Medical Policy

Continuous Glucose Monitoring Systems and Insulin Delivery Devices

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Product Applicability

- All Plan+ Products

Well Sense Health Plan
- New Hampshire Medicaid
- NH Health Protection Program

Boston Medical Center HealthNet Plan
- MassHealth
- Qualified Health Plans/ConnectorCare/Employer Choice Direct
- Senior Care Options ◊

Notes: 14
+ Disclaimer and audit information is located at the end of this document.
◊ The guidelines included in this Plan policy are applicable to members enrolled in Senior Care Options only if there are no criteria established for the specified service in a Centers for Medicare & Medicaid Services (CMS) national coverage determination (NCD) or local coverage determination (LCD) on the date of the prior authorization request. Review the member’s product-specific benefit documents at www.SeniorsGetMore.org to determine coverage guidelines for Senior Care Options.

Policy Summary

The Plan considers the use of short-term continuous glucose monitoring systems (CGMS) in the outpatient setting medically necessary to monitor glucose levels in interstitial fluid for up to 3 days (i.e., 72 hours) in type 1 and type 2 diabetics as an adjunct to finger stick testing when the Plan’s applicable medical criteria are met. Long-term use of CGMS or combined CGMS with external insulin pump using continuous subcutaneous insulin infusion (CSII) in the outpatient setting is considered medically necessary to monitor glucose levels in interstitial fluid as an adjunct to finger stick testing with type 1 diabetic members when the Plan’s medical criteria are met for long-term continuous

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glucose monitoring. See the Plan’s medical criteria in the Medical Policy Statement and Limitations sections of this policy. Insulin delivery devices are considered medically necessary according to applicable Plan criteria or guidelines established by Northwood, Inc. (Northwood). Prior authorization is required by the Plan or Northwood (managing durable medical equipment [DME] authorization on behalf of Plan members) for CGMS and/or external insulin delivery systems when provided in the outpatient setting, as specified below in this section and in the Description of Item or Service section (categorized by type of device).

It will be determined during the Plan’s prior authorization process if the service is considered medically necessary for the requested indication. See the Plan’s Medically Necessary medical policy (policy number OCA 3.14) for the product-specific definitions of medically necessary treatment. Plan or Northwood prior authorization is NOT required for the use of implantable insulin pumps (IIP). An additional Plan prior authorization is NOT required for CGMS and/or insulin delivery systems provided in an inpatient setting when the inpatient admission has been authorized by the Plan.

Prior authorization is required either by the Plan or Northwood (on behalf of Plan members) according to service/device and provider type. Acute, sub-acute/intermediate care, and rehabilitation hospitals/facilities, hearing aid providers, physician and mid-level clinicians and corresponding locations, allied health practitioners (including podiatrists, chiropractors, physical therapists, occupational therapists, speech therapists and optometrists), outpatient facilities (including outpatient hospitals, ambulatory surgery centers, labs, emergency rooms, and urgent care centers), cardiac monitoring providers, behavioral health providers, and ambulance providers must contact the Plan (rather than Northwood) to obtain prior authorization for CGMS, combined CGMS with external insulin pumps, and single-use, disposable and nonprogrammable/mechanical (non-electric) insulin infusion devices (e.g., V-Go™ Disposable Insulin Delivery Device). These provider types should contact Northwood (rather than the Plan) for prior authorization for the use of non-disposable external insulin infusion pumps and single-use, disposable and programmable external insulin infusion pumps (e.g., OmniPod® Insulin Management System) for Plan members.

DME providers, medical supply providers, pharmacy providers, home infusion providers, home care providers, and specialty pharmacy providers must contact Northwood (rather than the Plan) to verify member coverage, determine reimbursement guidelines, and obtain prior authorization for DME, including but not limited to long-term CGMS, combined CGMS with external insulin infusion pump, home blood glucose monitors, associated DME supplies and accessories, and external insulin infusion pumps (including non-disposable external insulin pumps and disposable external insulin infusion pumps programmable with wireless technology). These provider types (including DME providers) dispensing and billing for DME services should contact Northwood at www.northwoodinc.com or by phone at 1-866-802-6471 to obtain prior authorization. For single-use, disposable and nonprogrammable/mechanical (non-electric) insulin infusion pumps (e.g., V-Go™ Disposable Insulin Delivery Device), prior authorization requests are managed by the Plan rather than Northwood for all provider types.
Continuous Glucose Monitoring Systems (CGMS): Minimally invasive or noninvasive devices that measure glucose levels in the interstitial fluid surrounding skin cells (rather than measure blood glucose levels) over a short-term period of several days or for long-term use to provide continuous information about glucose fluctuations that is not otherwise captured by intermittent testing. The CGMS measures glucose levels with minimal invasiveness through continuous measurement of interstitial fluid (ISF) with a disposable transcutaneous implanted sensor, or with the noninvasive method of applying an electric current (i.e., reverse iontophoresis) through the skin to blood vessels in the body. The disposable transcutaneous sensor can continuously measure glucose for 3 to 7 days and then the sensor must be replaced, depending upon the specific device used. CGMS also have alarms designed to warn the patient about impending hypoglycemia or hyperglycemia. Although devices measure glucose in interstitial fluid on a periodic rather than a continuous basis, this type of monitoring is referred to as continuous glucose monitoring (CGM).

Monitoring glucose in interstitial fluid automatically measures glucose values throughout the day, producing data that show the trends in glucose levels to supplement the isolated glucose measurements. The readings from the CGMS are intended to supplement, NOT replace, information obtained from standard home glucose monitoring devices and finger sticks. Several CGMS have been approved by the U. S. Food and Drug Administration (FDA). In addition to stand-alone continuous glucose monitors, several insulin pump systems have included a built-in continuous glucose monitor. Continuous glucose monitoring (CGM) in conjunction with intensive insulin regimens can be a useful tool to lower hemoglobin A1c levels. Some types of CGMS are designed for short-term diagnostic or professional use, storing retrospective data to review at a later time. Other types of CGMS are designed for long-term use and display information in real-time to allow the patient to take action based on the data. Examples of FDA-approved CGMS include but are not limited to the following: MiniMed Continuous Subcutaneous Glucose Monitoring System and MiniMed iPRO2 for short-term CGM, Dexcom G4 PLATINUM Systems with Share, Dexcom G5 Mobile CGM System, and Guardian REAL-Time Continuous Glucose Monitoring System for long-term CGM. A long-term CGMS may be used as a stand-alone device or as a combined continuous subcutaneous insulin infusion and blood glucose monitoring system. In addition to stand-alone CGMs, several insulin pump systems have included a built-in CGMS (as specified in the description below). DME providers dispensing and billing for DME services ((including DME providers, medical supply providers, pharmacy providers, home infusion providers, home care providers, and specialty pharmacy providers) should contact Northwood at www.northwoodinc.com or by phone at 1-866-802-6471 to obtain prior authorization. Plan prior authorization (rather than Northwood authorization) is required for requests from all other provider types for CGMS, as specified in the Summary section of this policy.

Combined Continuous Glucose Monitoring System (CGMS) with External Insulin Pump Using Continuous Subcutaneous Insulin Infusion (CSII): The device integrates an insulin pump with real-time continuous glucose monitoring, incorporating features such as predictive alerts to prevent and identify dangerous high or low blood glucose events. Types of combination devices include a CGMS (serving as sensor/transmitter) with external insulin pump using continuous subcutaneous insulin infusion (e.g.,
MiniMed Paradigm REAL-Time Revel System and Animas Vibe System) or CGMS (serving as sensor/transmitter) with wireless communication to a compatible external insulin pump and threshold suspend feature (e.g., MiniMed 530G System). A threshold suspend feature 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 and patient intervention may be required. The readings from the combined CGMS with external insulin pump are intended to supplement, not replace, information obtained from standard home glucose monitoring devices and finger sticks. A combination CGMS with external insulin pump using continuous subcutaneous insulin infusion is considered medically necessary in the outpatient setting when applicable criteria specified in the Medical Policy Statement and Limitations sections of this policy are met. Although devices measure glucose in interstitial fluid on a periodic rather than a continuous basis, this type of monitoring is referred to a combination CGMS with external insulin pump. DME providers dispensing and billing for DME services (including DME providers, medical supply providers, pharmacy providers, home infusion providers, home care providers, and specialty pharmacy providers) should contact Northwood at www.northwoodinc.com or by phone at 1-866-802-6471 to obtain prior authorization. **Plan prior authorization (rather than Northwood authorization) is required for requests from all other provider types for combined CGMS with external insulin pumps,** as specified in the Summary section of this policy.

