

## Insulin Delivery Systems and Continuous Glucose Monitoring

### 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. Members with more advanced disease or those requiring more frequent insulin may qualify for continuous glucose monitoring and specialized insulin delivery systems. Coverage of diabetic supplies and equipment requires a prescription or recommendation from a physician and/or other licensed health care professional.

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

For information on coverage and criteria of diabetes equipment and supplies, please refer to Oscar Clinical Guideline: Diabetes Equipment and Supplies (CG028).

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 for specialized situations, such as those for members with visual impairments.

**"Continuous Glucose Monitoring (CGM)"** serve as an alternative to self-monitoring of blood glucose (SMBG) with a home glucose monitor for patients who have Type 1 diabetes and require multiple daily measurements.

**"Basal Rate"** is a steady trickle of low levels of longer-acting insulin, such as that used in insulin pumps. This type of insulin therapy controls blood sugar between meals and during sleep.

**“Bolus”** is an extra amount of insulin taken to cover an expected rise in blood glucose, often related to a meal or snack.

**“Cartridge”** (or a reservoir) holds the insulin and is locked into an external continuous subcutaneous insulin infusion pump device.

**“External Continuous Subcutaneous Insulin Infusion (CSII) Pump”** or **“Insulin Infusion Pump”** is an insulin-delivering device that can be worn on a belt or kept in a pocket. An insulin pump connects to narrow, flexible plastic tubing that ends with a needle inserted just under the skin. Users set the pump to give a basal amount of insulin continuously throughout the day. Pumps release bolus doses of insulin (several units at a time) at meals and at times when blood glucose is too high, based on programming done by the user. Insulin infusion pumps serve as an alternative to multiple daily injections of insulin. The infusion cannula should be changed every 2-3 days to avoid lipohypertrophy at the infusion site.

**“Implantable Insulin Pump”** is a device similar in function to an external insulin pump, however the components are implanted rather than worn or carried externally.

**“Artificial Pancreas”** devices contain an integrated continuous blood glucose monitor and insulin delivery system. Special built-in software measures the blood glucose and automatically releases a specified amount of insulin in real-time and without patient interaction. The system may also have a glucagon administration component for episodes of hypoglycemia.

**“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.

**“Infusion Set”** connects the insulin in an external continuous subcutaneous insulin infusion pump delivery device to a person’s body. The set consists of narrow, flexible plastic tubing that ends with a needle inserted just under the skin.

**“Insulinopenia”** is defined as inadequate insulin production. This is determined by obtaining a fasting C-peptide level, which must be less than or equal to 110% of the lower limit of normal. In patients with renal insufficiency and correct creatinine clearance  $\leq 50$  ml/minute, insulinopenia is defined as a fasting C-peptide level that is less than or equal to 200% of the lower limit of normal. Fasting C-peptide levels are only considered valid when concurrently obtained fasting glucose  $\leq 225$  mg/dL. Levels only need to be documented once in the medical records.

## Clinical Indications and Coverage

### General Coverage Criteria

When insulin infusion pumps or continuous glucose monitoring are found to be medically necessary, **ALL** of the following general coverage criteria must also be met:

1. Diagnosis of diabetes; **and**
2. Records are provided or shown to be **<6 months old** from the time of the request for equipment or supplies, or the start of services. These **must be updated every 6 months**, in order to show compliance with treatment options. If any of the following are more than 6 months 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.
  - b. Hemoglobin A1c test results; **and**
  - c. Primary Care Physician, Endocrinologist, or treating physician’s signed and dated notes documenting medical necessity.

## External Insulin Infusion Pump

Oscar covers continuous subcutaneous insulin infusion pumps and supplies when **ALL** of the following are met:

1. Diagnosis of Type 1 DM or Type 2 DM with insulinopenia; **and**
2. Multiple daily injections of insulin (3 or more) with frequent self-adjustments for at least 6 months; **and**
3. Documented completion of a comprehensive diabetic education program; **and**
4. Glucose self-testing of at least 4 times per day for the immediate 2 months prior to the request for an insulin pump, as documented in the medical record; **and**
5. The member meets at least **ONE** of the following:
  - a. Dawn phenomenon unresponsive to management with long-acting insulin agents (e.g., insulin glargine or detemir); **or**
  - b. Children, where multiple daily insulin injections would be impractical or inappropriate; **or**
  - c. Complications of inadequate glycemic control (e.g., neuropathy, nephropathy, retinopathy) indicative of more intensive insulin regimens; **or**
  - d. Recurrent hypoglycemia (<60 mg/dL on at least two occasions despite adherence to recommended diabetic treatment plan); **or**
  - e. HbA1c greater than 7%, despite an adequate regimen of multiple daily injections; **or**
  - f. Hypoglycemic episodes requiring 3rd party assistance (e.g., seizure, loss of consciousness, glucagon administration, transport to an emergency room, hospitalization); **or**
  - g. Pregnancy or planned pregnancy; **or**
    - i. **Note:** Earlier initiation of insulin infusion pumps may be indicated in women at high risk of fetal or maternal complications of diabetes and pregnancy.
  - h. Wide swings in blood glucose values before meal time (e.g., regular fluctuations of preprandial blood glucose to levels <60 mg/dL and/or >140 mg/dL).
6. Member or designated caregiver can be adequately trained and is motivated to adhere to blood glucose monitoring at least 3 times per day, or the patient qualifies for continuous glucose monitoring; **and**
7. Provider team is experienced in the management and support of patients with insulin infusion pumps; **and**
8. For patients diagnosed with Type 2 diabetes with insulinopenia,  $\geq 4$  insulin injections and  $\geq 4$  blood glucose measurements are required daily.

