

Medical Policy

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

Policy Number: OCA 3.966

Version Number: 27

Version Effective Date: 03/01/22

Product Applicability		<input checked="" type="checkbox"/> All Plan⁺ Products
WellSense Health Plan		Boston Medical Center HealthNet Plan
<input checked="" type="checkbox"/> NH Medicaid	<input checked="" type="checkbox"/> NH Medicare Advantage	<input checked="" type="checkbox"/> MassHealth ACO
		<input checked="" type="checkbox"/> MassHealth MCO
		<input checked="" type="checkbox"/> Qualified Health Plans/ConnectorCare/Employer Choice Direct
		<input checked="" type="checkbox"/> Senior Care Options

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

Policy Summary

This policy applies to the following devices: 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) provided in the outpatient setting. Plan prior authorization is required.

The Plan’s Pharmacy Department manages requests for intermittent or flash CGM device (e.g., FreeStyle Libre Flash Glucose Monitoring System), single-use/disposable and nonprogrammable external insulin pump (e.g., V-Go), and Omnipod DASH from prescribers when covered through the member’s pharmacy benefit (rather than the member’s medical benefit). A provider may submit a prescription for the requested device.

All requests for durable medical equipment (DME), including non-disposable external insulin pumps, single-use and disposable, programmable external insulin infusion pumps (e.g., other OmniPod

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

⁺ Plan refers to Boston Medical Center Health Plan, Inc. and its affiliates and subsidiaries offering health coverage plans to enrolled members. The Plan operates in Massachusetts under the trade name Boston Medical Center HealthNet Plan and in other states under the trade name WellSense Health Plan.

products), home blood glucose monitors, and associated DME supplies and accessories should be submitted to Northwood at www.northwoodinc.com or by phone at 1-866-802-6471 to obtain prior authorization. Requests for services managed as a DME benefit from DME providers, pharmacy providers, home infusion providers, and home care providers related to CGMS, combined CGMS with external insulin infusion pump, and associated supplies and accessories should also be submitted to Northwood.

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

1. Medical Necessity Criteria for Stand-Alone CGMS, Combined CGMS External Insulin Pump using CSII, or Artificial Pancreas Device System in the Outpatient Setting:

ONE (1) of the criteria must be met in items a through c:

a. Stand-Alone CGMS:

ALL criteria are met in items (1) through (6) 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 a pregnant member):

- (1) Member requires the use of an insulin pump or multiple daily insulin injections or the provider submits documentation to the Plan confirming that the member is not receiving insulin due to 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) The 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

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

[†] Plan refers to Boston Medical Center Health Plan, Inc. and its affiliates and subsidiaries offering health coverage plans to enrolled members. The Plan operates in Massachusetts under the trade name Boston Medical Center HealthNet Plan and in other states under the trade name WellSense Health Plan.

(6) The member is still experiencing or remains at risk for ANY of the conditions 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; 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 a pregnant member):

- (1) Member meets criteria for continuous glucose monitoring in items 1a-1f; AND
- (2) The requested device is being prescribed according to its FDA-approved clearance and guideline information for a combined CGMS with an external insulin pump with subcutaneous insulin, including intended use for the member's age and medical condition; 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:

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

- (1) Member with type 1 diabetes meets criteria for continuous glucose monitors in items 1a-1f and the member is NOT pregnant; AND
- (2) The 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

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

[†] *Plan* refers to Boston Medical Center Health Plan, Inc. and its affiliates and subsidiaries offering health coverage plans to enrolled members. The Plan operates in Massachusetts under the trade name Boston Medical Center HealthNet Plan and in other states under the trade name WellSense Health Plan.

- (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.

2. Plan Medical Director Review Required:

ANY of the following types of prior authorization requests require 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 and Plan Medical Director review is required. 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:

Plan Medical Director review is required for the 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) consistently is unable to manage the device properly, the member (or family member or caregiver on behalf of the member) does not routinely use the device according to product guidelines, and/or the device consistently fails to resolve hypoglycemia, improve or maintain A1C, and/or prevent hospitalization related to glucose management for the member. In these cases, applicable clinical information will be evaluated by the Plan Medical Director to determine the medical necessity for the ongoing use of a CGMS or discontinuation of the device with the implementation of an alternate treatment plan. Applicable clinical information must be submitted to the Plan by the treating provider and include the member's medical history, 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

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

[†] Plan refers to Boston Medical Center Health Plan, Inc. and its affiliates and subsidiaries offering health coverage plans to enrolled members. The Plan operates in Massachusetts under the trade name Boston Medical Center HealthNet Plan and in other states under the trade name WellSense Health Plan.