**External Insulin Infusion Pumps:** External insulin delivery devices are used to administer insulin via subcutaneous or intraperitoneal routes in a programmed and controlled manner to diabetic individuals (e.g., ACCU-CHEK Spirit Insulin Pump). These devices work with a separate glucometer through manual or remote functions. The goals of insulin pump therapy are to achieve near-normal control of blood glucose levels. External insulin infusion pumps may be non-disposable or disposable; a disposable, single-use pump may be programmable with wireless technology (e.g., OmniPod® Insulin Management System by Insulin Corp. with each unit used up to three [3] days before replacement) or a disposable, single-use and nonprogrammable, mechanical (non-electric) insulin infusion device (e.g., V-Go™ Disposable Insulin Delivery Device by Valeritas Inc. with each unit replaced daily). **Requests for non-disposable external insulin pumps and single-use and disposable, programmable external insulin infusion pumps (and associated components and supplies) are managed for members by Northwood for all provider types.** For single-use, disposable and nonprogrammable/mechanical (non-electric) insulin infusion devices (e.g., V-Go™ Disposable Insulin Delivery Device), prior authorization requests are managed by the Plan rather than Northwood for all provider types. See the Limitations section of this policy for guidelines related to the use of single-use and disposable, programmable external insulin pumps with wireless technology as components of CGMS.

**V-Go® Disposable Insulin Delivery Device:** V-Go® is a mechanical (no electronics), self-contained, sterile, patient fillable, single-use disposable insulin infusion device with an integrated stainless steel subcutaneous needle. It is a wearable device for adults with type 2 diabetes designed for the subcutaneous infusion of insulin for the management of diabetes mellitus in persons requiring insulin. After filling the V-Go with insulin, the device is secured to the patient’s skin over the infusion site with an adhesive-backed foam pad, which is attached to the back of the pump. Once activated, the V-Go delivers a continuous infusion of insulin at a fixed rate; different device models (e.g., 20, 30 and 40 units/per single 24-hour period) are available for continuous subcutaneous infusion. In addition, the

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device allows the user to initiate bolus injections to supplement the patient’s daily basal insulin requirements in 2-unit increments (up to 36 units per a single 24-hour time period). A window in the top of the pump allows the user to see into the reservoir to check the drug and to monitor the progress of the infusion. The device was developed by Valeritas and has received 510(k) clearance from the FDA for adult patients requiring insulin but is not cleared specifically for use in pediatric patients. The Plan considers the use of a single-use, disposable and nonprogrammable/mechanical (non-electric) insulin infusion device (e.g., V-Go™ Disposable Insulin Delivery Device) NOT medically necessary under any circumstance because the effectiveness of this type of disposable insulin delivery system has not been established as a clinically appropriate alternative to standard pump insulin therapy, as stated in the Limitations section of this policy. Prior authorization requests for all single-use, disposable and nonprogrammable/mechanical (non-electric) insulin infusion devices are managed by the Plan (rather than by Northwood) for all provider types.

Implantable Insulin Pumps (IIPs): IIPs are used to deliver insulin to diabetic patients via intraperitoneal or intravenous routes in a programmed and controlled manner. The goal of IIP therapy is to achieve control of blood glucose levels, thereby reducing the risk of acute metabolic complications, such as hypoglycemic or hyperglycemic episodes and ketoacidosis, and delaying the onset and progression of late-stage macrovascular and microvascular complications. There is evidence that delivery of intraperitoneal insulin via implantable insulin pumps (IIPs) can provide improved glycemic control, reduce hyperinsulinemia, decrease risk of hypoglycemic episodes, and improve lipid profiles and liver function for patients with both type 1 and type 2 diabetes mellitus. The effects of the IIP are comparable or superior to those of intensive subcutaneous (SC) administration of insulin. Although further improvements in design are needed to reduce the incidence of catheter obstruction, IIPs are a promising new technology for the treatment of insulin-requiring diabetes. IIP therapy is considered to be safe and effective for the treatment of patients with type 1 or insulin-requiring type 2 diabetes mellitus who do not achieve adequate glycemic control with intensive insulin therapy delivered via SC injection or an external insulin pump. At the present time, IIPs are available only in a clinical trial setting. Although IIP therapy allows for the continuous infusion of insulin directly into the intraperitoneal or intravenous space, patients are still required to monitor their blood glucose frequently and may need occasional SC injections of insulin. Prior authorization from the Plan or Northwood is NOT required for the use of IIP.

Medical Policy Statement

The Plan considers the use of a single-use, disposable and nonprogrammable/mechanical insulin infusion device (e.g., V-Go®) to NOT be medically necessary under any circumstance because the effectiveness of this type of device has not been established as a clinically appropriate alternative to standard pump insulin therapy. See the Limitations section of this policy for guidelines related to the use of a disposable, programmable external insulin pump with wireless technology as a component of a continuous glucose monitoring system (CGMS).

The use of a continuous glucose monitoring system (CGMS) or combined CGMS with external insulin pump using continuous subcutaneous insulin infusion (CSII) is considered medically necessary when...
applicable Plan criteria are met. If a CGMS or combined CGMS with external insulin pump using CSII is approved by the Plan in the outpatient setting, the authorization period is six (6) months for the purchase of the receiver and transmitter. A lifetime authorization will be granted for sensors and supplies related to continuous glucose monitoring devices if the service is approved by the Plan. An additional Plan prior authorization is NOT required for CGMS and insulin delivery systems provided in an inpatient setting when the inpatient admission has been authorized by the Plan. (Note: When the device, sensor, and/or related supplies are authorized by Northwood rather than the Plan, the authorization period and guidelines for purchase are established by Northwood. Northwood will notify the requesting provider of these requirements.)

For CGMS or combined CGMS external insulin pump with CSII to be considered medically necessary, the following applicable medical criteria must be met and documented in the member’s medical record, as specified below in item 1 (Member Criteria for CGMS or Combined CGMS with External Insulin Pump) and item 2 (Medical Criteria by Treatment Time Frame):

1. Member Criteria for CGMS or Combined CGMS with External Insulin Pump:

   ALL of the following member criteria must be met, as specified below in items a through e:

   a. Member has had a consultation with an endocrinologist; AND

   b. Member is compliant with frequent self-monitoring with at least four (4) finger sticks per day; AND

   c. CGMS will be used by the member as an adjunct to finger stick testing of blood glucose; AND

   d. The member has type 1 diabetes (for short-term and long-term continuous glucose monitoring) or type 2 diabetes (for short-term continuous glucose monitoring up to three [3] days) according to criteria in item 2 of this section (i.e., Medical Criteria by Treatment Time Frame); AND

   e. The applicable age-specific member criteria are met, as specified below in item 1 (for adult members) or item 2 (for pediatric members):

      (1) Criteria for Adult Members (Age 18 or Older on the Date of Service):

      At least ONE (1) of the following conditions is applicable for the adult member at the time CGM is initiated, as specified below in items (a) through (f):

      (a) Discordance between A1c and blood glucose levels; OR

      (b) Hypoglycemic unawareness; OR

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(c) Postprandial hyperglycemia; OR

(d) Pregnancy with poorly controlled type 1 diabetes (according to the definition of type 1 diabetes in the Definitions section of this policy); OR

(e) Recurrent diabetic ketoacidosis; OR

(f) Recurrent episodes of severe hypoglycemia (i.e., blood glucose less than 50mg/dl) despite appropriate modifications in medication regime; OR

(2) Criteria for Pediatric Members (Under the Age of 18 on the Date of Service):

ALL of the following conditions are applicable for the pediatric member at the time CGM is initiated, as specified below in items (a) through (c):

(a) Member is two (2) years of age or older on the date of service; AND

(b) The endocrinologist managing the member’s diabetes confirms the member or caregiver is capable of using a long-term CGM system; AND

(c) At least ONE (1) of the following criteria is met, as specified below in item i or item ii:

   i. The member has HbA1c levels below 7.0%, and the CGM device is medically necessary to limit the risk of hypoglycemia; OR

   ii. A member with HbA1c levels greater than 7.0% is willing and able to use the CGM device on a daily basis; AND

