GUIDELINES
This policy does not certify benefits or authorization of benefits, which is designated by each individual policyholder contract. Paramount applies coding edits to all medical claims through coding logic software to evaluate the accuracy and adherence to accepted national standards. This guideline is solely for explaining correct procedure reporting and does not imply coverage and reimbursement.

DESCRIPTION
Continuous Glucose Monitoring (CGM) Systems
These devices measure glucose levels in interstitial fluid at programmable intervals. These readings help detect any patterns or trends with a patient’s glucose levels and are intended to assist in calculating the insulin dosage needed to manage glycemic control. CGM systems use sensors that are inserted under the skin in the abdomen, arm or buttocks and work by extracting glucose from the interstitial fluid, measuring and recording the glucose level and converting these measurements into equivalent blood glucose readings.

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.

Long-term Continuous Glucose Monitoring (CGM) Systems
These devices are owned by individuals and provide real-time glucose values that allow users to track patterns and possibly identify episodes of low and high blood glucose levels. The data can be downloaded to PC software and stored for historical analysis. The system will purportedly alert the user if a glucose level falls below or rises above a preset value.

Examples of FDA approved long-term CGM systems include, but may not be limited to:

- **Guardian REAL-Time**
  Approved for patients over 18 years of age. The sensor and monitor are connected through a wireless transmitter and the monitor displays real-time glucose results every five minutes. The continuous data can be stored up to 21 days and downloaded any time into a computer. The data can then be reviewed with proprietary software provided by the manufacturer.

- **Dexcom G5 Mobile**
  Provides increasing sensor accuracy and allows users to obtain glucose monitoring data and alerts directly via their smart device and share data with others via the Dexcom Share App. A fingerstick confirmation is not needed for making treatment decisions, except in situations in which the glucose is rapidly changing, or glucose value is unexpected and does not match the patient's symptoms. Calibration is required every 12 hours and the device is inaccurate in the setting of acetaminophen use.

- **FreeStyle Libre Flash**
  The sensor utilizes Wired Enzyme™ technology in which the enzyme and mediator are co-immobilized on the sensor. It offers factory calibration, and therefore nearly eliminates the need for fingerstick monitoring. However, patients are still advised to perform SMBG whenever an alert appears on the reader display (which occurs when the glucose is rising or falling rapidly) or whenever the glucose value does not fit the patient's symptoms. The reader contains a built-in meter for this purpose. The sensor is FDA approved for 10 days of use. The system is not approved for use in children under age 18, or during pregnancy or in persons requiring hemodialysis. The Libre has minimized the interference by acetaminophen which is present in other devices but interference from other substances such as ascorbic acid or aspirin may be possible. The Libre does not alert the user for glucose values surpassing a high or low threshold. In addition, glucose values are not automatically made available to the user but are easily and instantly accessed by scanning the sensor with a handheld reader. However, the product may be attractive option for patients who are averse to the hassle imposed by other RT-CGM devices and SMBG only. Glucoses are measured every minute and recorded every 15 minutes. Data can be accessed using the reader or downloaded to LibreView cloud based online management system, or using the FreeStyle Libre desktop software. The MARD is reported by the manufacturer to be 9.7% overall, and as with other CGM devices, less accurate on day 1 of wear and in hypoglycemia range.

- **Dexcom G6**
  On March 27, 2018, the FDA approved the Dexcom G6 integrated continuous glucose monitoring (iCGM) system for determining blood glucose levels in people 2 years of age and older with diabetes. This is the first type of continuous glucose monitoring system that can be used as part of an integrated system with other compatible medical devices and electronic interfaces, which may include automated insulin dosing systems, insulin pumps, blood glucose meters or other electronic devices used for diabetes management. The Dexcom G6 is a patch device, about the size of a quarter, that is
applied to the skin of the abdomen and contains a small sensor that continuously measures the amount of glucose in body fluid. The device transmits real-time glucose readings every five minutes to a compatible display device such as a mobile medical app on a cell phone and will trigger an alarm when a patient’s blood sugar enters a danger zone soaring too high or dropping too low. If it’s integrated with an automated insulin dosing system, a rise in blood sugar would trigger the release of insulin from the pump. The patch device should be replaced every 10 days. The Dexcom G6 is factory calibrated and does not require users to calibrate the sensor with fingerstick blood glucose measurements.

