Department of Origin: Integrated Healthcare Services	Effective Date: 06/05/24
Approved by: Medical Policy Quality Management Subcommittee	**Date Approved:** 06/04/24
Clinical Policy Document: DMEPOS, Continuous Glucose Monitoring Systems for Long-term Use	**Replaces Effective Clinical Policy Dated:** 01/01/24
Reference #: MC/L008	**Page:** 1 of 7

PURPOSE:
The intent of this clinical policy is to ensure services are medically necessary.

Please refer to the member's benefit document for specific information. To the extent there is any inconsistency between this policy and the terms of the member's benefit plan or certificate of coverage, the terms of the member's benefit plan document will govern.

POLICY:
Benefits must be available for health care services. Health care services must be ordered by a provider. Health care services must be medically necessary, applicable conservative treatments must have been tried, and the most cost-effective alternative must be requested for coverage consideration.

GUIDELINES:
Medical Necessity Criteria – Must satisfy any of the following: I - II

I. Member has any of the following: A – B

   A. Type 1 or Type 2 diabetes on multiple daily insulin injections (MDI) (ie, greater than 1 [includes insulin infusion pump]); or

   B. Type 1 or Type 2 diabetes and documentation supports any of the following: 1 - 3
      1. Level 2 hypoglycemia (defined as a blood glucose concentration <54 mg/dL [3.0 mmol/L]); or

      2. Level 3 hypoglycemia (defined as a severe event characterized by altered mental and/or physical functioning that requires assistance from another person for recovery); or

      3. Glycogen storage disease (eg, Type I [von Gierke disease], Type III [Cori or Forbes disease], or Type IV [Andersen disease]).

II. Member has Type 1 or Type 2 diabetes and is pre-conception or currently pregnant.

EXCLUSIONS (not limited to):
Refer to member's Certificate of Coverage or Summary Plan Description.

DEFINITIONS:
Adjunctive/Non-Therapeutic continuous glucose monitor (CGM):
Adjunctive/non-therapeutic CGM are devices used as an adjunct to blood glucose monitor (BGM) testing (i.e., primary therapeutic decisions regarding diabetes treatment must be made with a standard home BGM, not the CGM).

Malfunctioning:
The failure of a device to meet its performance specifications or otherwise perform as intended. Performance specifications include all claims made in the labeling for the device.[15]

Non-adjunctive/Therapeutic continuous glucose monitor (CGM):
Non-adjunctive/therapeutic CGM are defined as CGM used as a replacement for fingerstick blood glucose testing for diabetes treatment decisions i.e., non-adjunctive use.

Type 1 Diabetes:
Type 1 diabetes is usually diagnosed in children and young adults and was previously known as juvenile diabetes. Only 5% of people with diabetes have this form of the disease. In type 1 diabetes, the body does not produce insulin. The body breaks down the sugars and starches you eat into a simple sugar called glucose, which it uses for energy. Insulin is a hormone that the body needs to get glucose from the bloodstream into the cells of the body.

Type 2 Diabetes - Intensive Insulin Therapy:
3 or more insulin injections/day or on an insulin pump

BACKGROUND:

Continuous Glucose Monitoring Systems

Continuous glucose monitoring systems (CGMS) are devices that measure glucose levels in interstitial fluid at programmable intervals. These readings help detect any patterns or trends with an individual's glucose levels to help improve diabetes management. The majority of the FDA approved CGMS are intended to assist in calculating the insulin dosage needed to manage glycemic control. CGMS readings may also be used as adjunctive devices to complement, not replace, information obtained from standard home glucose monitoring and to supplement, not replace, a fingerstick (*non-therapeutic continuous glucose monitor*)

CGMS use sensors that are inserted under the skin in the abdomen and work by extracting glucose from the interstitial fluid, measuring and recording the glucose level and converting these measurements into equivalent blood glucose readings.