2. Medical Criteria by Treatment Time Frame:

ONE (1) of the following applicable criteria must be met, as specified below in item a (for short-term use of CGMS), item b (for long-term use of CGMS), or item c (for long-term use of a combination CGMS with external insulin pump using continuous subcutaneous insulin infusion):

a. **Short-Term Use of Continuous Glucose Monitoring System (CGMS):**

   BOTH of the following criteria are met for short-term use of a CGMS, as specified below in item (1) and item (2):

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(1) ONE (1) of the following applicable criteria is met for short-term use of a CGMS, as specified below in item (a) for a member with type 2 diabetes or item (b) for a member with type 1 diabetes:

(a) Up to 3 Days (72 Hours):

The member is diagnosed with type 2 diabetes according to the definition of type 2 diabetes in the Definitions section of this policy (and this criterion is not applicable for pediatric members, as specified above in the criteria for pediatric members); OR

(b) Up to 7 Days:

The member is diagnosed with type 1 diabetes according to the definition of type 1 diabetes in the Definitions section of this policy; AND

(2) The requested device is being prescribed according to its FDA-approved clearance and guideline information, including intended use for the member’s age and medical condition; OR

b. Long-Term Use of Continuous Glucose Monitoring System (CGMS) for Greater than 7 Days:

A long-term CGMS may be used as a stand-alone device or as a combined CGMS (serving as sensor/transmitter) with external insulin pump using continuous subcutaneous insulin infusion. (See item c below for medical necessity criteria for the use of a combined CGMS with external insulin pump with continuous subcutaneous insulin infusion.) ALL of the following criteria must be met for long-term CGMS as a stand-alone device to be considered medically necessary, as specified below in items (1) through (6):

(1) The member is diagnosed with type 1 diabetes (according to the definition of type 1 diabetes in the Definitions section of this policy); AND

(2) The member has had previous short-term CGM over the past year for an indication that meets Plan criteria, and the results of the CGM were used to make the necessary alterations in insulin administration, behavioral modifications, and hypoglycemic awareness; AND

(3) Previous use of CGM for the member has resulted in revisions to diabetic care management with a reduction of hypoglycemic events; AND

(4) The member requires insulin injections three (3) or more times per day or a medically necessary insulin pump is used for maintenance of blood sugar control; AND

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(5) The member is still experiencing or remains at risk for ONE (1) of the following conditions, as specified below in items (a) through (f):

(a) Discordance between A1c and blood glucose levels with A1c level above or below 7.0%; OR

(b) Hypoglycemic unawareness; OR

(c) Pregnancy with poorly controlled type 1 diabetes (according to the definition of type 1 diabetes in the Definitions section of this policy); an alternative criterion specified in this item (5) must be met for long-term CGM after completion of pregnancy; OR

(d) Recurrent diabetic ketoacidosis; OR

(e) Recurrent episodes of severe hypoglycemia (i.e., blood glucose less than 50mg/dl) despite appropriate modifications in medication regime; OR

(f) Suspected postprandial hyperglycemia; AND

(6) The requested device is being prescribed according to its FDA-approved clearance and guideline information, including intended use for the member’s age and medical condition; OR

c. **Long-Term Use of Combined Continuous Glucose Monitoring System (CGMS) with External Insulin Pump Using Continuous Subcutaneous Insulin Infusion for Greater than 7 Days:**

A long-term CGMS may be used as a stand-alone device or as a combined CGMS (serving as sensor/transmitter) with an external insulin pump using continuous subcutaneous insulin infusion. (See item b above for medical necessity criteria for the use of long-term CGMS as a stand-alone device.) ALL of the following criteria must be met for a combined CGMS with external insulin pump using continuous subcutaneous insulin infusion to be considered medically necessary, as specified below in items (1) through (3):

(1) The criteria for a long-term continuous glucose monitoring system has been met as noted above in item b of this section; AND

(2) Member does NOT have existing devices that are fully functional and duplicate the same purpose that is served by a combined CGMS with wireless communication capability to an external insulin pump; AND
The requested device is being prescribed according to its FDA-approved clearance and guideline information for a combined CGMS with an external insulin pump with subcutaneous insulin, including intended use for the member’s age and medical condition.

Limitations

The Plan considers the use of continuous glucose monitoring systems (CGMS) to be experimental and investigational when applicable criteria specified in the Medical Policy Statement section of this policy are NOT met. The device must be FDA approved and used according to FDA-approved indications and guidelines. Review the Plan’s Experimental and Investigational Treatment medical policy (policy number OCA 3.12) for product-specific definitions of experimental or investigational treatment. Additional limitations are specified below in items 1 through 8:

1. **Authorization Period for Receiver, Transmitter, Sensor, and Supplies in Outpatient Setting:**

   If a CGMS or combined CGMS with external insulin pump using continuous subcutaneous insulin infusion (CSII) is approved by the Plan in the outpatient setting, the authorization period is **six (6) months** for the purchase of the receiver and transmitter. A **lifetime authorization** will be granted for sensors and supplies related to continuous glucose monitoring devices if the service is approved by the Plan. (Note: When the device, sensor, and/or related supplies are authorized by Northwood rather than the Plan, the authorization period and guidelines for purchase are established by Northwood. Northwood will notify the requesting provider of these requirements.)

2. **Closed-loop Glucose Management Systems:**

   The Plan considers engineered closed-loop glucose management systems NOT medically necessary when used in the **outpatient setting** due to insufficient evidence to assess the long-term impact on the health outcomes or patient management (even when the device is FDA approved). Closed-loop systems function as **continuous** and automatic glucose management systems with little or no input from the patient and include closed-loop CGMS combined with continuous insulin infusion, fully automated “artificial pancreas” (or bi-hormonal bionic pancreas), and/or hybrid closed-loop insulin delivery systems (e.g., MiniMed 670G by Medtronic). See the Definitions section of this policy for a description of these systems. According to the Centers for Medicare & Medicaid Services (CMS) National Coverage Determination (NCD) for Closed-Loop Blood Glucose Control Device (CBGCD) (40.3), the use of the CBGCD is covered **ONLY for short-term management of insulin dependent diabetics in crisis situations, in a hospital inpatient setting, and only under the direction of specially trained medical personnel.** The use of CBGCD for Senior Care Options (SCO) members must follow clinical guidelines included in NCD 40.3 and Plan authorization for the service would be included in the authorization and reimbursement of the member’s inpatient admission (rather than a separate prior authorization for this device).
3. **Fully Implanted Glucose Sensor:**

The Plan considers the use of a fully implantable glucose sensor (e.g., GlySens ICGM system and the Eversense CGM sensor) to be experimental and investigational. It is proposed that a fully implantable CGM sensor (implanted subcutaneously up to 90 days for Eversense CGM) may provide additional ease of use over currently marketed CGMS with a transcutaneous sensor (which is replaced under the skin every 3 to 7 days); the clinical effectiveness for a fully implanted glucose sensor has NOT been established.

4. **Inpatient Admission:**

An additional Plan prior authorization is NOT required for CGMS and insulin delivery systems provided in an inpatient setting when the inpatient admission has been authorized by the Plan.

5. **Plan Medical Director Review Required:**

ANY of the following types of prior authorization requests require Plan Medical Director review, as specified below in items a through d:

a. **Member Younger than Two (2) Years of Age:**

Plan Medical Director review is required for requests for a CGMS (or combined CGMS with external insulin pump using continuous subcutaneous insulin infusion) when a member is younger than two (2) years of age (i.e., before the member’s second birthday) on the date of service. Applicable clinical information must be submitted by the treating provider with documentation that the device is FDA approved for the member’s age and can be adequately maintained by the member’s caregiver.

b. **Noncompliance or Ineffective Use of CGMS:**

Plan Medical Director review is required for the ongoing use of a CGMS (or combined CGMS with external insulin pump using continuous subcutaneous insulin infusion) when the member (or family member or caregiver on behalf of the member) consistently is unable to manage the device properly, the member (or family member or caregiver on behalf of the member) does not routinely use the device according to product guidelines, and/or the device consistently fails to resolve hypoglycemia, improve or maintain A1c, and/or prevent hospitalization related to glucose management for the member. In these cases, applicable clinical information will be evaluated by the Plan Medical Director to determine the medical necessity for the ongoing use of a CGMS (or use of a combined CGMS with external insulin pump using continuous subcutaneous insulin infusion) or discontinuation of the device with the implementation of an alternate treatment plan. Applicable clinical information must be submitted to the Plan by the treating provider and include the member’s medical history,

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documentation of diabetes education received by the member (or family member or caregiver on behalf of the member), treatment to date, glucose reading logs, pertinent laboratory testing, and individualized treatment plan.

c. **Replacement System Expected to Provide Clinically Significant Improvements:**

When the replacement system is expected to provide clinically significant improvements for the member’s glucose management, medical record documentation must be submitted to the Plan’s Medical Director for individual consideration in support of the prior authorization request (including documentation of the member’s medical condition and how the product-specific features of the device will be clinically useful to the member’s medical management beyond those features included in the member’s current CGMS).

d. **Short-term Use More Frequent Than Every Three (3) Months:**

A request for short-term use of continuous glucose monitoring (CGM) for a member more often than every three (3) months requires Plan Medical Director review (excluding a member who meets criteria for long-term use of CGM). Applicable clinical information must be submitted by the treating provider and include the member’s medical history, documentation of diabetes education received by the member (or family member or caregiver on behalf of the member), treatment to date, glucose reading logs, pertinent laboratory testing, and individualized treatment plan.

