

Continuous Glucose Monitoring System

WellSense Health Plan Members (MH/MHCP/ACO Products or SCO Product): Requests **only** need to meet Appendix A criteria. See Appendix A for policy guidelines – <u>CLICK HERE</u>.

Description

A Continuous Glucose Monitoring System (CGMS) is a minimally invasive or noninvasive device that measures glucose levels in the interstitial fluid surrounding skin cells and provides continuous information about glucose fluctuations that is not otherwise captured by intermittent testing. The CGMS is considered medically necessary for the management of difficult to control insulin-treated diabetes mellitus.

A non-adjunctive CGMS can be used to make treatment decisions *without* the need for a standalone blood glucose monitor to confirm testing results.

An adjunctive CGMS requires the user to verify their glucose levels or trends displayed on a CGMS *with* a blood glucose monitor prior to making treatment decisions.

The CGMS must include a durable component (a component that CMS determines can withstand repeated use and has an expected lifetime of at least 3 years) that is capable of displaying the trending of the continuous glucose measurements.

Policy

Use of a CGMS is considered reasonable and necessary in diabetics meeting the criteria listed below.

Policy Guidelines

Use of a Continuous Glucose Monitoring System (CGMS) is reasonable and necessary in **diabetics** who:

- require the use of an insulin pump or multiple daily insulin injections; AND
- have recurrent episodes of severe hypoglycemia (blood glucose <50mg/dl) despite appropriate modifications in insulin regimen, OR



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- hypoglycemic unawareness, OR
- A1C greater than or equal to 7.0%, OR
- postprandial hyperglycemia, OR
- recurrent diabetic ketoacidosis, OR
- are pregnant and have poorly controlled diabetes requiring insulin, including unexplained hypoglycemic episodes, hypoglycemic unawareness, postprandial hyperglycemia or recurrent diabetic ketoacidosis.

All other uses of a CGMS are considered experimental and investigational. A CGMS is not considered reasonable and necessary when the applicable criteria outlined are not met.

Limitations

Non-invasive continuous glucose monitors (S1030, S1031) and related supplies are considered **experimental/investigational**, and therefore not reasonable and necessary. Despite the fact that these devices may have received FDA approval, there is a lack of long-term studies demonstrating that the use of these devices is associated with an improvement in final health outcomes, i.e., improved diabetic control based either on decreasing hemoglobin A1c values and/or decreasing incidence of hypoglycemia.

Artificial Pancreas (Closed loop glucose monitoring system)

Use of an artificial pancreas system, including but not limited to closed-loop monitoring devices with low-glucose suspend (LGS) features, are considered **investigational**.

Current studies in medical literature do not provide conclusive evidence that closed-loop systems lead to improved health outcomes in persons with diabetes. There is insufficient evidence that improved health outcomes, if any, are durable over time. Further controlled studies with larger numbers of patients and longer periods of closed-loop insulin management are needed to assess the safety and efficacy of these systems.

HCPCS Level II Codes and Description



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| A4238 | Supply allowance for adjunctive, non-implanted continuous glucose monitor (CGM), includes all supplies and accessories, 1 month supply = 1 unit of service |
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| A4239 | Supply allowance for non-adjunctive, non-implanted continuous glucose monitor (CGM), includes all supplies and accessories, 1 month supply = 1 unit of service. |
| A9276 | Sensor; invasive (e.g., subcutaneous), disposable, for use with interstitial continuous glucose monitoring system, 1 unit = 1 day supply |
| A9277 | Transmitter, external for use with interstitial continuous glucose monitoring system |
| A9278 | Receiver (monitor); external for use with interstitial continuous glucose monitoring system |
| E2102 | Adjunctive, non-implanted continuous glucose monitor or receiver |
| E2103 | Non-adjunctive, non-implanted continuous glucose monitor or receiver |
| S1030 | Continuous non-invasive glucose monitoring device, purchase |
| S1031 | Continuous non-invasive glucose monitoring device, rental, including sensor, sensor placement, and download to monitor. |
| S1034 | 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 |
| S1035 | Sensor; invasive (e.g., subcutaneous), disposable, for use with artificial pancreas device system |
| S1036 | Transmitter; external, for use with artificial pancreas device system |
| S1037 | Receiver (monitor); external, for use with artificial pancreas device system |

Important Note:



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Northwood's Medical Policies are developed to assist Northwood in administering plan benefits and determining whether a particular DMEPOS product or service is reasonable and necessary. Equipment that is used primarily and customarily for a non-medical purpose is not considered durable medical equipment.

Coverage determinations are made on a case-by-case basis and are subject to all of the terms, conditions, limitations, and exclusions of the member's contract including medical necessity requirements.

The conclusion that a DMEPOS product or service is reasonable and necessary does not constitute coverage. The member's contract defines which DMEPOS product or service is covered, excluded or limited. The policies provide for clearly written, reasonable and current criteria that have been approved by Northwood's Medical Director.

