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.

SCOPE
X Professional
_ Facility

DESCRIPTION
Continuous Glucose Monitoring (CGM) Systems
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. The system components vary and can include transmitters, sensors, and readers.

- A therapeutic CGM is classified as a device that can be used to make insulin dosing decisions as the accuracy rate is much higher than a traditional glucose monitor and test strips.
- 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.

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 and some are designed for use in conjunction with a CGM. Features can include high/low warnings, automatic suspension of insulin, or adjustment of basal rates (hybrid closed loop systems).

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.
Artificial Pancreas or Bi-hormonal Bionic Endocrine Pancreas (closed loop pumps)
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

Effective 11/1/2019

Commercial HMO, PPO
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 insulin pumps and continuous glucose monitoring (CGM) systems on both pharmacy and medical benefits. A9274, A9276, A9277, A9278, E0784, K0553 and K0554.

Individual Marketplace, ACA small group
CGM systems and insulin pumps are covered under the medical benefit. Prior authorization is required for all insulin pumps and continuous glucose monitoring (CGM) systems. A9274, A9276, A9277, A9278, E0784, K0553 and K0554.

Advantage and Elite/ProMedica Medicare Plan
No prior authorization required for CGM systems or insulin pumps.
- Covered under medical benefit
- Advantage coverage follows the Ohio Department of Medicaid
- Elite/ProMedica Medicare Plan coverage follow CMS/Medicare

Non-Covered for all product lines, not all-inclusive:
- Implantable interstitial glucose sensors (0446T-0448T)
- Implantable insulin pumps
- Artificial pancreas device systems (S1034-S1037) or bi-hormonal bionic endocrine pancreas
- MiniMed Connect and remote monitoring systems

COVERAGE CRITERIA
HMO, PPO, Individual Marketplace, Advantage and Elite/ProMedica Medicare Plan

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

1. Type 1 diabetes and is managed by an endocrinologist; OR

2. Type 2 insulin dependent diabetes or gestational diabetes; AND all of the following:
   - Being managed in conjunction with an endocrinologist or provider with expertise in diabetes care; and
   - Documentation that the patient has completed a comprehensive diabetes education program and has ongoing oversight by a certified diabetes educator; and
   - Self-monitoring at least 3 times per day is needed; and
• Uncontrolled with current monitoring plan or frequent asymptomatic hypoglycemia (or severe hypoglycemia with no obviously preventable precipitation cause); and
• Clinical notes supporting all of the above criteria are required for approval consideration.
• Dual test strip use beyond 50 strips per month limited to those who need to calibrate for Minimed pump.

Continuation of CGM use after one year or device replacement is considered medically necessary for the following:
• The device is malfunctioning and 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.

Initial approval of Continuous Glucose Monitoring (CGM) systems includes transmitters, sensors, and receivers/monitors.

Coverage Devices: Covered under the Medical Benefit

**Advantage**
A therapeutic CGM is classified as a device that can be used to make insulin dosing decisions as the accuracy rate is much higher than a traditional glucose monitor and test strips. The devices that are considered therapeutic are the Freestyle Libre and the Dexcom G6. These systems are coded as below:

- K0553-includes sensors, transmitters, test strips, lancets. (We cannot bill separately for the test strips as these are only provided in the event the patient believes that the reading from the sensor is incorrect.)
- K0554-reader (sometimes this piece of equipment is built into the insulin pump (e.g. Tandem) Currently this is only available with the Dexcom G6. The Libre systems require a reader.

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. These systems are coded as below:

- A9276-sensors
- A9277-transmitter
- A9278-receiver

These CGM systems are covered by Medicaid for those patients that meet the criteria.

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 (code K0554) and associated supply allowance (code K0553), will be denied.

**Elite/ProMedica Medicare Plan – CMS coverage CGS Local Coverage Article: Glucose Monitor – Policy Article (A52464)**
A therapeutic CGM is classified as a device that can be used to make insulin dosing decisions as the accuracy rate is much higher than a traditional glucose monitor and test strips. CMS/Medicare approved these specific CGM systems to be a replacement for finger stick testing. (strips and lancets) glucose monitor and test strips. The devices that are considered therapeutic are the Freestyle Libre and the
Dexcom G6. These systems are coded as below:

- K0553-includes sensors, transmitters, test strips, lancets. (We cannot bill separately for the test strips as these are only provided in the event the patient believes that the reading from the sensor is incorrect.)

