Harvard Pilgrim Health Care | TUFTS Health Plan

Pharmacy Medical Necessity Guidelines:
Insulin and Diabetes Supplies

Effective: September 1, 2023

Guideline Type	☒ Prior Authorization ☐ Non-Formulary ☐ Step-Therapy ☐ Administrative

Applies to:

Commercial Products

☒ Harvard Pilgrim Health Care Commercial products; Fax: 617-673-0988

☒ Tufts Health Plan Commercial products; Fax: 617-673-0988

CareLink℠ – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

Public Plans Products

☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); Fax: 617-673-0988

Note: While you may not be the provider responsible for obtaining prior authorization, as a condition of payment you will need to ensure that prior authorization has been obtained.

Overview

To promote appropriate utilization of flash glucose monitoring with **Freestyle Flash Continuous Glucose Monitors**. Appropriate use should include device training and support. In addition, device readings should be shared and interpreted by a healthcare professional on a regular basis.

To promote appropriate utilization of insulin pump supplies, such as **Omnipod 5 System**. The Plan considers external insulin infusion pumps and related supplies as reasonable and medically necessary for the management of diabetes mellitus when the criteria below are met.

This guideline applies to the following products:

Freestyle Libre 14 Day Sensor
Freestyle Libre 14 Day Reader
Freestyle Libre 2 Sensor
Freestyle Libre 2 Reader
Freestyle Libre 3 Sensor
Omnipod 5 Intro Kit
Omnipod 5 Pods

Clinical Guideline Coverage Criteria

Freestyle Libre Sensor or Reader

The plan may authorize Freestyle Libre Sensor or Reader when the following criteria is met:

1. The Patient has insulin dependent type 1 or type 2 diabetes mellitus or gestational diabetes

AND

2. The Patient is 18 years of age or older

AND

3. The Patient is insulin dependent with either insulin pump therapy OR 3 or more injections per day

AND

4. The Patient has inadequately controlled blood glucose as evidenced by one of the following:
   a. Indicated by recurrent unexplained, severe, symptomatic hypoglycemia (generally blood glucose levels less than 50 mg/dl) which puts the Member or others at risk;

   OR

   b. Gestational diabetes and poorly controlled diabetes endangering fetal health (e.g., unexplained hypoglycemic episodes, hypoglycemic unawareness, suspected postprandial hyperglycemia, or recurrent diabetic ketoacidosis);

   OR

   c. Glycosylated hemoglobin (HbA1c) > 7% on multiple consecutive readings that include a test taken in the past three months

Freestyle Libre 2 Sensor or Reader and Freestyle Libre 3 Sensor

The plan may authorize the Freestyle Libre 2 Sensor or Reader and Freestyle Libre 3 Sensor when the following criteria is met:

1. The Patient has insulin dependent type 1 or type 2 diabetes mellitus or gestational diabetes

AND

2. The Patient is 4 years of age or older

AND

3. The Patient is insulin dependent with either insulin pump therapy OR 3 or more injections per day

AND

4. The Patient has inadequately controlled blood glucose as evidenced by one of the following:
   a. Indicated by recurrent unexplained, severe, symptomatic hypoglycemia (generally blood glucose levels less than 50 mg/dl) which puts the Member or others at risk;

   OR

   b. Gestational diabetes and poorly controlled diabetes endangering fetal health (e.g., unexplained hypoglycemic episodes, hypoglycemic unawareness, suspected postprandial hyperglycemia, or recurrent diabetic ketoacidosis);

   OR

   c. Glycosylated hemoglobin (HbA1c) > 7% on multiple consecutive readings that include a test taken in the past three months

Omnipod 5 Intro Kit and Omnipod 5 Pods

The plan may authorize the Omnipod 5 Intro Kit and Omnipod 5 Pods when the following criteria is met:

1. The patient meets all of the following:
   a. The patient has a diagnosis of Type 1 diabetes mellitus and is age 6 years or older

   AND

   b. The patient is currently using a Dexcom G6 continuous glucose monitor (CGM)

OR

2. The patient meets **all** of the following:
   a. The patient has a diagnosis of Type 1 diabetes mellitus and is age 6 years or older

   AND

   b. The member requires insulin injections, at least 3 times per day, or the use of an insulin pump

   AND

   c. The member has been recommended to perform frequent home blood glucose monitoring (4 or more times per day)

Limitations

1. Dexcom G6 and G7 are subject to Medical benefit review for Commercial members and are only available through DME. For Direct members, these products are non-formulary under the pharmacy benefit and Freestyle Libre is preferred. Additional approval is required, where non-formulary and above CGM criteria must be met for approval, and rationale is provided why Freestyle Libre cannot be used.
2. For a non-formulary medication request, please refer to the Pharmacy Medical Necessity Guidelines for Formulary Exceptions and submit a formulary exception request to the plan as indicated.
3. The following quantity limitations apply:

Description	NDC	Refills/Limit
Freestyle Libre 14 Day Sensor	57599-0001-01	Limit 2 in 28 days (display says 30)
Freestyle Libre 14 Day Reader	57599-0002-00	Limit 1 in 365 days
Freestyle Libre 2 Sensor	57599-0800-00	Limit 2 in 28 days
Freestyle Libre 2 Reader	57599-0803-00	Limit 1 in 365 days
Freestyle Libre 3 Sensor	57599-0818-00	Limit 2 in 28 days
Omnipod 5 Intro Kit	08508-3000-01	Limit 1 per 365 days
Omnipod 5 Pods (5 pack)	08508-3000-21	Limit 2 boxes (10 pods)/30 days

Codes

None

References

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Approval And Revision History

September 12, 2022: Reviewed by the Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

- September 2022 P&T evote: Updated overview and limitations section to include the list of products included in the MNG.
- June 13, 2023: Effective 9/1/23, updated CGM criteria to include gestational diabetes, removed requirement for frequent at home blood glucose monitoring, updated criteria for inadequately controlled blood glucose and clarified the limitation on access and coverage of Dexcom G6 and G7.

Background, Product and Disclaimer Information

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Pharmacy Medical Necessity Guideline and a self-insured Member’s benefit document, the provisions of the benefit document will govern.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.