The clinical criteria and medical policies provide guidelines for determining the medical necessity for specific DMEPOS products or services. In all cases, final benefit determinations are based on the applicable contract language. To the extent there are any conflicts between medical policy guidelines and applicable contract language, the contract language prevails.

Medical policy is not intended to override the policy that defines the member's benefits, nor is it intended to dictate to providers how to direct care. Northwood Medical policies shall not be interpreted to limit the benefits afforded to Medicare or Medicaid members by law and regulation and Northwood will use the applicable state requirements to determine required quantity limit guidelines.

Northwood's policies do not constitute medical advice. Northwood does not provide or recommend treatment to members. Members should consult with their treating practitioner in connection with diagnosis and treatment decisions.

Northwood follows all CMS National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), as applicable.

References:

Centers for Medicaid and Medicare Services, LCD (L33822) Glucose Monitors. Accessed/reviewed 12-9-24.



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Health Net National Medical Policy: Continuous Glucose Monitoring Devices.

 $\underline{https://www.healthnet.com/static/general/unprotected/pdfs/national/policies/ContinuousGlucoseMonitoringDevices.}\\ pdf$

Cigna: Home Blood Glucose Monitors

http://www.cigna.com/customer_care/healthcare_professional/coverage_positions/medical/mm_0106_coveragepositioncriteria_blood_glucose_monitors.pdf Last Accessed/reviewed 12/9/24.

Aetna: Diabetes Tests, Programs and Supplies

http://www.aetna.com/cpb/medical/data/1 99/0070.html#dummyLink1 Last accessed December 9, 2024.

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WellSense Health Plan: Continuous Glucose Monitoring Systems, Artificial Pancreas Device Systems, and Insulin Delivery Devices Medical Policy, Policy Number: OCA 3.966, Version Number: 34, Version Effective Date: 04/01/24.

SPECIAL COVERAGE INFORMATION PER PLAN:

| SHP Badger Care | Follow the Northwood Medicaid CGMS |
|-----------------|---|
| | policy guidelines as noted for codes A9276, |
| | A9277, A9278. |
| | |



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Medical Policy

Policy Number: OCA 3.966

Version Number: 34

Version Effective Date: 04/01/24

Impacted Products

- ☑ All Products
- ⋈ NH Medicaid
- ⋈ NH Medicare Advantage
- ⋈ MA MassHealth ACO
- ⋈ MA MassHealth MCO
- ☑ MA Clarity plans/Employer Choice Direct
- ☑ MA Senior Care Options

Note: Disclaimer and audit information is located at the end of this document.

Policy Summary

The Plan considers continuous glucose monitoring systems (CGMS), combined CGMS with external insulin pumps using continuous subcutaneous insulin infusion (CSII), and artificial pancreas device



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system (sensor-augmented pump therapy, closed-loop glucose management system, automated insulin delivery system/AIDS) provided in the outpatient setting to be medically necessary when guidelines are met in the Clinical Criteria section. Plan prior authorization is required.

The Plan's Pharmacy Department currently manages requests for devices used for CGM or insulin delivery (e.g., Omnipod DASH, Dexcom G6, FreeStyle Libre/Libre 2, V-Go) if it is covered through the member's pharmacy benefit (rather than the member's medical benefit) for all Plan products. A provider may submit a prescription for the requested device. Pharmacy prior authorization may be required when these devices are requested for a MassHealth, Clarity plans/Employer Choice Direct, or NH Medicaid member.

When DME and associated supplies and accessories are covered through the member's DME benefit, the request should be submitted directly to Northwood for authorization from DME providers, pharmacy providers, home infusion providers, or home care providers (including DME, supplies, and accessories related to CGMS or external insulin infusion pumps). Prior authorization is NOT required by the Plan or Northwood 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.

Clinical Criteria

Criteria must be met in EITHER item 1 (medical necessity criteria for stand-alone CGMS, combined CGMS with external insulin pump using CSII, or artificial pancreas device system in the outpatient setting) or item 2 (requests that require Medical Director review and approval) for services managed through the member's medical benefit:

- 1. Applicable criteria must be met in item a, item b, or item c:
 - a. Stand-Alone CGMS:

ALL criteria must be met in items (1) through (7) for members 2 years of age or older on the date of service with type 1 or type 2 diabetes, including but not limited to pregnant members:

- (1) Member requires the use of an insulin pump or at least 3 daily insulin injections for glucose control (and not receiving insulin solely related to member's physical disability, visual impairment, and/or cognitive impairment); AND
- (2) CGM is recommended by the endocrinologist or member's primary care provider; AND



