the combined testing. These findings are reflected in the Petitti study as well.[14, 15, 19]
2. GlucoWatch Biographer Monitor (Cygnus Inc.) or any other hypoglycemic wristband alarm
    a. *Rationale:* The clinical utility of these devices has not yet been demonstrated in any randomized clinical trials. The MITRE (Minimally Invasive Technology Role and

Evaluation) study was a large clinical trial on 400 patients with diabetes on insulin. The study concluded that there was a small, short-term clinical benefit that subsided over time. Furthermore, the Biographer monitor had less impact on HbA1C than both standard treatment and continuous blood glucose monitoring.[7, 28, 32, 34, 38]

3. Home Glycated Hemoglobin Monitors (e.g. A1cNow Diabetes Monitor) [83037]
    a. *Rationale:* Evidence does not demonstrate improved compliance or benefits with home A1c testing over lab A1c testing during scheduled office visits. A California Technology Assessment Forum (CTAF - 2003) analysis revealed that "Day to day clinical decisions about diabetes therapy are based on daily glucose testing, not HbA1c. HbA1c levels are usually used to make long-term changes in care in consultation between the patient and their doctor. It is unlikely that home HbA1c testing will improve clinical outcomes for patients with diabetes."[33]
4. Infrared Thermometer Devices
    a. *Rationale:* There have been several studies demonstrating the predictive ability of infrared thermometer devices for foot ulcers, and that they may serve as an "early warning sign". Armstrong et al (2007) randomized 225 patients to standard foot examinations and therapy vs. dermal thermometry and found that the thermometer group was ⅓ as likely to develop ulcerations. Despite these findings, it is difficult to conclude how much of the risk reduction is due to more frequent examination and increased patient awareness vs. the use of the device. Because of these limitations, the current evidence is insufficient in showing its effectiveness in reducing the risk of diabetic foot ulceration.[30-31]
5. Personal Digital Assistant-based Blood Glucose Monitors (e.g., TheraSense FreeStyle Tracker, Accu-Check Advantage Module) [E0607, E2100, E2101]
    a. *Rationale:* The ENHANCE trial (Sevick et al 2008) was a randomized controlled study of PDA-based self monitoring vs. standard care in 151 patients. Only 85% of the patients completed the study, and while the PDA was perceived as useful and acceptable, there were no demonstrated clinical benefits.[27]
6. Subcutaneous insulin infusers, including but not limited to, i-Port
    a. *Rationale:* There is a lack of clinical evidence supporting the use of insulin infusers and diabetes outcomes. Blevins et al (2008) conducted a randomized controlled crossover trial comparing outcomes of i-Port vs. standard insulin injection in 74 patients. A1c levels were similar among all subjects at the initiation and completion of the study, demonstrating no observable clinical benefit. Patients did report that it was more difficult to control their blood sugar levels with standard insulin injections; however, the differences were non-significant ($p=0.16$).[25]

7. Other excluded devices or products:
    a. Combination devices (e.g., blood glucose monitor combined with lipid measuring device or cell phone)
    b. Remote glucose monitoring devices (e.g., mySentry, MiniMed Connect, Dexcom SHARE)
    c. Lasette™ Laser Blood Glucose Monitoring Device or other similar laser lancets [E0620]
    d. Skin autofluorescence to measure glycation end-products
8. Blood glucose monitoring devices or supplies for indications other than diagnosed diabetes mellitus

Applicable Billing Codes (CPT/HCPCS/ICD-10 Codes)

CPT/HCPCS Codes considered medically necessary if criteria are met:	
Code	**Description**
A4206	Syringe with needle, sterile 1 cc or less, each
A4207	Syringe with needle, sterile 2 cc, each
A4208	Syringe with needle, sterile 3 cc, each
A4209	Syringe with needle, sterile 5 cc or greater, each
A4210	Needle-free injection device, each
A4211	Supplies for self-administered injections
A4212	Non-coring needle or stylet with or without catheter
A4213	Syringe, sterile, 20 cc or greater, each
A4215	Needle, sterile, any size, each
A4233	Replacement battery, alkaline (other than J cell), for use with medically necessary home blood glucose monitor owned by patient, each
A4234	Replacement battery, alkaline, J cell, for use with medically necessary home blood glucose monitor owned by patient, each

A4235	Replacement battery, lithium, for use with medically necessary home blood glucose monitor owned by patient, each
A4236	Replacement battery, silver oxide, for use with medically necessary home blood glucose monitor owned by patient, each
A4244	Alcohol or peroxide, per pint
A4245	Alcohol wipes, per box
A4246	Betadine or pHisoHex solution, per pint
A4247	Betadine or iodine swabs/wipes , per box
A4250	Urine test or reagent strips or tablets (100 tablets or strips)
A4252	Blood ketone test or reagent strip, each
A4253	Blood glucose test or reagent strips for home blood glucose ,monitor, per 50 strips
A4255	Platforms for home blood glucose monitor, 50 per box
A4256	Normal, low, and high calibrator solution/chips
A4258	Spring-powered device for lancet, each
A4259	Lancets, per box of 100
A9275	Home glucose disposable monitor, includes test strips
E0607	Home blood glucose monitor
E2100	Blood glucose monitor with integrated voice synthesizer
E2101	Blood glucose monitor with integrated lancing/blood sample
S5565	Insulin cartridge for use in insulin delivery device other than pump; 150 units
S5566	Insulin cartridge for use in insulin delivery device other than pump; 300 units
S5570	Insulin delivery device, disposable pen (including insulin); 1.5 ml size

S5571	Insulin delivery device, disposable pen (including insulin); 3 ml size
S8490	Insulin syringes (1084900 syringes, any size)
ICD-10 codes considered medically necessary if criteria are met:	
E08.00 - E13.9	Diabetes mellitus
O24.011 - O24.93	Diabetes mellitus in pregnancy, childbirth, and the puerperium
O99.810 - O99.815	Abnormal glucose complicating pregnancy, childbirth, and the puerperium

CPT/HCPCS codes *not* considered medically necessary:	
Code	*Description*
A4257	Replacement lens shield cartridge for use with laser skin piercing device, each
A9280	Alert or alarm device, not otherwise classified [hypoglycemic wristband alarm (e.g., Sleep Sentry)]
E0620	Skin piercing device for collection of capillary blood, laser, each
E0607, E2100, E2101	Blood Glucose Monitors [Personal Digital Assistant-based Blood Glucose Monitors]

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