Medical Necessity Guidelines
Medical Benefit Drugs

# Continuous Glucose Monitoring Systems: Freestyle and Dexcom Products

*Effective: October 1, 2026*

| **Prior Authorization Required**<br>If REQUIRED, submit supporting clinical documentation pertinent to service request. | Yes ☒ No ☐ |
|---|---|

**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
☐ Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans; Fax 617-673-0939
☐ Tufts Health RITogether – A Rhode Island Medicaid Plan; Fax 617-673-0939
☒ Tufts Health One Care-- A dual-eligible product; Fax 617-673-0956

**Senior Products**

☒ Tufts Health Plan Senior Care Options (SCO), (a dual-eligible product); Fax 617-673-0956
☒ Tufts Medicare Preferred HMO, (a Medicare Advantage product); Fax 617-673-0956
☒ Tufts Medicare Preferred PPO, (a Medicare Advantage product); Fax 617-673-0956

**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

The pancreas is an organ in the body that secretes several hormones, including insulin and glucagon, as well as digestive enzymes that help break down food. Insulin is a hormone that the body needs to get glucose, which it uses for energy, from the bloodstream into the cells of the body. Diabetes (diabetes mellitus) is a condition of impaired insulin production and variable degrees of insulin resistance, leading to hyperglycemia (high levels of glucose in the bloodstream). Type 1 diabetes occurs when the pancreas produces little or none of the insulin needed to regulate blood glucose. Type 2 diabetes occurs when the pancreas does not produce enough insulin or the body becomes resistant to the insulin that is present.

The goal of treatment for diabetes regardless of the type is to keep blood glucose levels within a target range. Poorly controlled glucose levels can lead to numerous acute and chronic complications, some of which can be life threatening. Continuous glucose monitoring systems (CGMS) are minimally invasive or noninvasive devices that measure glucose levels in interstitial fluid at frequent intervals. CGMS are designed to obtain information regarding diurnal patterns in glucose levels that, when evaluated in real time or reviewed retrospectively by a physician, can guide adjustments to therapy, with the goal of improving overall glycemic control.

Tufts Health Plan uses guidance from the Centers for Medicare and Medicaid Services (CMS) and MassHealth for coverage determinations for its Dual Product Eligible plan members and CMS for its Medicare Advantage plan members. CMS National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), Local Coverage Articles (LCAs) and documentation included in the Medicare manuals and MassHealth Medical Necessity Determinations are the basis for coverage determinations where available. For the Plan's members, the following criteria is used: LCD - Glucose Monitors (L33822) (cms.gov)

The general term CGM refers to both therapeutic/non-adjunctive and non-therapeutic/adjunctive CGMs. For the purpose of this LCD, the term "therapeutic" may be used interchangeably with the term "non-adjunctive." Likewise, the term "non-therapeutic" may be used interchangeably with the term "adjunctive."

A therapeutic or non-adjunctive CGM can be used to make treatment decisions without the need for a stand-alone BGM to confirm testing results. A non-therapeutic or adjunctive CGM requires the user verify their glucose levels or trends displayed on a CGM with a BGM prior to making treatment decisions. On February 28, 2022, CMS determined that both therapeutic/non-adjunctive and non-therapeutic/adjunctive CGMs may be classified as DME.

**Note:** Members may obtain the Freestyle or Dexcom systems either through a network pharmacy or medical supply company. Freestyle and Dexcom are covered under Medicare Part B benefits.

**Note:** The Plans *preferred* GCM system is Freestyle and Dexcom systems

## Clinical Guideline Coverage Criteria

**Diabetes mellitus**

The Plan may cover Freestyle or Dexcom when **ALL** the following clinical criteria is met:

1. The Member has a diagnosis of diabetes mellitus (DM) type-1 or type-2

**AND**

2. The Member for whom a CGM is being prescribed, to improve glycemic control, meets at least one (1) of the following:
    a. The Member is insulin- treated
    b. The Member has a history of problematic hypoglycemia with documentation of at least one of the following
        i. Recurrent (more than one) level 2 hypoglycemic events (glucose <54mg/dL (3.0mmol/L)) that persist despite multiple (more than one) attempts to adjust medication(s) and/or modify the diabetes treatment plan

