Medical Policy

PARAMOUNT

HMO AND PPO
ELITE (MEDICARE ADVANTAGE)
MARKETPLACE

Diabetes Management: Continuous Glucose Monitoring Systems & Insulin Pumps

Policy Number: PG0177
Last Reviewed Date: 04/01/2025
Last Revised: 05/01/2025

GUIDELINES:

- This policy does not certify benefits or authorization of benefits, which is designated by each individual policyholder terms, conditions, exclusions, and limitations contract. It does not constitute a contract or guarantee regarding coverage or reimbursement/payment. Self-Insured group specific policy will supersede this general policy when group supplementary plan document or individual plan decision directs otherwise.
- Paramount applies coding edits to all medical claims through coding logic software to evaluate the accuracy and adherence to accepted national standards.
- This medical policy is solely for guiding medical necessity and explaining correct procedure reporting used to assist in making coverage decisions and administering benefits.
- Durable Medical Equipment (DME) frequency limitations are calculated based on The Center for Medicare and Medicaid Services (CMS) criteria and guidelines, National Coverage Determinations (NCD), and Local Coverage Determinations (LCD) rules and regulations.

SCOPE:

X Professional
_ Facility

DESCRIPTION:

Continuous Glucose Monitoring (CGM) Systems

The American Diabetes Association (ADA) defines the continuous glucose monitoring system as “a method of continuously following glucose levels in the interstitial fluid as a base for improving metabolic control. This includes increasing time in the target glucose range by reducing hyperglycemia and minimizing the occurrence of low glucose values (including symptomatic hypoglycemia).”

CGM systems take glucose measurements at regular intervals, 24 hours a day, and translate the readings into reportable data, generating glucose direction and rate of change. They help with proactively management of glucose highs and lows, and give added insight into impacts that meals, exercise, and illness may have on an individual’s glucose levels. These systems can be used short term and evaluated by the provider to help determine medication needs or long term by the member and provider to improve blood sugar control. The information obtained may identify unrecognized trends and patterns of blood glucose fluctuation that can be improved with modifications of eating habits, medication dosing and exercise routine.

- A therapeutic CGM can be used as a replacement for fingerstick blood glucose testing for diabetes treatment decisions.
- A non-therapeutic CGM cannot be used to make insulin-dosing decisions and is used in conjunction with finger stick testing with a standard, home glucose monitor.

The CGM system components vary, however, CGM devices consist of the same basic components:

- A disposable short-term glucose sensor (a fine wire about the diameter of two hairs) which is placed under the skin with a range from 5-14 days depending on the system, and
- A reusable transmitter that is wirelessly attached to the sensor and conveys data to a receiver within a 5–10-foot range of the sensor, and
- A receiver that displays current glucose values and recent trends. The receiver can be worn on the belt or carried in a pocket or purse.

There is no “one-size-fits-all” approach to technology use in patients with diabetes. When prescribing CGM devices, robust diabetes education, training, and support are required for optimal CGM device implementation and ongoing use.

Insulin Pumps

The purpose of the insulin pump is to provide an accurate, continuous, controlled delivery of insulin, which can be regulated by the user to achieve intensive glucose control objectives and to prevent the metabolic complications of hypoglycemia, hyperglycemia and diabetic ketoacidosis.

External Insulin Pumps

An insulin pump provides continuous delivery of short acting insulin. The insulin pump substitutes the need for long-acting insulin and replaces the need for multiple daily injections of short acting insulin. A pump delivers small doses of short acting insulin continuously (basal rate). The device also can be used to deliver variable amounts of insulin when a meal is eaten (bolus). Technology and features vary between products, some insulin pump devices come equipped with the capacity to be combined with CGM devices to create automated insulin delivery systems.
Features can include high/low warnings, automatic suspension of insulin, or adjustment of basal rates (hybrid closed loop systems). Closed loop systems operate with a CGM and automatically adjust insulin and glucagon doses based on the blood glucose readings.

Another type of external insulin pump combines an insulin reservoir placed on the skin with a wireless device to manage dosing and perform self-monitoring of blood glucose, i.e. Omnipod, V-Go. 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.

Implantable Insulin Pumps

These pumps are surgically implanted rather than worn externally to deliver insulin via intraperitoneal or intravenous routes.

Artificial Pancreas or Bi-hormonal Bionic Endocrine Pancreas

Fully automated, closed-loop glucose management systems with a continuous glucose monitor and an insulin pump programmed with a computer algorithm that calculates insulin and glucagon doses from the CGM readings and tells the pump to deliver or temporarily suspend or reduce insulin based upon specified thresholds of measured glucose levels.