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.

c. Replacement System Expected to Provide Clinically Significant Improvements:

When the replacement system is expected to provide clinically significant improvements for the member's glucose management, medical record documentation must be submitted to the Plan's Medical Director for individual consideration in support of the prior authorization request with the following documentation: 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:

Plan Medical Director review is required for individual consideration of an upgraded system requested by the member's treating physician when it is expected to significantly improve the member's A1C target level and this improvement cannot be achieved with the member's current CGMS.

Limitations and Exclusions

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

If a CGMS or combined CGMS with external insulin pump using continuous subcutaneous insulin infusion (CSII) is approved by the Plan in the outpatient setting, the authorization period is **six (6) months** for the purchase of the receiver and transmitter. A **lifetime authorization** will be granted for sensors and supplies for the CGM device currently used by the member if the CGM 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; Northwood will notify the requesting provider of these requirements.

2. Fully Implanted Glucose Sensor:

The Plan considers the use of a fully implantable glucose sensor to be experimental and investigational or NOT reasonable and necessary due to limited evidence documenting the clinical utility and clinical validity of the device.

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

[†] Plan refers to Boston Medical Center Health Plan, Inc. and its affiliates and subsidiaries offering health coverage plans to enrolled members. The Plan operates in Massachusetts under the trade name Boston Medical Center HealthNet Plan and in other states under the trade name WellSense Health Plan.

3. Remote Wireless Monitoring:

Remote wireless glucose monitoring may either be a feature of a CGMS or an attachment device such as a mobile application with real-time display of interstitial glucose readings. **The Plan provides no additional reimbursement for a wireless transmission feature/device**, even when it is a component of an artificial pancreas device system, integrated into a CGMS, or combined with CGMS with external insulin pump and the system is authorized by the Plan.

4. Noninvasive Continuous Glucose Monitoring System:

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. Upgrade for New Technology:

Technology-based methods may be used for diabetes management, but 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 as a feature of the replacement device or an added component for CGMS, including the use of the internet and/or smart phone application for including uploading, monitoring, and/or sharing blood glucose levels as a convenience feature. .

Variations

The Plan uses guidance from the Centers for Medicare & Medicaid Services (CMS) for medical necessity and coverage determinations for Senior Care Options (SCO) members and WellSense 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.

In response to the COVID-19 pandemic, CMS will NOT be enforcing clinical indications for coverage for a LIMITED number of NCDs and LCDs (and corresponding services, treatments, and devices included in those documents) for care provided to the Plan's SCO and WellSense Medicare Advantage HMO members. The suspension of clinical indications for coverage for limited number of services, treatments, and devices will be in effect on an interim basis for maximum flexibility and will allow SCO and WellSense Medicare Advantage members to receive care in an unexpected setting such as the home. The list of NCDs and LCDs with waived clinical review criteria may be revised periodically by CMS and does NOT apply to other aspects of CMS guidelines such as benefit category determinations. It is expected that CMS will return to the enforcement of all clinical review criteria included in NCDs

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

[†] Plan refers to Boston Medical Center Health Plan, Inc. and its affiliates and subsidiaries offering health coverage plans to enrolled members. The Plan operates in Massachusetts under the trade name Boston Medical Center HealthNet Plan and in other states under the trade name WellSense Health Plan.

and LCDs used to make medical necessity determinations at the conclusion of this public health emergency. **As of March 31, 2020, CMS will NOT enforce clinical indications for coverage included in NCD 280.14 for infusion pumps and LCD L33794 for external infusion pumps until the conclusion of the COVID-19 pandemic. Prior authorization is required for these services even when clinical indications for coverage are not enforced for SCO and WellSense Medicare Advantage HMO members.** The Plan recommends that providers verify coverage and CMS guidelines for the requested service, treatment, and device on the date of service using the CMS website.

Applicable Coding

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

Providers are responsible for obtaining prior authorization for the services specified in the Policy Summary, Clinical Criteria, and Limitations and Exclusions sections of this Plan policy, even if an applicable code appropriately describing the service that is the subject of this Plan policy is not included in this Applicable Coding section. Review the Plan’s reimbursement policies for Plan billing guidelines. Coverage for services is subject to benefit eligibility under the member’s benefit plan in effect at the time of the service. Member benefit documents are available at the following websites: www.bmchp.org for BMC HealthNet Plan members, www.SeniorsGetMore.org for Senior Care Options members, www.wellsense.org for WellSense New Hampshire Medicaid members, and www.WellSense.org/Medicare for WellSense Medicare Advantage HMO members.