- (3) Member or caregiver is consistently compliant with self-monitoring of blood glucose at least 3 times per day (finger sticks, alternative site testing) or the provider submits documentation to the Plan confirming that the member is not compliant due to physical disability, visual impairment, and/or cognitive impairment; AND
- (4) Endocrinologist or primary care provider managing the member's diabetes confirms the member or caregiver is capable of using the CGM system on a daily basis; AND
- (5) CGMS/CGM device will be used as an adjunct to self-monitoring of blood glucose (finger stick testing or alternative site testing) or an enhanced, FDA-approved CGM device will be used to make treatment decisions, including insulin dosage, without regular confirmatory self-monitoring of blood glucose; AND
- (6) Member is experiencing or remains at risk for ANY condition in items (a) through (f):
 - (a) A1C greater than or equal to 6.5%; OR
 - (b) Hypoglycemic unawareness; OR
 - (c) Hyperglycemia or hyperglycemic crisis, a random plasma glucose ≥200 mg/dL (≥11.1 mmol/L). Random is any time of the day without regard to time since previous meal.; OR
 - (d) History of emergency room visit or hospitalization related to ketoacidosis or hypoglycemia; OR
 - (e) Recurrent episodes of severe hypoglycemia (i.e., blood glucose less than 50mg/dl) despite appropriate modifications in medication regimen; OR
 - (f) Another non-diabetes-based condition causing disorder of glucose metabolism or improper endogenous insulin secretion; AND
- (7) If an implantable continuous glucose monitor/sensor (I-CGM) is prescribed as an alternative to a standard continuous glucose monitor, the I-CGM is FDA approved and will be used according to its FDA-approved clearance, including intended use for member's age and medical condition (e.g., Eversense E₃ CGM System is approved for individuals age 18 or older for up to 180 days); OR
- b. Combined CGMS with External Insulin Pump Using CSII:



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ALL criteria must be met in items (1) through (3) for members 2 years of age or older on the date of service with type 1 or type 2 diabetes, including but not limited to pregnant members:

- (1) Criteria are met above in item 1a for continuous glucose monitoring; AND
- (2) Requested device is 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; AND
- (3) Member does NOT have existing devices that are fully functional and duplicate the same purpose served by a combined CGMS with wireless communication capability to an external insulin pump; OR
- c. Artificial Pancreas Device System/Sensor-Augmented Pump Therapy/Closed-Loop Glucose Management System/Automated Insulin Delivery System:

ALL criteria must be met in items (1) through (3) for a member with type 1 diabetes:

- (1) Criteria are met in item 1a for continuous glucose monitoring and member is NOT pregnant; AND
- (2) Requested artificial pancreas device system will be used according to its FDA-approved clearance and guideline information, including member's age and medical condition (with Medical Director review required for members younger than age 2 on the date of service); AND
- (3) Member does NOT have existing devices that are fully functional and duplicate the same purpose that is served by an artificial pancreas device system/sensor-augmented pump therapy; OR
- 2. ANY request listed in items (a) through (d) requires Plan Medical Director review and approval:
 - a. Indications Considered Experimental and Investigational or NOT Medically Necessary:

When applicable medical necessity criteria are NOT met for the requested device, the Plan considers the service either experimental and investigational or NOT reasonable and necessary. Individual consideration will be conducted by the Plan Medical Director based on the clinical documentation submitted by the treating provider and will take into account the following



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factors: member's age and diagnosis; comorbidities and relevant past medical/surgical/behavioral health/pharmacotherapy history (e.g., history of severe hypoglycemia, limited life expectancy, microvascular or macrovascular complications, long-standing diabetes in whom the A1C goal is difficult to achieve despite diabetes self-management and medical treatment); duration of diabetes; diagnostic (including laboratory test) results; glycemic control targets; complications; progression of the member's clinical condition, illness, or injury; progress of treatment; psychosocial circumstances; home environment and other environmental factors (if applicable); available treatment options; member motivation and adherence; and verification the requested device/system is being prescribed and will be utilized according to its FDA-approved clearance and guideline information, including intended use for the member's age and medical condition.

b. Noncompliance or Ineffective Use of CGMS:

Requests for ongoing use of a CGMS (or combined CGMS with external insulin pump using CSII) when the member (or family member or caregiver on behalf of the member) is consistently unable to manage the device properly, 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. Applicable clinical information must be submitted to the Plan 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, individualized treatment plan, and documentation supporting that the member's plan of care is compliant with the latest standards of medical care in diabetes established by the American Diabetes Association to determine if it is medically necessity to continue the use CGMS or discontinue the device with the implementation of an alternate 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, the following medical record documentation must be submitted by the treating provider: description of the member's medical condition, 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, and documentations supporting that the member's plan of care is compliant with the latest standards of medical care in diabetes established by the American Diabetes Association.

d. Upgrade for New Technology:



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The member's treating physician must submit documentation to the Plan demonstrating how the upgrade is expected to significantly improve the member's A1C target level and that this improvement cannot be achieved with the member's current CGMS.