POLICY:

Paramount Commercial Insurance Plans and Elite (Medicare Advantage) Plans

- **Coverage is subject to the specific terms of the member’s benefit plan. Please refer the Member’s Benefit Plan documents for details.**
- **Coverage for Continuous Glucose Monitoring Systems may be obtained from an in-network Durable Medical Equipment (DME) provider or Pharmacy.**
- **Coverage for insulin pumps may be obtained from an in-network Durable Medical Equipment (DME) provider.**
- **Coverage for insulin pump supplies may be obtained from an in-network Durable Medical Equipment (DME) provider or Pharmacy.**

Paramount Commercial Insurance Plans

- **Preferred coverage is through the pharmacy benefit for all Diabetes Supplies except insulin pumps and related pump supplies. Refer to member’s pharmacy formulary for covered product.**
- **Prior authorization is required for all continuous glucose monitoring (CGM) systems and insulin pumps, on both pharmacy and medical benefits. (A4238, A4239, A9274, E0784, E2102, E2103).**
- **Effective 01/01/2023 procedures A9276, A9277, and A9278 will be denied as noncovered.**

Elite (Medicare Advantage) Plans

- **Coverage for Continuous Glucose Monitoring Systems and Diabetes Supplies, except insulin pumps and related pump supplies, is through either in-network DME providers or CVS/caremark network pharmacies.**
- **No prior authorization required for Continuous Glucose Monitoring Systems or Insulin Pumps and related supplies**

The Prior Authorization request form can be located at:
https://www.paramounthealthcare.com/services/providers/prior-authorization-criteria/drug-prior-authorization-and-procedure-forms

Paramount Commercial Insurance Plans and Elite (Medicare Advantage) Plans
Non-Covered, not all-inclusive:

- **Implantable interstitial glucose sensors (0446T-0448T)**
  - **Exception: covered when criteria is met for the Medicare Advantage Plans product line**
- **Implantable insulin pumps**
- **Artificial pancreas device systems (S1034-S1037) or bi-hormonal bionic endocrine pancreas**
- **MiniMed Connect and remote monitoring systems**

COVERAGE CRITERIA:
Paramount Commercial Insurance Plans and Elite (Medicare Advantage) Plans

- When a CGM (code E2102 or E2103) is covered, the related supply allowance (code A4238 or A4239) is also covered. (Therapeutic/Non-Adjunctive = E2103, A4239, Non-Therapeutic/Adjunctive = E2102, A4238)
- A therapeutic or non-adjunctive CGM can be used to make treatment decisions without the need for a stand-alone blood glucose monitor (BGM) to confirm testing results.
- A non-therapeutic or adjunctive CGM requires the user verify their glucose levels or trends displayed on a CGM with a BGM prior to making treatment decisions.
- Both therapeutic/non-adjunctive and non-therapeutic/adjunctive CGMs are classified as DME.
- Paramount limits the frequency of short-term continuous glucose monitoring (CPT Codes 95249, 95250, and 95251) to two episodes within a 365-day period. This frequency limitation applies only when the scenario is a medical interpretation of the continuous glucose monitoring (CPT Code 95250) and does not apply to the analysis, interpretation, and report alone (CPT Code 95251). Requests for more frequent monitoring will be forwarded for review of medical necessity

Continuous Glucose Monitoring

Elite (Medicare Advantage) Plans

Paramount has determined that CGMs and associated supplies are covered when the following criteria is met:

1. Member is diagnosed with Type 1 diabetes or Type 2 diabetes, AND
   a. Insulin dependent on a regimen that includes short acting insulin (e.g., Admelog, Afrezza, Apidra, Fiasp, Humalog, Novolog)
      i. On an insulin pump OR on a sliding scale or mealtime short acting insulin regimen requiring testing at least 3 times daily to determine insulin doses; and
   b. Patient's insulin treatment regimen requires frequent adjustment by the patient or caregiver based on BGM or CGM testing results; and
   c. There is an in-person visit with the provider within six months prior to ordering the CGM, to evaluate the needed diabetes control; and
   d. Every six months following the initial prescription of the CGM, there is, and in-person visit* with the provider to evaluate the patient's diabetes assess adherence to the CGM regimen and diabetes treatment plan

i. Provider will be using CGM data downloads to evaluate the patient and make necessary adjustments at follow up visits.

e. The device used must be approved by the FDA for use in the age range appropriate for the patient.

f. Monitoring must be performed for a minimum of 24 hours. If the service is performed less than 24 hours, the service is not considered medically necessary.

2. Member is managed by an endocrinologist or has completed a comprehensive diabetes education program and has ongoing oversight by a certified diabetes educator; and

3. Member has demonstrated an understanding of the technology, is motivated to use the device correctly and consistently, is expected to adhere to a comprehensive diabetes treatment plan supervised by a qualified provider and can use the device to recognize alerts and alarms.

4. Gestational Diabetes: Patients with gestational diabetes or diabetes during pregnancy are exempted from previous management provisions of this policy and are eligible for CGM coverage during the pregnancy.

Clinical notes supporting all the above criteria are required for approval consideration.