When the general coverage criteria and insulin infusion pump criteria is met, Oscar considers the following quantities medically necessary:

<b>Insulin Infusion Supply</b>	<b>Quantity Limits * Per 3 Months</b>	<b>Quantity Limits * Per 1 Year</b>
Infusion set (A4230, A4231)	45	180
Needles or syringes (A4206, A4215, A4232)	60	240
External ambulatory infusion pump, insulin (E0784)	-	1
Cartridges or syringe reservoirs (S5565-S5566, J1817)	30	120
Sterile insertion-site dressing (i.e., Tegaderm) (A6257)	45 / 3 boxes	180

\*Quantity limits are suggested guidance and are subject to review of the prescribed quantity. Requests that exceed the suggested quantity limits must be submitted with clinical documentation of medical necessity.

#### *Replacement Insulin Pumps*

Replacement insulin pumps are **NOT** covered for the purpose of adding convenience features or new technologies (e.g., adding a wireless communication system to the glucose monitor). Replacement insulin pumps are covered when the member continues to meet all criteria for coverage and at least **ONE** of the following:

- A. Children requiring a replacement pump with a larger insulin reservoir as they grow; **or**
- B. Replacement of an out of warranty or malfunctioning pump that cannot be refurbished.

#### **Continuous Glucose Monitoring (CGM)**

Oscar covers CGM when **ALL** of the following criteria are met:

- A. The "general coverage criteria" for equipment and supplies above are met; **and**
- B. Diagnosis of Type 1 diabetes mellitus; **and**
- C. The member meets at least **ONE** of the following:
  - a. Long-term CGM is necessary, as indicated by **ALL** of the following:
    - i. At least 3 insulin injections per day, or use of insulin pump; **and**
    - ii. Member consistently checks blood sugar at least 3 times per day; **and**
    - iii. The member meets either **ONE** of the following:
      - 1. At least 25 years of age or older; **or**

- 2. At least 8 years of age with 2 episodes of hypoglycemia (glucose <50) in the last 30 days with unawareness.
- iv. Hemoglobin A1c is greater than 7.0% for patients requesting initial CGM, despite appropriate changes in insulin therapy and compliance with the treatment plan; **and**
- v. Member has documented adherence to diabetic treatment plan and can be trained to use a CGM.
- b. Short-term CGM is necessary, as indicated by **ALL** of the following:
  - i. Additional information on blood glucose levels is needed, as indicated by at least **ONE** of the following:
    - 1. Dawn phenomenon, known or suspected; **or**
    - 2. Hypoglycemic unawareness; **or**
    - 3. Nocturnal hyperglycemia, known or suspected; **or**
    - 4. Postprandial hyperglycemia, known or suspected; **or**
    - 5. Significant change to the treatment regimen, such as starting insulin or transitioning from multiple daily doses to an insulin pump; **or**
    - 6. Unexplained hyperglycemia.
  - ii. Monitoring is limited to a maximum of 3-7 days and for no more than 2 episodes within a 12-month period; **and**
  - iii. The member is at least 8 years of age or older.

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

<b>CGM Supply</b>	<b>Quantity Limits * Per 3 Months</b>	<b>Quantity Limits * Per 1 Year</b>
Sensors (A9276)	90	365
Transmitter (A9277)	Dependent on Brand	Dependent on Brand
Receiver/Monitor (A9278)	-	1

\*Quantity limits are suggested guidance and are subject to review of the prescribed quantity. Requests that exceed the suggested quantity limits must be submitted with clinical documentation of medical necessity.

## Coverage Exclusions

Oscar does not cover the replacement or repair of units or associated equipment when lost or damaged due to neglect or improper care.

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

1. Artificial pancreas device systems (S1034)
  - a. *Rationale for non-coverage:* The existing evidence is insufficient to guide clinical recommendations for artificial pancreas systems. Luijf et al (2013) conducted a multicenter, 3-way, randomized cross-over study on 47 adults with type 1 DM for artificial pancreas vs. self-management and found no significant differences in glycemic control. Other randomized, controlled trials have demonstrated increased percentage of time spent in the target glucose range and fewer episodes/durations of hypoglycemia. Despite the promising results, long-term safety data and long-term outcomes have yet to be established. The data for pediatric patients and adults with type 2 DM have been much more limited and are insufficient to guide clinical use without long-term, large sample, randomized trials.<sup>37, 39, 47, 51-53, 68, 70, 82</sup>
2. Continuous Glucose Monitoring for members:
  - a. With Type 2 diabetes
    - i. *Rationale for non-coverage:* Vigersky et al (2012) conducted a randomized controlled trial on 100 patients with type 2 DM demonstrating improved glycemic control at the 3 month follow-up point, however long-term outcomes and the impact on over disease progression were not available. Furthermore, a systematic review article including 12 studies on CGM in type 2 DM found that only 5 of the 12 studies found a decrease in the HbA1c levels. Overall, the current evidence is insufficient to guide clinical recommendations for CGM in this patient population.<sup>52, 87</sup>
  - b. Pregnant women or women with gestational diabetes
    - i. *Rationale for non-coverage:* Petrovski et al (2011) conducted a pilot study that randomized a small number of women (n=25) with type 1 DM treated with an insulin pump to either CGM or limited CGM (14 days per month). They found improved glycemic control in both groups but no differences in maternal or fetal outcomes were detected. Overall the evidence for this population is insufficient to guide clinical use of CGM. Similarly, the evidence for CGM in gestational diabetes (GDM) is limited and requires further large, long-term studies to



