Harvard Pilgrim Health Care | TUFTS Health Plan

Pharmacy Medical Necessity Guidelines:
Insulin and Diabetes Supplies

Effective: November 10, 2026

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

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.

To promote appropriate utilization **of CeQur Simplicity**, a mealtime insulin delivery device for T1 and T2 diabetes patients on multiple daily injections (MDIs)

This guideline applies to the following products:

Freestyle Libre 14 Day Sensor
Freestyle Libre 14 Day Reader
Freestyle Libre 2 Sensor
Freestyle Libre 2 Plus Sensor
Freestyle Libre 2 Reader
Freestyle Libre 3 Sensor
Freestyle Libre 3 Plus Sensor
Freestyle Libre 3 Reader
Omnipod 5 Intro Kit
Omnipod 5 Pods
CeQur Simplicity
CeQur Simplicity Extnd Wear

Clinical Guideline Coverage Criteria

Freestyle Libre Sensor or Reader (14 day)

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 OR a long-acting basal insulin

AND

4. For patients with Type 2 diabetes mellitus, the Patient has inadequately controlled blood glucose as evidenced by one of the following:
   a. Recurrent unexplained, severe, symptomatic hypoglycemia (generally blood glucose levels less than 50 mg/dl) which puts the Member or others at risk;

   OR

   b. 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 a test taken in the past four months

   OR

   d. **Member is new to the plan does not need to meet the criteria for “Poorly controlled blood glucose” if they are stable and have been successfully using the device prior to becoming a member and the device was authorized for use by their prior insurance. Supporting documentation is required.

Freestyle Libre 2 Sensor or Reader and Freestyle Libre 3 Sensor or Reader (14 day)

The plan may authorize the Freestyle Libre 2 Sensor or Reader and Freestyle Libre 3 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 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 OR a long-acting basal insulin

   AND

4. For patients with Type 2 diabetes mellitus, the Patient has inadequately controlled blood glucose as evidenced by one of the following:
   a. Recurrent unexplained, severe, symptomatic hypoglycemia (generally blood glucose levels less than 50 mg/dl) which puts the Member or others at risk;

   OR

   b. 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 a test taken in the past four months

   OR

   d. **Members is new to the plan do not need to meet the criteria for “Poorly controlled blood glucose” if they are stable and have been successfully using the device prior to becoming a member and the device was authorized for use by their prior insurance. Supporting documentation is required.

Freestyle Libre 2 Plus Sensor or Freestyle Libre 3 Plus Sensor (15 day)

The plan may authorize the Freestyle Libre 2 Sensor Plus or Freestyle Libre 3 Plus 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 2 years of age and older

   AND

3. The Patient is insulin dependent with either insulin pump therapy OR 3 or more injections per day OR a long-acting basal insulin

   AND

4. For patients with Type 2 diabetes mellitus, the Patient has inadequately controlled blood glucose as evidenced by one of the following:
   a. Recurrent unexplained, severe, symptomatic hypoglycemia (generally blood glucose levels less than 50 mg/dl) which puts the Member or others at risk;

   OR

   b. 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 a test taken in the past four months

   OR

d. Member is new to the plan does not need to meet the criteria for “Poorly controlled blood glucose” if they are stable and have been successfully using the device prior to becoming a member and the device was authorized for use by their prior insurance. Supporting documentation is required.

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. One of the following:
      i. The patient has a diagnosis of Type 1 diabetes mellitus and is 2 years of age or older

      OR

      ii. The patient has a diagnosis of Type 2 diabetes and is 18 years of age or older

      AND

   b. The patient is currently using a Dexcom G6 or G7 or Freestyle Libre 2 Plus Sensor continuous glucose monitor (CGM)

   OR

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

      OR

      ii. The patient has a diagnosis of Type 2 diabetes and is 18 years of age 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)

CeQur Simplicity and CeQur Simplicity Extnd Wear

The plan may authorize CeQur Simplicity or CeQur Simplicity Extnd Wear when the following criteria is met:

1. The patient meets **ALL** of the following:
   a. The patient is age 21 or older

   AND

   b. The patient is diagnosed with diabetes mellitus requiring mealtime insulin

   AND

2. The member has tried and failed, or is unable to demonstrate proper use with both of the following:
   a. Mealtime insulin administration with needle/pen needle