Continuation of CGM use after one year or device replacement is considered medically necessary for the following:

- The device is malfunctioning and/or out of warranty. CGM receivers/readers will only be replaced every 4 years unless malfunctioning or upgrade to new version is medically necessary. Expiration of 1-year warranty is not considered an automatic reason for replacement.
- There is objective documented evidence of improvement in control of diabetes (specific to baseline status of disease for individual patients)
- There is documented evidence of compliance with use and reporting, and the data obtained is being used for modifications in lifestyle and/or medication regimens or correcting hypoglycemia.

Replacement of currently functional and warranted continuous interstitial glucose monitoring devices is considered not medically necessary when the replacement of continuous interstitial glucose monitoring devices medically necessary criteria above have not been met.

Paramount Commercial Insurance Plans

CGMs and associated supplies are covered when clinical notes are submitted documenting all the following criteria are met:

1. The patient is diagnosed with Type 1 or Type 2 Diabetes

2. The patient is being managed by or in conjunction with an endocrinologist or other qualified provider with expertise in the management of Diabetes.

3. The patient completed a comprehensive diabetes education program and had ongoing oversight by a certified diabetes educator

4. The patient is using one of the following: A) insulin pump, B) basal-bolus insulin regimen, C) rapid-acting insulin sliding scale,
OR
The patient has a medical need to monitor blood sugars 3 times daily due to a) frequent asymptomatic hypoglycemia, or b) severe unpredictable hypoglycemia of unknown cause or c) is pregnant and has gestational diabetes

5. If criteria in number 4 is not met, the patient has a need for short term CGM due to either a) difficulty understanding the effects of different foods and/or exercise on blood sugars and the monitor will be used for implementing lifestyle changes or b) more detailed information is needed to make medication adjustments
[Note approval duration for when criteria #4 is NOT met and criteria #5 is met is 6 months only and continuation of care criteria will not apply. Any further approval for patients with Type 2

Diabetes requires clinical notes supporting the medical need to continue CGM instead of occasional fingerstick testing and HbA1c monitoring.]

Continuation of care criteria for CGMs:

- The patient has Type 1 diabetes and continues to be under the care of a qualified diabetes professional.
  OR
- The request is for continuation of a CGM in a Type 2 diabetic previously approved by Paramount and both of the following apply:
  - The hemoglobin A1c (HbA1c) has improved or has been maintained at goal
    - AND
  - The member has a continued medical need to monitor blood sugars at least 3 times a day and the data is being used to monitor Diabetes control and make adjustments.

CGM receivers/readers will only be replaced every 4 years unless malfunctioning or upgrade to new version is medically necessary. Expiration of 1-year warranty is not considered an automatic reason for replacement.

Paramount Commercial Insurance Plans and Elite (Medicare Advantage) Plans

Initial approval of Continuous Glucose Monitoring (CGM) systems includes transmitters, sensors, and receivers/monitors. The supply allowance for supplies used with a CGM system encompasses all items necessary for the use of the device and includes but is not limited to, CGM sensors and transmitters. For non-adjunctive CGMs, the supply allowance also includes a home BGM and related supplies (test strips, lancets, lancing device, calibration solution, and batteries), if necessary. Supplies or accessories billed separately will be denied as unbundling.

For adjunctive CGMs, the supply allowance (A4238) encompasses all items necessary for the use of the device and includes but is not limited to, CGM sensors and transmitters. Separate billing of CGM sensors and transmitters will be denied as unbundling. Code A4238 does not include a home BGM (HCPCS codes E0607, E2100, E2101) and related BGM testing supplies (HCPCS codes A4233, A4234, A4235, A4236, A4244, A4245, A4246, A4247, A4250, A4253, A4255, A4256, A4257, A4258, A4259). These items may be billed separately, in addition to code A4238.

Coverage of a CGM system supply allowance (code A4238 or A4239) is available for CGM systems when the member uses a stand-alone receiver or insulin infusion pump classified as DME to display glucose data. In addition, coverage is available for a CGM system supply allowance if a non-DME device (watch, smartphone, tablet, laptop computer, etc.) is used in conjunction with the durable CGM receiver (code E2102 or E2103). The following are examples of this provision:

1. Coverage of a CGM supply allowance is available when a member uses a durable CGM receiver to display their glucose data and also transmits that data to a caregiver through a smart phone or other non-DME receiver.
2. Coverage of a CGM system supply allowance is available when a member uses a durable CGM receiver on some days to review their glucose data but uses a non-DME device on other days.

If a member never uses a DME receiver or insulin infusion pump to display CGM glucose data, the supply allowance is not covered. Smart devices are non-covered because they do not meet the definition of DME (i.e., not primarily medical in nature and are useful in the absence of illness).

