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5.99.014

Section: Prescription Drugs Effective Date: April 1, 2024

Subsection: Miscellaneous Products Original Policy Date: August 24, 2018

Subject: Continuous Glucose Monitors Page: 1 of 6

and Supplies

Last Review Date: March 8, 2024

Continuous Glucose Monitors (CGM) and Supplies

Description

Dexcom G6, Dexcom G7, Freestyle Libre 14 day, Freestyle Libre 2,

Freestyle Libre 3

Refer to the durable medical equipment benefit (DME) for coverage of all other CGM monitors and supplies.

Background

Continuous glucose monitors (CGMs) are devices that measure glucose levels in interstitial fluid at programmable intervals. CGMs use sensors that are inserted under the skin and work by extracting glucose from the interstitial fluid, measuring and recording the glucose level and converting these measurements into equivalent blood glucose readings. The sensor can determine if glucose levels are too high (hyperglycemia) or too low (hypoglycemia), and how glucose levels are changing. This can assist in calculating the insulin dosage needed to manage glycemic control. These monitors reduce the need for fingerstick testing in patients with diabetes and should be used as an adjunct to standard of care. Sensors can be used for a various number of days, depending on the product and manufacturer.

Regulatory Status

Continuous glucose monitors and supplies are approved by the FDA for the regular quantitative measurement of glucose levels.

Related policies

Diabetes Test Strips, Disposable Insulin Delivery Devices

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Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Continuous glucose monitors and supplies may be considered **medically necessary** if the conditions indicated below are met.

Continuous glucose monitors and supplies may be considered **investigational** for all other indications.

Prior-Approval Requirements

Patients who have filled at least one cumulative ≥84 day supply of a single insulin, a glucagon-like peptide-1 (GLP-1) agonist injection indicated for the treatment of diabetes mellitus, or an insulin/GLP-1 combination injection **OR** have filled CGM/CGM supplies in the past 180 days are exempt from these Prior Authorization (PA) requirements up to the PA quantity limits.

Diagnoses

Patient must have **ONE** of the following:

- 1. Type 1 Diabetes Mellitus
- 2. Type 2 Diabetes Mellitus **AND ALL** of the following:
 - a. Insulin and/or GLP-1 agonist dependent with **ONE** of the following:
 - i. > 3 insulin injections per day
 - ii. Insulin pump therapy with frequent dosage adjustments for > 6 months
 - iii. GLP-1 agonist injections, with or without insulin (See Appendix 1)
 - Diabetes is uncontrolled AND patient has a documented average frequency of glucose self-testing at least 5 times per day during the previous two months
 - c. HbA1c > 7.0% **OR** frequent hypoglycemic episodes
 - d. Patient has completed a comprehensive diabetes education program
 - e. Patient will share device readings with physician or healthcare professional as part of overall diabetes management
 - f. **NO** dual therapy with blood glucose test strips at Prior Authorization (PA) quantities

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Prior - Approval Renewal Requirements

Diagnoses

Patient must have **ONE** of the following:

- 1. Type 1 Diabetes Mellitus
- 2. Type 2 Diabetes Mellitus

AND the following for **ALL** diagnoses:

 NO dual therapy with blood glucose test strips at Prior Authorization (PA) quantities

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Quantity

System	Quantity Limit
Freestyle Libre 14 day	1 Monitor* per 365 days AND 6
Freestyle Libre 2	sensors per 84 days
Freestyle Libre 3	sensors per 64 days
Dexcom G6	1 Monitor per 365 days AND 9
Dexcom G7	sensors per 90 days AND 1
	transmitter* per 90 days

^{*}Not all systems require each component listed in this policy. Please refer to the documentation supplied with chosen system for its specific required components

Duration 12 months

Prior - Approval Renewal Limits

Same as above

Rationale

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Summary

Continuous glucose monitors (CGMs) are devices that measure glucose levels in interstitial fluid at programmable intervals. CGMs use sensors that are inserted under the skin and work by extracting glucose from the interstitial fluid, measuring and recording the glucose level and converting these measurements into equivalent blood glucose readings. The sensor can determine if glucose levels are too high (hyperglycemia) or too low (hypoglycemia), and how glucose levels are changing. This can assist in calculating the insulin dosage needed to manage glycemic control. These monitors reduce the need for fingerstick testing in patients with diabetes and should be used as an adjunct to standard of care. Sensors can be used for a various number of days, depending on the product and manufacturer.

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of continuous glucose monitors and supplies while maintaining optimal therapeutic outcomes.

Policy History	
Date	Action
August 2018	Addition to PA
November 2018 February 2019	Annual review Addition of statement: Refer to the durable medical equipment benefit (DME) for coverage of all other CGM monitors and supplies
March 2019 June 2020	Annual review Annual review
October 2020	Addition of Freestyle Libre 2 CGM System
December 2020	Annual editorial review. Removed Dexcom G5 CGM from policy due to discontinued availability of the sensors and transmitters
January 2021	Removed Freestyle Libre 10 day CGM from policy due to being discontinued
February 2021	Revised initiation requirements so patients with Type 1 diabetes do not have any additional criteria to meet
March 2021	Annual review
August 2021	Updated step out verbiage and criteria to include insulin/GLP-1 combination products or GLP-1 agonist alone as acceptable step edit or current regimen options. Changed diabetic test strips to blood glucose test strips. Added Appendix 1.
September 2021	Annual review
March 2022	Annual review
January 2023 February 2023	Addition of Dexcom G7 CGM system. Changed policy number to 5.99.014 Updated step edit verbiage to allow patients to qualify after an 84 day supply of qualifying products instead of 90 day. Added Mounjaro (tirzepatide) to Appendix 1

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March 2023 Combined CGM monitor and CGM supply into one policy; a PA is now

required for supplies.

June 2023 Annual review. Revised step-out language to remove requirement that

additional Monitors require a prior authorization

September 2023 Annual review March 2024 Annual review

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 8, 2024 and is effective on April 1, 2024.

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Appendix 1 - Injectable GLP-1 Receptor Agonists Indicated for the Treatment of Diabetes Mellitus

Generic Name	Brand Name
Dulaglutide	Trulicity
Exenatide	Byetta
Exenatide ER	Bydureon, Bydureon BCise
Insulin Degludec and Liraglutide	Xultophy
Insulin Glargine and Lixisenatide	Soliqua
Liraglutide	Victoza
Lixisenatide	Adlyxin
Semaglutide	Ozempic
Tirzepatide	Mounjaro