- K0554-reader (sometimes this piece of equipment is built into the insulin pump (e.g. Tandem). Currently this is only available with the Dexcom G6. The Libre systems require a reader.

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. These systems are coded as below:

- A9276-sensors
- A9277-transmitter
- A9278-receiver

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 (code K0554) and associated supply allowance (code K0553), will be denied.

CGM devices that do not meet the definition of a therapeutic CGM as defined in CMS Ruling 1682R will be denied as non-covered (no benefit).

The non-therapeutic CGM is made by Medtronic. Some of the CGM systems integrate with a Medtronic pump so if a Medicare member is on a Medtronic pump with CGM they face obstacles as most Medicare plans follow Medicare guidelines both for medical necessity criteria but also for the covered HCPCS.

**External Insulin Pumps:**
Paramount has determined that Omnipod, Omnipod DASH, Medtronic, and Tandem insulin pumps and associated supplies are covered when the following criteria is met:

1. Type 1 diabetes and is managed by an endocrinologist; OR
2. Type 2 insulin dependent diabetes or gestational diabetes; AND all of the following:
   - Being managed in conjunction with an endocrinologist or provider with expertise in diabetes care; and
   - Documentation that the patient has completed a comprehensive diabetes education program and has ongoing oversight by a certified diabetes educator; and
   - Compliance with blood glucose monitoring has been demonstrated; and
   - History of suboptimal blood sugar control despite current insulin regimen (ex. Repeated hypoglycemia, wide variations in blood sugars, frequent hyperglycemia, DKA).
   - Clinical notes supporting all of the above criteria are required for approval consideration.

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

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)
- Implantable insulin pumps
- Artificial pancreas device systems (S1034-S1037) 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
- Combinatin 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)

**Diabetes Management Software**

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.

**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.

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.

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

Paramount Commercial (HMO, PPO/CDH, POS, ACA Alliance), Marketplace

Paramount Diabetes Monitoring and Insulin Pump Supplies
Prior Authorization Form

**FAX Commercial and Marketplace requests to 1-866-214-2024**

Patient Information
Patient Name: ______________________________________  Patient ID: _________________________
Patient DOB: ________________________________

Physician Name: ________________________________  Certification/Specialty: __________________
Physician Phone: ________________________________  Office Fax: ______________________________
Office address: ________________________________________________________________________
Diagnosis: __________________________________________

Request is for:
☐ Medical coverage/billing through DME supplier
☐ Pharmacy coverage/billing through prescription; only available for commercial/employer sponsored insurance (pump supplies are only available through CVS mail order)

Please check boxes for ALL needed supplies and take note of the following:
- Clinical notes are required that document criteria for approval have been met (see last 2 pages).
- Approval duration will be for 1 year unless indicated otherwise.
- Approval for new CGM readers/receivers and insulin pumps will only be granted once every 4 years. If a CGM receiver malfunctions after 1-year warranty expires or newer model is needed, consideration will be given for early replacement.

Insulin Pumps and related supplies: [Note: original pump should be billed medically]
☐ Omnipod
  ☐ Freestyle test strips (Freestyle meter built in to system)
☐ Omnipod DASH
  ☐ Contour Next One test strips (obtain meter from manufacturer)
☐ VGo
☐ Medtronic (list specific pump type ________________________)
  ☐ Reservoirs/cartridges; note quantity if needs to change more often than every 72hrs ___
  ☐ Infusion set (ex. PARADIGM SILHOUETTE)
  ☐ Other: ______________________________________________________________
☐ Tandem (list specific pump type ________________________)
  ☐ Reservoirs/cartridges; note quantity if needs to change more often than every 72hrs ___
  ☐ Infusion Set (ex. Autosoft)
  ☐ Other: ______________________________________________________________
Continuous Glucose Monitors (CGM): [Note: Dexcom is preferred for pharmacy formulary, but exceptions are considered]
☐ Dexcom (list specific product/model) ______________________________
  ☐ Transmitter (approval will be for 1 every 90 days)
  ☐ Sensor (1 per every 7 days for G5, 1 per 10 days for G6)
  ☐ Receiver (1 every 4 years)
☐ Free Style Libre reason for use over Dexcom ______________________________
  ☐ Reader (1 every 4 years)
  ☐ Sensor (indicate 10 day sensor or 14 day sensor) __________________________
☐ Medtronic Guardian Connect reason for use over Dexcom __________________________
  ☐ Transmitter (1 per year)
  ☐ Sensor (1 per 7 days)

Standard test strips for blood glucose monitor:
• Initial monitor should be obtained from manufacturer or with copay card.
• One Touch test strips are the preferred formulary option and pay without prior authorization within quantity limits (QL).
• Brand exceptions are considered for use with certain pump systems that require a specific brand. QL of 5 per day apply (50 per month if also using Dexcom or FreeStyle Libre).