Remote Glucose Monitoring
An integrated wireless communication system that is built into the receiver, enabling remote monitoring capabilities and sharing of data through a compatible internet-accessible device application.

An example of a remote glucose monitor device includes, but may not be limited to:

- **Dexcom SHARE**

Implantable Interstitial Glucose Sensors
These sensors are intended for long term use (e.g., 90 days) and are implanted subcutaneously in the upper arm to measure glucose in the interstitial fluid. The measurement is then relayed to the smart transmitter. The measurement and display of glucose values is done automatically without the need for user intervention. Currently there are no devices that have received FDA approval.

- **NO FDA APPROVED PRODUCTS**

External Insulin Pumps
A standard portable external insulin infusion pump is a small battery-operated pump about the size of a personal pager that is filled with insulin, and is connected to thin tubing ending in a needle. The needle is inserted into the skin around the abdomen and supplies a regulated dose of insulin to the user for a day or more at a time. The pump may be carried in a pocket, or in a case worn attached to a belt fastened around a consumer’s waist.

Examples of FDA approved external insulin pumps include, but may not be limited to:

- **Accu-Chek® Aviva Combo System or Spirit Combo Insulin Pump Systems**
  (Roche Diagnostics, Indianapolis, IN)
  Combined insulin pump with finger stick blood glucose meter for the treatment of insulin requiring diabetes and for the quantitative measurement of glucose in fresh capillary whole blood from the finger

- **OmniPod™ Insulin Management System**
  (Insulet Corporation, Boston, MA)
  A wireless insulin pump that consists of a disposable insulin pod and Personal Diabetes Manager that includes a built-in FreeStyle® glucose meter. The pod is filled with insulin by the patient and replaced every 72 hours.

- **Animas® OneTouch® Ping™**
  (Animas Corp., Frazer, PA)
  Insulin pump with a OneTouch® Ping™ Meter Remote for diabetics requiring continuous subcutaneous insulin delivery and measurement of glucose

- **Solo™ MicroPump**

- **t:flex™ Insulin Delivery System**
  (Tandem Diabetes Care, Inc., San Diego CA)
  A t:slim predicate device intended for the subcutaneous delivery of insulin for individuals 12 years of age and greater. The t:flex includes a 4.8 mL cartridge vs. 3.0 mL cartridge in the t:slim.

- **V-Go Disposable Insulin Delivery Device**
  A fully disposable, non-electronic device for the delivery of basal-bolus insulin therapy for adults with diabetes. It provides a continuous preset basal rate of insulin and allows for on-demand bolus dosing around mealtimes. It is applied to the skin daily for one 24-hour period.

Implantable Insulin Pumps
These pumps are surgically implanted rather than worn externally to deliver insulin via intraperitoneal or intravenous routes. Currently there are not any devices that have received FDA approval for use outside of a clinical trial.

- **NO FDA APPROVED PRODUCTS**
  The Eversense system (Senseonics) is a 90-day implantable sensor that uses fluorescent technology to send measures via a transmitter which rests just above the skin to a smartphone app. The system received the CE mark and is under review at the FDA as of 2017. The system is approved for adjunctive use, and thus may not replace self-monitored blood glucose (SMBG).
Combined External Insulin Pumps with Continuous Glucose Monitoring (CGM) Systems

A device that integrates an insulin pump with real-time continuous glucose monitoring and is not intended to replace finger sticks. These systems incorporate features including predictive alerts that give early warnings so action can be taken to prevent dangerous high or low blood glucose events.

Examples of FDA approved combined external insulin pumps with CGM systems include, but may not be limited to:

- Animas® Vibe® Insulin Pump
  Intended for the continuous subcutaneous infusion of insulin for the management of insulin-requiring diabetes.