Sensors are designed to be worn three days to two weeks, depending on the product. The exception is Eversense (sensor is implanted and replaced every 180 days). Calibration is required whenever a new glucose sensor is inserted, which in most devices, requires obtaining blood glucose from a traditional fingerstick sample.

https://consumerguide.diabetes.org/collections/cgm

Examples of US Food and Drug Administration (FDA) approved devices include, but are not limited to:

Stand-Alone Continuous Glucose Monitors

- **Abbott FreeStyle Libre 14-day System**: Reads glucose levels through a sensor that is worn on the back of the upper arm. It communicates continuously with the reader, but you have to scan the sensor to get a reading. FreeStyle LibreLink app allows users to view their real-time glucose levels, access their eight-hour glucose history, and see changes in glucose on a smartphone instead of the reader. Glucose levels are displayed as number values as well as trends. The reader has a built-in meter. No finger-stick confirmation required when making treatment decisions. The LibreLinkUp app allows up to 20 people to track a user's glucose data and trends on select Apple and Android smartphones. Water-resistant for up to 3 feet deep for 30 minutes, so you can wear it while bathing. Approved for use by adults 18 and over. (HCPCS K0553, K0554) *Non-adjunctive/therapeutic continuous glucose monitor*

- **Dexcom G5 Mobile:** Users can get CGM data and alerts in real time on their smart device, including the Apple Watch. A receiver is available but is not necessary. No finger-stick confirmation required when making treatment decisions. Built-in hypoglycemia safety alarm alerts user when glucose hits 55 mg/dl and is always on. Customizable alerts with a number of different tones tell user when glucose falls below or rises above user-selected limits and when glucose is rising or falling rapidly. When calibrating, manually enter a glucose reading from any meter. Sensor with attached transmitter is water-resistant for up to 8 feet deep for 24 hours, so you can wear it while bathing and swimming. The receiver should not get wet. Using Dexcom's Follow app, up to five caregivers can view real-time glucose readings on Apple or select Android devices. Approved for use by adults and children 2 and over. (HCPCS K0553, K0554) *Non-adjunctive/therapeutic continuous glucose monitor*

- **Dexcom G6 System:** Users can get CGM data and alerts in real time on their smart device, including the Apple Watch. A receiver is available but is not necessary. No finger-stick confirmation required when making treatment decisions. Built-in hypoglycemia safety alarm alerts user when glucose hits 55 mg/dl and is always on. Customizable alerts with a number of different tones tell user when glucose falls below or rises above user-selected limits and when glucose is rising or falling rapidly. Sensor with attached transmitter is water-resistant for up to 8 feet deep for 24 hours, so you can wear it while bathing and swimming. The receiver should not get wet. Using Dexcom's Follow app, up to 10 caregivers can view real-time glucose readings on Apple or select Android devices. Approved for use by adults and children 2 and over. (HCPCS K0553, K0554) *Non-adjunctive/therapeutic continuous glucose monitor*

- **Medtronic Diabetes Guardian Connect:** Users can get CGM data and alerts in real time on their smart device, including the Apple Watch. Alerts users 10 to 60 minutes before high or low blood glucose levels are expected. Also works with the Sugar.IQ app, which can track specified meals and predict the likelihood of low blood glucose within the next four hours. Water-resistant for up to 8 feet deep for 30 minutes, so you can wear it while bathing and swimming. Approved for use by adults and children 14 and over.

- **Senseonics Eversense**: Provides continuous glucose monitoring for up to 180 days via a pill-sized sensor implanted just under the skin by a health care provider. A removable and rechargeable transmitter sits on top of the skin and sends data to a mobile app for Android and Apple devices. A separate receiver is not required. No finger-stick confirmation required when making treatment decisions. Predictive alerts help users know if glucose is trending high or low. Eversense is the only CGM approved for use during an MRI. Using the Eversense Now app, up to five caregivers can view real-time glucose readings and receive alerts on Apple devices. The transmitter is water resistant. It also vibrates against the body when glucose hits a preset high or low level, even if the smart device is not in range. Approved for use by adults 18 and older.

Combination Continuous Glucose Monitors - Insulin Pumps

- **Medtronic Diabetes MiniMed 630G System:** Functions as both an insulin pump and a CGM. (More on its pump functions on p. 60.) SmartGuard technology automatically stops insulin delivery for up to 2 hours when glucose values reach a user-selected low threshold and there is no response to the alarm. Alerts user up to 30 minutes before glucose hits a user-selected upper or lower limit, when glucose is rising or falling rapidly, and when glucose reaches a preset high or low limit. The Contour Next Link 2.4 meter wirelessly communicates with the system, so no manual entry is needed for calibration, insulin dosing, or remote bolus delivery. You can manually enter a glucose reading from any meter. Sensor with attached transmitter is waterproof for 8 feet deep for up to 30 minutes, so you can wear it when bathing and swimming. Pump is waterproof for 12 feet deep for up to 24 hours. The 630G with Guardian Sensor

3 is approved for use by adults and children 14 and over. The 630G with Enlite Sensor is approved for use by adults and children 16 and over.

