

Continuous Glucose Monitoring System

WellSense Health Plan Members: Requests **only** need to meet the Appendix A criteria. See Appendix A for policy guidelines – [CLICK HERE](#).

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 stand-alone 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

A Continuous Glucose Monitoring System (CGMS) is considered reasonable and necessary when a member meets coverage criteria.

Policy Guidelines

Medicare Member Coverage Criteria:

Refer to Medicare policy (L33822) and article (A52464) for coverage criteria.

Non-Medicare Member Coverage Criteria:

Coverage Criteria:

The CGM is prescribed to improve glycemic control for the insulin treated member.

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

- have recurrent episodes of severe hypoglycemia (blood glucose <54mg/dl) despite appropriate modifications in insulin regimen, OR
- 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.
- The member's treating practitioner has concluded that the member (or member's caregiver) has sufficient training using the CGM prescribed as evidenced by providing a prescription.

All other uses of CGMS are considered experimental and investigational. CGMS are 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 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**.



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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

A4238	Supply allowance for adjunctive, non-implanted continuous glucose monitor (CGM), includes all supplies and accessories, 1 month supply = 1 unit of service EFFECTIVE 1-1-24, 3 UNITS OF SERVICE PER 90 DAYS
A4239	Supply allowance for non-adjunctive, non-implanted continuous glucose monitor (CGM), includes all supplies and accessories, 1 month supply = 1 unit of service. EFFECTIVE 1-1-24, 3 UNITS OF SERVICE PER 90 DAYS
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

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S1036	Transmitter; external, for use with artificial pancreas device system
S1037	Receiver (monitor); external, for use with artificial pancreas device system

Important Note:

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.

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

References:

Centers for Medicare and Medicaid Services, Local Coverage Determination (L33822) Glucose Monitors. Accessed and reviewed 12/9/24.

Health Net National Medical Policy: Continuous Glucose Monitoring Devices.
<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 Accessed December 9, 2024.

Aetna: Diabetes Tests, Programs and Supplies
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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: 32, Version effective date: 06-01-23.

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Appendix A: (Page 6-33 of 37)



Medical Policy

Continuous Glucose Monitoring Systems, Artificial Pancreas Device Systems, and Insulin Delivery Devices

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 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.



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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

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- (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:

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

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- (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 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;

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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 necessary 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:

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

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the Plan. 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.

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 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.

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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 the 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
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	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	<p>External ambulatory insulin delivery system, disposable, each, includes all supplies and accessories</p> <p>Plan notes:</p> <ol style="list-style-type: none"> 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 reimbursement guidelines for all other types of disposable external ambulatory insulin 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 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.

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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.

Appendix: Policy History

Original Approval Date	Original Effective Date* and Version	Policy Owner	Original Policy Approved by
Regulatory Approval: N/A Internal Approval: 07/08/08: Medical Policy, Criteria, and Technology Assessment Committee (MPCTAC) 07/22/08: Utilization Management Committee (UMC) 08/13/08: Quality Improvement Committee (QIC)	11/10/08 Version 1	Senior Medical Director as Chair of Utilization Management Committee (UMC)	MPCTAC, QIC, and UMC

*Effective date for MassHealth product: 11/10/08

*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

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

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			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 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.	Version 5	07/18/12: MPCTAC 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	11/01/13 Version 7	07/17/13: MPCTAC 08/15/13: QIC

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	specified in the Summary section). Added definition for diabetes mellitus and added text to Clinical Background Information section. Updated references.		
12/01/13	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.	05/01/14 Version 8	12/18/13: MPCTAC 01/21/14: QIC
12/01/14	Review for effective date 04/01/15. Updated Clinical Background Information section. Revised criteria in Medical Policy Statement section and Limitations section.	04/01/15 Version 9	12/17/14: MPCTAC 01/14/15: QIC
10/01/15	Review for effective date 12/01/15. Updated template with list of applicable products and corresponding notes.	12/01/15 Version 10	10/21/15: MPCTAC 11/11/15: QIC
10/21/15	Review for effective date 02/01/16. Revised the Limitations section and updated references. Clarified criteria in the Medical Policy Statement section.	02/01/16 Version 11	10/21/15: MPCTAC 11/11/15: QIC
11/25/15	Review for effective date 02/01/16. Revised language in the Applicable Coding section. Updated Summary and References sections.	02/01/16 Version 12	11/25/15: MPCTAC (electronic vote) 12/09/15: QIC
08/01/16	Review for effective date 11/01/16. Updated Summary, Description of Item or Service, Definitions, Clinical Background 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.	11/01/16 Version 13	08/08/16: MPCTAC (electronic vote) 08/10/16: QIC
10/01/16	Review for effective date 12/01/16. Updated Clinical Background Information and References sections. Administrative	12/01/16 Version 14	10/19/16: MPCTAC 11/09/16: QIC