A therapeutic CGM is classified as a device that can be used to make insulin-dosing decisions. The devices that are considered therapeutic are those classified by CMS as therapeutic according to CMS Ruling CMS-1682-R. These are currently the Freestyle Libre and the Dexcom G6 but will include new CGMs that CMS classifies as therapeutic unless this policy states otherwise. CGMs such as Free-style Libre 3 and Dexcom 7 that use a smart phone rather than a receiver are not considered DME and do not qualify for billing under these codes. These systems are coded as below:

- E2103 – Nonadjunctive, nonimplanted continuous glucose monitor or receiver (CGM)

- A4239 – Supply allowance for nonadjunctive, nonimplanted continuous glucose monitor (GCM), includes all supplies and accessories, 1 month supply = 1 unit of service

Therapeutic CGM devices replace a standard home blood glucose monitor (HCPCS codes E0607, E2100, E2101) and related supplies (HCPCS codes A4233-A4236, A4244-A4247, A4250, A4253, A4255-A4259). Claims for a BGM and related supplies, billed in addition to an approved CGM device and associated supply allowance, will be denied.

A non-therapeutic CGM cannot be used alone to make insulin-dosing decisions and is used in conjunction with finger stick testing with a standard, home glucose monitor. This currently includes Medtronic brand CGMs. These systems are only covered when used in conjunction with a Medtronic smart pump and are coded as below:

- E2102 – Adjunctive, nonimplanted continuous glucose monitor (CGM) or receiver
- A4238 – Supply allowance for adjunctive, nonimplanted continuous glucose monitor (CGM), includes all supplies and accessories, 1 month supply = 1 unit of service

Sensors and transmitters that do not transmit signals to a receiver (E2103 or E2102) are not considered DME and are not covered. Billing under codes A9278, A9277, and A9276 for dates of service after January 1, 2023, will be denied. Any CGM supplies that do not qualify for coverage under the definitions of E2102, E2103, A4238, and A4239 are not covered by Paramount for all lines of business.

Benefit Coverage:

Paramount Commercial Insurance Plans

Coverage for Continuous Glucose Monitoring Systems and Diabetes Supplies, except insulin pumps and related pump supplies, is through either in-network DME providers or CVS/Caremark network pharmacies. Prior authorization is under for both the in-network DME providers and CVS/Caremark network pharmacies.

Elite (Medicare Advantage) Plans

- Coverage for Continuous Glucose Monitoring Systems and Diabetes Supplies, except insulin pumps and related pump supplies, is through either in-network DME providers or CVS/caremark network pharmacies.
- No prior authorization required for Continuous Glucose Monitoring Systems or Insulin Pumps and related supplies

External Insulin Pumps

Elite (Medicare Advantage) Plans

Coverage Criteria:

Paramount has determined that External Insulin Infusion Pumps and associated supplies are covered when the following criteria is met:

1. Member is diagnosed with Type 1 diabetes or Type 2 diabetes, and
2. Documentation that the member is managed by an endocrinologist or has completed a comprehensive diabetes education program and has ongoing oversight by a certified diabetes educator; and
3. The member has been on a program of multiple daily injections (i.e., at least three (3) injections per day), with frequent self-adjustments of insulin dose for at least six (6) months to initiation of the insulin pump; and
4. The member has documented frequency of glucose self-testing an average of at least four (4) times per day during the two months prior to initiation of the insulin pump or utilizing a continuous glucose monitor; and
5. The member meets at least one of the following criteria while on multiple daily injections (more than three (3) injections per day) of insulin, despite current insulin regimen (ex. Repeated hypoglycemia, wide variations in blood sugars, frequent hyperglycemia, DKA):

a. Glycosylated hemoglobin level (HbAlc) greater than 7.0%; or o History of recurring hypoglycemia; or
b. Wide fluctuations in blood glucose before mealtime; or
c. Dawn phenomenon with fasting blood sugars frequently exceeding 200 mg/dl; or
d. History of severe glycemic excursions; or
e. The member has been on a pump prior to enrollment in the health plan, and has documented frequency of glucose self-testing an average of at least four (4) times per day during the month prior to health plan enrollment

Pump replacements of external insulin pumps is considered medically necessary when the following criteria have been met:

- Current insulin pump is out of warranty; and
- The devices are malfunctioning; and
- The device cannot be refurbished.

Note: The medical necessity of the replacement of an external insulin pump for pediatric individuals (under 18 years of age) who require a larger insulin reservoir will be considered on a case-by-case basis.

Continued coverage of an external insulin pump and supplies, when the insulin pump has been approved initially, includes the following:

- The member must be evaluated by the treating provider at least every six (6) months; and
- Follow-up care must be rendered by a provider who manages multiple individuals on continuous subcutaneous insulin infusion therapy, and who works closely with a diabetes care team including nurses, diabetic educators, and dieticians who are knowledgeable and trained in the use of continuous subcutaneous insulin infusion.

Replacement of currently functional and warranted external insulin pumps is considered not medically necessary when the replacement of external insulin pumps medically necessary criteria above have not been met.

Paramount Commercial Insurance Plans

Paramount has determined that External Insulin Infusion Pumps and associated supplies are covered when the following criteria is met, [clinical notes required for all requests]:

1. The patient has Type 1 Diabetes and is being managed by or in conjunction with an endocrinologist;
   OR
2. The patient has Type 2 Diabetes plus ALL the following
   a. the patient is being managed by or in conjunction with an endocrinologist
   b. The patient completed a comprehensive diabetes education program and had ongoing oversight by a certified diabetes educator
   c. The patient has a history of suboptimal blood sugar control despite current insulin regimen [e.g., repeated hypoglycemia, wide variations in blood sugars, frequent hyperglycemia, diabetic ketoacidosis (DKA).