Rationale for needing to exceed QL of 5 per day or use a different brand other than One Touch:
__________________________________________________________________________
__________________________________________________________________________

Lancets are covered within QL of 5 per day unless rationale provided above for more frequent testing.

Continuous Glucose Monitors (CGMs)

New start Criteria
☐ Patient is a Type 1 Diabetic currently managed by an endocrinologist OR a provider with expertise in Diabetes care working in conjunction with an endocrinologist.

OR

☐ Patient is a Type 2 Diabetic or has Gestational Diabetes and meets ALL of the following:
  ☐ The patient has completed a comprehensive diabetes education program and has ongoing oversight by a certified diabetes educator.
  ☐ The patient has a need to monitor blood sugars at least 3 times a day and the data will be used to adjust therapy and/or make lifestyle changes.
  ☐ The patient’s blood sugars are uncontrolled with the current monitoring plan or the patient is experiencing frequent asymptomatic hypoglycemia (or severe hypoglycemia with no obviously preventable precipitating cause).
  ☐ The patient is insulin dependent.

Explanation of medical necessity if above not met ______________________________
Continuation of care renewals for CGM:

☐ The patient is already using the requested CGM.
☐ HbA1c has improved or the number of hypoglycemic episodes has been reduced since starting the CGM.
☐ Data is being collected and reviewed on a regular basis.

**Please confirm and attest that ALL criteria are met by signing the form and submitting clinical documentation for support.**

[Continue to next page for insulin pump criteria or sign here if request is only for CGM]

Signature of provider/provider representative ________________________    date _________________

Insulin Pumps

New start Criteria

☐ Patient is a Type 1 Diabetic currently managed by an endocrinologist OR a provider with expertise in Diabetes care working in conjunction with an endocrinologist.

OR

☐ Patient is a Type 2 Diabetic or has Gestational Diabetes, is insulin dependent and meets ALL of the following:
   ☐ The patient has completed a comprehensive diabetes education program and has ongoing oversight by a certified diabetes educator.
   ☐ The patient has demonstrated compliance with blood glucose monitoring.
   ☐ The patient has a history of suboptimal blood sugar control despite current insulin regimen (ex. repeated hypoglycemia, wide variations in blood sugars, frequent hyperglycemia, DKA).

Explanation of medical necessity if above not met __________________________________________

Continuation of care renewals for insulin pumps:

☐ The insulin pump has resulted in positive outcomes regarding blood sugar control.
☐ The patient has demonstrated the ability to appropriately manage pump settings and monitoring.

**Please confirm and attest that ALL criteria are met by signing the form and submitting clinical documentation for support.**

Signature of provider/provider representative ________________________    date _________________
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.

<table>
<thead>
<tr>
<th>HCPCS CODES</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>A4222</td>
<td>Infusion supplies for external drug infusion pump, per cassette or bag</td>
</tr>
<tr>
<td>A4223</td>
<td>Infusion supplies not used with external infusion pump, per cassette or bag</td>
</tr>
<tr>
<td>A4224</td>
<td>Supplies for maintenance of insulin infusion catheter, per week</td>
</tr>
<tr>
<td>A4225</td>
<td>Supplies for external insulin infusion pump, syringe type cartridge, sterile, each</td>
</tr>
<tr>
<td>A4226</td>
<td>Supplies for maintenance of insulin infusion pump with dosage rate adjustment using therapeutic continuous glucose sensing, per week</td>
</tr>
<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 <em>(used for the Omni Pods)</em></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>E0607</td>
<td>Home blood glucose monitor <em>(Omnipod Personal Diabetes Manager (PDM))</em> <em>(supplied by the manufacturer)</em></td>
</tr>
<tr>
<td>E0784</td>
<td>External ambulatory infusion pump, insulin <em>(should not be used for the Omnipo, this is no separate “pump” for Omnipo)</em></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</td>
</tr>
<tr>
<td>K0554</td>
<td>Receiver (monitor); dedicated, for use with therapeutic continuous glucose monitoring system</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>
</tr>
<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 <em>(for physician interpretation of data, use CPT code)</em></td>
</tr>
<tr>
<td>S1031</td>
<td>Continuous noninvasive glucose monitoring device rental including sensor, sensor replacement, and download to monitor <em>(for physician interpretation of data, use CPT code)</em></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>
</tbody>
</table>