Limitations and Exclusions

- 1. The authorization period is six (6) months for the purchase of the receiver and transmitter for a CGMS approved by the Plan in the outpatient setting. A lifetime authorization will be granted for sensors and supplies for the CGM device currently used by the member if the device is approved by the Plan. When the device, sensor, and/or related supplies are authorized by Northwood rather than the Plan, the authorization period and quidelines for purchase are established by Northwood.
- 2. The Plan considers the use of a fully implantable continuous glucose monitoring system/sensor (I-CGMS) (e.g., Eversense E₃ CGM System) NOT medically necessary for short-term use (72 hours to 1 week) for diagnostic purposes and may not be used for members age 17 or younger due to limited evidence documenting the clinical utility and clinical validity of the device. Members with I-CGMS must follow the appropriate safety guidelines before undergoing an MRI procedure.
 - 3. The Plan provides no additional reimbursement for wireless glucose monitoring, either as an attached transmission device or a component of a Plan-authorized artificial pancreas device system or CGMS.
 - 4. The Plan considers the use of a continuous noninvasive glucose monitoring device (including the purchase or rental of this device) to NOT be reasonable and necessary.
 - 5. The Plan considers the replacement of a member's currently functional CGMS or functional combined CGMS with external insulin pump for the sole purpose of receiving an upgraded system or the most recent technology to NOT be medically necessary; this includes upgrades for enhanced information/wireless communication technology for uploading, monitoring, and/or sharing blood glucose levels as a convenience feature.

Variations

The Plan uses guidance from the Centers for Medicare & Medicaid Services (CMS) for medical necessity and coverage determinations for the Plan's MA Senior Care Options (SCO) members and New Hampshire Medicare Advantage HMO members, including but not limited to national coverage determinations (NCDs), local coverage determinations (LCDs), local coverage articles (LCAs), and documentation included in Medicare manuals. At the time of the Plan's most recent policy review, LCD L38623 includes guidelines for the use of implantable continuous glucose monitors. CMS NCD 40.3 is DMEPOS Standard Medical Policy (Medicaid)

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applicable for closed-loop blood glucose control devices used in an inpatient setting. Verify CMS guidelines in effect on the date of the prior authorization request. When there is no guidance from CMS for the requested service, Plan-adopted clinical review criteria will be used to determine the medical necessity of the service.

Applicable Coding

The Plan utilizes up-to-date, industry-standard Current Procedural Terminology (CPT) codes, Health Care Common Procedure Coding System (HCPCS) codes, and International Statistical Classification of Diseases and Related Health Problems, 10th revision (ICD-10) diagnosis codes in the Plan's medical policies. Since these codes may be updated at different intervals than the medical policy review cycle, the list of applicable codes included in a policy is informational only and may not be all inclusive. Applicable codes are subject to change without prior notification and do not guarantee member coverage or provider reimbursement. Review the Plan's reimbursement policies for Plan billing guidelines. Providers are responsible for obtaining prior authorization for the services specified in the Clinical Criteria section and Limitations and Exclusions section of a medical policy, even if an applicable code appropriately describing the service is not included in the policy's Applicable Coding section. Providers are expected to report all services using the most up-to-date, industry-standard procedures and diagnosis codes at the time of the service.

| HCPCS Codes | Description: Codes Covered When Medically Necessary | | |
|-------------|---|--|--|
| | Plan note for HCPCS codes listed in this table: DME providers, medical supply providers, pharmacy providers, home infusion providers, home care providers, and specialty pharmacy providers must contact Northwood (rather than then Plan) to determine coverage and reimbursement guidelines for these components and to obtain authorization. Other provider types must contact the Plan to obtain authorization for services. All HCPCS codes listed in this table are managed by Northwood. | | |
| A4238 | Supply allowance for adjunctive, non-implanted continuous glucose monitor (cgm), includes all supplies and accessories, 1 month supply = 1 unit of service | | |
| A4239 | Supply allowance for non-adjunctive, non-implanted continuous glucose monitor (cgm), includes all supplies and accessories, 1 month supply = 1 unit of service | | |
| A9276 | Sensor; invasive (e.g., subcutaneous), disposable, for use with non-durable medical equipment interstitial continuous glucose monitoring system, 1 unit = 1-day supply | | |
| A9277 | Transmitter; external, for use with non-durable medical equipment interstitial continuous glucose monitoring system | | |
| A9278 | Receiver (monitor); external, for use with non-durable medical equipment interstitial continuous glucose monitoring system | | |
| E2102 | Adjunctive, non-implanted continuous glucose monitor or receiver | | |
| E2103 | Non-adjunctive, non-implanted continuous glucose monitor or receiver | | |



| CPT Codes | Description: Codes Considered Medically Necessary for Implantable Interstitial Glucose Sensor |
|-----------|---|
| 0446T | Creation of subcutaneous pocket with insertion of implantable interstitial glucose sensor, including system activation and patient training |
| | Plan note: Code used for 90-day monitoring period. |
| 0448T | Removal of implantable interstitial glucose sensor with creation of subcutaneous pocket at different anatomic site and insertion of new implantable sensor, including system activation |
| | Plan note: Code used for 90-day monitoring period. |