CPT Code	Description: Codes Covered When Medically Necessary
95250	Ambulatory continuous glucose monitoring of interstitial tissue fluid via a subcutaneous sensor for a minimum of 72 hours; sensor placement, hook-up, calibration of monitor, patient training, removal of sensor, and printout of recording

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

[†] Plan refers to Boston Medical Center Health Plan, Inc. and its affiliates and subsidiaries offering health coverage plans to enrolled members. The Plan operates in Massachusetts under the trade name Boston Medical Center HealthNet Plan and in other states under the trade name WellSense Health Plan.

HCPCS Codes	Description: Codes Covered When Medically Necessary
	Plan note applicable for the HCPCS codes listed below: 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.
A9276	Sensor; invasive (e.g., subcutaneous), disposable, for use with interstitial continuous glucose monitoring system, 1 unit = 1-day supply Plan note: Code is NOT payable for the WellSense Medicare Advantage HMO product.
A9277	Transmitter; external, for use with interstitial continuous glucose monitoring system Plan note: Code is NOT payable for the WellSense Medicare Advantage HMO product.
A9278	Receiver (monitor); external, for use with interstitial continuous glucose monitoring system Plan note: Code is NOT payable for the WellSense Medicare Advantage HMO product.
K0554	Receiver (monitor), dedicated, for use with therapeutic glucose continuous monitor system

CPT Codes	Description: Codes Considered Experimental and Investigational or NOT Medically Necessary for CGMS with Implantable Interstitial Glucose Sensor
0446T	Creation of subcutaneous pocket with insertion of implantable interstitial glucose sensor, including system activation and patient training
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

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

[†] Plan refers to Boston Medical Center Health Plan, Inc. and its affiliates and subsidiaries offering health coverage plans to enrolled members. The Plan operates in Massachusetts under the trade name Boston Medical Center HealthNet Plan and in other states under the trade name WellSense Health Plan.

HCPCS Codes	Description: Codes Covered When Medically Necessary for Artificial Pancreas Device System in the Outpatient Setting Plan note applicable for the HCPCS codes listed below: 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.
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 Plan note: Code is NOT payable for the Senior Care Options and WellSense Medicare Advantage HMO products.
S1035	Sensor; invasive (e.g., subcutaneous), disposable, for use with artificial pancreas device system Plan note: Code is NOT payable for the Senior Care Options and WellSense Medicare Advantage HMO products.
S1036	Transmitter; external, for use with artificial pancreas device system Plan note: Code is NOT payable for the Senior Care Options and WellSense Medicare Advantage HMO products.
S1037	Receiver (monitor); external, for use with artificial pancreas device system Plan note: Code is NOT payable for the Senior Care Options and WellSense Medicare Advantage HMO products.

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 WellSense Medicare Advantage HMO product. 2. Code may be used for single-use, disposable and nonprogrammable/mechanical insulin infusion device (e.g., V-Go). V-Go is covered through the member's pharmacy benefit rather than managed by the Plan's medical or DME benefit coverage. 3. DME providers, medical supply providers, pharmacy providers, home

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

[†] Plan refers to Boston Medical Center Health Plan, Inc. and its affiliates and subsidiaries offering health coverage plans to enrolled members. The Plan operates in Massachusetts under the trade name Boston Medical Center HealthNet Plan and in other states under the trade name WellSense Health Plan.

	infusion providers, home care providers, and specialty pharmacy providers must contact Northwood at 1-866-802-6471 (rather than then Plan) to determine coverage and reimbursement guidelines for all other types of disposable external ambulatory insulin delivery systems (including supplies and accessories) except for single-use, disposable and nonprogrammable/mechanical (non-electric) insulin infusion devices (e.g., V-Go®).
--	---

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):24-29. 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):1811-1819. 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). Handelsman Y, Bloomgarden ZT, Grunberger G, Umpierrez G, Zimmerman RS, Bailey TS, Blonde L, Bray GA, Cohen AJ, Dagogo-Jack S, Davidson JA, Einhorn D, Ganda OP, Garber AJ, Garvey WT, Henry RR,

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

[†] Plan refers to Boston Medical Center Health Plan, Inc. and its affiliates and subsidiaries offering health coverage plans to enrolled members. The Plan operates in Massachusetts under the trade name Boston Medical Center HealthNet Plan and in other states under the trade name WellSense Health Plan.