- Minimed Paradigm® Real-Time Insulin Pump
  (Medtronic Minimed, Northridge, CA)
  For the management of diabetes mellitus in persons requiring continuous delivery of insulin (MMT-523/723 for adults and MMT-523K/723K for ages 7–17 years)
  - mySentry
    This remote monitoring system is an optional monitoring device for the MiniMed Paradigm REAL-Time Revel System. The mySentry consists of a remote outpost and monitor. Blood glucose levels collected by the CGM are sent to the remote (wireless) monitor, which also has alarms to alert the user of high or low blood glucose levels.

- t:slim® Micro-Delivery Insulin Pump
  (Tandem Diabetes Care, Inc., San Diego CA)
  This pump provides a subcutaneous delivery of insulin for the management of diabetes mellitus in persons requiring insulin, for individuals 12 years of age and greater

- MiniMed 530G System
  This system is intended for automatic, continuous delivery of basal insulin (at user selectable rates) and manual administration of insulin boluses (in user selectable amounts) in persons, 16 years of age and older, requiring insulin as well as for the continuous monitoring and trending of glucose levels in the fluid under the skin. This device has SmartGuard technology which automatically stops insulin delivery (for up to two hours) when sensor glucose values reach a preset level and when the individual does not respond to the suspend on low alarm.
  - MiniMed Connect
    Compatible with MiniMed 530G with Enlite and MiniMed Paradigm® Real-Time insulin pump. This optional wireless device can be used to access continuous glucose monitor sensor data. Information can be viewed using an internet application through a smart device or via a browser accessible website and can be shared as needed.

- MiniMed 630G
  This system is intended for automatic, continuous delivery of basal insulin (at user selectable rates) and manual administration of insulin boluses (in user selectable amounts) for persons sixteen years of age and older, requiring insulin as well as for the continuous monitoring and trending of glucose levels in the fluid under the skin. The MiniMed 630G system includes SmartGuard which can be programmed to temporarily suspend delivery of insulin for up to two hours when the sensor glucose value falls below a predefined threshold value. The MiniMed 630G system with SmartGuard consists of the following devices: MiniMed 630G insulin pump, Enlite sensor, One-Press serter, Guardian Link transmitter system, CareLink USB and Contour NEXT Link 2.4 wireless glucose meter.

Combined External Insulin Pumps and CGM System with Suspend on Low Feature

Suspend on low is the first step towards an artificial pancreas device system (APDS). This technology combines CGMS with an insulin pump which allows the user to set a low blood sugar threshold value. When the CGM sensor detects the preset low glucose threshold, insulin delivery is suspended.

Examples of combined external insulin pumps with CGM with suspend on low feature include, but may not be limited to:

- MiniMed 530G System
  This system is intended for automatic, continuous delivery of basal insulin (at user selectable rates) and manual administration of insulin boluses (in user selectable amounts) in persons, 16 years of age and older, requiring insulin as well as for the continuous monitoring and trending of glucose levels in the fluid under the skin. This device has SmartGuard technology which automatically stops insulin delivery (for up to two hours) when sensor glucose values reach a preset level and when the individual does not respond to the suspend on low alarm.
  - MiniMed Connect
    Compatible with MiniMed 530G with Enlite and MiniMed Paradigm® Real-Time insulin pump. This optional wireless device can be used to access continuous glucose monitor sensor data. Information can be viewed using an internet application through a smart device or via a browser accessible website and can be shared as needed.

- MiniMed 630G
  This system is intended for automatic, continuous delivery of basal insulin (at user selectable rates) and manual administration of insulin boluses (in user selectable amounts) for persons sixteen years of age and older, requiring insulin as well as for the continuous monitoring and trending of glucose levels in the fluid under the skin. The MiniMed 630G system includes SmartGuard which can be programmed to temporarily suspend delivery of insulin for up to two hours when the sensor glucose value falls below a predefined threshold value. The MiniMed 630G system with SmartGuard consists of the following devices: MiniMed 630G insulin pump, Enlite sensor, One-Press serter, Guardian Link transmitter system, CareLink USB and Contour NEXT Link 2.4 wireless glucose meter.

Hybrid Closed Loop System

Along with the suspend on low feature mentioned above, this newly FDA approved system has a suspend before low feature that purportedly stops insulin delivery when the sensor is predicted to reach a low limit and resumes after sensor glucose levels recover.

