Medical Policy

Northwood

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.

Continuous Glucose Monitoring System

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.**

Continuous Glucose Monitoring System

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

Continuous Glucose Monitoring System

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.

Continuous Glucose Monitoring System

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

References:

Centers for Medicare and Medicaid Services, National Coverage Determination Manual. 280.1 Durable Medical Equipment Reference List. Accessed December 13, 2022.

Centers for Medicare and Medicaid Services, Local Coverage Determination (L33822) Glucose Monitors. Accessed and reviewed 4/19/23.

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 18, 2023.

Aetna: Diabetes Tests, Programs and Supplies http://www.aetna.com/cpb/medical/data/1_99/0070.html#dummyLink1 Last accessed and reviewed December 18, 2023.

Chase HP, Roberts MD, Wightman C, Klingensmith G, Garg SK, Van Wyhe M, et al. Use of the GlucoWatch biographer in children with type 1 diabetes. Pediatrics. 2003 Apr;111(4 Pt 1):790-4.

Chase HP, Beck R, Tamborlane W, Buckingham B, Mauras N, Tsalikian E, et al. the diabetes research in children (DirectNet) study group. A randomized multicenter trial comparing the GlucoWatch Biographer with standard glucose monitoring in children with type 1 diabetes. Diabetes Care. 2005 May;28(5):1101-6.

Hayes, Inc. Continuous glucose monitoring systems. Hayes Medical Technology Directory. May 22, 2007.

Newman SP, Cooke D, Casbard A, Walker S, Meredith S, Nunn A, et al. A randomized controlled trial to compare minimally invasive glucose monitoring devices with conventional monitoring in the management of insulin-treated diabetes mellitus (MITRE). Health Technol Assess 2009;13(28).

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.

Medical Policy

Northwood

Continuous Glucose Monitoring System

Appendix A: (Page 6-33 of 37)

WellSense HEALTH PLAN

Medical Policy

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

Policy Number: OCA 3.966
Version Number: 32
Version Effective Date: 06/01/23

Impacted Products

- ☒ **All Products**
- ☒ NH Medicaid
- ☒ NH Medicare Advantage
- ☒ MA MassHealth ACO
- ☒ MA MassHealth MCO
- ☒ MA Qualified Health 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.

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, QHP, 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 multiple 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 4 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 (e):

(a) A1C greater than or equal to 7.0%; OR

(b) Hypoglycemic unawareness; OR

(c) Postprandial hyperglycemia; OR

(d) Recurrent diabetic ketoacidosis; OR

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

(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; 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:

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 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. 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.

Continuous Glucose Monitoring System

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: 1. Code is NOT payable for the NH Medicare Advantage HMO product. 2. Code may NOT be used for single-use, disposable and nonprogrammable/mechanical insulin infusion device (e.g., V-Go). 3. 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).

References

Abbott. FreeStyle Libre Pro. Flash Glucose Monitoring System. Professional Continuous Glucose Monitoring. Billing and Reimbursement Guide.

Adolfsson P, Parkin CG, Thomas A, Krinelke LG. Selecting the Appropriate Continuous Glucose Monitoring System - a Practical Approach. Eur Endocrinol. 2018 Apr;14(1):24-9. doi: 10.17925/EE.2018.14.1.24. Epub 2018 Apr 18. PMID: 29922348.

Agrawal P, Zhong A, Welsh JB, Shah R, Kaufman FR. Retrospective Analysis of the Real World Use of Threshold Suspend Feature of Sensor-Augmented Insulin Pumps. Diabetes Technol Ther. 2015 May 1;17(5):316–9. doi: 10.1089/dia.2014.0257. Epub 2015 Jan 22. PMID: 25611577.

Alexopoulos AS, Blair R, Peters AL. Management of Preexisting Diabetes in Pregnancy: A Review. JAMA. 2019 May 14;321(18):1811-9. doi: 10.1001/jama.2019.4981. PMID: 31087027.

Allen N, Gupta A. Current Diabetes Technology: Striving for the Artificial Pancreas. Diagnostics (Basel). 2019 Mar 15;9(1):31. doi: 10.3390/diagnostics9010031. PMID: 30875898.

American Association of Clinical Endocrinologists (AACE), American College of Endocrinology (ACE). Bailey TS, Grunberger G, Bode BW, Handelsman Y, Hirsh IB, Jovanovič L, Roberts VL, Rodbard D, Tamborlane WV, Walsh J. AACE and ACE 2016 Outpatient Glucose Monitoring Consensus Statement. Endocr Pract. 2016 Feb;22(2):231-61 doi: 10.4158/EP151124.CS. Epub 2016 Jan 27. PMID: 26848630.

American Association of Clinical Endocrinologists (AACE)/ American College of Endocrinology (ACE). Comprehensive Type 2 Diabetes Management Algorithm (2020).

American Association of Clinical Endocrinologists (AACE), American College of Endocrinology (ACE). Grunberger G, Abelseth JM, Bailey TS, Bode BW, Handelsman Y, Hellman R, Jovanovič L, Lane WS, Raskin P, Tamborlane WV, Rothermel C. Consensus Statement by the AACE/ACE Insulin Pump Management Task Force. Endocr Pract. 2014 May 20(5):463-89. doi: 10.4158/EP14145.PS. PMID: 24816754.

American Association of Clinical Endocrinologists (AACE), American College of Endocrinology (ACE). Berga S, Blonde L, Bush M, Chandrasejarab S, DeFronzo R, Einhorn D, Galindo R, Gardner T, Garg R, Garvey WT, McGill JB, Hirsch IB, Hurley DL, Izuora K, Kosiborod M, Olson D, Patel S, Pop-Busui R, Reddy S, Sadhu A, Samson S, Stec C, Tamborlane WV Jr, Tuttle K, Twining C, Umpierrez G, Vella A, Vellanki P, Weber S AACE and ACE - Clinical Practice Guidelines for Developing a Diabetes Mellitus Comprehensive Care Plan 2022 Update - 2022 Oct;28(10):923-1049.doi: 10.1016/j.eprac.2022.08.002. Epub 2022 Aug 11. PMID: 35963508.