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	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 addition of 2017 applicable CPT codes 0446T and 0448T effective 01/01/17.	01/01/17 Version 15	Not applicable because industry-wide code revision.
04/01/17	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.	07/08/17 Version 16	04/15/17: MPCTAC
06/01/17	Review for effective date 07/08/17. Industry-standard code update in the Applicable Coding section.	07/08/17 Version 17	06/21/17: MPCTAC
10/01/17	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.	01/01/18 Version 18	10/18/17: MPCTAC
03/01/18	Review for effective date 06/01/18. Administrative changes made to Policy Summary, Definitions, References, and Other Applicable Policies sections. Updated criteria in the Medical Policy Statement and Limitations sections.	06/01/18 Version 19	03/21/18: MPCTAC
10/01/18	Review for effective date 01/01/19. Administrative changes made to the Policy Summary, Clinical Background Information, References, and Other Applicable Policies sections. Criteria revised in the Medical Policy Statement and Limitations sections. Coding updated in the Applicable Coding section.	01/01/19 Version 20	10/17/18: MPCTAC
09/01/19	Review for effective date 12/01/19. Revised the policy title. Administrative changes made to Policy Summary, Description of Item or Service, Definitions, Clinical Background Information, References, and	12/01/19 Version 21	09/18/19: MPCTAC

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	Reference to Applicable Laws and Regulations sections. Revised criteria in the 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. Administrative changes made the 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.	12/01/19 Version 22	11/20/19: MPCTAC
09/25/20	Review for effective date 10/01/20. Administrative changes made to the 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.	10/01/20 Version 23	09/25/20: MPCTAC (electronic vote)
09/01/20 and 09/25/20	Review for effective date 12/01/20. Administrative changes made to the Policy Summary, Description of Item or Service, Definitions, Clinical Background Information, References, and Other 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.	12/01/20 Version 24	09/16/20: MPCTAC and 09/25/20: MPCTAC (electronic vote)
10/01/21	Review for effective date 01/01/21. Adopted new medical policy template; removed administrative sections, Medical Policy Statement section renamed Clinical Criteria, the Limitations section renamed Limitations and Exclusions section. Added	01/01/22 Version 25	10/20/21: MPCTAC

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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. Removed prior authorization requirement for the interpretation and report of authorized ambulatory continuous glucose monitoring (CPT code 95251).	03/01/22 Version 26 Not implemented – replaced with Version 27	12/15/21: MPCTAC
01/01/22	Review for effective date 03/01/22. Administrative changes made to the Policy Summary and References sections. Non-material revisions made to the Clinical Criteria and Limitations and Exclusions sections. Revisions approved in version 26 implemented.	03/01/22 Version 27	01/19/22: MPCTAC
04/01/22	Review for effective date 05/01/22. Updated Plan notes and added codes 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.	05/01/22 Version 28	04/20/22: MPCTAC
07/01/22	Review for effective date 08/01/22. Administrative changes made to the Policy 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.	08/01/22 Version 29	07/20/22: MPCTAC
12/01/22	Review for effective date 01/01/23. Industry-wide code updates made to the Applicable Coding section. HCPCS code A4239 replaced K0553. HCPCS code E2103 replaced K0554. Removed codes not payable for any Plan product.	01/01/23 Version 30	12/21/22: MPCTAC
02/01/23	Review for effective date 03/01/23. Administrative changes made to the Policy Summary, Clinical Criteria, Applicable	03/01/23 Version 31	02/15/23: MPCTAC