An example of a hybrid closed loop system includes, but may not be limited to:

- MiniMed 670G
  This system is intended for automatic, continuous delivery of basal insulin (at user selectable rates) and manual administration of insulin boluses (in user selectable amounts) for Type 1 diabetes mellitus (T1DM) in persons 14 years of age and older, requiring insulin as well as for the continuous monitoring and trending of glucose levels in the fluid under the skin. The MiniMed 670G System includes advanced SmartGuard technology, which can be programmed to automatically adjust delivery of basal insulin based on CGM sensor glucose values and can suspend delivery of insulin when the sensor glucose value falls below or is predicted to fall below predefined threshold values. The MiniMed 670G system consists of the following devices: MiniMed 670G insulin pump, the Guardian Link 3 transmitter, the Guardian Sensor 3, One-Press serter and the Contour NEXT Link 2.4 wireless glucose meter.
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

Requires prior authorization for all product lines:
- Long-term continuous glucose monitoring (CGM) systems with or without an external insulin pump (A9276, A9277, A9278, K0553, K0554, S1030, S1031)
- Combined external insulin pumps and CGM systems with suspend on low feature (e.g., MiniMed 530G, MiniMed 630G)
- Hybrid closed loop system (e.g., MiniMed 670G)

Does not require prior authorization for all product lines:
- External insulin pumps (e.g., Accu-Chek® Spirit, Animas® OneTouch® Ping™, t:flex™ Insulin Delivery System) (E0784)
- Disposable external insulin pumps (A9274) with wireless communication capability to a hand-held control unit (e.g., OmniPod™)

Does not warrant separate reimbursement for all product lines:
Remote glucose monitoring (e.g., the Dexcom SHARE) does not warrant separate reimbursement.

Non-Covered for all product lines:
- Implantable interstitial glucose sensors (0446T-0448T)
- Implantable insulin pumps
- Artificial pancreas device systems (S1034-S1037) or bi-hormonal bionic endocrine pancreas
- MiniMed Connect
- mySentry remote monitoring system

Elite:
- Disposable insulin infusion devices/pumps (e.g., V-GO™, Omnipod™) are covered under Medicare Part D (prescription).

HMO, PPO, Individual Marketplace, Advantage:
- Nonprogrammable disposable insulin delivery systems (e.g., V-Go™ Disposable Insulin Delivery Device) are non-covered.

Paramount has determined that the use of FDA approved long-term continuous glucose monitoring systems (A9276, A9277, A9278, K0553, K0554, S1030, S1031) with or without an external insulin pump is covered under the following guidelines:
1. Approved with prior authorization for Type 1 diabetes when evidence of hypoglycemia exists on 3 consecutive days OR
2. Recurrent episodes of severe hypoglycemia (blood glucose less than 80mg/dl) and hypoglycemia unawareness despite appropriate modifications in insulin regimen and compliance with frequent self-monitoring OR
3. Women who are pregnant with uncontrolled diabetes mellitus HbA1c >9% with fluctuating blood sugar 80-400mg/dl.

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

FDA approved external insulin pumps are medically necessary for members with type 1 diabetes mellitus documented by a C-peptide level less than 0.5 and when all of the following medical necessity criteria are met:
1. The member has completed a diabetes education program within the last twenty four months of being prescribed an insulin infusion pump.
2. The member has been on a program of multiple daily injections of insulin (i.e., at least 3 injections per day), with frequent self-adjustments of insulin dose, for at least 6 months before initiation of the insulin infusion pump.
3. The member had documented frequency that is kept in the member's medical record of glucose self-testing an average of at least 4 times per day during the 2 months before initiation of the insulin infusion pump.
4. The member is at high risk for preventable complications of diabetes. Early signs of diabetic complications include micro-albuminuria and/or documented in the member's medical record persistent difficulty in achieving optimal control of blood sugar levels despite good compliance with an intensive multiple injection regimens.