American Diabetes Association (ADA). ADA Position Statements.

American Diabetes Association (ADA). Advances in Artificial Pancreas Development.

American Diabetes Association (ADA). The Artificial Pancreas in 2016.

American Diabetes Association (ADA). Chiang J, Kirkman MS, Laffel L, Peters A. Type 1 Diabetes Through the Life Span: A Position Statement of the American Diabetes Association. Diabetes Care. 2014 Jul;37(7):2034-54. doi: 10.2337/dc14-1140. PMID: 24935775.

American Diabetes Association (ADA). Jackson CC, Albanese-O'Neill A, Butler KL, Chiang JL, Deeb LC, Hathaway K, Kraus E, Weissberg-Benchell, J, Yatvin AL, Siminerio LM. Diabetes Care in the School Setting: A Position Statement of the American Diabetes Association. Diabetes Care. 2015 Oct;38(10):1958–63. doi: 10.2337/dc15-1418. PMID: 26404925.

American Diabetes Association (ADA). Standards of Care in Diabetes-2023. Diabetes Care. 2023 Jan;46(Supple 1):S1-291.

Ascensia. Eversense 6-Month CGM Sensor. 2022.

Bailey KJ, Little JP, Jung ME. Self-monitoring using continuous glucose monitors with real-time feedback improves exercise adherence in individuals with impaired blood glucose: a pilot study. Diabetes Technol Ther. 2016 Mar;18(3):185-93. doi: 10.1089/dia.2015.0285. Epub 2016 Feb 17. PMID: 26885934.

Barnard KD, Kropff J, Choudhary P, et al. Acceptability of implantable continuous glucose monitoring sensor. J Diabetes Sci Technol. 2018;12(3):634-8. doi:10.1177/1932296817735123.

Beck RW, Riddlesworth T, Ruedy K, Ahmann A, Bergenstal R, Haller S, Kollman C, Kruger D, McGill JB, Polonsky W, Toschi E, Wolpert H, Price D; DIAMOND Study Group. Effect of Continuous Glucose Monitoring on Glycemic Control in Adults With Type 1 Diabetes Using Insulin Injections: The DIAMOND Randomized Clinical Trial. JAMA. 2017 Jan 24;317(4):371-8. doi: 10.1001/jama.2016.19975. PMID: 28118453.

Beck RW, Riddlesworth TD, Ruedy K, Ahmann A, Haller S, Kruger D, McGill JB, Polonsky W, Price D, Aronoff S, Aronson R, Toschi E, Kollman C, Bergenstal R; DIAMOND Study Group. Continuous Glucose Monitoring Versus Usual Care in Patients With Type 2 Diabetes Receiving Multiple Daily Insulin Injections: A Randomized Trial. Ann Intern Med. 2017 Sep 19;167(6):365-74. doi: 10.7326/M16-2855. Epub 2017 Aug 22. PMID: 28828487.

Bekiari E, Kitsios K, Thabit H, Tauschmann M, Athanasiadou E, Karagiannis T, Haidich AB, Hovorka R, Tsapas A. Artificial pancreas treatment for outpatients with type 1 diabetes: systematic review and meta-analysis. BMJ. 2018 Apr 18;361:k1310. doi: 10.1136/bmj.k1310. PMID: 29669716.

Benkhadra K, Alahdab F, Tamhane S, Wang Z, Prokop LJ, Hirsch IB, Raccah D, Riveline JP, Kordonouri O, Murad MH. Real-time continuous glucose monitoring in type 1 diabetes: a systematic review and individual patient data meta-analysis. Clin Endocrinol (Oxf). 2017 Mar;86(3):354-60. doi: 10.1111/cen.13290. Epub 2017 Jan 16. PMID: 27978595.

Bergenstal RM, Garg S, Weinzimer SA, Buckingham BA, Bode BW, Tamborlane WV, Kaufman FR. Safety of a Hybrid Closed-Loop Insulin Delivery System in Patients With Type 1 Diabetes. JAMA. 2016 Oct 4;316(13):1407-8. doi: 10.1001/jama.2016.11708. PMID: 27629148.

Bergenstal RM, Klonoff DC, Garg SK, Bode BW, Meredith M, Slover RH, Ahmann AJ, Welsh JB, Lee SW, Kaufman FR for the ASPIRE In-Home Study Group. Threshold-Based Insulin-Pump Interruption for Reduction of Hypoglycemia. N Engl J Med. 2013 Jul 18;369(3):224-32. doi: 10.1056/NEJMoa1303576. Epub 2013 Jun 22. PMID: 23789889.

Bolinder J, Antuna R, Geelhoed-Duijvestijn P, Kröger J, Weitgasser R. Novel glucose-sensing technology and hypoglycemia in type 1 diabetes: a multicentre, non-masked, randomized controlled trial. Lancet. 2016 Nov 5;388(10057):2254-63. doi: 10.1016/S0140-6736(16)31535-5. Epub 2016 Sep 12. PMID: 27634581.

Boughton CK, Hovorka R. Advances in artificial pancreas systems. Sci Transl Med. 2019 Mar 20;11(484):eaaw4949. doi: 10.1126/scitranslmed.aaw4949. PMID: 30894501.

Boughton CK, Hovorka R. Is an artificial pancreas (closed-loop system) for Type 1 diabetes effective? Diabet Med. 2019 Mar;36(3):279-86. doi: 10.1111/dme.13816. Epub 2018 Oct 16. PMID: 30183096.

Boscari F, Vettoretti M, Cavallin F, Amato AML, Uliana A, Vallone V, Avogaro A, Facchinetti A, Bruttomesso D. Implantable and transcutaneous continuous glucose monitoring system: a randomized cross over trial comparing accuracy, efficacy and acceptance. J Endocrinol Invest. 2022 Jan;45(1):115-24. doi:10.1007/s40618-021-01624-2. Epub 2021 Jul 1. PMID: 34196924.