| HCPCS Codes | Description: Codes Covered When Medically Necessary for Artificial Pancreas Device System in the Outpatient Setting | | |
|-------------|---|--|--|
| | Plan note for HCPCS codes listed in this table: DME providers, medical supply providers, pharmacy providers, home infusion providers, home care providers, and specialty pharmacy providers must contact Northwood (rather than then Plan) to determine coverage and reimbursement guidelines for components of the system and to obtain authorization. Other provider types must contact the Plan to obtain authorization for services. All HCPCS codes listed in this table for artificial pancreas device system are managed by Northwood. | | |
| S1034 | 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 | | |
| S1035 | Sensor; invasive (e.g., subcutaneous), disposable, for use with artificial pancreas device system | | |
| S1036 | Transmitter; external, for use with artificial pancreas device system | | |
| S1037 | Receiver (monitor); external, for use with artificial pancreas device system | | |

| HCPCS Code | Description: Code Considered NOT Medically Necessary for Single-Use, Disposable and Nonprogrammable/Mechanical Insulin Infusion Devices |
|------------|---|
| A9274 | External ambulatory insulin delivery system, disposable, each, includes all supplies and accessories |
| | Plan notes: Code is NOT payable for the NH Medicare Advantage HMO product. Code may NOT be used for single-use, disposable and nonprogrammable/mechanical insulin infusion device (e.g., V-Go). 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 |



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| reimbursement quidelines for all other types of disposable external ambulatory insulin |
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| delivery systems (including supplies and accessories). |

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Next Review Date

02/01/25

Authorizing Entity

UMC

Appendix

Appendix: Policy History

Disclaimer Information:

Plan refers to Boston Medical Center Health Plan, Inc. which operates under the trade name WellSense Health Plan. Medical Policies are the Plan's guidelines for determining the medical necessity of certain services or supplies for purposes of



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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 System

Appendix: Policy History

| Original Approval Date | Original Effective Date* and Version | Policy Owner | Original Policy Approved by |
|---|---|--|--------------------------------|
| Regulatory Approval: N/A Internal Approval: o7/08/08: Medical Policy, Criteria, and Technology Assessment Committee (MPCTAC) | 11/10/08 Version 1 | Senior Medical Director as Chair of Utilization Management Committee (UMC) | MPCTAC, QIC, and UMC |
| o7/22/08: Utilization Management Committee (UMC) o8/13/08: Quality Improvement Committee (QIC) | | | |

^{*}Effective date for MassHealth product: 11/10/08

Note: Policy title was *Continuous Glucose Monitoring Systems* until 10/31/16. Policy title effective 11/01/16 to 11/30/19 was *Continuous Glucose Monitoring Systems and Insulin Delivery Devices*. As of 12/01/19, the policy title has been changed to the following: *Continuous Glucose Monitoring Systems, Artificial Pancreas Delivery Systems, and Insulin Delivery Devices*.

| Policy Revisions History | | | | |
|--------------------------|---|--|--|--|
| Review Date | Summary of Revisions | Revision Effective Date and Version Number | Approved by | |
| 07/28/09 | No changes. | Version 2 | 07/28/09: MPCTAC 07/28/09: UMC 08/26/09: QIC | |
| 07/01/10 | Updated clinical criteria with additional criteria for the short and long term use of CGMS. Updated references. | Version 3 | 08/18/10: MPCTAC 09/22/10: QIC | |
| 08/01/11 | Updated references. No changes to criteria or code list. | Version 4 | 08/17/11: MPCTAC 09/28/11: QIC | |
| 07/01/12 | Updated references. Added following | Version 5 | 07/18/12: MPCTAC | |

^{*}Effective date for MA Clarity plans (formerly known as QHP Product)/Employer Choice Direct: 01/01/12

^{*}Effective date for MA Senior Care Options product: 01/01/16

^{*}Effective date for NH Medicare Advantage HMO product: 01/01/22



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| | 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. | | 08/22/12: QIC |
| 07/29/12 | Off cycle review for NH Medicaid product, revised Summary statement, reformatted Medical Policy Statement, added Definitions section, revised Limitations statement. | Version 6 | 08/03/12: MPCTAC 09/05/12: QIC |
| 07/01/13 | 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 stating that CGMS is used as an adjunct to finger stick 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. | 11/01/13 Version 7 | 07/17/13: MPCTAC 08/15/13: QIC |
| 12/01/13 | Review for effective date 05/01/14. Revised Summary, Description of Item or Service, | 05/01/14 Version 8 | 12/18/13: MPCTAC 01/21/14: QIC |