**OR**

        ii. A history of one level 3 hypoglycemic event (glucose <54mg/dL (3.0mmol/L)) characterized by altered mental and/or physical state requiring third-party assistance for treatment of hypoglycemia

**AND**

3. Within six (6) months prior to ordering the CGM, the treating practitioner has an in-person or Medicare approved telehealth visit with the Member to evaluate their diabetes control and determined that criteria (1-2) above are met

**AND**

4. Every six (6) months following the initial prescription of the CGM, the treating practitioner has an in-person or Medicare approved telehealth visit with the Member to assess adherence to their CGM regimen and diabetes treatment plan

Note: The Plan considers continuous glucose monitoring systems as reasonable and medically necessary for gestational diabetes for the duration of the pregnancy only. The CGM must be prescribed by a professional provider with an expertise in treating diabetes. **For continued glucose monitoring post-partum, the criteria listed in section above, titled "Diabetes mellitus" would apply**.

**<u>For Tufts Health Senior Care Options (SCO) and Tufts Health One Care only</u>**

**CGMs for Hypoglycemia**

**Initial Authorization Criteria:**

The Plan may cover Freestyle Dexcom when ALL the following clinical criteria is met

1. Member has a diagnosis of Hypoglycemia, or nocturnal hypoglycemia, or hypoglycemic unawareness due to a non-diabetes-based condition

**AND**

2. Member has clinical rationale for use of CGM instead of capillary blood glucose monitoring using test strips and a blood glucose meter

*Non-diabetes based conditions may include: seizure disorder, insulinoma, genetic conditions causing hyperinsulinemia, effects from post-surgical conditions including post esophagectomy, post fundoplication, post gastrectomy, post gastric bypass, and post sleeve gastrectomy. Documentation should include why the Member is at hypoglycemic risk and other events.

**Reauthorization Criteria:**
The Plan may reauthorize cover Freestyle or Dexcom when **ALL** the following clinical criteria is met:

1. Documented evidence of improvement in control of diabetes (specific to baseline status of disease for individual members); **or**
2. Documented evidence of compliance with a current CGM treatment plan based on log data of the device; **or**
3. A member is new to the Plan from another insurer and is stable on CGM.

**Note:** The continuous glucose device must be FDA approved and follow the FDA recommendations for use in children and adults

**FOR ALL LINES OF BUSNIESS:** In addition to the above criteria, the Plan may cover any other non-preferred CGM) when the following criteria is met:

1. Any other non-preferred CGM may be covered if there is a clinical rationale why the preferred product, Freestyle or Dexcom Product, is not clinically appropriate for the member and that the non-preferred CGM is covered by Medicare.

## Limitations

- The Plan will only authorize coverage of CGM products that are covered by Medicare (see LCD L33822) or MassHealth for One Care and SCO.
- This MNG only applies to continuous glucose monitoring systems for use by Members in the home. It does not apply to systems used for 14-day physician monitoring.
- The Plan considers the supply of disposable supplies and parts for diabetes management devices (e.g. sensors for CGM systems) as not medically necessary outside of FDA labelling on use and replacement frequency.
- The replacement of non-implanted continuous interstitial glucose monitoring devices is considered medically necessary when the following criteria have been met:
    - The device is out of warranty; and
    - The device is malfunctioning; and
    - The device cannot be refurbished.
- For Hypoglycemia due to a diagnosis other than Diabetes mellitus initial approval by the Plan will be limited to 12 months. Reauthorizations will be provided in 12- month intervals

## Codes

**Table 1: HCPCS Codes**

| HCPCS Codes | Description |
|---|---|
| A4238 | Supply allowance for adjunctive continuous glucose monitor (CGM), includes all supplies and accessories, 1 month supply = 1 unit of service |
| E2102 | Adjunctive continuous glucose monitor or receiver |