Buschur EO, Faulds E, Dungan K. CGM in the Hospital: Is It Ready for Prime Time? Curr Diab Rep. 2022;22(9):451-60. doi: 10.1007/s11892-022-01484-x. PMID: 35796882.

Centers for Disease Control and Prevention (CDC). National Diabetes Statistics Report.

Centers for Medicare & Medicaid Services (CMS). Local Coverage Determination (LCD) for Implantable Continuous Glucose Monitors (I-CGM) L38623. 2020 Dec 1. National Government Services, Inc.

Centers for Medicare & Medicaid Services (CMS). Manuals. Publication # 100-02. Medicare Benefit Policy Manual.

Centers for Medicare & Medicaid Services (CMS). Manuals. Publication # 100-03. Medicare National Coverage Determinations (NCD) Manual.

Centers for Medicare & Medicaid Services (CMS). Medicare Coverage Database.

Centers for Medicare & Medicaid Services (CMS). National Coverage Determination (NCD) for Closed-Loop Blood Glucose Control Device (CBGCD). 40.3. 1983 Jul 1.

Centers for Medicare & Medicaid Services (CMS). Transmittals.

Centers for Medicare & Medicaid Services (CMS). MLN Matters®. Current Medicare Coverage of Diabetes Supplies. Number SE18011.

Centers for Medicare & Medicaid Services (CMS). National Coverage Determination (NCD) for Infusion Pumps 280.14. Version 2. 2004 Dec 17.

Centers for Medicare & Medicaid Services (CMS). National Coverage Determination (NCD) for Medical Nutrition Therapy 180.1. 2022 Jan 1

Centers for Medicare and Medicaid Services (CMS). National Coverage Determination (NCD) for Routine Costs in Clinical Trials 310.1. Version 2. 2007 Jul 9.

Centers for Medicare & Medicaid Services (CMS). National Coverage Determination (NCD) for Surgery for Diabetes 100.14. 2013 Sept 24

Centers for Medicare & Medicaid Services (CMS). Transmittals.

Choudhary P, Reuasauv S, Green L, Gallen G, Pender S, Brackenridge A, Amiel S, Pickup JC. Real-Time Continuous Glucose Monitoring Significantly Reduces Severe Hypoglycemia in Hypoglycemia-Unaware Patients with Type I Diabetes. Diabetes Care. 2013 Dec;36(12):4160-2. doi: 10.2337/dc13-0939. Epub 2013 Oct 8. PMID: 24103902.

Choudhary P, Rickels MR, Senior PA, Vantyghem MC, Maffi P, Kay TW, Keymeulen B, Inagaki N, Saudek F, Lehmann R, Hering B. Evidence-Informed Clinical Practice Recommendation for Treatment of Type in Diabetes complicated by Problematic Hypoglycemia. Diabetes Care. 2015 Jun;38(6):1016-29. doi: 10.2337/dc15-0090. PMID: 25998294.

Christiansen MP, Klaff LJ, Brazg R, Chang AR, Levy CJ, Lam D, Denham DS, Atiee G, Bode BW, Walters SJ, Kelley L, Bailey TS. A prospective multicenter evaluation of the accuracy of a novel implanted continuous glucose sensor: PRECISE II. Diabetes Technol Ther. 2018 Mar;20(3):197-206. doi:10.1089/dia.2017.0142. Epub 2018 Jan 30. PMID: 29381090.

Christiansen MP, Klaff LJ, Bailey TS, Brazg R, Carlson G, Tweden KS. A prospective multicenter evaluation of the accuracy and safety of an implanted continuous glucose sensor: the PRECISION study. Diabetes Technol Ther. 2019 May;21(5):231-7. doi:10.1089/dia.2019.0020. PMID: 30925083.

Commonwealth of Massachusetts. Division of Insurance (DOI) Bulletins.

Commonwealth of Massachusetts. MassHealth Provider Bulletins.

Commonwealth of Massachusetts. MassHealth Provider Manuals.

Commonwealth of Massachusetts. MassHealth Transmittal Letters.

Dai X, Luo ZC, Zhai L, Zhao WP, Huang F. Artificial Pancreas as an Effective and Safe Alternative in Patients with Type 1 Diabetes Mellitus: A Systematic Review and Meta-Analysis. Diabetes Ther. 2018 Jun;9(3):1269-77. doi: 10.1007/s13300-018-0436-y. Epub 2018 May 9. PMID: 29744820.

Deiss D, Irace C, Carlson G, Tweden KS, Kaufman FR. Real-world safety of an implantable continuous glucose sensor over multiple cycles of use: a post-market registry study. Diabetes Technol Ther. 2020 Jan;22(1):48-52. doi:10.1089/dia.2019.0159. PMID: 31418587.

Department of Veterans Affairs (VA) and Department of Defense (DoD). The Management of Type 2 Diabetes Mellitus in Primary Care Work Group. VA/DoD Clinical Practice Guideline for the Management of Type 2 Diabetes Mellitus in Primary Care. 2017 Apr;5.0:1-160.

Dexcom. FDA Authorizes Marketing of the New Dexcom G6® CGM Eliminating the Need for Fingerstick Blood Testing for People with Diabetes. 2018 Mar 27.

Endocrine Society. Klonoff DC, Buckingham B, Christiansen JS, Montori VM, Tamborlane WV, Vigersky RA, Wolpert H. Continuous Glucose Monitoring: An Endocrine Society Clinical Practice Guideline. J Clin Endocrinol Metab. 2011 Oct;96(10):2968-79. doi: 10.1210/jc.2010-2756. PMID: 21976745.

Endocrine Society. Peters AL, Ahmann AJ, Battelino T, Evert A, Hirsch IB, Murad MH, Winter WE, Wolpert H. Diabetes Technology-Continuous Subcutaneous Insulin Infusion Therapy and Continuous Glucose Monitoring in Adults: An Endocrine Society Clinical Practice Guideline. J Clin Endocrinol Metab. 2016 Nov;101(11):3922-37. Epub 2016 Sep 2. PMID: 27588440.