6. **Remote Wireless Monitoring:**

The Plan considers remote wireless glucose monitoring unproven and NOT medically necessary for managing patients with diabetes due to insufficient published evidence on clinical outcomes, either as a feature of a CGMS or as an attachment device such as a mobile application with real-time display of interstitial glucose readings. Additional examples of wireless glucose monitoring devices include the OmniPod® Insulin Management System (by Insulet Corp.), Dexcom G5® Mobile CGM System (by Dexcom, Inc.), and Eversense CGM System (by Senseonics). The Plan provides no additional reimbursement for a wireless transmission feature that is integrated into a CGMS or combined with CGMS with external insulin pump because the wireless transmission function is considered a convenience feature.

7. **Single-use, Disposable, and Nonprogrammable External Insulin Pump:**

The use of a single-use, disposable and nonprogrammable/mechanical (non-electric) external insulin pump (e.g., V-Go™ Disposable Insulin Delivery Device) is considered NOT medically necessary under any circumstance because the effectiveness of this type of device has not been established as a clinically appropriate alternative to standard pump insulin therapy.
8. **Upgrade for New Technology:**

The replacement of a member’s currently functional CGMS or combined CGMS with external insulin pump for the sole purpose of receiving an upgraded system or the most recent technology is considered NOT medically necessary; this includes upgrades for enhanced information/wireless communication technology as a feature of the replacement device (e.g., mySentry) or an added component for CGMS, including the use of the internet and/or smart phone application for including uploading, monitoring, and/or sharing blood glucose levels as a convenience feature (e.g., MiniMed Connect).

**Definitions**

*Closed-loop Artificial Pancreas Device (APD) System:* A type of closed-loop insulin delivery system with a device or series of devices that work in concert with one another to automatically give the correct amount of insulin in response to food intake and rising blood glucose. Components of a closed-loop artificial pancreas system include continuous glucose monitoring, an algorithm that utilizes data on blood glucose levels to convert into insulin dosage calculations, and the control device that sends commands to the insulin pump to administer the calculated insulin dosage. Closed-loop APD systems are externally worn medical devices that are developed to enable people with type 1 diabetes to regulate their blood glucose levels in a more automated manner. It is a hands-free, **continuous** glycemic control utilizing digital communication technology and advanced computer algorithms. According to the Centers for Medicare & Medicaid Services (CMS) National Coverage Determination (NCD) for Closed-Loop Blood Glucose Control Device (CBGCD) (40.3), the use of the CBGCD is covered by Medicare ONLY for short-term management of insulin dependent diabetics in crisis situations, in a hospital inpatient setting, and only under the direction of specially trained medical personnel. The Plan considers the use of a closed-loop APD system NOT medically necessary when used in the outpatient setting due to insufficient evidence to assess the long-term impact on the health outcomes or patient management (even when the device is FDA approved).

*Closed-loop Insulin Delivery System:* A system to maintain glucose control with **continuous** glucose monitoring and minimal involvement from the diabetic patient. An effective closed-loop system must determine the insulin requirement in real time, regardless of the situation, and deliver the proper insulin dosage based on the patient’s changing activity levels. Ideally, the closed-loop system would exist internally (eliminating the requirement of wearing external equipment) and would aim to significantly reduce the number of injections (or eliminate injections) required. The best closed-loop delivery system would repair the body’s natural ability to infuse insulin with methods such as pancreas transplant, implanting encapsulated islet cells from a healthy pancreas (in the hopes that the immune response will be avoided and the islet beta cells will produce insulin consistent with a healthy pancreas), or engineered solutions such as a closed-loop artificial pancreas device system or hybrid closed-loop glucose management system. According to the Centers for Medicare & Medicaid Services (CMS) National Coverage Determination (NCD) for Closed-Loop Blood Glucose Control Device (CBGCD) (40.3), the use of the CBGCD is covered by Medicare ONLY for short-term management of insulin dependent diabetics in crisis situations, in a hospital inpatient setting, and only under the direction of
specially trained medical personnel. The Plan considers the use of a closed-loop insulin delivery system NOT medically necessary when used in the outpatient setting due to insufficient evidence to assess the long-term impact on the health outcomes or patient management (even when the device is FDA approved).

**Dawn Phenomenon:** A spontaneous rise in blood glucose that occurs at the end of the night/early morning in patients with either type 1 or type 2 diabetes as a person's body prepares to wake up (usually 4 a.m. to 8 a.m.), because of natural changes in hormone levels (presumably to prepare the body for daytime activity after a period of fasting). The dawn phenomenon and the Somogyi effect can both cause high blood sugar levels, especially in the morning before breakfast, in people who have diabetes. To determine if an early morning high blood glucose level is caused by the dawn phenomenon or Somogyi effect for an individual with type 1 or type 2 diabetes on a traditional sleep cycle, check blood sugar levels at bedtime, around 2 a.m. to 3 a.m., and again at normal wake-up time for several days/night. If the blood glucose level is low at 2 a.m. to 3 a.m., etiology is expected to be the Somogyi effect. If the blood glucose level is normal or high at 2 a.m. to 3 a.m., the change is more likely related to the dawn phenomenon.

**Diabetes Mellitus (DM or Diabetes):** Condition characterized by hyperglycemia due to impaired pancreatic insulin secretion or inefficient use of insulin by the body. Patients with insulin-dependent (type 1) DM or insulin-requiring non-insulin-dependent (type 2) DM require chronic treatment with exogenous insulin.

**FDA Categorization of Investigational Devices:** The U.S. Food and Drug Administration (FDA) assigns a device with an FDA-approved investigational device exemption (IDE) to one of two categories: (1) experimental/investigational (Category A) devices; or (2) non-experimental/investigational (Category B) devices. The FDA notifies the Centers of Medicare & Medicaid Services (CMS), when the FDA notifies the sponsor, that the device is categorized by FDA as experimental/investigational (Category A) or non-experimental/investigational (Category B). CMS uses the categorization of the device as a factor in making Medicare coverage decisions. Non-experimental/investigational (Category B) device refers to a device believed to be in Class I or Class II, or a device believed to be in Class III for which the incremental risk is the primary risk in question (that is, underlying questions of safety and effectiveness of that device type have been resolved), or it is known that the device type can be safe and effective because, for example, other manufacturers have obtained FDA approval for that device type. (Source: 42 CFR 405.201.)

**Hemoglobin A1c (Glycated Hemoglobin, HbA1c, Hemaglobin A1c, or A1c):** Level reflects the average blood glucose concentration over the course of the red blood cell lifespan, roughly 120 days in normal individuals. It provides different, and complementary, information to a single glucose concentration. A1c provides information comparable to what might be provided by having frequent glucose values throughout the day over the course of three (3) months, determining the degree of overall glucose control in patients with diabetes mellitus. Intensive glucose control in diabetic patients, reflected in lower hemoglobin A1c values, has been shown to delay the onset and slow the progression of diabetic retinopathy, nephropathy, and neuropathy. The goal of therapy is to attain an A1c value of less than
7.0% (while minimizing hypoglycemic episodes). Lowering A1C to below or around 7% has been shown to reduce microvascular and neuropathic complications of diabetes and, if implemented soon after the diagnosis of diabetes, is associated with long-term reduction in macrovascular disease.