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	Coding, and References sections.		
03/01/23	Review for effective date 06/01/23. Administrative changes made to the Policy Summary section. Removed prior authorization requirement CPT code 95250 in the Applicable Coding section.	06/01/23 Version 32 Version 32 not implemented	03/15/23: MPCTAC
04/01/23	Review for effective date 4/6/01/23. Removed language in the Variations section related to CMS guidelines associated with the COVID-19 pandemic. Incorporated all revisions approved for Version 32. Non-material 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	1-10-	Including experimental/investigational	Susan Glomb	Dr. B. Almasri	Jan. 2012	

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	12	exclusions. Updated references.				
04	04-03-12	Added reference to NH Medicaid	Susan Glomb	Dr. B. Almasri		
05	11-28-12	Annual Review – No changes	Susan Glomb	Dr. B. Almasri	Nov 12	
06	12-18-13	Annual Review. No changes	Susan Glomb	Dr. B. Almasri	Dec 13	
07	12-29-14	Annual Review. No changes	Susan Glomb	Dr. B. Almasri		
08	11-23-15	Annual Review. Updated policy regarding Medicare non-coverage and added Artificial Pancreas codes and policy.	Lisa Wojno	Dr. B. Almasri	November 2015	
09	12-14-16	Annual review. No Changes.	Lisa Wojno	Dr. B. Almasri	December 2016	
10	08-02-17	Updated Policy regarding Medicare coverage of new K Codes for Therapeutic Continuous Glucose Monitors under the DME MAC	Lisa Wojno	Dr. C. Lerchin	August 2017	

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11	12-11-17	Annual review. No changes since 8-2-17.	Carol Dimech	Dr. C. Lerchin	December 2017	
12	12-6-18	Annual review. No changes.	Carol Dimech	Dr. C. Lerchin	December 2018	
13	12-06-19	Annual review. Additional reference added to policy.	Carol Dimech	Dr. C. Lerchin	December 2019	December 6, 2019
14	12-08-20	Annual review. Per CMS: revised “physician” to “practitioner”; revised “month” to “30 days,” as clarification of billing K0553.	Carol Dimech	Dr. C. Lerchin	December 8, 2020	December 8, 2020
15	12-9-21	Annual review. Removed: four times or more per day testing with blood glucose monitor as prerequisite for CGM coverage. Added NCD, LCD verbiage to “Important Note”.	Carol Dimech	Dr. C. Lerchin	December 9, 2021	December 9, 2021
16	03-01-22	Policy updated to reflect guidelines for Wellsense members; refer to Appendix A.	Carol Dimech/Susan Glomb	Dr. C. Lerchin	03-01-22	03-01-22
17	04-29-22	Policy updated to reflect guidelines for Wellsense members effective 5-1-22; refer to Appendix A.	Carol Dimech	Dr. C. Lerchin	4-29-22	05-01-22

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18	7-11-22	Added HCPCS E2102, A4238 non-therapeutic CGMS. Added general CGMS information for clarity.	Carol Dimech	Dr. C. Lerchin	7-11-22	
19	8-1-22	Policy updated to reflect guidelines for WellSense members effective 8-1-22; refer to Appendix A.	Carol Dimech	Dr. C. Lerchin	8-1-22	8-1-22
20	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
21	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
22	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
23	4-19-23	Per CMS: Removed terms therapeutic and non-therapeutic. Removed HCPCS codes A9279, K0553 and K0554. Added HCPCS E2103 and A4239. Revised HCPCS descriptor for Codes E2102, A4238.	Susan Glomb/Carol Dimech	Dr. C. Lerchin	4-19-23	4-19-23
24	6-1-23	Appendix A WellSense criteria updated to reflect	Carol Dimech	Dr. C. Lerchin	6-1-23	6-1-23

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		Version 32, effective 6-1-23.				
25	12-18-23	Annual review. Policy updated to include CMS changes. Removed reference requirement of daily insulin. And Effective 1-1- 24, A4238 and A4239 to show 3 units of service per 90 days.	Carol Dimech/Susan Glomb	Dr. C. Lerchin	12-18-24	December 2023
26	4-22-24	Appendix A WellSense criteria updated to reflect Version 34, effective 4-1-24.	Carol Dimech	Dr. C. Lerchin	4-22-24	4-22-24
27	12-9-24	Annual review. Updated references.	Carol Dimech	Dr. C. Lerchin	12-9-24	12-9-24