Farmer TG, Edgar TF, Peppas NA. The Future of Open and Closed-Loop Insulin Delivery for Diabetes Mellitus. J Pharm Pharmacol. 2008 Jan;60(1):1–13. doi: 10.1211/jpp.60.1.0001. PMID: 18088499.

Feig DS, Donovan LE, Corcoy R, Murphy KE, Amiel SA, Hunt KF, Asztalos E, Barrett JFR, Sanchez JJ, de Leiva A, Hod M, Jovanovic L, Keely E, McManus R, Hutton EK, Meek CL, Stewart ZA, Wysocki T, O'Brien R, Ruedy K, Kollman C, Tomlinson G, Murphy HR; CONCEPTT Collaborative Group. Continuous glucose monitoring in pregnant women with type 1 diabetes (CONCEPTT): a multicentre international randomised controlled trial. Lancet. 2017 Nov 25;390(10110):2347-59. doi: 10.1016/S0140-6736(17)32400-5. Epub 2017 Sep 15. Erratum in: Lancet. 2017 Nov 25;390(10110):2346. doi: 10.1016/S0140-6736(17)32712-5. Epub 2017 Oct 20. PMID: 29061296.

Fonda S, Salkind S, Walker S, Chellappa M, Ehrhardt N, Vigersky RA. Heterogeneity of Responses to Real-Time Continuous Glucose Monitoring (RT-CGM) in Patients with Type 2 Diabetes and Its Implications for Application. Diabetes Care. 2013 Apr;36(4):786-92. doi: 10.2337/dc12-1225. Epub 2012 Nov 19. PMID: 23172975.

Fowler MJ. Microvascular and Macrovascular Complications of Diabetes. Clinical Diabetes. 2018 Apr;26(2):77-82. doi:10.2337/diaclin.26.2.77.

Gandhi GY, Kovalaske M, Kudva Y, Walsh K, Elamin MB, Beers M, Coyle C, Goalen M, Murad MS, Erwin PJ, Corpus J, Montori VM, Murad MH. Efficacy of continuous glucose monitoring in improving glycemic control and reducing hypoglycemia: a systematic review and meta-analysis of randomized trials. J Diabetes Sci Technol. 2011 Jul 1;5(4):952-65. PMID: 21880239.

Garg S, Brazg RL, Bailey TS, Buckingham BA, Slover RH, Klonoff DC, Shin J, Welsh JB, Kaufman FR. Reduction in duration of hypoglycemia by automatic suspension of insulin delivery: the in-clinic ASPIRE study. Diabetes Technol Ther. 2012 Mar;14(3):205-9. doi: 10.1089/dia.2011.0292. Epub 2012 Feb 8. PMID: 22316089.

Garg SK, Liljenquist D, Bode B, Christiansen MP, Bailey TS, Brazg RL, Denham DS, Chang AR, Akturk HK, Dehennis A, Tweden KS, Kaufman FR. Evaluation of accuracy and safety of the next-generation up to 180-day long-term implantable Eversense Continuous Glucose Monitoring System: the PROMISE study. Diabetes Technol Ther. 2022 Feb;24(2):84-92. doi:10.1089/dia.2021.0182. PMID: 34515521.

Garg SK, Weinzimer SA, Tamborlane WV, Buckingham BA, Bode BW, Bailey TS, Brazg RL, Ilany J, Slover RH, Anderson SM, Bergenstal RM, Grosman B, Roy A, Cordero TL, Shin J, Lee SW, Kaufman FR. Glucose Outcomes with the In-Home Use of a Hybrid Closed-Loop Insulin Delivery System in Adolescents and Adults with Type 1 Diabetes. Diabetes Technol Ther. 2017 Mar;19(3):155-63. doi: 10.1089/dia.2016.0421. Epub 2017 Jan 30. PMID: 28134564.

Gehlaut RR, Dogbey GY, Schwartz FL, Marling CR, Shubrook JH. Hypoglycemia in type 2 diabetes--more common than you think: a continuous glucose monitoring study. J Diabetes Sci Technol. 2015 Apr 27;9(5):999-1005. doi: 10.1177/1932296815581052. PMID: 25917335.

Grosman B, Ilany J, Roy A, Kurtz N, Wu D, Parikh N, Voskanyan G, Konvalina N, Mylonas C, Gottlieb R, Kaufman F, Cohen O. Hybrid Closed-Loop Insulin Delivery in Type 1 Diabetes During Supervised Outpatient Conditions. J Diabetes Sci Technol. 2016 May 3;10(3):708-13. doi: 10.1177/1932296816631568. Print 2016 May. PMID: 26880389.

Haak T, Hanaire H, Ajjan R, Hermanns N, Riveline JP, Rayman G. Use of Flash Glucose-Sensing Technology for 12 months as a Replacement for Blood Glucose Monitoring in Insulin-treated Type 2 Diabetes. Diabetes Ther. 2017 Jun;8(3):573-86. doi: 10.1007/s13300-017-0255-6. Epub 2017 Apr 11. PMID: 28401454.

Hakami H. FDA Approves MiniMed 670G System – World's First Hybrid Closed Loop System. Medtronic. 2016 Sep 28.

Hawa M, Kolb H, Schloot N, Beyan H, Paschou SA, Buzzetti R, Mauricio D, De Leiva A, Yderstraede K, Beck-Neilsen H, Tuomilehto J, Sarti C, Thivolet C, Hadden D, Hunter S, Schernthaner G, Scherbaum WA, Williams R, Brophy S, Pozzilli P, Leslie RD, on behalf of Action LADA consortium. Adult-onset autoimmune diabetes in Europe Is prevalent with a broad clinical phenotype Action LADA 7. Diabetes Care. 2013 Apr;36(4):908-13. doi: 10.2337/dc12-0931. PMID: 23248199.

Hayes. Evolving Evidence Review. Dexcom G6 (Dexom, Inc.) Continuous Glucose Monitoring System for Type 2 Diabetes Mellitus. Dallas, TX: Hayes; 2022 Apr 5.

