Medical Policy

Continuous Glucose Monitoring Systems

Policy Number: OCA 3.966
Version Number: 12
Version Effective Date: 02/01/16

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:

+ 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) for up to three (3) days (i.e., 72 hours) to be medically necessary in type 1 and type 2 diabetics when the Plan’s medical criteria are met for this service. Long-term use of CGMS is considered medically necessary as an adjunct to finger stick testing with type 1 diabetic members when the Plan’s medical criteria are met for long-term continuous glucose monitoring, as specified in the Medical Policy Statement section of this policy. Prior authorization is required.
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 policy, *Medically Necessary* (policy number OCA 3.14), for the product-specific definitions of medically necessary treatment.

Durable medical equipment, prosthetics, orthotics and supplies (DMEPOS) dispensed and billed by DMEPOS providers and all oral enterals are managed by Northwood, Inc. DMEPOS providers dispensing and billing for DMEPOS, as well as home infusion providers dispensing and billing for oral enterals, should contact Northwood at [www.northwoodinc.com](http://www.northwoodinc.com) or by phone at 1-866-802-6471 to obtain prior authorization.

**Description of Item or Service**

**Continuous Glucose Monitoring Systems (CGMS):** Minimally invasive or noninvasive devices that measure glucose levels in the interstitial fluid surrounding skin cells 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 continuous glucose monitoring systems measure blood glucose with minimal invasiveness through continuous measurement of interstitial fluid (ISF) with a subcutaneously 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 readings from the CGMS are intended to supplement, not replace, information obtained from standard home glucose monitoring devices. Several CGMS have been approved by the 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.

**Medical Policy Statement**

Use of a continuous glucose monitoring system (CGMS) is considered medically necessary when the following medical criteria are met and documented in the member’s medical record, as specified below in item 1 (member criteria) and item 2 (medical criteria by treatment time frame):

1. **Member Criteria for CGMS:**

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

   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

   *Continuous Glucose Monitoring Systems*

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d. 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

(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 has type 1 diabetes mellitus; 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 achieved 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) or item b (for long-term use):

a. **Short-Term Use of CGM:**

   (1) 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 not applicable for pediatric members, as specified above in the criteria for pediatric members); OR

   (2) 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; OR

b. **Long-Term Use of CGM (Greater than 7 Days):**

   ALL of the following criteria are met, as specified below in items (1) through (5):

   (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

   (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

**Note:** Long-term continuous glucose monitoring may be used as a stand-alone device or as a combined continuous subcutaneous insulin infusion and blood glucose monitoring system.

**Limitations**

1. The Plan considers the use of continuous glucose monitoring systems (CGMS) to be experimental and investigational for indications not specified in this Plan policy. See Plan policy, *Experimental and Investigational Treatment* (policy number OCA 3.12), for product-specific definitions of experimental or investigational treatment.

2. Closed-loop subcutaneous insulin infusion and continuous interstitial glucose monitoring systems are not covered because they are considered experimental and investigational or unproven.

3. Glucowatch G2 Biographer® (S1030, S1031) is considered experimental and investigational and is no longer available in the United States as of July 31, 2007.

4. 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).

5. The Plan considers the use of CGMS or combined continuous subcutaneous insulin infusion and blood glucose monitoring systems that are not FDA approved for this indication to be experimental and investigational.

6. The use of information communication technology (including the use of smart phone applications) to upload or monitor blood glucose levels is considered experimental and investigational.
Definitions

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.

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).

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.

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.

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 times.

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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.

Note: If continuous glucose monitoring is approved by the plan, 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.

<table>
<thead>
<tr>
<th>CPT Codes</th>
<th>Description: Codes Covered When Medically Necessary</th>
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</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>
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</tbody>
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<thead>
<tr>
<th>HCPCS Codes</th>
<th>Description: Codes Covered When Medically Necessary</th>
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</thead>
<tbody>
<tr>
<td>A9276</td>
<td>Sensor; invasive (e.g., subcutaneous), disposable, for use with interstitial continuous glucose monitoring system, 1 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>
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</tbody>
</table>
### 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.

