

## Diabetes Equipment and Supplies

### Disclaimer

*Clinical guidelines are developed and adopted to establish evidence-based clinical criteria for utilization management decisions. Oscar may delegate utilization management decisions of certain services to third-party delegates, who may develop and adopt their own clinical criteria.*

*The clinical guidelines are applicable to all commercial plans. Services are subject to the terms, conditions, limitations of a member's plan contracts, state laws, and federal laws. Please reference the member's plan contracts (e.g., Certificate/Evidence of Coverage, Summary/Schedule of Benefits) or contact Oscar at 855-672-2755 to confirm coverage and benefit conditions.*

### Summary

Diabetes mellitus (DM) is a chronic medical condition characterized by hyperglycemia, resulting from the body's inability to process glucose (sugar). In Type 1 diabetes, the pancreas is unable to secrete insulin and therefore blood glucose cannot enter cells to be used for energy. In Type 2 diabetes, either the pancreas doesn't secrete enough insulin or the body is resistant to the 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 sometimes medications, to control blood glucose levels and minimize further risk of diabetes-related complications. Oscar members who have been diagnosed with Type 1 or 2 DM, and meet certain medical necessity criteria, may be eligible for coverage of specific supplies and equipment, such as those used to monitor blood sugar and inject insulin. Coverage of supplies and equipment requires a prescription or recommendation from a physician or other licensed health care professional.

For information on coverage and criteria of medical nutrition therapy in diabetic patients, please refer to Oscar Clinical Guideline: Medical Nutrition Therapy (CG010).

For information on coverage and criteria of continuous glucose monitoring and insulin infusion pumps, please refer to Oscar Clinical Guideline: Insulin Delivery Systems and Continuous Glucose Monitoring (CG029).

Please contact CVS/Caremark, Oscar's Prescription Benefit Manager, to obtain a blood glucose meter from the preferred brand.

## Definitions

**"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 medications that can increase insulin production, increase the body's sensitivity to existing insulin, or reduce blood sugar. Insulin can also be injected or infused when lifestyle and oral 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 often 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 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 oral medications, although insulin can be required later in the disease course.

**"Blood Glucose"** is the main sugar found in the blood and the body's main source of energy. Also called 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 then places the blood on a test strip, which is 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 usually disappears upon delivery, but increases the risk that the mother will develop diabetes later. GDM is managed with meal planning, activity, and, in some cases, 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”.

**“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.

## Clinical Indications and Coverage

### General Coverage Criteria

Oscar covers diabetes equipment and supplies when **ALL** of the following criteria are met:

1. Diagnosis of diabetes; **and**
2. Records are provided or shown to **<1 year old** from the time of the request for equipment or supplies, or the start of services. These **must be updated every 12 months**, in order to show compliance with treatment options. If any of the following are more than one year old, it must be updated as soon as possible, prior to any request for continuation of care:
  - a. A prescription for medication, insulin, supplies, etc. with **ALL** of the following:

- i. Item to be dispensed; **and**
- ii. Number to be dispensed (or frequency of testing); **and**
- iii. Physician's signature and date; **and**
- b. Hemoglobin A1c test results; **and**
- c. Certificate of medical necessity; **and**
- d. Primary Care Physician, Endocrinologist, or treating physician's signed and dated notes.

### **Blood Glucose Monitors**

#### *Standard Home Blood Glucose Monitors*

Oscar covers standard home blood glucose monitors **once annually** when **ALL** of the following criteria are met:

- A. The "general coverage criteria" for 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 covered blood glucose monitors must be designed for home, rather than clinical use.
  - a. **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*

Oscar covers specialized home blood glucose monitors for the visually impaired once annually when **ALL** of the following general criteria are met:

- 1. The criteria (A-C) for 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
  - b. Automatic timers
  - c. Specially designed supplies to promote self-management
  - d. Integrated lancet/monitoring devices.