Hayes. Health Technology Assessment. Artificial Pancreas with the MiniMed 670G for the Management of Diabetes Mellitus. Dallas, TX: Hayes; 2020 Nov 6. Annual Review 2021 Dec 16

Hayes. Health Technology Assessment. Artificial Pancreas with the t:slim X2 for the Management of Diabetes Mellitus. Dallas, TX: Hayes; 2020 Nov 17. Annual Review 2022 Jan 4.

Hayes. Health Technology Assessment. Continuous Subcutaneous Insulin Infusion with OmniPod Insulin Management System (Insulet Corporation) for Management of Diabetes Mellitus. Dallas, TX: Hayes; 2020 Jan 23. Annual Review 2021 Apr 22.

Hayes. Health Technology Assessment. Eversense Continuous Glucose Monitoring System for Maintaining Glycemic Control in Adults with Diabetes Mellitus. Dallas, TX: Hayes; 2022 Mar 14.

Hayes. Medical Code Brief. G0308 – G0309 – HCPCS codes. Dallas, TX: Hayes; 2022 Jun 15.

Health Quality Ontario. Continuous Monitoring of Glucose for Type 1 Diabetes: A Health Technology Assessment. Ontario Health Technology Assessment Series. 2018 Feb 21;18(2):1-160. eCollection 2018. PMID: 29541282.

Hermanides J, Phillip M, DeVries JH. Current Application of Continuous Glucose Monitoring in the Treatment of Diabetes - Pros and Cons. Diabetes Care. 2011 May;34(Suppl 2):S197–201. doi: 10.2337/dc11-s219. PMID: 21525455.

Hommel E, Olsen B, Battelino T, Conget I, Schütz-Fuhrmann I, Hoogma R, Schierloh U, Sulli N, Gough H, Castañeda J, de Portu S, Bolinder J, and The SWITCH Study Group. Impact of continuous glucose monitoring on quality of life, treatment satisfaction, and use of medical care resources: analyses from the SWITCH Study. Acta Diabetol. 2014 Oct;51(5):845-51. doi: 10.1007/s00592-014-0598-7. Epub 2014 Jul 19. PMID: 25037251.

Institute for Clinical and Economic Review (ICER). The New England Comparative Effectiveness Public Advisory Council (CEPAC). Public Meeting – October 29, 2014. Controversies in the Management of Patients with Type 2 Diabetes. 2014 Dec.

Insulet Corporaton. Poducts. Omnipod 5. Prescribe Omnipod 5 Exclusively through the Pharmacy with Less Hassle. 2022.

International Society for Pediatrics and Adolescent Diabetes (ISPAD). DiMeglio LA, Acerini CL, Codner E, Craig ME, Hofer SE, Pillay K, Maahs DM. ISPAD Clinical Practice Consensus Guidelines 2018: Glycemic control targets and glucose monitoring for children, adolescents, and young adults with diabetes. Pediatr Diabetes. 2018 Oct;19 Suppl 27:105-14. doi: 10.1111/pedi.12737. PMID: 30058221.

International Society for Pediatrics and Adolescent Diabetes (ISPAD). Rewers MJ, Pillay K, de Beaufort C, Craig ME, Hanas R, Acerini CL, Maahs DM. ISPAD Clinical Practice Consensus Guidelines 2014. Assessment and monitoring of glycemic control in children and adolescents with diabetes. Pediatr Diabetes. 2014 Sep;15(Suppl 20):102-14. doi: 10.1111/pedi.12190. PMID: 25182311.

Irace C, Cutruzzolà A, Nuzzi A, et al. Clinical use of a 180-day implantable glucose sensor improves glycated haemoglobin and time in range in patients with type 1 diabetes. Diabetes Obes Metab. 2020;22(7):1056-1061. doi:10.1111/dom.13993.

Jafri RZ, Balliro CA, El-Khatib F, et al. A three-way accuracy comparison of the Dexcom G5, Abbott Freestyle Libre Pro, and Senseonics Eversense continuous glucose monitoring devices in a home-use study of subjects with type 1 diabetes. Diabetes Technol Ther. 2020;22(11):846-52. doi:10.1089/dia.2019.0449.

Johns BR, Jones TC, Sink JH, Cooke CE. Real-World Assessment of Glycemic Control After V-Go® Initiation in an Endocrine Practice in the Southeastern United States. J Diabetes Sci Technol. 2014 Sep;8(5):1060–1. doi: 10.1177/1932296814537041. PMID: 24876455.

Juvenile Diabetes Research Foundation Continuous Glucose Monitoring Study Group. Effectiveness of continuous glucose monitoring in a clinical care environment: evidence from the Juvenile Diabetes Research Foundation continuous glucose monitoring (JDRF-CGM) trial. Diabetes Care. 2010 Jan;33(1):17-22. doi: 10.2337/dc09-1502. Epub 2009 Oct 16. PMID: 19837791.

Juvenile Diabetes Research Foundation Continuous Glucose Monitoring Study Group, Beck RW, Buckingham B, Miller K,Wolpert H, Xing D, Block JM, Chase HP, Hirsch I, Kollman C, Laffel L, Lawrence JM, Milaszewski K, Ruedy KJ, Tamborlane WV. Factors predictive of use and of benefit from continuous glucose monitoring in type 1 diabetes. Diabetes Care. 2009 Nov;32(11):1947-53. doi: 10.2337/dc09-0889. Epub 2009 Aug 12. PMID: 19675206.

Juvenile Diabetes Research Foundation Continuous Glucose Monitoring Study Group, Tamborlane WV, Beck RW, Bode BW,Buckingham B, Chase HP, Clemons R, Fiallo-Scharer R, Fox LA, Gilliam LK, Hirsch IB, Huang ES, Kollman C, Kowalski AJ,Laffel L, Lawrence JM, Lee J, Mauras N, O'Grady

M, Ruedy KJ, Tansey M, Tsalikian E, Weinzimer S, Wilson DM, Wolpert H, Wysocki T, Xing D. Continuous glucose monitoring and intensive treatment of type 1 diabetes. N Engl J Med. 2008 Oct 2;359(14):1464-76. doi: 10.1056/NEJMoa0805017. Epub 2008 Sep 8. PMID: 18779236.