Hirsch IB, Horton ES, Hurley DL, Jellinger PS, Jovanović L, Lebovitz HE, LeRoith D, Levy P, McGill JB, Mechanick JI, Mestman JH, Moghissi ES, Orzeck EA, Pessah-Pollack R, Rosenblit PD, Vinik AI, Wyne K, Zangeneh F. AACE and ACE - Clinical Practice Guidelines for Developing a Diabetes Mellitus Comprehensive Care Plan - 2015. *Endocr Pract*. 2015 Apr;21 Suppl 1:1-87. doi: 10.4158/EP15672.GL. PMID: 25869408.

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 Medical Care in Diabetes-2021. *Diabetes Care*. 2022 Jan;45(Supple 1).

American Diabetes Association (ADA). Summary of Revisions: Standards of Medical Care in Diabetes-2022. *Diabetes Care*. 2022 Jan;45(Supplement 1):S4-S7.

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.

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):371-378. 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. Aronoff S, Aronson R, Toschi E, Kollman C, Bergenstal R; DIAMOND

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

[†] *Plan* refers to Boston Medical Center Health Plan, Inc. and its affiliates and subsidiaries offering health coverage plans to enrolled members. The Plan operates in Massachusetts under the trade name Boston Medical Center HealthNet Plan and in other states under the trade name WellSense Health Plan.

Study Group. *Ann Intern Med*. 2017 Sep 19;167(6):365-374. 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):354-360. 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):1407-1408. 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):2254-2263. 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):279-286. doi: 10.1111/dme.13816. Epub 2018 Oct 16. PMID: 30183096.

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.

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

[†] *Plan* refers to Boston Medical Center Health Plan, Inc. and its affiliates and subsidiaries offering health coverage plans to enrolled members. The Plan operates in Massachusetts under the trade name Boston Medical Center HealthNet Plan and in other states under the trade name WellSense Health Plan.

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. 2002 Oct 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. 2009 Feb 12.

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

Choudhary P, Reusasauv 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, Vantighem MC, Maffi P, Kay TW, Keymeulen B, Inagaki N, Saudek F, Lehmann R, Hering B. Evidence-Informed Clinical Practice Recommendation for Treatment of Type 1 Diabetes complicated by Problematic Hypoglycemia. *Diabetes Care*. 2015 Jun;38(6):1016-29. doi: 10.2337/dc15-0090. PMID: 25998294.

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.

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

[†] *Plan* refers to Boston Medical Center Health Plan, Inc. and its affiliates and subsidiaries offering health coverage plans to enrolled members. The Plan operates in Massachusetts under the trade name Boston Medical Center HealthNet Plan and in other states under the trade name WellSense Health Plan.

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):1269-1277. doi: 10.1007/s13300-018-0436-y. Epub 2018 May 9. PMID: 29744820.

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):3922-3937. 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.

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

[†] *Plan* refers to Boston Medical Center Health Plan, Inc. and its affiliates and subsidiaries offering health coverage plans to enrolled members. The Plan operates in Massachusetts under the trade name Boston Medical Center HealthNet Plan and in other states under the trade name WellSense Health Plan.

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, 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.

Gomez AM, Umpierrez GE. Continuous Glucose Monitoring in Insulin-Treated Patients in Non-ICU Settings. *J Diabetes Sci Technol*. 2014 Sep;8(5):930-6. doi: 10.1177/1932296814546025. PMID: 25125454.

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):573-586. 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. Published online 2013 Mar 14. doi: 10.2337/dc12-0931. PMID: 23248199.

Hayes. Evidence Analysis Research Brief. Dexcom G6 Continuous Glucose Monitoring System. Dallas, TX: Hayes; 2021 Mar 5.

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

[†] *Plan* refers to Boston Medical Center Health Plan, Inc. and its affiliates and subsidiaries offering health coverage plans to enrolled members. The Plan operates in Massachusetts under the trade name Boston Medical Center HealthNet Plan and in other states under the trade name WellSense Health Plan.

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

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

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.

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.

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 27:105-114. 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.

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.

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

[†] *Plan* refers to Boston Medical Center Health Plan, Inc. and its affiliates and subsidiaries offering health coverage plans to enrolled members. The Plan operates in Massachusetts under the trade name Boston Medical Center HealthNet Plan and in other states under the trade name WellSense Health Plan.

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.

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 2020 Dec.

National Institute for Health and Care Excellence (NICE). Type 1 diabetes in adults: diagnosis and management. NICE Guideline NG17. 2015 Aug 26. Last Updated 2021 Jul.