- **Medtronic Diabetes MiniMed 670G System:** Functions as both an insulin pump and a CGM. (More on its pump functions on p. 62.) In Auto Mode, SmartGuard technology automatically adjusts basal insulin delivery every five minutes based on the user's sensor glucose values and recent insulin delivery, though it still requires users to enter carb grams and confirm mealtime and correction bolus recommendations. System can stop insulin delivery before glucose levels reach a user-selected low limit and resume delivery when glucose levels recover. The Contour Next Link 2.4 meter wirelessly communicates with the system, so no manual entry is needed for calibration, insulin dosing, or remote bolus delivery. You can manually enter a glucose reading from a non-linked meter. Sensor with attached transmitter is waterproof for 8 feet deep for up to 30 minutes, so you can wear it when bathing and swimming. Pump is waterproof for 12 feet deep for up to 24 hours. Approved for use by adults and children 7 and over with type 1 diabetes

- **Medtronic Diabetes MiniMed 770G System:** Functions as both an insulin pump and a CGM. The system has two modes; Manual Mode and Auto Mode. While in Manual Mode, the system can be programmed by the user to deliver basal insulin at a preprogrammed constant rate. The system will automatically suspend delivery of insulin if the sensor glucose value falls below or is predicted to fall below a predetermined threshold. The system will automatically resume delivery of insulin once sensor glucose values rise above or are predicted to rise above a predetermined threshold. While in Auto Mode, the system can automatically adjust basal insulin by continuously increasing, decreasing, or suspending delivery of insulin based on CGM values (different from Manual Mode where basal insulin is delivered at a constant rate). Although Auto Mode can automatically adjust basal insulin delivery without input from the user, the user must still manually deliver insulin therapy during meals. Approved for use by adults and children 2 and over with type 1 diabetes.

- **Medtronic MiniMed 780G System:** The MiniMed 780G is a hybrid closed-loop insulin pump by Medtronic. The pump's automated insulin delivery system, SmartGuard, uses CGM data in an algorithm to adjust basal insulin and give correction boluses as frequently as every 5 minutes. The pump communicates wirelessly with either the Guardian 3 and 4 Sensor, the latter of which does not require calibration. The device features meal detection technology designed to detect missed or miscalculated carbohydrate boluses based on sensor glucose rate of change and give larger correction boluses. The device has 3 adjustable glucose target rates: 100, 110, and 120 mg/dl. It is approved for people with Type 1 diabetes using 8 units or more per day.

- **Tandem Diabetes Care T:slim X2 Pump with Basal-IQ Technology**: Functions as both an insulin pump and a CGM, once integrated with the Dexcom G6 sensor and transmitter. (More on its pump functions on p. 62.) Basal-IQ technology predicts glucose levels and temporarily stops insulin delivery if glucose is expected to drop below 80 mg/dl in the next 30 minutes. No finger-stick confirmation required when making treatment decisions. Built-in hypoglycemia safety alarm alerts user when glucose hits 55 mg/dl and is always on. Customizable alerts with a number of different tones tell user when glucose falls below or rises above user-selected limits and when glucose is rising or falling rapidly. Sensor with attached transmitter is water-resistant for up to 8 feet deep for 24 hours, so you can wear it while bathing and swimming. Pump is watertight for up to 3 feet deep for 30 minutes. Approved for use by adults and children 6 and over.

- **Tandem Diabetes Care T:slim X2 Pump with Control-IQ Technology**: Functions as both an insulin pump and a CGM, once integrated with the Dexcom G6 sensor and transmitter. (More on its pump functions on p. 62.) Automatically adjusts basal insulin delivery based on sensor glucose readings. With Control-IQ technology, the system can automatically deliver a correction bolus, though it still requires users to bolus for meals. No finger-stick confirmation required when making treatment decisions. Built-in hypoglycemia safety alarm alerts user when glucose hits 55 mg/dl and is always on. Customizable alerts with a number of different tones tell user when glucose falls below or rises above user-selected limits and when glucose is rising or falling rapidly. Sensor with attached transmitter is water-resistant for up to 8 feet deep for 24 hours, so you can wear it while bathing and swimming. Pump is watertight for up to 3 feet deep for 30 minutes. Approved for use by adults and children 6 and over.