Karageorgiou V, Papaioannou TG, Bellos I, Alexandraki K, Tentolouris N, Stefanadis C, Chrousos GP, Tousoulis D. Effectiveness of artificial pancreas in the non-adult population: A systematic review and network meta-analysis. Metabolism. 2019 Jan;90:20-30. doi: 10.1016/j.metabol.2018.10.002. Epub 2018 Oct 12. PMID: 30321535.

Knapp PE, Showers KM, Phipps JC, Speckman JL, Sternthal E, Freund KM, Ash AS, Apovian CM. Self-Monitoring of Blood Glucose with Finger Tip Versus Alternative Site Sampling: Effect on Glycemic Control in Insulin-Using Patients with Type 2 Diabetes. Diabetes Technol Ther. 2009 Apr;11(4):219-24. doi: 10.1089/dia.2008.0060. PMID: 19344196.

Kovatchev B. The artificial pancreas in 2017: The year of transition from research to clinical practice. Nat Rev Endocrinol. 2018 Feb;14(2):74-6. doi: 10.1038/nrendo.2017.170. Epub 2017 Dec 22. PMID: 29286043.

Kropff J, Choudhary P, Neupane S, et al. Accuracy and longevity of an implantable continuous glucose sensor in the PRECISE study: a 180-day, prospective, multicenter, pivotal trial. Diabetes Care. 2017;40(1):63-68. doi: 10.2337/dc16-1525.

Lal RA, Maahs DM. Clinical Use of Continuous Glucose Monitoring in Pediatrics. Diabetes Technol Ther. 2017 May 1;19(Suppl 2):S37–43. doi: 10.1089/dia.2017.0013. PMID: 28541138.

Lane AS, Mlynarczyk MA, de Veciana M, Green LM, Baraki DI, Abuhamad AZ. Real-Time Continuous Glucose Monitoring in Gestational Diabetes: A Randomized Controlled Trial. Am J Perinatol. 2019 Jul;36(9):891-7. doi: 10.1055/s-0039-1678733. Epub 2019 Feb 28. PMID: 30818406.

Lind M, Polonsky W, Hirsch IB, Heise T, Bolinder J, Dahlqvist S, Schwarz E, Ólafsdóttir AF, Frid A, Wedel H, Ahlén E, Nyström T, Hellman J. Continuous Glucose Monitoring vs Conventional Therapy for Glycemic Control in Adults With Type 1 Diabetes Treated With Multiple Daily Insulin Injections: The GOLD Randomized Clinical Trial. JAMA. 2017 Jan 24;317(4):379-87. doi: 10.1001/jama.2016.19976. Erratum in: JAMA. 2017 May 9;317(18):1912. PMID: 28118454.

Ly TT, Nicholas JA, Retterath A, Lim EM, Davis EA, Jones TW. Effect of sensor-augmented insulin pump therapy and automated insulin suspension vs standard insulin pump therapy on hypoglycemia in patients with type 1 diabetes: a randomized clinical trial. JAMA. 2013 Sep 25;310(12):1240-7. doi: 10.1001/jama.2013.277818. PMID: 24065010.

Maahs DM, Buckingham BA, Castle JR, Cinar A, Damiano ER, Dassau E, DeVries JH, Doyle FJ 3rd, Griffen SC, Haidar A, Heinemann L, Hovorka R, Jones TW, Kollman C, Kovatchev B, Levy BL, Nimri R, O'Neal DN, Philip M, Renard E, Russell SJ, Weinzimer SA, Zisser H, Lum JW. Outcome Measures for Artificial Pancreas Clinical Trials: A Consensus Report. Diabetes Care. 2016 Jul;39(7):1175-9. doi: 10.2337/dc15-2716. PMID: 27330126.

MassHealth Guidelines for Medical Necessity Determination. Ambulatory Infusion Pumps (Insulin Pumps). Executive Office of the Health and Human Services. 2014 Nov.

McAdams BH, Rizvi AA. An Overview of Insulin Pumps and Glucose Sensors for the Generalist. J Clin Med. 2016 Jan 4;5(1). pii: E5. doi: 10.3390/jcm5010005. PMID: 26742082.

McGill JB, Ahmann A. Continuous Glucose Monitoring with Multiple Daily Insulin Treatment: Outcome Studies. Diabetes Technol Ther. 2017 Jun 1;19(Suppl 3):S3–12. doi: 10.1089/dia.2017.0090. PMID: 28585875.

Meneghini LF. Intensifying insulin therapy: what options are available to patients with type 2 diabetes? Am J Med. 2013 Sep;126(9 Suppl 1):S28-37. doi: 10.1016/j.amjmed.2013.06.011. PMID: 23953077.

National Institute for Health and Care Excellence (NICE). Dexcom G6 for real-time continuous glucose monitoring. Medtech innovation briefing MIB233. 2020 Nov 3.

National Institute for Health and Care Excellence (NICE). Diabetes in pregnancy: management from preconception to the postnatal period. NICE Guideline NG3. 2015 Feb 25. Last Updated 2020 Dec 16.

National Institute for Health and Care Excellence (NICE). Diabetes (type 1 and type 2) in children and young people: diagnosis and management. NICE Guideline NG18. 2015 Aug 1. Updated 2022 June 29.

National Institute for Health and Care Excellence (NICE). Type 1 diabetes in adults: diagnosis and management. NICE Guideline NG17. 2015 Aug 26. Last Updated 2022 August 17.

National Institute for Health and Care Excellence (NICE). Type 2 diabetes in adults: management. NICE Guideline [NG28]. 2015 Dec 2. Last Updated 2022 June 29.

New Hampshire Department of Health and Human Services. Billing Manuals.