**** For requests for Medtronic pump and CGM combinations, an explanation for medical necessity over pumps that work in conjunction with therapeutic, non-adjunctive CGMs is also required.

Continuation of Care criteria:

1. The pump use has resulted in positive outcomes regarding blood sugar control.
2. Member has demonstrated adherence and competency with pump settings and glucose monitoring.
3. The current pump is out of warranty [4-year warranty] and is malfunctioning or cannot be updated with a software upload.

Paramount Commercial Insurance Plans and Elite (Medicare Advantage) Plans

Supplies (code A4238) for an adjunctive CGM integrated with an external insulin infusion pump are covered when the member meets both the CGM coverage criteria and the coverage criteria for an external insulin infusion pump.

The requested device must be prescribed according to its FDA approved clearance and guideline information.

Note: Programmable disposable external insulin pumps (e.g., OmniPod) are considered clinically equivalent to standard insulin pumps. Consideration should be given to the limitations of delivering 200 units per pod vs 300 units for traditional smart pumps. Members with high insulin requirements are not good candidates for Omnipod. Omnipod DASH and Omnipod 5 are available on the pharmacy benefit only.

Dispensing

The following components are considered "inclusive" with any external (portable) continuous insulin infusion pump rental or purchase payment made by the department on behalf of a member and cannot be submitted to the department for separate reimbursement:

1. Any supporting wires, power supply, cables, attachment kits, or disposable items associated with the operation of the pump
2. Pump education, training, monitoring, or counseling in support of the member's ordered treatment
3. Maintenance, repair, or cleaning charges in association with the three-month trial rental period
4. Delivery, set-up, or pick-up charges

The provider of the standard portable external insulin infusion pump must assure that the member utilizing the device is properly instructed on how to use the device in support of his or her ordered treatment and is aware of and understands any emergency procedures regarding the use of the pump. The provider must maintain written documentation regarding the member's instruction on the use of the pump in the provider's records.

When purchasing an external insulin infusion pump, the member must be provided with a product warranty that covers any required maintenance or repairs for duration of at least one year and commences on the date the infusion pump was authorized for purchase.

Implantable Continuous Glucose Monitors (I-CGM)

Elite (Medicare Advantage) Plans, only:

Coverage Criteria:

The FDA recently approved expanding the indications of an implantable CGM product to replace fingerstick blood glucose measurements for diabetes treatment decisions. In order to be considered medically reasonable and necessary, the FDA approved indication must include use as a therapeutic/non-adjunctive and nontherapeutic/adjunctive CGM.

Therapeutic/non-adjunctive and non-therapeutic/adjunctive I-CGMs are considered medically reasonable and necessary when ALL the following coverage criteria is met:

- The patient has diabetes mellitus: and
- The patient has been using a blood glucose monitor (BGM) and performing frequent (four or more times a day) testing; and,
    - The patient has been using a blood glucose monitor (BGM) and/or external continuous glucose monitor (E-CGM) to facilitate frequent (≥ 4 times per day) testing; and
- Impediments medically compromising to the patient (i.e., lipodystrophy, site disruption, adhesive allergies, impaired dexterity) precludes the practical and efficient use of an E-CGM device; and
- The patient's insulin treatment regimen requires frequent adjustment by the patient based on blood glucose monitor (BGM) or CGM testing results; and
- Within six (6) months prior to ordering the I-CGM, the treating practitioner has an in-person visit with the beneficiary to evaluate their diabetes control and determined that criteria (1-3) above are met; and
- Routine recommended follow-up care is expected.

Limitations

I-CGM devices will not be considered medically reasonable and necessary for the following:

- Individuals that do not require insulin therapy.
- Short-term I-CGM (72 hours to 1 week) for diagnostic use.

Exception: for those beneficiaries who have previously met the coverage criteria for a non-implantable therapeutic/nonadjunctive, and non-therapeutic/adjunctive continuous glucose monitor and subsequently choose to switch to the implantable device, they may do so with a provider order. However, all other coverage criteria above must be fulfilled.