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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<table>
<thead>
<tr>
<th>S1030</th>
<th>Continuous noninvasive glucose monitoring device, purchase (for physician interpretation of data, use CPT code)</th>
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<tbody>
<tr>
<td>S1031</td>
<td>Continuous noninvasive glucose monitoring device, rental, including sensor, sensor replacement, and download to monitor (for physician interpretation of data, use CPT code)</td>
</tr>
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References


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U.S. Food and Drug Administration. FDA Approval Letter September 26, 2013. Accessed at:

U.S. Food and Drug Administration. Medical Devices. Accessed at:
http://www.fda.gov/MedicalDevices/default.htm

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

<table>
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<tr>
<th>Policy Revisions History</th>
<th>Revision Effective Date and Version Number</th>
<th>Approved by</th>
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<tbody>
<tr>
<td><strong>Review Date</strong></td>
<td><strong>Summary of Revisions</strong></td>
<td><strong>Approved by</strong></td>
</tr>
<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 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 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</td>
<td>Version 5 07/18/12: MPCTAC 08/22/12: QIC</td>
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### Policy Revisions History

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<tr>
<th>Date</th>
<th>Description</th>
<th>Revisions</th>
<th>Date</th>
<th>Revisions</th>
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<tr>
<td>07/29/12</td>
<td>Off cycle review for Well Sense Health Plan, revised Summary statement, reformatted Medical Policy Statement, added Definitions statement.</td>
<td>Version 6</td>
<td>08/03/12</td>
<td>MPCTAC 09/05/12: QIC</td>
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<tr>
<td>07/01/13</td>
<td>Review for effective date 11/01/13. Updated Summary section to include reference to Northwood, Inc. Deleted duplicate text and reformatted Medical Policy Statement section. Added criterion that CGMS is used as an adjunct to fingerstick testing to the Medical Policy Statement section (as specified in the Summary section). Added definition for diabetes mellitus and added text to Clinical Background Information section. Updated references.</td>
<td>11/01/13</td>
<td>07/17/13</td>
<td>MPCTAC 08/15/13: QIC</td>
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<tr>
<td>12/01/13</td>
<td>Review for effective date 05/01/14. Revised Summary, Description of Item or Service, Clinical Background Information, and References sections. Revised criteria in Medical Policy Statement and categorized criteria into short-term and long-term use of CGM. Limitations added.</td>
<td>05/01/14</td>
<td>12/18/13</td>
<td>MPCTAC 01/21/14: QIC</td>
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<tr>
<td>12/01/14</td>
<td>Review for effective date 04/01/15. Updated Clinical Background Information section. Revised criteria in Medical Policy Statement section and Limitations section.</td>
<td>04/01/15</td>
<td>12/17/14</td>
<td>MPCTAC 01/14/15: QIC</td>
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<tr>
<td>10/01/15</td>
<td>Review for effective date 12/01/15. Updated template with list of applicable definitions.</td>
<td>12/01/15</td>
<td>10/21/15</td>
<td>MPCTAC 11/11/15: QIC</td>
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**Policy Revisions History**

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<tr>
<td>10/21/15</td>
<td>Review for effective date 02/01/16. Revised the Limitations section and updated references. Clarified criteria in the Medical Policy Statement section.</td>
<td>02/01/16 Version 11</td>
<td>10/21/15: MPCTAC 11/11/15: QIC</td>
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<tr>
<td>11/25/15</td>
<td>Review for effective date 02/01/16. Revised language in the Applicable Coding section.</td>
<td>02/01/16 Version 12</td>
<td>11/25/15: MPCTAC (electronic vote) 12/09/15: QIC</td>
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**Last Review Date**

11/25/15

**Next Review Date**

10/01/16

**Authorizing Entity**

QIC

**Other Applicable Policies**

Medical Policy - *Experimental and Investigational Treatment*, policy number OCA 3.12
Medical Policy - *Medically Necessary*, policy number OCA 3.14

**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

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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.