New Hampshire Department of Health and Human Services. Provider Notices.

New JP, Ajjan R, Pfeiffer AFH, Freckmann G. Continuous glucose monitoring in people with diabetes: the randomized controlled Glucose Level Awareness in Diabetes Study (GLADIS). Diabet Med. 2015 May;32(5):609-17. doi: 10.1111/dme.12713. Epub 2015 Feb 20. PMID: 25661981.

Oppel E, Kamann S, Heinemann L, Reichl F-X, Högg C. The implanted glucose monitoring system Eversense: an alternative for diabetes patients with isobornyl acrylate allergy. Contact Dermat. 2020 Feb;82(2):101-4. doi: 10.1111/cod.13392. Epub 2019 Sep 17. PMID: 31463958.

Patti ME, Goldfine A. Hypoglycemia after Gastric Bypass: The Dark Side of GLP-1. Gastroenterology. 2014 Mar;146(3):605–8. doi: 10.1053/j.gastro.2014.01.038. PMID: 24468184.

Pazos-Couselo M, Garcia-Lopez JM, Gonzalez-Rodriguez M, Gude F, Mayán-Santos JM, Rodríguez-Segade S, Rodríguez-García J, Casanueva F. High incidence of hypoglycemia in stable insulin-treated type 2 diabetes mellitus: continuous glucose monitoring vs. self-monitored blood glucose. Observational prospective study. Can J Diabetes. Oct 2015;39(5):428-33. doi: 10.1016/j.jcjd.2015.05.007. Epub 2015 Aug 5. PMID: 26254702.

Pitocco D, Rizzi A, Scavone G, Tanese L, Zaccardi F, Manto A, Ghirlanda G. Fields of application of continuous subcutaneous insulin infusion in the treatment of diabetes and implications in the use of rapid-acting insulin analogues. Minerva Endocrinol. 2013 Sep;38(3):321-8. PMID: 24126552.

Polonsky WH, Hessler D, Ruedy KJ, Beck RW; DIAMOND Study Group. The Impact of Continuous Glucose Monitoring on Markers of Quality of Life in Adults with Type 1 Diabetes: Further Findings from the DIAMOND Randomized Clinical Trial. Diabetes Care. 2017 Jun;40(6):736-41. doi: 10.2337/dc17-0133. Epub 2017 Apr 7. PMID: 28389582.

Raccah D, Sulmont V, Reznik Y, Guerci B, Renard E, Hanaire H, Jeandidier N, Nicolino M. Incremental value of continuous glucose monitoring when starting pump therapy in patients with poorly controlled type 1 diabetes: the RealTrend study. Diabetes Care. 2009 Dec;32(12):2245-50. doi: 10.2337/dc09-0750. Epub 2009 Sep 18. PMID: 19767384.

Renard E, Riveline JP, Hanaire H, Guerci B. Reduction of clinically important low glucose excursions with a long-term implantable continuous glucose monitoring system in adults with type 1 diabetes prone to hypoglycaemia: the France Adoption Randomized Clinical Trial. Diabetes Obes Metab. 2022 May;24(5):859-67. doi: 10.1111/dom.14644. Epub 2022 Feb 7. PMID: 34984786.

Riddlesworth T, Price D, Cohen N, Beck RW. Hypoglycemic Event Frequency and the Effect of Continuous Glucose Monitoring in Adults with Type 1 Diabetes Using Multiple Daily Insulin Injections. Diabetes Ther. 2017 Aug;8(4):947-51. doi: 10.1007/s13300-017-0281-4. Epub 2017 Jun 14. PMID: 28616804.

Rodbard D. Continuous Glucose Monitoring: A Review of Successes, Challenges, and Opportunities. Diabetes Technol Ther. 2016 Feb;18 Suppl 2:S3-13. doi: 10.1089/dia.2015.0417. PMID: 26784127.

Rosenfeld CR, Bohannon NJ, Bode B, Kelman AS, Mintz SN, Schorr AB, Sandberg MI, Nambi S, Agarwala SK, Leichter SB, Larrabee B, Shi L, Strange P. The V-Go insulin delivery device used in clinical practice: patient perception and retrospective analysis of glycemic control. Endocr Pract. 2012 Sep-Oct;18(5):660-7. doi: 10.4158/EP11362. PMID: 22548944.

Saboo BD, Talaviya PA. Continuous subcutaneous insulin infusion: practical issues. Indian J Endocrinol Metab. 2012 Dec;16(Suppl 2): S259–62. doi: 10.4103/2230-8210.104055. PMID: 23565394.

Sanchez P, Ghosh-Dastidar S, Tweden KS, Kaufman FR. Real-World Data from the First U.S. Commercial Users of an Implantable Continuous Glucose Sensor. Diabetes Technol Ther. 2019 Dec;21(12):677-81. doi: 10.1089/dia.2019.0234. Epub 2019 Aug 28.

Sato J, Kanazawa A, Ikeda F, Shigihara N, Kawaguchi M, Komiya K, Uchida T, Ogihara T, Mita T, Shimizu T, Fujitani Y, Watada H. Effect of treatment guidance using a retrospective continuous glucose monitoring system on glycemic control in outpatients with type 2 diabetes mellitus: A randomized controlled trial. J Int Med Res. 2016 Feb;44(1):109-21. doi: 10.1177/0300060515600190. Epub 2015 Dec 7. PMID: 26647072.

Schnell O, Hinzmann R, Kulzer B, Freckmann G, Erbach M, Lodwig V, Heinemann L. Assessing the analytical performance of systems for self-monitoring of blood glucose: concepts of performance evaluation and definition of metrological key terms. J Diabetes Sci Technol. 2013 Nov 1;7(6):1585-94. PMID: 24351185.

Thabit H, Hovorka R. Coming of age: the artificial pancreas for type 1 diabetes. Diabetologia. 2016 Sep;59(9):1795-805. doi: 10.1007/s00125-016-4022-4. Epub 2016 Jun 30. PMID: 27364997.