Insulin Pumps
Insulin pumps are devices used to deliver insulin in a programmed and controlled manner to diabetic individuals. These devices work with a separate glucometer through manual or remote functions. The goal of insulin pump therapy is to achieve near-normal control of blood glucose levels. Insulin pumps are categorized as follows:

External insulin pumps: Deliver insulin via subcutaneous or intraperitoneal routes. External insulin pumps may be either disposable or have disposable components.

https://consumerguide.diabetes.org/collections/pumps

Examples of FDA approved external insulin pumps include, but are not limited to:

- **Insulet Corp. OmniPod**: Does not use tubing. The system includes a pod that is worn for up to 72 hours and a remote personal diabetes manager (PDM) that controls the pod's functions and has a built-in blood glucose meter. Pod must be within 5 feet of the PDM to deliver bolus doses. The pod delivers basal insulin regardless of how close it is to the PDM. The PDM contains more than 1,000 common foods (with nutrition information) and stores up to 36 preset carb values. Pod is waterproof for up to 25 feet deep for 60 minutes, so there's no need to disconnect while swimming or bathing. The PDM is not waterproof. Works with Glooko, Tidepool, and Diasend data-management systems. Approved for use by adults and children.

- **Insulet Corp. OmniPod Dash**: Does not use tubing. The system includes a pod that is worn for up to 72 hours and a personal diabetes manager (PDM) with color touch screen that controls the pod's functions. The PDM connects to the Contour Next One blood glucose meter so users can see blood glucose readings in the PDM's bolus calculator. OmniPod Display app allows users to view PDM data on their smartphones, and the View app shares data with up to 12 friends or family members. Pod must be within 5 feet of the PDM to deliver bolus doses. The pod delivers basal insulin regardless of how close it is to the PDM. The PDM features CalorieKing, with 80,000 foods and drinks (English only), and stores up to 50 preset carb values. Pod is waterproof for up to 25 feet deep for 60 minutes, so there's no need to disconnect while swimming or bathing. The PDM is not waterproof. Works with Glooko, Tidepool, and Diasend data-management systems. Approved for use by adults and children 2 and over.

- **Sooil Development Dana Diabecare IIS**: Menu uses icons instead of words. Available in five colors. Pump is waterproof for 3.3 feet deep for up to 1 hour. Does not work with data-management software. Approved for use by adults and children 7 and over.

Prior Authorization: Yes, for CGMS receiver (monitor) (A9278, E2102, E2103, S1030, S1034, S1037) initial and replacement requests, per network provider agreement
Prior authorization is not required for supplies (A4238, A4329, A9276, A9277, S1035, S1036)

CODING: HCPCS 2024
A4238 Supply allowance for adjunctive, nonimplanted continuous glucose monitor (CGM), includes all supplies and accessories, 1 month supply = 1 unit of service
A4239 Supply allowance for nonadjunctive, nonimplanted 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 nondurable medical equipment interstitial continuous glucose monitoring system (CGM), one unit = 1 day supply
A9277 Transmitter; external, for use with nondurable medical equipment interstitial continuous glucose monitoring system (CGM)
A9278 Receiver (monitor); external, for use with nondurable medical equipment interstitial continuous glucose monitoring system (CGM)
E2102 Adjunctive, nonimplanted continuous glucose monitor
E2103 Nonadjunctive, nonimplanted continuous glucose monitor (CGM) or receiver
0446T Creation of subcutaneous pocket with insertion of implantable interstitial glucose sensor, including system activation and patient training
S1030 Continuous noninvasive glucose monitoring device, purchase
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 (eg, 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

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2. Clinical Policy: DMEPOS, Insulin Infusion Pump (MC/L011)
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Nondiscrimination & Language Access Policy

Discrimination is Against the Law. Aspirus Health Plan, Inc. complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability, or sex, (including sex characteristics, including intersex traits; pregnancy or related conditions; sexual orientation, gender identity and sex stereotypes), consistent with the scope of sex discrimination described at 45 CFR § 92.101(a)(2). Aspirus Health Plan, Inc. does not exclude people or treat them less favorably because of race, color, national origin, age, disability, or sex.

Aspirus Health Plan, Inc.:
Provides people with disabilities reasonable modifications and free appropriate auxiliary aids and services to communicate effectively with us, such as:

- Qualified sign language interpreters.
- Written information in other formats (large print, audio, accessible electronic formats, other formats).

Provides free language assistance services to people whose primary language is not English, which may include:

- Qualified interpreters.
- Information written in other languages.

If *you* need reasonable modifications, appropriate auxiliary aids and services, or language assistance services, contact the Nondiscrimination Grievance Coordinator at the address, phone number, fax number, or email address below.