   AND

   b. Insulin delivery devices: Omnipod DASH, Omnipod 5, or V-go

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. If additional approval is required, where non-formulary and above CGM criteria must be met for approval, a minimum 90-day trial of Freestyle Libre and clinical rationale is provided why Freestyle Libre cannot be used. Adhesive issues/allergies, inaccurate readings, compatibility with insulin pumps do not quality as a clinical reason 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 approval duration for non-formulary products is limited to 12 months of treatment.
4. Requests for reauthorizations and for members new to the plan and stable on a non-formulary product should be reviewed against non-formulary exception criteria and rationale is needed as to why the preferred product can’t be used.
5. The Plan considers CGMs as reasonable and medically necessary for gestational diabetes when prescribed by a professional provider with experience in treating gestational diabetes, therefore prior authorization is not required and approvals may be entered for 9 months. Subsequent requests after pregnancy will require PA review..
6. The following quantity limitations apply:

Description	NDC	Refills/Limit
Freestyle Libre 14 Day Sensor	57599-0001-01	Limit 2 in 28 days
Freestyle Libre 14 Day Reader	57599-0002-00 57599-0000-21	Limit 1 in 365 days
Freestyle Libre 2 Sensor	57599-0800-00	Limit 2 in 28 days
Freestyle Libre 2 Plus Sensor	57599-0835-00	Limit 2 in 30 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
Freestyle Libre 3 Plus Sensor	57599-0844-00	Limit 2 in 30 days
Freestyle Libre 3 Reader	57599-0820-00	Limit 1 in 365 days
Omnipod 5 Intro Kit G6/G7	08508-3000-01 08508-3000-50	Limit 1 per 365 days
Omnipod 5 Pods (5 pack)	08508-3000-21	Limit 2 boxes (10 pods)/30 days
Omnipod 5 FSL2 Plus G6 Intro kit	08508-3000-88	Limit 1 per 365 days
Omnipod 5 FSL2 Plus G6 Pods	08508-3000-42	Limit 10 pods/30 days
Cequr Simplicity patches	73108-0000-01	Limit 10 patches/30 days
Cequr Simplicity patches	73108-0000-08	Limit 8 patches/30 days
Cequr Simplicity Inserter	73108-0001-00	Limit 1 per 365 days
Cequr Simplicity 1u Extnd Wear	73108-0000-11	Limit 4 patches/28 days
Cequr Simplicity 2u Extnd Wear	73108-0000-13	Limit 5 patches/30 days
Cequr Simplicity Extended Wear Inserter	73108-0000-14	Limit 1 per 365 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.
- November 14, 2023: Effective 1/1/24, added coverage criteria for CeQur Simplicity.
- February 13, 2024: Added coverage criteria for Freestyle Libre 3 Reader.
- February 11, 2025: Added Freestyle Libre 2 and 3 Plus Sensors and Omnipod 5 G7 products. Updated Freestyle Libre CGM criteria to specify requirements for type 2 diabetes vs type 1 and gestational. Updated criteria for Omnipod 5 to include expanded indications (type 2 diabetes and ages).
- July 8, 2025: Effective August 1, 2025, Expanded CGM eligibility by adding long-acting basal insulin as a criteria option for insulin use, removed PA requirement for CGMs for gestational diabetes, and expanded A1C test requirement allowed to be taken within the past four months.
- February 10, 2026: Effective May 1, 2026, Removed any mention of “poorly controlled diabetes” to support members who are new to the plan, but stable on an existing CGM, and added new limitations to clarify the approval duration for non-formulary products is limited to 12 months, and reauthorization requests, and requests for members new to the plan stable on a non-formulary product should be reviewed against non-formulary exception criteria and rationale is needed as to why the preferred product can’t be used.
- February 2026: Administrative update to remove CareLink from Medical Necessity Guideline template.
- April 14, 2026: Effective July 1, 2026, removed non-rebated NDCs from coverage chart and updated limitations stating a minimum 90-day trial of a preferred product is required prior to a non-formulary approval, and listed what does not quality as a clinical reason why a non-preferred product should be approved.
- November 10, 2026: Added CeQur Simplicity Extnd Wear products and updated CeQur Simplicity NDCs. (eff 11/10/26) and clarified authorizations for gestational diabetes will be approved for 9 months.

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.