LIMITATIONS

Paramount Commercial Insurance Plans and Elite (Medicare Advantage) Plans

Paramount does not cover any of the following, not all-inclusive, because each is considered experimental/investigational, or unproven or convenience items:

- Implantable interstitial glucose sensors (0446T-0448T) [Exception, covered for the Elite Medicare Plan when the criteria above are met.]
- Implantable insulin pumps
- Insulin infuser ports
- Nonprogrammable transdermal insulin delivery systems (V-Go)
- Artificial pancreas device systems or bi-hormonal bionic endocrine pancreas
- MiniMed Connect and remote monitoring systems
- I-Port Injection Port (Patton Medical)
- Hypoglycemic Wristband Alarm (e.g., Diabetes Sentry™)
- Remote glucose monitoring device (e.g., mySentry™)
- Lasette™ Laser Blood Glucose Monitoring Device
- GlucoWatch® Biographer Monitor
- Personal Digital Assistant-Based Blood Glucose Monitor
- Combination devices that include a home blood glucose monitor combined with a cellular telephone or other device not specifically indicated for the management of diabetes mellitus (e.g., blood pressure monitor, cholesterol screening analyzer)
- Alcohol or peroxide (codes A4244, A4245), betadine or hexachlorophene (pHisohex) (codes A4246, A4247) are non-covered since these items are not required for the proper functioning of the device.
- Urine test reagent strips or tablets (code A4250) are non-covered since they are not used with a glucose monitor.
- Reflectance colorimeter devices used for measuring blood glucose levels in clinical settings are not covered as durable medical equipment for use in the home because their need for frequent professional re-calibration makes them unsuitable for home use.
- Glucose monitors that are not designed for use in the home must be coded A9270 and will be denied as non-covered.
- Home blood glucose disposable monitors, including test strips (code A9275) are non-covered because these monitors do not meet the definition of DME.
- Computer software for analyzing blood glucose monitoring test results is part of a blood glucose monitor and not separately reimbursed. Self-management mobile application software (e.g., BlueStar) is experimental and investigational. In addition, software or hardware required for downloading data from a blood glucose monitor to a computer is part of a blood glucose monitor and not separately reimbursed.
- Replacement of a currently functioning insulin pump for the sole purpose of receiving the most recent insulin pump technology (i.e., “upgrading” for improved technology) is non-covered because it is considered a convenience item and not medically necessary.
- Equipment replacement is not eligible for reimbursement in instances where it is determined that the equipment was maliciously damaged, neglected, used or misused in a fashion not intended by the manufacturer.

- Additional software or hardware required for downloading data to a device such as personal computer, smart phone, or tablet to aid in self-management of diabetes mellitus is non-covered because it is considered a convenience item and not medically necessary.

References:

Services/Procedures	
Continuous Glucose Monitors (CGMs) and related supplies: • Therapeutic (HCPCS codes E2103, A4239) and • Non-Therapeutic (HCPCS codes E2102, A4238)	
External Insulin Infusion Pump (HCPCS codes E0784)	
Integrated Insulin Infusion Pumps with CGM Sensing Capabilities (HCPCS codes E0784 + K0554 or E0784 + E2102, depending on systems used)	
Implantable Continuous Glucose Monitors (I-CGM; CPT codes 0446T, 0447T, 0448T)	

CODING/BILLING INFORMATION:

The appearance of a code in this section does not necessarily indicate coverage. Codes that are covered may have selection criteria that must be met. Payment for supplies may be included in payment for other services rendered.

HCPCS CODES	
A4210	Needle-free injection device, each
A4222	Infusion supplies for external drug infusion pump, per cassette or bag
A4223	Infusion supplies not used with external infusion pump, per cassette or bag
A4224	Supplies for maintenance of insulin infusion catheter, per week
A4225	Supplies for external insulin infusion pump, syringe type cartridge, sterile, each
A4226	Supplies for maintenance of insulin infusion pump with dosage rate adjustment using therapeutic continuous glucose sensing, per week
A4230	Infusion set for external infusion pump non-needle cannula type
A4231	Infusion set for external infusion pump needle type
A4232	Syringe with needle for external pump
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 (GCM), includes all supplies and accessories, 1 month supply = 1 unit of service
A4244	Alcohol or peroxide, per pint
A4245	Alcohol wipes, per box
A4246	Betadine or pHiosHex solutions, per pint
A4247	Betadine or iodine swabs/wipes, per box
A4257	Replacement lens shield cartridge for use with laser skin piercing device, each
A4250	Urine test or reagent strips or tablets (199 tablets or strips)
A9270	Noncovered item or service
A9274	External ambulatory insulin delivery system, disposable, each, includes all supplies and accessories (used for the Omni Pods)
A9275	Home glucose disposable monitor, includes test strips
A9276	Sensor; invasive (e.g., subcutaneous), disposable, for use with nondurable medical equipment interstitial continuous glucose monitoring system (CGM), on unit = 1 month 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)
A9280	Alert or alarm device, not otherwise classified [hypoglycemic wristband alarm (e.g., Sleep Sentry)]
E0607	Home blood glucose monitor