determine any potential benefit of reduced macrosomia and perinatal complications of GDM.<sup>69, 72</sup>

- c. Under the age of 8
  - i. *Rationale for non-coverage:* The Endocrine Society published a clinical practice guideline on continuous glucose monitoring, stating that the quality of evidence is insufficient for the use of CGM in children under the age of 8. A randomized clinical trial on CGM in 146 children with a mean age 7.5 years found no improvement in glycemic control.<sup>47, 58</sup>
3. GlucoWatch Biographer Monitor (Cygnus Inc.) or any other hypoglycemic wristband alarm (A9280)
  - 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>15-16, 26, 67, 84</sup>
4. Implantable Insulin Pumps
  - a. *Rationale for non-coverage:* There have been studies demonstrating potential clinical benefit of Implantable insulin pumps, however they do not currently have U.S. Food and Drug Administration (FDA) approval at this time, and the ADA 2016 guidelines do not mention implantable insulin pumps as a recommended treatment for diabetes.
5. Implantable Glucose Sensors (0446T)
  - a. *Rationale for non-coverage:* Implantable Glucose Sensors for CGM do not currently have U.S. Food and Drug Administration (FDA) approval at this time, and the ADA 2016 guidelines do not mention Implantable Glucose Sensors as a recommended treatment for diabetes.
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>10</sup>

7. Non-Programmable Transdermal Insulin Delivery Systems (e.g., V-Go disposable insulin delivery device) (A9274)
  - a. *Rationale for non-coverage:* Rosenfeld et al (2012) performed a retrospective study on V-Go in 23 patients, and found significant improvements in HbA1c and fasting plasma glucose, while there were no differences in weight or frequency of hypoglycemic events. The remaining literature on V-Go is similar, in the form of small retrospective series or abstracts. Further large-scale, randomized controlled trials with long-term outcomes are required to determine potential clinical benefit.<sup>14, 76, 79</sup>
8. Remote Glucose Monitoring (e.g., mySentry, MiniMed Connect, Dexcom Share)
9. Single closed-loop systems that combine an external insulin pump with a CGMS

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

<b>CPT/HCPCS Codes covered if criteria are met:</b>	
<i>Code</i>	<i>Description</i>
A4224	Supplies for maintenance of insulin infusion catheter, per week
A4225	Supplies for external insulin infusion pump, syringe type cartridge, sterile, each
A6257	Transparent film, sterile, 16 sq in or less, each dressing
A9274	External ambulatory insulin delivery system, disposable, each, includes all supplies and accessories
A9275	Home glucose disposable monitor, includes test strips
A9276	Sensor; invasive (e.g., subcutaneous), disposable, for use with interstitial continuous glucose monitoring system, 1 unit = 1 day supply
A9277	Transmitter; external, for use with interstitial continuous glucose monitoring system
A9278	Receiver (monitor); external, for use with interstitial continuous glucose monitoring system
E0784	External ambulatory infusion pump, insulin
K0601 - K0605 patient, lithium, 4.5 volt, each	Replacement battery for Replacement battery for external infusion pump owned by patient, lithium, 4.5 volt, each

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)
<b>ICD-10 codes covered if criteria are met:</b>	
E08.00 - E13.9	Diabetes mellitus
<b>ICD-10 codes not covered for continuous glucose monitoring (CGM) S1030, S1031</b>	
E11.00 - E11.9	Type 2 Diabetes Mellitus

<b>CPT/HCPCS codes not covered:</b>	
<i>Code</i>	<i>Description</i>
0446T	Creation of subcutaneous pocket with insertion of implantable interstitial glucose sensor, including system activation and patient training
0447T	Removal of implantable interstitial glucose sensor from subcutaneous pocket via incision
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
A4210	Needle-free injection device, each
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)]
A9274	External ambulatory insulin delivery system, disposable, each, includes all supplies and accessories <b>[Non-Programmable Transdermal Insulin Delivery Systems (e.g., V-Go disposable insulin delivery device)]</b>
E0620	Skin piercing device for collection of capillary blood, laser, each

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

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**Clinical Guideline Revision/History Information**

<b>Original: Review/Revise Dates</b>	<b>Approval Signature/ Title</b>
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Signed:	Sean Martin, MD