

Pharmacy Medical Necessity Policy

Continuous Glucose Monitoring – Unified Formulary

Policy Number: 9.337

Version Number: 1.1

Version Effective Date: 1/1/2022

Product Applicability		<input type="checkbox"/> All Plan+ Products
Well Sense Health Plan	Boston Medical Center HealthNet Plan	
<input type="checkbox"/> New Hampshire Medicaid	<input checked="" type="checkbox"/> MassHealth ACO	
	<input checked="" type="checkbox"/> MassHealth MCO	
	<input type="checkbox"/> Qualified Health Plans/ConnectorCare/Employer Choice Direct	
	<input type="checkbox"/> Senior Care Options	
Benefit	<input checked="" type="checkbox"/> Pharmacy Benefit	
	<input type="checkbox"/> Medical Benefit	

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

Policy

Reference Table

Products that require PA	Products not covered through pharmacy*
Dexcom G6® ^{PD}	Dexcom G4
Freestyle Libre 14 day® ^{PD}	Dexcom G5
Freestyle Libre 2® ^{PD}	Enlite
	Eversense
	Freestyle Navigator
	Guardian

*These products are not available through the pharmacy benefit; however, may be covered under Durable Medical Equipment (DME). Any requests submitted to the pharmacy UM team should be faxed back for submission to DME.

^{PD} Preferred Drug. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class.

The following NDCs are included within the rebate agreement and will usually reject at the pharmacy as prior authorization required. Any NDC that is not listed here is not included in the rebate agreement and therefore will usually reject at the pharmacy level.

Dexcom G6®

- 08627-0091-11 Dexcom G6 Receiver Kit (GSN 065863)
- 08627-0016-01 Dexcom G6 Transmitter Kit (GSN 065873)
- 08627-0053-03 Dexcom G6 Sensor 3-pack (GSN 065744)

Freestyle Libre 14 day® and Freestyle Libre 2®

- 57599-0002-00 FreeStyle Reader Kit 14 Day (GSN 077832)
- 57599-0001-01 FreeStyle Sensor Kit 14 Day (GSN 077828)
- 57599-0803-00 FreeStyle 2 Reader (GSN 077832)
- 57599-0800-00 FreeStyle 2 Sensor (GSN 077828)

Approval Criteria:

<p><i>Dexcom G6®</i> <i>Freestyle Libre 14 day®</i> <i>Freestyle Libre 2®</i></p>	<p>Initial authorization criteria:</p> <ol style="list-style-type: none"> 1. Member had a diagnosis of diabetes mellitus; AND 2. Member’s current treatment plan involves testing blood glucose at least 4 times per day; AND 3. ONE of the following: <ol style="list-style-type: none"> a. Member is currently receiving multiple daily insulin administrations or an insulin pump; OR b. The provider submits documentation that member is not receiving insulin due to physical disability, visual impairment, cognitive impairment, or age <18 years old <p style="text-align: center;">AND</p> 4. Member meets ONE of the following: <ol style="list-style-type: none"> a. A1c ≥7% or value that does not meet documented target treatment goal; OR b. Frequent hypoglycemia (or nocturnal hypoglycemia); OR c. History of hypoglycemic unawareness; OR d. Dawn phenomenon with fasting blood sugars frequently exceeding 200 mg/dL.; OR e. History of emergency room visit or hospitalization related to ketoacidosis or hypoglycemia; OR f. Use with compatible insulin pump to achieve glycemic control; OR g. Pregnancy <p>Reauthorization criteria:</p> <ol style="list-style-type: none"> 1. The prescriber documents improvement in diabetic control/relative stability (e.g. provider attestation or A1c improvement can be considered to meet this requirement); AND 2. The provider attests that the member’s CGM data has been reviewed and is being used to monitor or adjust the
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	antidiabetic treatment plan
Duration of Authorization:	Prior authorization may be issued for 1 year .

Appendix:

Responsibility and Accountability

Policy History

Original Approval Date	Original Effective Date	Policy Owner	Approved by
5/13/2021	7/1/2021	Pharmacy Services	Pharmacy & Therapeutics (P&T) Committee

Policy Revisions History

Review Date	Summary of Revisions	Revision Effective Date	Approved by
5/13/2021	Created policy for MH Unified Formulary, policy date 3/1/21	7/1/2021	P&T Committee
10/1/2021	MH UPPL Update; Guideline updated to add six new agents to UPPL including: Dexcom G4, Dexcom G5, Enlite, Eversense, Freestyle Navigator, and Guardian. Guideline updated to reflect preferred agents with "PD". Additionally, the criteria were updated to remove blood glucose testing requirement and wording of the insulin requirement was updated from multiple daily insulin injections to multiple daily insulin administrations. Criteria for A1c not meeting goal was updated to remove requirement of education and adherence to blood glucose testing.	1/1/2022	P&T Committee

Next Review Date

5/2022

Other Applicable Policies

References

1. American Diabetes Association. Diabetes Technology: Standards of Medical Care in Diabetes 2019. Diabetes Care 2019; 42:S71
2. Kudva YC, Ahmann AJ, Bergenstal RM, et al. Approach to Using Trend Arrows in the FreeStyle Libre Flash Glucose Monitoring Systems in Adults. J Endocr Soc 2018; 2:1320
3. Welsh JB, Gao P, Derdzinski M, et al. Accuracy, Utilization, and Effectiveness Comparisons of Different Continuous Glucose Monitoring Systems. Diabetes Technol Ther 2019; 21:128

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.