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| | 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. | | |
| 12/01/14 | Review for effective date 04/01/15. | 04/01/15 | 12/17/14: MPCTAC |
| | Updated Clinical Background Information | Version 9 | 01/14/15: QIC |
| | section. Revised criteria in Medical Policy | | |
| | Statement section and Limitations section. | | |
| 10/01/15 | Review for effective date 12/01/15. Updated | 12/01/15 | 10/21/15: MPCTAC |
| | template with list of applicable products | Version 10 | 11/11/15: QIC |
| | and corresponding notes. | | |
| 10/21/15 | Review for effective date 02/01/16. | 02/01/16 | 10/21/15: MPCTAC |
| | Revised the Limitations section and | Version 11 | 11/11/15: QIC |
| | updated references. Clarified criteria in the | | |
| | Medical Policy Statement section. | | |
| 11/25/15 | Review for effective date 02/01/16. Revised | 02/01/16 | 11/25/15: MPCTAC |
| | language in the Applicable Coding section. | Version 12 | (electronic vote) |
| | Updated Summary and References | | 12/09/15: QIC |
| | sections. | | |
| 08/01/16 | Review for effective date 11/01/16. Updated | 11/01/16 | 08/08/16: MPCTAC |
| | Summary, Description of Item or Service, | Version 13 | (electronic vote) |
| | Definitions, Clinical Background | | 08/10/16: QIC |
| | Information, References, and Reference to | | |
| | Applicable Laws and Regulations sections. | | |
| | Revised policy title and criteria in the | | |
| | Medical Policy Statement and Limitations | | |
| | sections. Added Plan notes and additional | | |
| | administrative changes made to the | | |
| | Applicable Coding section. Added | | |
| | applicable code A9274 as a device NOT | | |
| | considered medically necessary by the Plan | | |
| | when billed for the use of single-use, | | |
| | disposable and nonprogrammable/ | | |
| | mechanical insulin infusion device. | | |
| 10/01/16 | Review for effective date 12/01/16. Updated | 12/01/16 | 10/19/16: MPCTAC |
| | Clinical Background Information and | Version 14 | 11/09/16: QIC |
| | 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. | | |



| 12/05/16 | Industry-wide code change with the | 01/01/17 | Not applicable because |
|-------------|---|------------------------|------------------------|
| | addition of 2017 applicable CPT codes | Version 15 | industry-wide code |
| | o446T and o448T effective o1/o1/17. | | revision. |
| 04/01/17 | Review for effective date 07/08/17. Clarified | 07/08/17 | 04/15/17: MPCTAC |
| | Limitations section without changing | Version 16 | |
| | 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. | | |
| 06/01/17 | Review for effective date 07/08/17. | 07/08/17 | 06/21/17: MPCTAC |
| | Industry-standard code update in the | Version 17 | |
| | Applicable Coding section. | | |
| 10/01/17 | Review for effective date 01/01/18. | 01/01/18 | 10/18/17: MPCTAC |
| | Administrative changes made to the Policy | Version 18 | |
| | Summary, Description of Item or Service, | | |
| | Definitions, Clinical Background | | |
| | Information, References, and Other | | |
| | Applicable Policies sections. Revised | | |
| | criteria in the Limitations section. | | |
| 03/01/18 | Review for effective date o6/o1/18. | 06/01/18 | 03/21/18: MPCTAC |
| <i>3.</i> . | Administrative changes made to Policy | Version 19 | <i>J.</i> . |
| | Summary, Definitions, References, and | | |
| | Other Applicable Policies sections. | | |
| | Updated criteria in the Medical Policy | | |
| | Statement and Limitations sections. | | |
| 10/01/18 | Review for effective date 01/01/19. | 01/01/19 | 10/17/18: MPCTAC |
| 10/01/10 | Administrative changes made to the Policy | Version 20 | 10/1//10: 11: 0:/10 |
| | Summary, Clinical Background Information, | V CISION 20 | |
| | References, and Other Applicable Policies | | |
| | sections. Criteria revised in the Medical | | |
| | Policy Statement and Limitations sections. | | |
| | Coding updated in the Applicable Coding | | |
| | section. | | |
| 00/01/10 | Review for effective date 12/01/19. Revised | 12/01/10 | 00/18/10: MPCTAC |
| 09/01/19 | the policy title. Administrative changes | 12/01/19 Version 21 | 09/18/19: MPCTAC |
| | made to Policy Summary, Description of | V CI 31011 21 | |
| | | | |
| | Item or Service, Definitions, Clinical | | |
| | Background Information, References, and | | |
| | Reference to Applicable Laws and | | |
| | Regulations sections. Revised criteria in the | | |