1. **Type 1 Diabetes Mellitus:** Chronic illness characterized by the body’s inability to produce insulin due to the autoimmune destruction of the beta cells in the pancreas. It is most common in juveniles, but it can also develop in adults in their 30s, 40s, 50s or older.

2. **Type 2 Diabetes Mellitus:** An array of dysfunctions characterized by hyperglycemia and resulting from the combination of resistance to insulin action, inadequate insulin secretion, and excessive or inappropriate glucagon secretion. Treatment for type 2 diabetes may include oral medications or insulin therapy.

**Hybrid Closed-loop Glucose Management System:** A type of closed-loop insulin delivery system that provides continuous glucose monitoring under the skin, trending of glucose levels in interstitial fluid, continuous delivery of basal insulin (at user selectable rates), and administration of insulin boluses (in user selectable amounts). These systems include a transmitter, glucose sensor, glucose meter, and an insulin pump programmed with a computer algorithm to calculate insulin doses; data are sent wirelessly to a combination insulin pump and display unit, which will automatically adjust insulin infusion to provide continuous control of glucose levels. The system requires minimal input from the individual; the user needs to enter mealtime carbohydrates, accept bolus correction recommendations, and periodically calibrate the sensor. The U. S. Food and Drug Administration (FDA) has approved the first hybrid closed-loop insulin delivery system, MiniMed 670G system (developed by Medtronic). MiniMed 670G is FDA approved for the management of Type 1 diabetes mellitus in individuals age 14 or older. The Plan considers the use of a hybrid closed-loop glucose management system NOT medically necessary when used in the outpatient setting due to insufficient evidence to assess the long-term impact on the health outcomes or patient management (even when the device is FDA approved).

**Open-loop Insulin Delivery System:** Methods of insulin delivery that focus on a patient administering insulin to oneself at different times of the day. The most common method of open-loop insulin delivery is the subcutaneous insulin injection; another example is the externally worn insulin pump.

**Somogyi Effect:** Also known as the “rebound” effect, the Somogyi effect is the tendency of the body to react to hypoglycemia by overcompensating, resulting in high blood glucose levels. The causes of Somogyi effect include excess or ill-timed insulin, missed meals or snacks, and/or inadvertent insulin administration. The Somogyi effect occurs in diabetes mellitus type 1 and is less common in diabetes mellitus type 2. The dawn phenomenon and the Somogyi effect can both cause high blood sugar levels, especially in the morning before breakfast, in people who have diabetes. To determine if an early morning high blood glucose level is caused by the dawn phenomenon or Somogyi effect for an individual with type 1 or type 2 diabetes on a traditional sleep cycle, check blood sugar levels at bedtime, around 2 a.m. to 3 a.m., and again at normal wake-up time for several days/night. If the blood glucose level is low at 2 a.m. to 3 a.m., etiology is expected to be the Somogyi effect. If the
blood glucose level is normal or high at 2 a.m. to 3 a.m., the change is more likely related to the dawn phenomenon.

**Type 1 Diabetes:**

1. **Type 1a:** Autoimmune type, characterized by positive autoantibody testing.

2. **Type 1b:** Idiopathic type, characterized by negative autoantibody testing with low C-peptide levels.

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**Applicable Coding**

The Plan uses and adopts up-to-date Current Procedural Terminology (CPT) codes from the American Medical Association (AMA), International Statistical Classification of Diseases and Related Health Problems, 10th revision (ICD-10) diagnosis codes developed by the World Health Organization and adapted in the United States by the National Center for Health Statistics (NCHS) of the Centers for Disease Control under the U.S. Department of Health and Human Services, and the Health Care Common Procedure Coding System (HCPCS) established and maintained by the Centers for Medicare & Medicaid Services (CMS). Because the AMA, NCHS, and CMS may update codes more frequently or at different intervals than Plan policy updates, the list of applicable codes included in this Plan policy is for informational purposes only, may not be all inclusive, and is subject to change without prior notification. Whether a code is listed in the Applicable Coding section of this Plan policy does not constitute or imply member coverage or provider reimbursement. Providers are responsible for reporting all services using the most up-to-date industry-standard procedure and diagnosis codes as published by the AMA, NCHS, and CMS at the time of the service.

Providers are responsible for obtaining prior authorization for the services specified in the Medical Policy Statement section and Limitation section of this Plan policy, even if an applicable code appropriately describing the service that is the subject of this Plan policy is not included in the Applicable Coding section of this Plan policy. Coverage for services is subject to benefit eligibility under the member’s benefit plan. Please refer to the member’s benefits document in effect at the time of the service to determine coverage or non-coverage as it applies to an individual member. See Plan reimbursement policies for Plan billing guidelines.

Prior authorization is required by the Plan or Northwood (managing durable medical equipment authorization on behalf of Plan members for specific provider types). Acute, sub-acute/intermediate care, and rehabilitation hospitals/facilities, hearing aid providers, physician and mid-level clinicians and corresponding locations, allied health practitioners (including podiatrists, chiropractors, physical therapists, occupational therapists, speech therapists and optometrists), outpatient facilities (including outpatient hospitals, ambulatory surgery centers, labs, emergency rooms, and urgent care centers), cardiac monitoring providers, behavioral health providers, and ambulance providers must contact the Plan (rather than Northwood) to obtain prior authorization for CGMS, combined CGMS with external insulin pumps, and single-use, disposable and nonprogrammable/mechanical (non-electric) insulin

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infusion devices (e.g., V-Go™ Disposable Insulin Delivery Device). These provider types should contact Northwood (rather than the Plan) for prior authorization for the use of non-disposable external insulin infusion pumps and single-use and disposable, programmable external insulin infusion pumps (e.g., OmniPod® Insulin Management System) for Plan members.

Durable medical equipment (DME) providers, medical supply providers, pharmacy providers, home infusion providers, home care providers, and specialty pharmacy providers must contact Northwood (rather than the Plan) to determine coverage and reimbursement guidelines for DME (and associated supplies and accessories) and to obtain authorization for devices that include but are not limited to home blood glucose monitors, CGMS, combined CGMS with external insulin infusion pump, associated DME supplies and accessories, non-disposable external insulin infusion pumps, and/or single-use and disposable, programmable external insulin infusion pumps using wireless technology (e.g., OmniPod® Insulin Management System). These provider types (including DME providers) must contact the Plan rather than Northwood for prior authorization requests for single-use and disposable, nonprogrammable/mechanical (non-electric) insulin infusion devices (e.g., V-Go™ Disposable Insulin Delivery Device).

All applicable codes for services managed by Northwood are NOT included in this Applicable Coding section. When Plan authorization is NOT required for a DME device, service, or supply (as specified below), the provider (regardless of provider type) should still contact Northwood at www.northwoodinc.com or by phone at 1-866-802-6471 to obtain prior authorization, as necessary.

<table>
<thead>
<tr>
<th>CPT Codes</th>
<th>Description: Codes Covered When Medically Necessary</th>
</tr>
</thead>
<tbody>
<tr>
<td>95250</td>
<td>Ambulatory continuous glucose monitoring of interstitial tissue fluid via a subcutaneous sensor for a minimum of 72 hours; sensor placement, hook-up, calibration of monitor, patient training, removal of sensor, and printout of recording (Do not report 95250 more than once per month. Do not report 95250 in conjunction with 99091.)</td>
</tr>
<tr>
<td>95251</td>
<td>Ambulatory continuous glucose monitoring of interstitial tissue fluid via a subcutaneous sensor for a minimum of 72 hours; interpretation and report (Do not report 95251 more than once per month. Do not report 95250 in conjunction with 99091.)</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>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>