5. The member needs to meet at least one of the following criteria in order to be eligible for an external insulin infusion pump:
   - Glycated hemoglobin level (HbA1c) > 7.0%
   - History of recurring hypoglycemia
   - Wide fluctuations in blood glucose before mealtime
   - Dawn phenomenon with fasting blood sugars frequently exceeding 200 mg/dL
   - History of severe glycemic excursions

Paramount provides no additional reimbursement for a wireless transmission feature that is integrated into a continuous glucose monitor (e.g., Dexcom SHARE) because it is considered a convenience feature.

Paramount considers a hybrid closed loop system (programmed to automatically adjust delivery of basal insulin based on continuous glucose monitor sensor glucose values) (e.g., MiniMed 670G) an equally acceptable alternative to a standard insulin pump and continuous glucose monitor for medically necessary indications.

Paramount considers a continuous glucose monitor and insulin pump with a low glucose suspend feature (e.g., MiniMed 530G, MiniMed 630G) an equally acceptable alternative to a standard insulin pump and continuous glucose monitor for medically necessary indications.

**Non-Coverage Determination**

External insulin pumps are non-covered if any of the following contraindications exist:

1. Member has non-insulin dependent (NIDDM or IR-NIDDM, Type II) diabetes, even if insulin is taken
2. Member has end-stage complications such as renal failure
3. Member is unable, because of behavioral, psychological problems or functional ability, to technically operate the pump and perform frequent blood glucose monitoring
4. Member is being prescribed pump therapy to be used for convenience purposes

Paramount does not cover any of the following because each is considered experimental, investigational or unproven:

- Implantable interstitial glucose sensors (0446T-0448T)
- Implantable insulin pumps
- Artificial pancreas device systems (S1034-S1037) or bi-hormonal bionic endocrine pancreas
- MiniMed Connect
- mySentry remote monitoring system

**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.
Elite
Disposable insulin infusion devices/pumps (e.g., V-GO™, Omnipod™) are coverable under Medicare Part D (prescription) as they are not covered under Medicare Part B (medical/DME). Some insulin pumps are covered under Part B as Durable Medical Equipment (DME). Disposable insulin pumps are not “durable,” and, therefore, are not covered under Part B.

CGM system supplies and accessories are 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. If a member never uses a DME receiver for a therapeutic CGM, the supply allowance is non-covered by Paramount. Smart devices are non-covered by Paramount because they do not meet the definition of DME (i.e., not primarily medical in nature and are useful in the absence of illness).

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.

HMO, PPO, Individual Marketplace, Advantage
Nonprogrammable disposable insulin delivery systems (e.g., V-Go™ Disposable Insulin Delivery Device) are experimental and investigational and therefore non-covered because there is insufficient evidence in the peer-reviewed medical literature of the effectiveness of these devices.

Paramount does not cover the following because each is considered a convenience item and not medically necessary:
- 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)
- 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