Trevitt S, Simpson S, Wood A. Artificial Pancreas Device Systems for the Closed-Loop Control of Type 1 Diabetes. J Diabetes Sci Technol. 2016 May;10(3):714–23. doi: 10.1177/1932296815617968. PMID: 26589628.

Tsalikian E, Fox L, Weinzimer S, Buckingham B, White NH, Beck R, Kollman C, Xing D, Ruedy K; Diabetes Research in Children Network Study Group. Feasibility of prolonged continuous glucose monitoring in toddlers with type 1 diabetes. Pediatr Diabetes. 2012 Jun;13(4):301-7. doi: 10.1111/j.1399-5448.2011.00837.x. Epub 2011 Dec 13. PMID: 22151826.

Tweden KS, Deiss D, Rastogi R, Addaguduru S, Kaufman FR. Longitudinal analysis of real-world performance of an implantable continuous glucose sensor over multiple sensor insertion and removal cycles. Diabetes Technol Ther. 2020 May;22(5):422-7. doi:10.1089/dia.2019.0342. PMID: 31697182.

U.S. Food and Drug Administration (FDA). FDA Premarket Approval Letter. MiniMed 630G System. 2022 Dec 16.

U.S. Food and Drug Administration (FDA). FDA News Release. FDA approves first automated insulin delivery device for type 1 diabetes. 2016 Sep 28.

U.S. Food and Drug Administration (FDA). FDA News Release. FDA authorizes first fully interoperable continuous glucose monitoring system, streamlines review pathway for similar devices. 2018 Mar 27.

U.S. Food and Drug Administration (FDA). Medical Devices. The Artificial Pancreas Device System. 2018 Aug 30.

U.S. Food and Drug Administration (FDA). Medical Devices. Eversense E3 Continuous Glucose Monitoring System – P160048/S016. Approval Date 2022 Feb 10.

U.S. Food and Drug Administration (FDA). Medical Devices. Premarket Approval (PMA). Dexcom G4 Platinum Continuous Glucose Monitoring System. 2019 Aug 20.

U.S. Food and Drug Administration (FDA). News & Events. FDA News Release. FDA expands indication for continuous glucose monitoring system, first to replace fingerstick testing for diabetes treatment decisions. 2016 Dec 20.

U.S. Food and Drug Administration (FDA). Premarket Approval (PMA). Eversense Continuous Glucose Monitoring System. 2018 Jun 21.

U.S. Food and Drug Administration (FDA). Premarket Approval (PMA). T:slim X2 Insulin Pump With Dexcom G5 Mobile CGM. PMA Number P140015. Decision Date 2017 Aug 25.

U.S. Food and Drug Administration (FDA). Summary of Safety and Effectiveness Data. GlucoWatch® G2 Biographer. 2002 Aug 26.

U.S. Food and Drug Administration (FDA). Types of Artificial Pancreas Device Systems. 2017 Dec 17.

U.S. Food and Drug Administration (FDA). What is the pancreas? What is an artificial pancreas device system? 2018 Aug 30.

Wei Q, Sun Z, Yang Y, Yu H, Ding H, Wang S. Effect of a CGMS and SMBG on Maternal and Neonatal Outcomes in Gestational Diabetes Mellitus: a Randomized Controlled Trial. Sci Rep. 2016 Jan 27;6:19920. doi: 10.1038/srep19920. PMID: 26814139.

Weinstock RS. Management of blood glucose in adults with type 1 diabetes mellitus. UpToDate. 2021 Feb 15.

Winter A, Lintner M, Knezevich E. V-Go Insulin Delivery System Versus Multiple Daily Insulin Injections for Patients with Uncontrolled Type 2 Diabetes Mellitus. J Diabetes Sci Technol. 2015 Apr 21;9(5):1111-6. doi: 10.1177/1932296815580361. PMID: 25904143.

Yeoh E, Choudhary P, Nwokolo M, Nwokolo M, Ayis S, Amiel SA. Interventions that restore awareness of hypoglycemia in adults with type 1 diabetes: a systematic review and meta-analysis. Diabetes Care. 2015 Aug;38(8):1592-609. doi: 10.2337/dc15-0102. PMID: 26207053.

Zealand Pharma. V-Go®. Prescribing & Dosing. Overview to Start Patients on V-Go®.

Next Review Date

02/01/24

Authorizing Entity

MPCTAC

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.

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

Medical Policy

Northwood

Continuous Glucose Monitoring System

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	Director of Medical Policy as Chair of MPCTAC	MPCTAC, QIC, and UMC

*Effective date for MassHealth product: 11/10/08
*Effective date for MA QHP product: 01/01/12
*Effective date for NH Medicaid product: 01/01/13
*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 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	Version 5	07/18/12: MPCTAC 08/22/12: QIC

	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.		
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, 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	04/01/15 Version 9	12/17/14: MPCTAC 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 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 changes made to the Limitations section. Plan notes made to applicable codes. No change to criteria and/or the applicable code list.	12/01/16 Version 14	10/19/16: MPCTAC 11/09/16: QIC
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	07/08/17 Version 16	04/15/17: MPCTAC

	section. Updated Definitions and References sections.		
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 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.	12/01/19 Version 21	09/18/19: MPCTAC
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 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.	01/01/22 Version 25	10/20/21: MPCTAC
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 Coding, and References sections.	03/01/23 Version 31	02/15/23: MPCTAC
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 44 not implemented	03/15/23: MPCTAC
04/01/23	Review for effective date 06/01/23. Removed language in the Variations section related to CMS guidelines associated with the COVID-19 pandemic. Incorporated all revisions approved for Version 32.	06/01/23 Version 33	05/01/23: MPCTAC (electronic vote)

End Appendix A

Continuous Glucose Monitoring System

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	1-10-12	Including experimental/investigational exclusions. Updated references.	Susan Glomb	Dr. B. Almasri	Jan. 2012	
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	
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
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 Version 32, effective 6-1-23.	Carol Dimech	Dr. C. Lerchin	6-1-23	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