Continuous Glucose Monitoring Systems and Insulin Delivery Devices

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<table>
<thead>
<tr>
<th>HCPCS Codes</th>
<th>Description: Codes Covered When Medically Necessary</th>
</tr>
</thead>
</table>
| A9276       | Sensor; invasive (e.g., subcutaneous), disposable, for use with interstitial continuous glucose monitoring system, 1 unit = 1 day supply  
Plan note: DME providers, medical supply providers, pharmacy providers, home infusion providers, home care providers, and specialty pharmacy providers must contact Northwood at 1-866-802-6471 (rather than the Plan) to determine coverage and reimbursement guidelines for this component and to obtain authorization. Other provider types must contact the Plan to obtain authorization for services. |
| A9277       | Transmitter; external, for use with interstitial continuous glucose monitoring system  
Plan note: DME providers, medical supply providers, pharmacy providers, home infusion providers, home care providers, and specialty pharmacy providers must contact Northwood at 1-866-802-6471 (rather than the Plan) to determine coverage and reimbursement guidelines for this component and to obtain authorization. Other provider types must contact the Plan to obtain authorization for services. |
| A9278       | Receiver (monitor); external, for use with interstitial continuous glucose monitoring system  
Plan note: DME providers, medical supply providers, pharmacy providers, home infusion providers, home care providers, and specialty pharmacy providers must contact Northwood at 1-866-802-6471 (rather than the Plan) to determine coverage and reimbursement guidelines for this component and to obtain authorization. Other provider types must contact the Plan to obtain authorization for services. |
| K0554       | Receiver (monitor), dedicated, for use with therapeutic glucose continuous monitor system  
Plan note: DME providers, medical supply providers, pharmacy providers, home infusion providers, home care providers, and specialty pharmacy providers must contact Northwood at 1-866-802-6471 (rather than the Plan) to determine coverage and reimbursement guidelines for this component and to obtain authorization. Other provider types must contact the Plan to obtain authorization for services. |
S1030  Continuous noninvasive glucose monitoring device, purchase (for physician interpretation of data, use CPT code)

Plan notes:
1. This code is not payable for the Well Sense Health Plan products and the Senior Care Options product.
2. DME providers, medical supply providers, pharmacy providers, home infusion providers, home care providers, and specialty pharmacy providers must contact Northwood at 1-866-802-6471 (rather than then Plan) to determine coverage and reimbursement guidelines for this device and to obtain authorization. Other provider types must contact the Plan to obtain authorization for services.

S1031  Continuous noninvasive glucose monitoring device, rental, including sensor, sensor replacement, and download to monitor (for physician interpretation of data, use CPT code)

Plan notes:
1. This code is not payable for the Well Sense Health Plan products and the Senior Care Options product.
2. DME providers, medical supply providers, pharmacy providers, home infusion providers, home care providers, and specialty pharmacy providers must contact Northwood at 1-866-802-6471 (rather than then Plan) to determine coverage and reimbursement guidelines for this device and to obtain authorization. Other provider types must contact the Plan to obtain authorization for services.

<table>
<thead>
<tr>
<th>HCPCS Code</th>
<th>Description: Codes Considered NOT Medically Necessary (for Artificial Pancreas Device) in the Outpatient Setting</th>
</tr>
</thead>
<tbody>
<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>
</tbody>
</table>

Plan notes:
1. According to CMS National Coverage Determination (NCD) for Closed-Loop Blood Glucose Control Device (CBGCD) (40.3), the use of the CBGCD is covered **ONLY for short-term management of insulin dependent diabetics in crisis situations, in a hospital inpatient setting, and only under the direction of specially trained medical personnel.** The use of CBGCD for Senior Care Options members must follow clinical guidelines included in NCD 40.3 and Plan authorization for the service would be included in the authorization and reimbursement of the member’s inpatient admission (rather than a separate prior authorization for this...
<table>
<thead>
<tr>
<th>HCPCS code</th>
<th>Description</th>
<th>Plan notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>S1035</td>
<td>Sensor; invasive (e.g., subcutaneous), disposable, for use with artificial pancreas device system</td>
<td>1. According to CMS National Coverage Determination (NCD) for Closed-Loop Blood Glucose Control Device (CBGCD) (40.3), the use of the CBGCD is covered <strong>ONLY for short-term management of insulin dependent diabetics in crisis situations, in a hospital inpatient setting, and only under the direction of specially trained medical personnel.</strong> The use of CBGCD for Senior Care Options members must follow clinical guidelines included in NCD 40.3 and Plan authorization for the service would be included in the authorization of the member’s inpatient admission rather than a separate prior authorization for this HCPCS code. This code is NOT payable for the Senior Care Options product. 2. See the Limitations section of this policy for clinical guidelines related to the use of an artificial pancreas system and associated devices in the <strong>outpatient setting</strong> for all other BMC HealthNet Plan members and Well Sense Health Plan members.</td>
</tr>
<tr>
<td>S1036</td>
<td>Transmitter; external, for use with artificial pancreas device system</td>
<td>1. According to CMS National Coverage Determination (NCD) for Closed-Loop Blood Glucose Control Device (CBGCD) (40.3), the use of the CBGCD is covered <strong>ONLY for short-term management of insulin dependent diabetics in crisis situations, in a hospital inpatient setting, and only under the direction of specially trained medical personnel.</strong> The use of CBGCD for Senior Care Options members must follow clinical guidelines included in NCD 40.3 and Plan authorization for the service would be included in the authorization of the member’s inpatient admission rather than a separate prior authorization for this HCPCS code. This code is NOT payable for the Senior Care Options product. 2. See the Limitations section of this policy for clinical guidelines related to the use of an artificial pancreas system and associated devices in the <strong>outpatient setting</strong> for all other BMC HealthNet Plan members and Well Sense Health Plan members.</td>
</tr>
</tbody>
</table>

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S1037

Receiver (monitor); external, for use with artificial pancreas device system

Plan notes:
1. According to CMS National Coverage Determination (NCD) for Closed-Loop Blood Glucose Control Device (CBGCD) (40.3), the use of the CBGCD is covered **ONLY for short-term management of insulin dependent diabetics in crisis situations, in a hospital inpatient setting, and only under the direction of specially trained medical personnel.** The use of CBGCD for Senior Care Options members must follow clinical guidelines included in NCD 40.3 and Plan authorization for the service would be included in the authorization of the member’s inpatient admission rather than a separate prior authorization for this HCPCS code. This code is NOT payable for the Senior Care Options product.
2. See the Limitations section of this policy for clinical guidelines related to the use of an artificial pancreas system and associated devices in the **outpatient setting** for all other BMC HealthNet Plan members and Well Sense Health Plan members.

<table>
<thead>
<tr>
<th>HCPCS Code</th>
<th>Description: Code Considered NOT Medically Necessary for Single-Use, Disposable and Nonprogrammable/Mechanical Insulin Infusion Devices</th>
</tr>
</thead>
<tbody>
<tr>
<td>A9274</td>
<td>External ambulatory insulin delivery system, disposable, each, includes all supplies and accessories</td>
</tr>
</tbody>
</table>

Plan notes:
1. Code used for **single-use, disposable and nonprogrammable/mechanical insulin infusion device** (e.g., V-Go®). The Plan considers this type of device NOT medically necessary for any indication and requires Plan prior authorization for all provider types, as specified in the Limitations section of this policy.
2. DME providers, medical supply providers, pharmacy providers, home infusion providers, home care providers, and specialty pharmacy providers must contact Northwood at 1-866-802-6471 (rather than then Plan) to determine coverage and reimbursement guidelines for all other **types of disposable external ambulatory insulin delivery systems** (including supplies and accessories) except for **single-use, disposable and nonprogrammable/mechanical (non-electric) insulin infusion devices** (e.g., V-Go®). According to the Limitations section of this Plan policy, the replacement of a member’s currently functional CGMS or combined CGMS with external insulin pump for the sole purpose of receiving an upgraded system or the most recent technology is NOT considered medically necessary; this includes upgrades for enhanced information/wireless communication technology as an added component for CGMS. An
example of a device with wireless remote technology is the OmniPod® Insulin Management System.

**Clinical Background Information**

Diabetes mellitus is a disease of impaired pancreatic insulin secretion or inadequate use of insulin by the body and is characterized by hyperglycemia. The three (3) primary types of diabetes mellitus are type 1, type 2, and gestational diabetes. However, there are other types of diabetes that account for approximately 1% to 2% of cases and are related to specific genetic syndromes such as maturity-onset diabetes of youth, drugs, surgery, malnutrition, infection, and other diseases. Diabetes mellitus is one of the leading causes of death in the United States. Improved glycemic control has been shown to slow the onset or progression of major complications. Management of diabetes involves efforts to maintain blood glucose levels near the normal range. Currently, self-monitoring of blood glucose (SMBG) and laboratory testing of glycosylated hemoglobin (A1C) to measure longer term glycemic control are the standard methods for glucose testing.