E0784	External ambulatory infusion pump, insulin (should not be used for the Omnipod, there is no separate “pump” for Omnipod)
E0787	External ambulatory infusion pump, insulin, dosage rate adjustment using therapeutic continuous glucose sensing
E0620	Skin piercing device for collection of capillary blood, laser, each
E2102	Adjunctive, nonimplantable continuous glucose monitor (CGM) or receiver
E2103	Nonadjunctive, nonimplanted continuous glucose monitor (CGM) or receiver
E2100	Blood glucose monitor with integrated voice synthesizer
K0552	Supplies for external drug infusion pump, syringe type cartridge, each
K0601	Replacement battery for external infusion pump owned by patient, silver oxide, 1.5 volt, each
K0602	Replacement battery for external infusion pump owned by patient, silver oxide, 3 volts, each
K0603	Replacement battery for external infusion pump owned by patient, alkaline, 1.5 volt, each
K0604	Replacement battery for external infusion pump owned by patient, lithium, 3.6 volt, each
K0605	Replacement battery for external infusion pump owned by patient, lithium, 4.5 volt, each
CPT CODES	
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 72 hours; analysis, interpretation, and report
0446T	Creation of subcutaneous pocket with insertion of implantable interstitial glucose sensor, including system activation and patient training **[Elite/ Medicare Plan covered only when criteria listed above is met]**
0447T	Removal of implantable interstitial glucose sensor from subcutaneous pocket via incision **[Elite/ Medicare Plan covered only when criteria listed above is met]**
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 **[Elite/ Medicare Plan covered only when criteria listed above is met]**
ICD-10 Codes that may apply:	
E08.00-E08.9	Diabetes mellitus due to underlying condition
E09.00-E09.9	Drug or chemical induced diabetes mellitus
E10.10-E10.9	Type 1 diabetes mellitus
E11.00-E11.9	Type 2 diabetes mellitus
E13.0-E13.9	Other specified 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

REVISION HISTORY EXPLANATION: ORIGINAL EFFECTIVE DATE: 12/01/2008

Date	Explanation & Changes
06/01/2009	• Updated

06/15/2009	• Clarification of verbiage
09/01/2011	• Updated
09/24/2011	• Replacement clarification
06/01/2012	• Updated
07/11/2012	• Added Exception for OmniPod coverage per TAWG approval
02/11/2014	• Policy reviewed and updated to reflect most current clinical evidence per Medical Policy Steering Committee
04/18/2014	• It was determined that Long Term Continuous Blood Glucose Monitoring Services will continue to be covered with prior authorization for all product lines • Policy reviewed and updated to reflect most current clinical evidence per TAWG Committee
09/09/2014	• Disposable external insulin pumps (A9274) with wireless communication capability to a hand-held control unit (e.g., OmniPod) are covered without prior authorization for all product lines • Policy reviewed and updated to reflect most current clinical evidence per Medical Policy Steering Committee
12/19/2014	• Added HCPCS codes S1034, S1035, S1036 and S1037 • It was determined by TAWG that Artificial Pancreas Device Systems (APDS) will be non-covered for all product lines • Policy reviewed and updated to reflect most current clinical evidence per TAWG Committee.
02/26/2015	• Added verbiage, “The DME supplier must meet eligibility and/or credentialing requirements as defined by the Plan to be eligible for reimbursement.” • Changes made to current criteria • Policy reviewed and updated to reflect most current clinical evidence per TAWG Committee
10/09/2015	• Changed “AND” to “OR” so criteria is no. 1 OR no. 2 OR no. 3 per administrative direction
02/26/2016	• Policy reviewed and updated to reflect most current clinical evidence per TAWG Committee
04/11/2017	• Combined this policy with PG0156 External Insulin Pumps • Added effective 01/01/17 new codes 0446T-0448T as non-covered • Policy reviewed and updated to reflect most current clinical evidence per TAWG Committee
07/11/2017	• Added effective 07/01/17 new codes K0553 & K0554 as covered with prior authorization for HMO, PPO, Individual Marketplace, & Elite per CMS guidelines and non-covered for Advantage per ODM guidelines • Policy reviewed and updated to reflect most current clinical evidence per Medical Policy Steering Committee
10/10/2017	• Added Dexcom G4 PLATINUM, iPro2 Professional with Enlite Sensor, & FreeStyle Libre Flash Glucose Monitoring System to examples of FDA approved long-term CGM • Policy reviewed and updated to reflect most current clinical evidence per Medical Policy Steering Committee
02/13/2018	• Disposable insulin infusion devices/pumps (e.g., V-GO™, Omnipod) are covered through the pharmacy benefit (Medicare Part D) for Elite • Policy reviewed and updated to reflect most current clinical evidence per Medical Policy Steering Committee
03/22/2018	• Effective 01/01/18 codes K0553 & K0554 are now covered with prior authorization for Advantage per ODM guidelines
04/10/2018	• Policy reviewed and updated to reflect most current clinical evidence per Medical Policy Steering Committee