<table>
<thead>
<tr>
<th>CPT CODES</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<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>
<tr>
<td>Code</td>
<td>Description</td>
</tr>
<tr>
<td>--------</td>
<td>-----------------------------------------------------------------------------</td>
</tr>
<tr>
<td>95250</td>
<td>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</td>
</tr>
<tr>
<td>95251</td>
<td>Ambulatory continuous glucose monitoring of interstitial tissue fluid via a subcutaneous sensor for a minimum 72 hours; analysis, interpretation and report</td>
</tr>
<tr>
<td>0446T</td>
<td>Creation of subcutaneous pocket with insertion of implantable interstitial glucose sensor, including system activation and patient training</td>
</tr>
<tr>
<td>0447T</td>
<td>Removal of implantable interstitial glucose sensor from subcutaneous pocket via incision</td>
</tr>
<tr>
<td>0448T</td>
<td>Removal of implantable interstitial glucose sensor with creation of subcutaneous pocket at different anatomic site and insertion of new implantable sensor, including system activation</td>
</tr>
</tbody>
</table>

**Non-Covered, not all-inclusive**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>A4210</td>
<td>Needle-free injection device, each</td>
</tr>
<tr>
<td>A4257</td>
<td>Replacement lens shield cartridge for use with laser skin piercing device, each</td>
</tr>
<tr>
<td>A9280</td>
<td>Alert or alarm device, not otherwise classified [hypoglycemic wristband alarm (e.g., Sleep Sentry)]</td>
</tr>
<tr>
<td>C1788</td>
<td>Prot, indwelling (implantable)</td>
</tr>
<tr>
<td>E0620</td>
<td>Skin piercing device for collection of capillary blood, laser, each</td>
</tr>
<tr>
<td>E2100</td>
<td>Blood glucose monitor with integrated voice synthesizer</td>
</tr>
</tbody>
</table>

**ICD-10 Codes** that may apply:

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>E08.00-E08.9</td>
<td>Diabetes mellitus due to underlying condition</td>
</tr>
<tr>
<td>E09.00-E09.9</td>
<td>Drug or chemical induced diabetes mellitus</td>
</tr>
<tr>
<td>E10.10-E10.9</td>
<td>Type 1 diabetes mellitus</td>
</tr>
<tr>
<td>E11.00-E11.9</td>
<td>Type 2 diabetes mellitus</td>
</tr>
<tr>
<td>E13.0-E13.9</td>
<td>Other specified diabetes mellitus</td>
</tr>
<tr>
<td>O24.011-O24.93</td>
<td>Diabetes mellitus in pregnancy, childbirth, and the puerperium</td>
</tr>
<tr>
<td>O99.810-O99.815</td>
<td>Abnormal glucose complicating pregnancy, childbirth and the puerperium</td>
</tr>
</tbody>
</table>

**REVISION HISTORY EXPLANATION**

**ORIGINAL EFFECTIVE DATE: 12/01/2008**

<table>
<thead>
<tr>
<th>Date</th>
<th>Description</th>
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</thead>
<tbody>
<tr>
<td>06/01/09</td>
<td>Updated</td>
</tr>
<tr>
<td>06/15/09</td>
<td>Clarification of verbiage</td>
</tr>
<tr>
<td>09/01/11</td>
<td>Updated</td>
</tr>
<tr>
<td>09/24/11</td>
<td>Replacement clarification</td>
</tr>
<tr>
<td>06/01/12</td>
<td>Updated</td>
</tr>
<tr>
<td>07/11/12</td>
<td>Added Exception for OmniPod coverage per TAWG approval.</td>
</tr>
<tr>
<td>02/11/14</td>
<td>Policy reviewed and updated to reflect most current clinical evidence per Medical Policy Steering Committee.</td>
</tr>
</tbody>
</table>
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 (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).

07/10/18: 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.

08/18/19: 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.

12/01/19: 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.


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 (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).

07/10/18: 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.

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12/01/19: 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.


PG0177 – 12/15/2020
REFERENCES/RESOURCES
Centers for Medicare and Medicaid Services, CMS Manual System and other CMS publications and services
Ohio Department of Medicaid
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