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| | Medical Policy Statement and Limitations | | |
| | sections. Updated coding and Plan notes in | | |
| | the Applicable Coding section. | | |
| 11/01/19 | Review for effective date 12/01/19. | 12/01/19 | 11/20/19: MPCTAC |
| | Administrative changes made the | Version 22 | |
| | Limitations and Applicable Coding sections | | |
| | to clarify that the FreeStyle Libre is covered | | |
| | as a pharmacy benefit (and would not be | | |
| | authorized as medically necessary under | | |
| | the member's medical benefit or DME | | |
| | benefit). Updated the References section. | | |
| 09/25/20 | Review for effective date 10/01/20. | 10/01/20 | 09/25/20: MPCTAC |
| 3. 3. | Administrative changes made to the | Version 23 | (electronic vote) |
| | Medical Policy Statement, Limitations, | | , |
| | Applicable Coding, Clinical Background | | |
| | Information, and Reference to Applicable | | |
| | Laws and Regulations sections to reference | | |
| | CMS guidelines for clinical indications for | | |
| | coverage for SCO members with Medicare | | |
| | coverage during the COVID-19 pandemic. | | |
| 09/01/20 and | Review for effective date 12/01/20. | 12/01/20 | 09/16/20: MPCTAC |
| 09/25/20 | Administrative changes made to the Policy | Version 24 | and |
| | Summary, Description of Item or Service, | 1 0.5.5 24 | 09/25/20: MPCTAC |
| | Definitions, Clinical Background | | (electronic vote) |
| | Information, References, and Other | | (creationing rote) |
| | Applicable Policies sections. Plan notes | | |
| | updated in the Applicable Coding section. | | |
| | Criteria revised in the Medical Policy | | |
| | Statement and Limitations sections. | | |
| | Renumbered to version 24 with electronic | | |
| | vote on 09/25/20 to incorporate additional | | |
| | revisions made to the policy version | | |
| | effective 10/01/20 (version 23) referencing | | |
| | CMS guidelines for clinical indications for | | |
| | coverage for SCO members during the | | |
| | COVID-19 pandemic. | | |
| 10/01/21 | Review for effective date 01/01/21. | 01/01/22 | 10/20/21: MPCTAC |
| 10/01/21 | Adopted new medical policy template; | Version 25 | 10/20/21. WII CIAC |
| | removed administrative sections, Medical | V 6131011 25 | |
| | Policy Statement section renamed Clinical | | |
| | Criteria, the Limitations section renamed | | |
| | Limitations and Exclusions section. Added | | |
| | Limitations and Exclusions section. Added | | |



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| | NH Medicare Advantage HMO as an | | |
| | applicable product effective 01/01/22. | | |
| | Administrative changes made to the Policy | | |
| | Summary, Applicable Coding, and | | |
| | References sections. Criteria revised in the | | |
| | Clinical Criteria and Limitations and | | |
| | Exclusions sections. | | |
| 12/01/21 | Review for effective date 03/01/22. | 03/01/22 | 12/15/21: MPCTAC |
| | Removed prior authorization requirement | Version 26 | |
| | for the interpretation and report of | | |
| | authorized ambulatory continuous glucose | Not implemented – | |
| | monitoring (CPT code 95251). | replaced with | |
| | | Version 27 | |
| 01/01/22 | Review for effective date 03/01/22. | 03/01/22 | 01/19/22: MPCTAC |
| | Administrative changes made to the Policy | Version 27 | |
| | Summary and References sections. Non- | , | |
| | material revisions made to the Clinical | | |
| | Criteria and Limitations and Exclusions | | |
| | sections. Revisions approved in version 26 | | |
| | implemented. | | |
| 04/01/22 | Review for effective date 05/01/22. | 05/01/22 | 04/20/22: MPCTAC |
| 04/04/22 | Updated Plan notes and added codes | Version 28 | 94,29,221 1111 21712 |
| | managed by Northwood as administrative | | |
| | changes to the Applicable Coding section. | | |
| | Industry-wide code updates made to the | | |
| | Applicable Coding section. Administrative | | |
| | changes made to the Policy Summary and | | |
| | Clinical Criteria sections. | | |
| 07/01/22 | Review for effective date 08/01/22. | 08/01/22 | 07/20/22: MPCTAC |
| -,,-, | Administrative changes made to the Policy | Version 29 | ", ", |
| | Summary and References sections. | | |
| | Industry-wide code updates made in the | | |
| | Applicable Coding section. Non-material | | |
| | revisions to criteria in the Clinical Criteria | | |
| | and Limitations and Exclusions sections. | | |
| 12/01/22 | Review for effective date 01/01/23. | 01/01/23 | 12/21/22: MPCTAC |
| , - , | Industry-wide code updates made to the | Version 30 | ,, |
| | Applicable Coding section. HCPCS code | | |
| | A4239 replaced Ko553. HCPCS code E2103 | | |
| | replaced Ko554. Removed codes not | | |
| | payable for any Plan product. | | |
| 02/01/23 | Review for effective date 03/01/23. | 03/01/23 | 02/15/23: MPCTAC |
| 02104123 | review for effective date 03/01/23. | 03104123 | 02/13/23. IVII CIAC |



Continuous Glucose Monitoring System

| | Administrative changes made to the Policy Summary, Clinical Criteria, Applicable Coding, and References sections. | Version 31 | |
|----------|---|---|------------------|
| 03/01/23 | Review for effective date o6/o1/23. Administrative changes made to the Policy Summary section. Removed prior authorization requirement CPT code 95250 in the Applicable Coding section. | o6/o1/23 Version 32 Version 32 not implemented | 03/15/23: MPCTAC |
| 04/01/23 | Review for effective date 46/01/23. Removed language in the Variations section related to CMS guidelines associated with the COVID-19 pandemic. Incorporated all revisions approved for Version 32. Nonmaterial changes to criteria in the Clinical Criteria section. | 04/01/23 Version 33 | 03/21/23: MPCTAC |
| 03/01/24 | Review for effective date 04/01/24. Non-material changes to Clinical Criteria section. Administrative changes to References section. | 04/01/24 Version 34 | 03/20/24: UMC |