**References:**


1. American Diabetes Association Professional Practice Committee for Diabetes*; 7. Diabetes Technology: Standards of Care in Diabetes—2026. Diabetes Care 1 January 2026; 49 (Supplement_1): S150–S165. https://doi.org/10.2337/dc26-S007.
2. Centers for Medicare & Medicaid Services (CMS) Local Coverage Determination for Glucose Monitors (L33822). Last updated October 1, 2024. https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=33822. Accessed August 12, 2026.
3. Centers for Medicare and Medicaid Services Glucose Monitor- Policy Article (A52464).. Last Updated February 18, 2025. https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleId=52464. Accessed August 12, 2026.
4. Commonwealth of Massachusetts. Executive Office of Health and Human Services. MassHealth Guidelines for Medical Necessity Determination for Continued Glucose Monitoring Products. January 2024. Available at https://www.mass.gov/doc/guidelines-for-medical-necessity-determination-for-diabetes-management-devices-continuous-glucose-monitoring-systems-and-insulin-pumps-0/download. Last Accessed July 8, 2026.
5. United States Food and Drug Administration. What is an Artificial Pancreas Device System? Available at fda.gov. Last accessed July 8, 2026.
6. United States Food and Drug Administration. Types of Artificial Pancreas Device Systems. Available at fda.gov. Last accessed July 8, 2026.
7. United States Department of Health and Human Services, National Institute of Diabetes and Digestive and Kidney Disorders. Diabetes Overview. Available at niddk.nih.gov. Last accessed July 8, 2026.

## Approval And Revision History

October 18, 2023: Reviewed by the Medical Policy Approval Committee (MPAC)

Subsequent endorsement date(s) and changes made:

- Originally approved December 13, 2022 by P&T and December 21, 2022 by MPAC committees effective January 1, 2023
- Administrative update: March 2023 added Medical Benefit Drugs to title and updated MATogether and RITogether fax numbers to 617-673-0939
- March 2023 updated criteria to be in alignment with LCD L33822 and added NCA A52464 to references effective April 16, 2023
- October 18, 2023: Added initial authorization and reauthorization criteria for SCO and Once Care Members for Hypoglycemia due to a diagnosis other than Diabetes mellitus, added limitation for authorization approval for Hypoglycemia due to a diagnosis other than Diabetes mellitus, and added MassHealth criteria reference effective January 1, 2024
- October 2023 updated preferred products, added clarifying LCD language, removed NDC grid, and rebranded Tufts Health Unify to Tufts Health One Care effective January 1, 2024
- December 2023: Reviewed and Approved at the UM Committee effective January 1, 2023
- June 13, 2024: Reviewed and approved by the UM Committee effective August 1, 2024
- June 20, 2024: Reviewed by MPAC, renewed without changes, effective August 1, 2024
- July 22, 2024: Reviewed at MPAC, added coverage of gestational diabetes as well as updated CGMs for hypoglycemia question 1 and reauthorization criteria to be in line with MassHealth effective December 1, 2024
- September 17, 2024: Reviewed and approved by the UM Committee, effective December 1, 2024
- August 20, 2025: Reviewed and approved by MPAC, renewed without changes effective October 1, 2025
- September 5, 2025: Template updated, language for Carelink removed
- September 17, 2025: Reviewed by the UM Committee, renewed without changes effective October 1, 2025
- August 19, 2026: Reviewed by MPAC, renewed without changes effective October 1, 2026

## Background, Product and Disclaimer Information

Medical Necessity Guidelines are developed to determine coverage for benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. We make coverage decisions using these guidelines, along with the Member's benefit document, and in coordination with the Member's physician(s) on a case-by-case basis considering the individual Member's health care needs.

Medical Necessity Guidelines are developed for selected therapeutic or diagnostic services found to be safe and proven 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 our service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. We revise and update 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 Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern. For Tufts Health Together (Medicaid), coverage may be available beyond these guidelines for pediatric members under age 21 under the Early and Periodic Screening, Diagnostic and Treatment (EPSDT) benefits of the plan in accordance with 130 CMR 450.140 and 130 CMR 447.000, and with prior authorization.

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