#### *Alternate Site Blood Glucose Monitors*

Oscar covers alternate site blood glucose monitors **once annually** when **ALL** of the following general criteria are met:

- 1. The criteria (A-C) for home blood glucose monitors above are met; **and**
- 2. The member meets **ONE** or more of the following:
  - a. Children aged 12 or younger; **or**

- b. Members who have used a conventional finger-stick blood glucose for at least 30 days and have been non-compliant with testing because of pain or heavily calloused fingertips.

*Replacement Blood Glucose Monitors*

Oscar covers >1 glucometer per year when **ONE** of the following criteria are met:

- 1. Current glucometer is unsafe, inaccurate, or no longer applicable to the members level of monitoring required; **or**
- 2. Current glucometer is not functioning or has been damaged, lost, or stolen. Approved replacement is only offered one time.

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

Oscar covers needle-free insulin injection systems when **ALL** of the following criteria are met:

- 1. The member meets the "general coverage criteria" above; **and**
- 2. The member meets *at least one* of the following:
  - a. Member has needle-phobia; **or**
  - b. Member and/or caregiver are unable to use standard syringes.

**Diabetic Supply Quantities**

When the general coverage criteria is met, Oscar considers the following quantities medically necessary:

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

Exceptions to diabetic supply allocations are subject to review and 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 for diabetic supplies and/or equipment are met; **and**
2. The member's physician has evaluated the patient within the past 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. Members 12 years of age or younger; **or**
  - b. Members with newly diagnosed diabetes or gestational diabetes; **or**
  - c. Members on an insulin pump; **or**
  - d. Members on insulin regimens such that blood glucose testing >3 times per day is indicated.

### Coverage Exclusions

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

1. Devices to measure glycated serum proteins (fructosamine assay) (e.g., Duet™ Glucose Control System by LXN Corporation) [82985]
  - a. *Rationale for non-coverage:* The literature has not demonstrated 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.<sup>30-32</sup>
2. GlucoWatch Biographer Monitor (Cygnum Inc.) or any other hypoglycemic wristband alarm
  - a. *Rationale for non-coverage:* 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.<sup>20, 23-</sup>

3. Home Glycated Hemoglobin Monitors (e.g. A1cNow Diabetes Monitor) [83037]
  - a. *Rationale for non-coverage:* 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."<sup>21</sup>
4. Infrared Thermometer Devices
  - a. *Rationale for non-coverage:* 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 developed 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.<sup>18-19</sup>
5. Personal Digital Assistant-based Blood Glucose Monitors (e.g., TheraSense FreeStyle Tracker, Accu-Check Advantage Module) [E0607, E2100, E2101]
  - a. *Rationale for non-coverage:* 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.<sup>17</sup>
6. Subcutaneous insulin infusers, including but not limited to, I-port (Patton Medical)
  - a. *Rationale for non-coverage:* There is a lack of clinical evidence supporting the use to 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 ( $p=0.16$ ).<sup>34</sup>
7. Other excluded devices or products:
  - a. Combination devices (e.g. blood glucose monitor combined with lipid measuring device or cell phone)
  - b. Implantable glucose sensors (e.g. Eversense or GlySens)

- c. Remote glucose monitoring devices (e.g. mySentry, MiniMed Connect, Dexcom SHARE)
  - d. Lasette™ Laser Blood Glucose Monitoring Device or other similar laser lancets [E0620]
  - e. Skin autofluorescence to measure glycation end-products
  - f. Sharps container for needle disposal
8. Blood glucose monitoring devices or supplies for indications other than diagnosed diabetes mellitus

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

<b>CPT/HCPCS Codes covered if criteria are met:</b>	
<b>Code</b>	<b>Description</b>
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
A9274	External ambulatory insulin delivery system, disposable, each, includes all supplies and accessories
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)
<b>ICD-10 codes covered if criteria are met:</b>	
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

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

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**Clinical Guideline Revision / History Information**

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