National Institute for Health and Care Excellence (NICE). Type 2 diabetes in adults: management. NICE Guideline [NG28]. 2015 Dec 2. Last Updated 2021 Nov 24.

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

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

[†] *Plan* refers to Boston Medical Center Health Plan, Inc. and its affiliates and subsidiaries offering health coverage plans to enrolled members. The Plan operates in Massachusetts under the trade name Boston Medical Center HealthNet Plan and in other states under the trade name WellSense Health Plan.

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.

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.

Racah 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.

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.

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

[†] *Plan* refers to Boston Medical Center Health Plan, Inc. and its affiliates and subsidiaries offering health coverage plans to enrolled members. The Plan operates in Massachusetts under the trade name Boston Medical Center HealthNet Plan and in other states under the trade name WellSense Health Plan.

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.

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.

U.S. Food and Drug Administration (FDA). FDA Premarket Approval Letter. MiniMed 630G System. 2021 Dec 17.

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. Premarket Approval (PMA). Dexcom G5 Platinum Continuous Glucose Monitoring System. 2016 Dec 12.

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

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

[†] *Plan* refers to Boston Medical Center Health Plan, Inc. and its affiliates and subsidiaries offering health coverage plans to enrolled members. The Plan operates in Massachusetts under the trade name Boston Medical Center HealthNet Plan and in other states under the trade name WellSense Health Plan.

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). 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®.

Policy History

Original Approval Date	Original Effective Date* and Version Number	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	Medical Policy Manager as Chair of MPCTAC	MPCTAC, QIC, and UMC

*Effective Date for the BMC HealthNet Plan Commercial Product: 01/01/12

*Effective Date for the WellSense New Hampshire Medicaid Product: 01/01/13

*Effective Date for Senior Care Options Product: 01/01/16

*Effective Date for WellSense 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 following criteria in Medical Policy	Version 5	07/18/12: MPCTAC 08/22/12: QIC

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

[†] Plan refers to Boston Medical Center Health Plan, Inc. and its affiliates and subsidiaries offering health coverage plans to enrolled members. The Plan operates in Massachusetts under the trade name Boston Medical Center HealthNet Plan and in other states under the trade name WellSense Health Plan.

Policy Revisions History

	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 WellSense Health Plan, 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 section. Revised criteria in Medical Policy	04/01/15 Version 9	12/17/14: MPCTAC 01/14/15: QIC

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

[†] *Plan* refers to Boston Medical Center Health Plan, Inc. and its affiliates and subsidiaries offering health coverage plans to enrolled members. The Plan operates in Massachusetts under the trade name Boston Medical Center HealthNet Plan and in other states under the trade name WellSense Health Plan.

Policy Revisions History

	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 section. Updated Definitions and References sections.	07/08/17 Version 16	04/15/17: MPCTAC

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

[†] Plan refers to Boston Medical Center Health Plan, Inc. and its affiliates and subsidiaries offering health coverage plans to enrolled members. The Plan operates in Massachusetts under the trade name Boston Medical Center HealthNet Plan and in other states under the trade name WellSense Health Plan.

Policy Revisions History

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,	10/01/20 Version 23	09/25/20: MPCTAC (electronic vote)

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

[†] Plan refers to Boston Medical Center Health Plan, Inc. and its affiliates and subsidiaries offering health coverage plans to enrolled members. The Plan operates in Massachusetts under the trade name Boston Medical Center HealthNet Plan and in other states under the trade name WellSense Health Plan.

Policy Revisions History

	Applicable Coding, Clinical Background Information, and Reference to Applicable Laws and Regulations sections to reference CMS guidelines for clinical indications for coverage for SCO members with Medicare coverage during the COVID-19 pandemic.		
09/01/20 and 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 WellSense 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	03/01/22 Version 27	01/19/22: MPCTAC

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

⁺ *Plan* refers to Boston Medical Center Health Plan, Inc. and its affiliates and subsidiaries offering health coverage plans to enrolled members. The Plan operates in Massachusetts under the trade name Boston Medical Center HealthNet Plan and in other states under the trade name WellSense Health Plan.

Policy Revisions History

	Criteria and Limitations and Exclusions sections. Revisions approved in version 26 implemented.		
--	---	--	--

Next Review Date

02/01/23

Authorizing Entity

MPCTAC

Disclaimer Information: ⁺

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

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

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

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

⁺ Plan refers to Boston Medical Center Health Plan, Inc. and its affiliates and subsidiaries offering health coverage plans to enrolled members. The Plan operates in Massachusetts under the trade name Boston Medical Center HealthNet Plan and in other states under the trade name WellSense Health Plan.