Pharmacy Policy Bulletin

Title:	Continuous Glucose Monitor
Policy #:	Rx.01.218

Application of pharmacy policy is determined by benefits and contracts. Benefits may vary based on product line, group, or contract. Some medications may be subject to precertification, age, quantity, or formulary restrictions (ie limits on non-preferred drugs). Individual member benefits must be verified.

This pharmacy policy document describes the status of pharmaceutical information and/or technology at the time the document was developed. Since that time, new information relating to drug efficacy, interactions, contraindications, dosage, administration routes, safety, or FDA approval may have changed. This Pharmacy Policy will be regularly updated as scientific and medical literature becomes available. This information may include new FDA-approved indications, withdrawals, or other FDA alerts. This type of information is relevant not only when considering whether this policy should be updated, but also when applying it to current requests for coverage.

Members are advised to use participating pharmacies in order to receive the highest level of benefits.

Intent:

The intent of this policy is to communicate the medical necessity criteria for Continuous Glucose Monitors (Dexcom®, Medtronic®) as provided under the member's prescription drug benefit.

Description:

The Continuous Glucose Monitors (CGMs) are indicated for use in individuals with type 1 diabetes who require insulin and need to be monitored for unexplained glycemic fluctuations and hypoglycemic unawareness. Hypoglycemic unawareness is the inability of an individual to notice and recognize symptoms of hypoglycemia while they are experiencing them.

CGMs devices are considered an adjunct to be used with a traditional blood glucose monitor. These adjunctive devices allow individuals to track glucose levels and detect episodes of high and low blood sugar in real-time on an ongoing basis. The device consists of a disposable subcutaneous sensor, an external transmitter, and an external receiver (monitor), which can be a stand-alone device or built into an insulin pump. Sensors are worn as indicated by the device manufacturer in accordance with US Food and Drug Administration (FDA) labeling and are replaced on an ongoing basis.

Depending on the device sensor longevity capability, a CGMs sensor measures interstitial glucose levels for 6 to 14 days. Use of this device requires the glucose sensor to be implanted subcutaneously, usually in the abdomen or in an area above the buttocks. The transmitter is connected to the sensor by an adhesive patch, and glucose signals are sent from the sensor to the receiver every five minutes. Interstitial glucose values appear on the receiver or mobile device, where they can be read and reviewed by the individual. This data may be stored and downloaded for analysis. CGMs devices also allow for customization of threshold settings, such as alarms, to detect high and low glucose levels.

The FDA has approved several CGMs devices to assist in analyzing glycemic trends in the ongoing evaluation and management of individuals with diabetes. The FDA requires that alterations to an individual's insulin dosage or therapy are made only after confirmation of blood glucose levels with a traditional blood glucose monitor.

Policy:

Continuous glucose monitor (CGM) products (receivers, transmitters and sensors) are approved when ALL of the following are met:

1. Diagnosis of diabetes; and
2. Member is adherent to current diabetes treatment plan and participates in ongoing diabetes education and support; and
3. Member is treated with insulin; and
4. For Freestyle Libre only, documentation of the member's inability to use Dexcom®

Authorization duration: 2 years.

Black Box Warning as shown in the drug Prescribing Information:

None

Guidelines:

Refer to the specific manufacturer's prescribing information for administration and dosage details and any applicable Black Box warnings.

BENEFIT APPLICATION

Subject to the terms and conditions of the applicable benefit contract, the applicable drug(s) identified in this policy is (are) covered under the prescription drug benefits of the Company's products when the medical necessity criteria listed in this pharmacy policy are met. Any services that are experimental/investigational or cosmetic are benefit contract exclusions for all products of the Company.

References:

Dexcom® CGM. Available at: https://www.dexcom.com/continuous-glucose-monitoring. Accessed April 20, 2023.

Freestyle Libre® CGM. Available at: https://www.freestyle.abbott/us-en/home.html. Accessed April 20, 2023.

Medtronic® CGM. Available at: https://www.medtronicdiabetes.com/treatments/continuous-glucose-monitoring. Accessed April 20, 2023.

Weinstock, R. Management of blood glucose in adults with type 1 diabetes mellitus. UpToDate website. Updated February 2021 www.uptodate.com. Accessed April 20, 2023.

Applicable Drugs:

Inclusion of a drug in this table does not imply coverage. Eligibility, benefits, limitations, exclusions, precertification/referral requirements, provider contracts, and Company policies apply.

Dexcom® line of products	Medtronic® line of products	Freestyle® line of products
Dexcom® G5 Receivers	Guardian™ Connect Transmitter	Freestyle Libre® 14 Day Reader
Dexcom® G6 Receivers	Guardian™ Sensor	Freestyle Libre® 14 Day Sensor
Dexcom® G7 Receiver	Enlite® Sensor	Freestyle Libre® 2 Reader
Dexcom® G5 Sensors	Eversense® Sensor/Holder	Freestyle Libre® 2 Sensor
Dexcom® G6 Sensors		Freestyle Libre® 3 Sensor
Dexcom® G7 Sensor		
Dexcom® G5 Transmitter Kit		
Dexcom® G6 Transmitter Kit		

Cross References:

Rx.01.33 Off-Label Use

Rx.01.76 Quantity Level Limits for Pharmaceuticals Covered Under the Prescription Drug Benefit

Policy Version Number:	5.00
P&T Approval Date:	March 16, 2023
Policy Effective Date:	July 01, 2023
Next Required Review Date:	September 15, 2023

The Policy Bulletins on this web site were developed to assist the Company in administering the provisions of the respective benefit programs, and do not constitute a contract. If you have coverage through the Company, please refer to your specific benefit program for the terms, conditions, limitations and exclusions of your coverage. Company does not provide health care services, medical advice or treatment, or guarantee the outcome or results of any medical services/treatments. The facility and professional providers are responsible for providing medical advice and treatment. Facility and professional providers are independent contractors and are not employees or agents of the Company. If you have a specific medical condition, please consult with your doctor. The Company reserves the right at any time to change or update its Policy Bulletins.