05/24/2018	• Hybrid closed loop system (e.g., MiniMed 670G) is now covered without prior authorization for all product lines • Policy reviewed and updated to reflect most current clinical evidence per The Technology Assessment Working Group (TAWG)
07/10/2018	• Added Dexcom G6 to examples of FDA approved long-term CGM systems • Hybrid closed loop system (e.g., MiniMed 670G) requires prior authorization for all product lines • Combined external insulin pumps and CGM with suspend on low feature (e.g., MiniMed 530G, MiniMed 630G) are now covered with prior authorization • For Elite only, CGM system supplies and accessories are now covered if a non-DME device (watch, smartphone, tablet, laptop computer, etc.) is used in conjunction with the durable CGM receiver (K0554) to display glucose data per CMS guidelines • Policy reviewed and updated to reflect most current clinical evidence per Medical Policy Steering Committee
08/18/2019	• Policy Update: Effective 11/1/2019, Criteria update to be consistent across all product lines • Coverage of diabetic Continuous Glucose Monitoring Systems and Insulin Pumps varies by medical and pharmacy plan • Commercial Product Lines – Continuous Glucose Monitoring Systems and Insulin Pumps will be processed through the Pharmacy area, both pharmacy and medical authorizations • For the Commercial Lines of Business, the following procedures require a prior authorization, effective 11/1/2019, A9274, A9276, A9277, A9278 and E0784 • All other Product Lines, Elite and Advantage – Continuous Glucose Monitoring Systems and Insulin Pumps will be monitored through Utilization for the Elite and Advantage product line, and will not require a prior authorization
12/01/2019	• Policy Updated: Effective 02/01/2020, For the Commercial Lines of Business, additional procedures K0553 and K0554 require prior authorization
01/29/2020	• Clarified that the 'coverage criteria' is for all product lines, coverage criteria effective regardless of requiring or not requiring a prior authorization • Medical Policy PG0156 External Insulin Pumps achieved because the coverage is now addressed in this Medical Policy PG0177 Continuous Glucose Monitoring Systems and Insulin Pumps
04/30/2020	• Policy Updated to document device coverage criteria for the Advantage and Elite product lines
12/15/2020	• Medical policy placed on the new Paramount Medical Policy Format
01/04/2021	• Policy Updated to the most current industry standards. • The policy has been updated to reflect the types of CGMs that are covered, the criteria for approval of insulin pumps and CGMs, and the billing codes that are approved for use for CGM billing: a.Medtronic brand CGMs are considered non-therapeutic CGMs and should not be used alone to make therapeutic insulin dosing decisions. These Medtronic sensors and transmitters will only be covered when used in conjunction with a Medtronic insulin pump running in auto mode and the codes A9278, A9277, and A9276 are the covered codes. b.Dexcom G6 and FreeStyle Libre are considered therapeutic CGMs and are covered using therapeutic CGM billing codes K0553 and K0554 when criteria are met. c. Coverage criteria have changed for CGMs and insulin pumps to allow for prescribing by all providers with expertise in Diabetes Care; for non-endocrinology providers, oversight by a certified Diabetes educator is required. d.Criteria for both pumps and CGMs requires use of short acting insulin with multiple daily blood glucose testing requirements or hypoglycemia unawareness
10/01/2022	• Policy Updated to the most current industry standards • Added new codes A4238 and E2102 to the policy, effective 4/1/2022 • Added new codes G0308 and G0309 to the policy, effective 7/1/2022

	• Implantable interstitial glucose sensors (0446T-0448T) are noncovered with the Exception, covered for the Elite/ Medicare Plan when the criteria above are met.] • Added Effective 12/01/2022 procedures A4238 and E2102 require a prior authorization for the Commercial product lines
02/01/2023	• Policy Updated to the most current industry standards • Updated Coding/Billing Information with 01/01/2023 HCPCS changes; added A4239, E2103 replacing K0553, K0554 deleted 12/31/2022, and revised descriptors for A4238, A9276, A9277, A9278, E2102 • Moved procedures codes A9276, A9277 and A9278 under the noncovered procedure code listing • Added Effective 04/01/2023 procedures A4239 and E2103 require a prior authorization for the Commercial product lines
02/09/2023	• Medical Policy updated to reflect Medicaid coverage to Anthem as of 02/01/2023
03/30/2023	• Medical Policy updated to reflect DME limits calculated by CMS criteria/guidelines.
03/04/2024	• Medical Policy placed on the new Paramount Medical Policy format
11/01/2024	• Medical Policy updated to the most current industry standards • Removed deleted codes G0308, G0309, K0553, K0554 • Removed S-codes S1030, S1031, S1031, S1035, S1036, S1037 as Paramount does not reimburse for S-codes • No coverage criteria changes
04/01/2025	• Medical Policy reviewed and updated to reflect the most current clinical evidence • Changed Policy title from Continuous Glucose Monitoring Systems and Insulin Pumps to Diabetes Management: Continuous Glucose Monitoring Systems and Insulin Pumps • Added codes G0564 and G0565 to require a prior authorization, effective 1/1/2025
05/01/2025	• Removed cancelled HCPCS G0564 and G0565

Paramount reserves the right to review and revise our policies periodically when necessary. When there is an update, we will publish the most current policy to https://www.paramounthealthcare.com/providers/medical-policies/policy-library

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National Physician Fee Schedule Relative Value File Calendar Year XXXX, Centers for Medicare & Medicaid Services (CMS) https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Relative-Value-Files

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