Patients with type 1 (insulin-dependent) diabetes or insulin-requiring type 2 (non-insulin dependent) diabetes require long-term treatment with exogenous insulin with performance of self-monitoring of blood glucose (SMBG) to calculate the appropriate dose of insulin. SMBG is performed by using blood samples obtained by finger sticks, but frequent SMBG may not detect all the significant deviations in blood glucose specifically found in patients who have rapidly fluctuating glucose levels.

Continuous glucose monitoring systems (CGMS) are minimally invasive or noninvasive devices that measure glucose levels in the interstitial fluid surrounding skin cells to provide continuous information about glucose fluctuations that is not otherwise captured by intermittent testing with SMBG. CGMS can guide adjustments to treatment with the goal of improvement in overall glycemic control. The sensor measures glucose levels and transmits the information to an external monitor. The system automatically records an average glucose value every five (5) minutes for up to several days of monitoring. These devices require calibration with blood glucose levels (using finger stick test results that are entered into the monitor). In addition, the patient maintains a diary of meals, exercise, and medication administration during the continuous glucose monitoring. Blood glucose levels stored by the CGMS and other collected data are evaluated to identify trends in blood glucose levels and establish a care plan for the individual.

The readings from a CGMS are intended to supplement, not replace, information obtained from standard home glucose monitoring devices. CGMS are generally considered safe with few reports of side effects. The most commonly reported symptoms include discomfort, redness, itching, irritation, and bleeding at the sensor insertion or contact site. Since SMBG is still performed as usual during CGMS use, it is unlikely that failure of a CGMS device would lead to inappropriate insulin dosing. Continuous glucose monitors may be stand-alone systems or the continuous glucose monitors can be built into insulin pump systems (e.g., OmniPod® Insulin Management System or the MiniMed Paradigm® REAL-Time System).

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Remote wireless glucose monitoring is unproven and NOT medically necessary for managing patients with diabetes due to insufficient evidence to evaluate the clinical utility of this technology. An example of a device with wireless monitoring, remote technology is the OmniPod® Insulin Management System (by Insulet Corp.) and the Dexcom G5 Continuous Glucose Monitoring (CGM) System (by Dexcom, Inc.). The OmniPod® Insulin Management System (by Insulet Corp.) is a single use, disposable and programmable device that consolidates the pump, tubing, and subcutaneous needle into one (1) compact unit, using wireless remote technology to control the insulin pump and is worn up to three (3) days before requiring replacement. The Dexcom G5 Continuous Glucose Monitoring (CGM) System provides real-time glucose readings for patients with type 1 or type 2 diabetes every five (5) minutes, and the device received FDA premarket approval in 2015 as a supplement to the previously approved Dexcom G4 Platinum CGMS. The Dexcom G5 CGM System is comprised of a sensor located underneath the skin, a transmitter to send glucose data wirelessly, and a display device with reporting results (including audio and text alerts).

The GlucoWatch G2 Biographer was a glucose monitoring device indicated for detecting trends and tracking patterns in glucose levels in adults (age 18 and older) and children/adolescents (age 7 to 17) with diabetes. The device was intended for use by patients at home and in health care facilities and was available only with a prescription. Glucowatch G2 Biographer® (S1030, S1031) is considered experimental and investigational and is no longer available in the United States as of July 31, 2007.

At the time of the Plan’s most recent policy review, no clinical guidelines were found from the Centers for Medicare & Medicaid Services (CMS) for the following services when provided in the outpatient setting: CGMS; combined CGMS with an external insulin pump using continuous subcutaneous insulin infusion (CSII); single-use, disposable and nonprogrammable/mechanical external insulin pump (e.g., V-Go™ Disposable Insulin Delivery Device); and/or glucose monitoring with remote transmission, software supported data management, and wireless monitoring. Determine if applicable CMS criteria are in effect for the service and the indication for treatment in a national coverage determination (NCD) or local coverage determination (LCD) on the date of the prior authorization request for a Senior Care Options member.

During the policy review period, the following CMS guidelines were identified for associated services. CMS covers home blood glucose monitors according to CMS applicable clinical criteria. CMS covers the use of external infusion pumps for indications specified in NCD 280.14 (e.g., treatment of iron poisoning or thromboembolic disease, chemotherapy administrative for liver cancer, morphine infusion for intractable cancer pain, and continuous subcutaneous insulin infusion for diabetic patients); in addition, CMS covers all other uses of continuous subcutaneous insulin infusion (CSII) in accordance with the Category B investigational device exemption clinical trials regulation (42 CFR 405.201) or as a routine cost under the clinical trials policy (Medicare National Coverage Determinations Manual 310.1/NCD for Routine Costs in Clinical Trials 310.1). According to NCD 280.14, an implanted infusion pump for the infusion of insulin to treat diabetes is not covered by CMS because there are not sufficient data to demonstrate that an implanted infusion pump provides effective administration of insulin.

Continuous Glucose Monitoring Systems and Insulin Delivery Devices

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CMS may cover continuous subcutaneous insulin infusion (CSII) and related drugs/supplies for the treatment of diabetic patients when applicable criteria are met. Included in NCD 280.14 are the following indications for the treatment of diabetic patients with infusion pumps: CSII and related drugs/supplies are covered as medically reasonable and necessary in the home setting for the treatment of diabetic patients who either meet the updated fasting C-Peptide testing requirement or are beta cell autoantibody positive and additional CMS applicable criteria are met for CSII.

According to NCD 40.3, CMS covers the use of closed-loop blood glucose control device (CBGCD) for short-term management of insulin dependent diabetics in crisis situations in a hospital inpatient setting, and only under the direction of specially trained medical personnel. The CBGCD is a hospital bedside device designed for short-term management of patients with insulin dependent diabetes mellitus (Type I). The device consists of a rapid on-line glucose analyzer, a computer with a controller for the calculation and control of the infusion (of either insulin or dextrose), a multi-channel infusion system, and a printer designed to record continuous glucose values and to provide cumulative totals of the substances infused.

Medical nutrition services (MNT) may or may not also be necessary for individuals with diabetes. CMS NCD 180.1 includes medically necessary indications for MNT for a beneficiary with a diagnosis of renal disease and/or diabetes according to CMS established criteria based on duration of treatment, episode of care, date of service, and number of units administered per day. Additional MNT may be considered medically necessary and covered if the treating physician determines that there is a change in the beneficiary’s medical condition, diagnosis, and/or treatment regimen, and the physician orders additional MNT during that episode of care (as stated in NCD 180.1). There is an NCD on Surgery for Diabetes (100.14) which states that open and laparoscopic Roux-en-Y gastric bypass (RYGB) are covered for Medicare beneficiaries who have a body mass index (BMI) ≥ 35 kilograms per square meter (kg/m²), have at least 1 comorbidity related to obesity, and have been previously unsuccessful with medical treatment for obesity. The CMS has determined that type 2 diabetes mellitus is comorbidity related to obesity. For a Senior Care Options member, verify CMS criteria in the applicable NCD, LCD, and/or coverage guidelines in effect for the requested service and specified indication on the date of prior authorization request and date of service. See the Plan’s Medical Nutrition Therapy in the Outpatient or Office Setting medical policy (policy number OCA 3.66) or Bariatric Surgery medical policy (policy number OCA 3.49) for applicable Plan guidelines related to these services.

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Continuous Glucose Monitoring Systems and Insulin Delivery Devices

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<table>
<thead>
<tr>
<th>Original Approval Date</th>
<th>Original Effective Date* and Version Number</th>
<th>Policy Owner</th>
<th>Original Policy Approved by</th>
</tr>
</thead>
<tbody>
<tr>
<td>Regulatory Approval:  N/A</td>
<td>11/10/08 Version 1</td>
<td>Medical Policy Manager as Chair of MPCTAC</td>
<td>MPCTAC, QIC, and UMC</td>
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<tr>
<td>Internal Approval: 07/08/08: Medical Policy, Criteria, and Technology Assessment Committee (MPCTAC)</td>
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<tr>
<td>07/22/08: Utilization Management Committee (UMC)</td>
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<tr>
<td>08/13/08: Quality Improvement Committee (QIC)</td>
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*Effective Date for the BMC HealthNet Plan Commercial Product(s): 01/01/12

Continuous Glucose Monitoring Systems and Insulin Delivery Devices

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*Effective Date for the Well Sense Heath Plan New Hampshire Medicaid Product(s): 01/01/13
*Effective Date for Senior Care Options Product(s): 01/01/16

Note: Policy title was *Continuous Glucose Monitoring Systems* until 10/31/16; effective 11/01/16 the policy title has been changed to *Continuous Glucose Monitoring Systems and Insulin Delivery Devices*.