If *you* believe that Aspirus Health Plan, Inc. has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability, or sex, *you* can file a *grievance* with:

Nondiscrimination Grievance Coordinator
Aspirus Health Plan, Inc.
PO Box 1890
Southampton, PA 18966-9998
Phone: 1-866-631-5404 (TTY: 711)
Fax: 763-847-4010
Email: customerservice@aspirushealthplan.com

You can file a *grievance* in person or by mail, fax, or email. If *you* need help filing a *grievance*, the Nondiscrimination Grievance Coordinator is available to help *you*.

You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at https://ocrportal.hhs.gov/ocr/portal/lobby.jsf, or by mail or phone at:

U.S. Department of Health and Human Services
200 Independence Avenue, SW
Room 509F, HHH Building
Washington, D.C. 20201
1.800.368.1019, 800.537.7697 (TDD)

Complaint forms are available at http://www.hhs.gov/ocr/office/file/index.html. This notice is available at Aspirus Health Plan, Inc.'s website: https://aspirushealthplan.com/webdocs/70021-AHP-NonDiscrim_Lang-Assist-Notice.pdf.

Language Assistance Services

Albanian: KUJDES: Nëse flitni shqip, për ju ka në dispozicion shërbime të asistencës gjuhësore, pa pagesë.Telefononi në 1-800-332-6501 (TTY: 711).

Arabic تنبيه :إذا كنت تتحدث اللغة العربية، فإن خدمات المساعدة اللغوية متاحة لك مجاناً .اتصل بن اعلى رقم الهاتف1-800-332-6501(رقم هاتف الصم والبك : 711)

French: ATTENTION: Si vous parlez français, des services d'aide linguistique vous sont proposés gratuitement. Appelez le 1-800-332-6501 (ATS: 711).

German: ACHTUNG: Wenn Sie Deutsch sprechen, stehen Ihnen kostenlos sprachliche Hilfsdienstleistungen zurVerfügung. Rufnummer: 1-800-332-6501 (TTY: 711).

Hindi: _यान द_: य_द आप िहंदी बोलते ह_ तो आपके िलए मु_त म_ भाषा सहायता सेवाएं उपल_ध ह_।1-800-332-6501 (TTY: 711) पर कॉल कर_।

Hmong: LUS CEEV: Yog tias koj hais lus Hmoob, cov kev pab txog lus, muaj kev pab dawb rau koj. Hu rau 1-800-332-6501 (TTY: 711).

Korean: 주의: 한국어를 사용하시는 경우, 언어 지원 서비스를 무료로 이용하실 수 있습니다.1-800-332-6501 (TTY: 711)번으로 전화해 주십시오.

Polish: UWAGA: Jeżeli mówisz po polsku, możesz skorzystać z bezpłatnej pomocy językowej. Zadzwoń pod numer1-800-332-6501 (TTY: 711).

Russian: ВНИМАНИЕ: Если вы говорите на русском языке, то вам доступны бесплатные услуги перевода.Звоните 1-800-332-6501 (телетайп: 711).

Spanish: ATENCIÓN: si habla español, tiene a su disposición servicios gratuitos de asistencia lingüística. Llame al1-800-332-6501 (TTY: 711).

Tagalog: PAUNAWA: Kung nagsasalita ka ng Tagalog, maaari kang gumamit ng mga serbisyo ng tulong sa wika nangwalang bayad. Tumawag sa 1-800-332-6501 (TTY: 711).

Traditional Chinese: 注意：如果您使用繁體中文， 您可以免費獲得語言援助服務。請 致電 1-800-332-6501 (TTY: 711)

Vietnamese: CHÚ Ý: Nếu bạn nói Tiếng Việt, có các dịch vụ hỗ trợ ngôn ngữ miễn phí dành cho bạn. Gọi số 1-800-332-6501 (TTY: 711).

Pennsylvania Dutch: Wann du Deitsch (Pennsylvania German / Dutch) schwetzscht, kannscht du mitaus Koschte ebbergricke, ass dihr helft mit die englisch Schprooch. Ruf selli Nummer uff: Call 1-800-332-6501 (TTY: 711).

Lao: ໂປດຊາບ: ຖ້າວ່າ ທ່ານເວົ້າພາສາ ລາວ, ການບໍລິການຊ່ວຍເຫຼືອດ້ານພາສາ,ໂດຍບໍ່ເສັຽຄ່າ, ແມ່ນມີພ້ອມໃຫ້ທ່ານ. ໂທຣ 1-800-332-6501 (TTY: 711).