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

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>A4230</td>
<td>Infusion set for external infusion pump non-needle cannula type</td>
</tr>
<tr>
<td>A4231</td>
<td>Infusion set for external infusion pump needle type</td>
</tr>
<tr>
<td>A4232</td>
<td>Syringe with needle for external pump</td>
</tr>
<tr>
<td>A9274</td>
<td>External ambulatory insulin delivery system, disposable, each, includes all supplies and accessories</td>
</tr>
<tr>
<td>A9276</td>
<td>Sensor - invasive (e.g. subcutaneous) disposable for use with interstitial continuous glucose monitoring system, one unit = 1 day supply</td>
</tr>
<tr>
<td>A9277</td>
<td>Transmitter - external for use with interstitial continuous glucose monitoring system</td>
</tr>
<tr>
<td>A9278</td>
<td>Receiver (monitor) - external for use with interstitial continuous glucose monitoring system</td>
</tr>
<tr>
<td>E0784</td>
<td>External ambulatory infusion pump. insulin</td>
</tr>
<tr>
<td>K0552</td>
<td>Supplies for external drug infusion pump, syringe type cartridge, each</td>
</tr>
<tr>
<td>K0553</td>
<td>Supply allowance for therapeutic continuous glucose monitor (CGM), includes all supplies and accessories, 1 month supply = 1 unit of service (Code effective 07/01/2017)</td>
</tr>
<tr>
<td>K0554</td>
<td>Receiver (monitor); dedicated, for use with therapeutic continuous glucose monitoring system (Code effective 07/01/2017)</td>
</tr>
<tr>
<td>K0601</td>
<td>Replacement battery for external infusion pump owned by patient, silver oxide, 1.5 volt, each</td>
</tr>
<tr>
<td>K0602</td>
<td>Replacement battery for external infusion pump owned by patient, silver oxide, 3 volt, each</td>
</tr>
<tr>
<td>K0603</td>
<td>Replacement battery for external infusion pump owned by patient, alkaline, 1.5 volt, each</td>
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<tr>
<td>K0604</td>
<td>Replacement battery for external infusion pump owned by patient, lithium, 3.6 volt, each</td>
</tr>
<tr>
<td>K0605</td>
<td>Replacement battery for external infusion pump owned by patient, lithium, 4.5 volt, each</td>
</tr>
<tr>
<td>S1030</td>
<td>Continuous noninvasive glucose monitoring device, purchase (for physician interpretation of data, use CPT code)</td>
</tr>
<tr>
<td>S1031</td>
<td>Continuous noninvasive glucose monitoring device rental including sensor, sensor replacement, and download to monitor (for physician interpretation of data, use CPT code)</td>
</tr>
<tr>
<td>S1034</td>
<td>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</td>
</tr>
<tr>
<td>S1035</td>
<td>Sensor; invasive (e.g., subcutaneous), disposable, for use with artificial pancreas device system</td>
</tr>
<tr>
<td>S1036</td>
<td>Transmitter; external, for use with artificial pancreas device system</td>
</tr>
<tr>
<td>S1037</td>
<td>Receiver (monitor); external, for use with artificial pancreas device system</td>
</tr>
<tr>
<td>95249</td>
<td>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</td>
</tr>
</tbody>
</table>
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

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

**TAWG REVIEW DATES:**

Long term Continuous Blood Glucose Monitoring Services - 01/14/2009, 02/18/2009, 02/10/2010, 02/09/2011, 04/11/2012, 05/15/2013, 04/18/2014, 02/26/2015, 02/26/2016, 05/24/2018

External Insulin Pumps - 07/11/2012

Artificial Pancreas Device Systems (APDS) – 12/19/2014, 02/26/2016

**REVISION HISTORY EXPLANATION**

06/01/09: Updated

06/15/09: Clarification of verbiage

09/01/11: Updated

09/24/11: Replacement clarification

06/01/12: Updated

07/11/12: Added Exception for OmniPod coverage per TAWG approval.

02/11/14: Policy reviewed and updated to reflect most current clinical evidence per Medical Policy Steering Committee.

04/18/14: 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.

09/09/14: 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.

12/19/14: 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.

02/26/15: 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.

10/09/15: Changed “AND” to “OR” so criteria is no. 1 OR no. 2 OR no. 3 per administrative direction.

02/26/16: Policy reviewed and updated to reflect most current clinical evidence per TAWG Committee.

04/11/17: 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.

07/11/17: 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.

10/10/17: 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.

02/13/18: 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.

03/22/18: Effective 01/01/18 codes K0553 & K0554 are now covered with prior authorization for Advantage per ODM guidelines.

04/10/18: Policy reviewed and updated to reflect most current clinical evidence per Medical Policy Steering Committee.

05/24/18: Hybrid closed loop system (eg, 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).

07/10/18: Added Dexcom G6 to examples of FDA approved long-term CGM systems. Hybrid closed loop system (eg, MiniMed 670G) requires prior authorization for all product lines. Combined external insulin pumps and CGM
with suspend on low feature (eg, 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.

REFERENCES/RESOURCES
Centers for Medicare and Medicaid Services, CMS Manual System and other CMS publications and services
Ohio Department of Medicaid http://jfs.ohio.gov/
American Medical Association, Current Procedural Terminology (CPT®) and associated publications and services
Centers for Medicare and Medicaid Services, Healthcare Common Procedure Coding System, HCPCS Release and Code Sets
Industry Standard Review
Hayes, Inc