### Policy Revisions History

<table>
<thead>
<tr>
<th>Review Date</th>
<th>Summary of Revisions</th>
<th>Revision Effective Date and Version Number</th>
<th>Approved by</th>
</tr>
</thead>
<tbody>
<tr>
<td>07/28/09</td>
<td>No changes.</td>
<td>Version 2</td>
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<tr>
<td>07/01/10</td>
<td>Updated clinical criteria with additional criteria for the short and long term use of CGMS. Updated references.</td>
<td>Version 3</td>
<td>08/18/10: MPCTAC 09/22/10: QIC</td>
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<tr>
<td>08/01/11</td>
<td>Updated references. No changes to criteria or code list.</td>
<td>Version 4</td>
<td>08/17/11: MPCTAC 09/28/11: QIC</td>
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<tr>
<td>07/01/12</td>
<td>Updated references. Added following statement to Description of Item or Service section: “Continuous glucose monitoring (CGM) in conjunction with intensive insulin regimens can be a useful tool to lower A1c.” Revised Summary section. Added the following criteria in Medical Policy Statement for medically necessary use of 72 hour and long-term continuous glucose monitoring (CGM): (1) Consultation with an endocrinologist, (2) suspected postprandial hyperglycemia, (3) recurrent diabetic ketoacidosis, and/or (4) type 1 diabetic who is pregnant and has poorly controlled diabetes. Added the following criterion for CGM up to 72 hours: There is discordance between A1c and blood glucose levels. Added definition of type 1 diabetes. Added language regarding prior authorization guidelines for the receiver, transmitter, sensors, and supplies related to a continuous glucose monitoring device. Revised language in Applicable Coding section and updated applicable code definitions.</td>
<td>Version 5</td>
<td>07/18/12: MPCTAC 08/22/12: QIC</td>
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<tr>
<td>07/29/12</td>
<td>Off cycle review for Well Sense Health Plan,</td>
<td>Version 6</td>
<td>08/03/12: MPCTAC</td>
</tr>
</tbody>
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<table>
<thead>
<tr>
<th>Date</th>
<th>Description</th>
<th>Version</th>
<th>Effective Date</th>
<th>Reviewing Body</th>
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<tbody>
<tr>
<td>09/05/12</td>
<td>revised Summary statement, reformatted Medical Policy Statement, added</td>
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<td>QIC</td>
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<td>Definitions section, revised Limitations statement.</td>
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<tr>
<td>07/01/13</td>
<td>Review for effective date 11/01/13. Updated Summary section to include</td>
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<td>reference to Northwood, Inc. Deleted duplicate text and reformatted Medical</td>
<td>Version 7</td>
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<td></td>
<td>Policy Statement section. Added criterion stating that CGMS is used as an</td>
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<td></td>
<td>adjunct to finger stick testing to the Medical Policy Statement section</td>
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<tr>
<td></td>
<td>(as specified in the Summary section). Added definition for diabetes</td>
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<td></td>
<td>mellitus and added text to Clinical Background Information section.</td>
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<tr>
<td></td>
<td>Updated references.</td>
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<td>12/01/13</td>
<td>Review for effective date 05/01/14. Revised Summary, Description of Item or</td>
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<tr>
<td></td>
<td>Service, Clinical Background Information, and References sections. Revised</td>
<td>Version 8</td>
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<td>01/21/14: QIC</td>
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<td>criteria in Medical Policy Statement and categorized criteria into short-term</td>
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<td>and long-term use of CGM. Limitations added.</td>
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<td>12/01/14</td>
<td>Review for effective date 04/01/15. Updated Clinical Background Information</td>
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<td>section. Revised criteria in Medical Policy Statement section and Limitations</td>
<td>Version 9</td>
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<td>01/14/15: QIC</td>
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<td>10/01/15</td>
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<td>products and corresponding notes.</td>
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<td>11/11/15: QIC</td>
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<td>10/21/15</td>
<td>Review for effective date 02/01/16. Revised the Limitations section and</td>
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<td>11/25/15</td>
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<td>02/01/16</td>
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<td>Coding section. Updated Summary and References sections.</td>
<td>Version 12</td>
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<td>Revised policy title and criteria in the</td>
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<td>12/09/15: QIC</td>
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<td>08/01/16</td>
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<td>Service, Definitions, Clinical Background Information, References, and</td>
<td>Version 13</td>
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<td></td>
<td>Reference to Applicable Laws and Regulations sections. Revised policy title</td>
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<td>08/10/16: QIC</td>
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<tr>
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<td>and criteria in the</td>
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</tbody>
</table>

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### Policy Revisions History

<table>
<thead>
<tr>
<th>Date</th>
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<th>Version</th>
<th>Reviewer</th>
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<tr>
<td>10/01/16</td>
<td>Review for effective date 12/01/16. Updated Clinical Background Information and References sections. Administrative changes made to the Limitations section. Plan notes made to applicable codes. No change to criteria and/or the applicable code list.</td>
<td>12/01/16</td>
<td>Version 14</td>
<td>10/19/16: MPCTAC</td>
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<td>12/05/16</td>
<td>Industry-wide code change with the addition of 2017 applicable CPT codes 0446T and 0448T effective 01/01/17.</td>
<td>01/01/17</td>
<td>Version 15</td>
<td>Not applicable because industry-wide code revision.</td>
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<tr>
<td>04/01/17</td>
<td>Review for effective date 07/08/17. Clarified Limitations section without changing criteria. Add experimental and investigational codes to applicable code list for services already listed as experimental and investigational in the Limitations section. Updated Definitions and References sections.</td>
<td>07/08/17</td>
<td>Version 16</td>
<td>04/15/17: MPCTAC</td>
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<td>06/01/17</td>
<td>Review for effective date 07/08/17. Industry-standard code update in the Applicable Coding section.</td>
<td>07/08/17</td>
<td>Version 17</td>
<td>06/21/17: MPCTAC</td>
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<td>10/01/17</td>
<td>Review for effective date 01/01/18. Administrative changes made to the Policy Summary, Description of Item or Service, Definitions, Clinical Background Information, References, and Other Applicable Policies sections. Revised criteria in the Limitations section.</td>
<td>01/01/18</td>
<td>Version 18</td>
<td>10/18/17: MPCTAC</td>
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</tbody>
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### Last Review Date

10/01/17

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Next Review Date

10/01/18

Authorizing Entity

MPCTAC

Other Applicable Policies

Medical Policy - *Bariatric Surgery*, policy number OCA 3.49
Medical Policy - *Experimental and Investigational Treatment*, policy number OCA 3.12
Medical Policy - *Medical Nutrition Therapy in the Outpatient or Office Setting*, policy number OCA 3.66
Medical Policy - *Medically Necessary*, policy number OCA 3.14

Reference to Applicable Laws and Regulations


Continuous Glucose Monitoring Systems and Insulin Delivery Devices

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Disclaimer Information:

Medical Policies are the Plan’s guidelines for determining the medical necessity of certain services or supplies for purposes of determining coverage. These Policies may also describe when a service or supply is considered experimental or investigational, or cosmetic. In making coverage decisions, the Plan uses these guidelines and other Plan Policies, as well as the Member’s benefit document, and when appropriate, coordinates with the Member’s health care Providers to consider the individual Member’s health care needs.

Plan Policies are developed in accordance with applicable state and federal laws and regulations, and accrediting organization standards (including NCQA). Medical Policies are also developed, as appropriate, with consideration of the medical necessity definitions in various Plan products, review of current literature, consultation with practicing Providers in the Plan’s service area who are medical experts in the particular field, and adherence to FDA and other government agency policies. Applicable state or federal mandates, as well as the Member’s benefit document, take precedence over these guidelines. Policies are reviewed and updated on an annual basis, or more frequently as needed. Treating providers are solely responsible for the medical advice and treatment of Members.

The use of this Policy is neither a guarantee of payment nor a final prediction of how a specific claim(s) will be adjudicated. Reimbursement is based on many factors, including member eligibility and benefits on the date of service; medical necessity; utilization management guidelines (when applicable); coordination of benefits; adherence with applicable Plan policies and procedures; clinical coding criteria; claim editing logic; and the applicable Plan – Provider agreement.

Continuous Glucose Monitoring Systems and Insulin Delivery Devices

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