End Appendix A

Change/Authorization History:

| Revision Number | Date | Description of Change | Prepared / Reviewed by | Approved by | Review Date: | Effective Date: |
|--------------------|--------------|--|---------------------------|------------------|-----------------|--------------------|
| A | 1-31- 11 | Initial Release | Susan Glomb | Kenneth G. Fasse | | |
| 01 | 07-20- 11 | Added Important Note to all Medical Policies | Susan Glomb | Dr. B. Almasri | | |
| 02 | 11-08- 11 | Added Reference to Policy | Susan Glomb | Dr. B. Almasri | Nov. 2011 | |



| 03 | 11-28- 12 | Annual review – no changes. | Susan Glomb | Dr. B. Almasri | Nov. 2012 | |
|----|--------------|---|--------------|----------------|-----------------|--|
| 04 | 12-18- 13 | Annual review. No changes | Susan Glomb | Dr. B. Almasri | | |
| 05 | 12-29- 14 | Annual Review. No changes | Susan Glomb | Dr. B. Almasri | | |
| 06 | 11-23- 15 | Annual Review. Added Artificial Pancreas codes and policy. Updated references. | Lisa Wojno | Dr. B. Almasri | November 2015 | |
| 07 | 7-6-16 | Policy updated. Removed short term use information as short term use is non- covered. | Susan Glomb | Dr. B. Almasri | | |
| 08 | 12-14- 16 | Annual Review. No Changes. | Lisa Wojno | Dr. B. Almasri | December 2016 | |
| 09 | 12-11- 17 | Annual review. New K codes added for Therapeutic Continuous Glucose Monitor. | Carol Dimech | Dr. C. Lerchin | December 2017 | |
| 10 | 1-9-18 | New K codes removed as these apply to Medicare only. | Carol Dimech | Dr. C. Lerchin | January 2018 | |



| 13 12-06- 19 Additional reference added to policy. Carol Dimech Dr. C. Lerchin December 2019 6, | |
|--|----------------|
| 13 12-06- 19 Additional reference added to policy. Carol Dimech Dr. C. Lerchin December 2019 6, | ļ |
| 14 12-08- CMS: revised Carol Dimech Dr. C. Lerchin December 8, 2 | ecember, 2019 |
| "practitioner". | cember 2020 |
| | cember 2021 |
| Policy updated to reflect guidelines for WellSense.members (formerly BMCHP); refer to Appendix A. Carol Dimech Dr. C. Lerchin March 1, 2022 | arch 1, 22 |
| 17 | |



| | 22 | WellSense.members (formerly BMCHP) effective 5/1/22; refer to Appendix A. | | | | 5-1-22 |
|----|--------------|---|--------------|----------------|----------|----------|
| 18 | 8-1-22 | Policy updated to reflect guidelines for WellSense.members (formerly BMCHP); refer to Appendix A effective 8/1/22. | Carol Dimech | Dr. C. Lerchin | 8-1-22 | 8-1-22 |
| 19 | 12-13- 22 | Annual review. Per industry standard, removed Type I Diabetes requirement to now reflect qualifying diagnosis of "diabetes"; also listed additional criteria. | Carol Dimech | Dr. C. Lerchin | 12-13-22 | 12-13-22 |
| 20 | 12-29- 22 | Appendix A WellSense criteria updated to reflect Version 30, effective 1-1-23. | Carol Dimech | Dr. C. Lerchin | 12-29-22 | 12-29-22 |
| 21 | 3-1-23 | Appendix A WellSense criteria updated to reflect Version 31, effective 3-1-23. | Carol Dimech | Dr. C. Lerchin | 3-1-23 | 3-1-23 |
| 22 | 4-19- | Per CMS: Removed terms therapeutic and | Carol Dimech | Dr. C. Lerchin | 4-19-23 | 4-19-23 |



| | 23 | non-therapeutic. Added HCPCS E2103 and A4239. Revised HCPCS descriptor for Codes E2102, A4238. | | | | |
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| 23 | 6-1-23 | Appendix A WellSense criteria updated to reflect Version 32, effective 6-1-23. | Carol Dimech | Dr. C. Lerchin | 6-1-23 | 6-1-23 |
| 24 | 12-18- 23 | Annual review. No changes | Carol Dimech/Susan Glomb | Dr. C. Lerchin | 12-18-23 | December 2023 |
| 25 | 4-22- 24 | Appendix A WellSense criteria updated to reflect Version 34, effective 4-1-24. | Carol Dimech | Dr. C. Lerchin | 4-22-24 | April 2024 |
| 26 | 12-9- 24 | Annual review. Updated references. | Susan Glomb/Carol Dimech | Dr. C. Lerchin | 12-9-24 | 12-9-24 |