Harvard Pilgrim Health Care | TUFTS Health Plan

Medical Necessity Guidelines:

Continuous Glucose Monitoring and Diabetes Management Devices

Effective: November 1, 2024

Prior Authorization Required If REQUIRED, submit supporting clinical documentation pertinent to service request to the FAX numbers below	Yes ☒ No ☐
Notification Required IF REQUIRED, concurrent review may apply	Yes ☐ No ☒

Applies to:

Commercial Products

☒ Harvard Pilgrim Health Care Commercial products; 800-232-0816

☒ Tufts Health Plan Commercial products; 617-972-9409

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); 888-415-9055

☐ Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans; 888-415-9055

☒ Tufts Health RITogether – A Rhode Island Medicaid Plan; 857-304-6404

☒ Tufts Health One Care-- A dual-eligible product; 857-304-6304

Senior Products

☐ Harvard Pilgrim Health Care Stride Medicare Advantage; 866-874-0857

☐ Tufts Health Plan Senior Care Options (SCO), (a dual-eligible product); 617-673-0965

☐ Tufts Medicare Preferred HMO, (a Medicare Advantage product); 617-673-0965

☐ Tufts Medicare Preferred PPO, (a Medicare Advantage product); 617-673-0965

Note: While you may not be the provider responsible for obtaining prior authorization or notifying Point32Health, as a condition of payment you will need to ensure that any necessary prior authorization has been obtained and/or Point32Health has received proper notification. If notification is required, providers may additionally be required to provide updated clinical information to qualify for continued service.

Overview

This policy applies to the following devices and related supplies: continuous glucose monitoring systems (CGMS), automated Insulin Dosing (AID) Device Systems, including Paired Interoperable Insulin Pumps and Integrated Continuous Glucose Monitoring (iCGM) Systems, and Hybrid Closed Loop Systems (Artificial Pancreas System). Insulin infusion pumps which work independently and do not communicate with or work in conjunction with a CGM device do not require prior authorization.

Access and Coverage (CGMS may be obtained via DME or pharmacy. See grid below for specifics)

Plan	CGMs obtained via DME or Pharmacy	Guidelines
Tufts Health RITogether	Pharmacy (Device and Supplies are accessible only at pharmacy and not through a DME provider)	**Through Pharmacy** https://tuftshealthplan.com/documents/providers/guidelines/pmngs/cgms-dexcom-g6-rit-pmng

Plan	CGMs obtained via DME or Pharmacy	Guidelines
Commercial	DME with exception	Dexcom G6 and G7 are subject to medical benefit review **in this policy** for Commercial members and are only available through DME.
Direct	Pharmacy with exception (Device and Supplies are accessible only at pharmacy and not through a DME provider, unless the CGM is used as part of an artificial pancreas or equivalent)	For Direct members, Freestyle Libre is preferred, and is available through the pharmacy benefit. Requests for any other CGM device will require clinical documentation explaining why the Freestyle Libre device cannot be used. CGM devices which are used as part of an artificial pancreas or equivalent (i.e., Dexcom, Medtronic) are subject to medical benefit review. **Through Pharmacy**: https://tuftshealthplan.com/documents/providers/guidelines/pmngs/insulin-and-diabetes-supplies-comm-pmng)
Tufts Health One Care	Pharmacy or DME	**Through Pharmacy**: https://tuftshealthplan.com/documents/providers/guidelines/md-mngs/cgms-dexcom-g6-and-freestyle-mdmng . **Through DME**: **See specific criteria for Tufts Health One Care in the below section: titled *Continuous Glucose Monitors for Tufts Health One Care.***

Diabetes is a group of metabolic diseases characterized by impaired secretion and/or function of insulin resulting in high glucose levels. A major goal of diabetes management is adequate glycemic control by keeping the daily blood glucose levels and HbA1c within the recommended target range without frequent hypoglycemia lows. While typically controlled through dietary and activity adjustment and, at times, the administration of insulin, practicing a successful regimen can in some cases be difficult. A continuous glucose monitoring system is a minimally invasive device comprised of a small catheter sensor, generally replaced every one to three weeks depending on the system, which measures interstitial fluid glucose concentration, a monitor that displays and records the readings of the sensor, and a transmission system, typically replaced once to four times a year, connecting the two. While not able to replace self-monitoring of blood glucose (SMBG), these systems can provide detailed data to aid in planning glucose control strategies and warn a user of the need to perform SMBG.

Continuous glucose monitoring systems come in two varieties: short-term “professional” systems store data for retrospective analysis by a physician to help develop more successful management regimens and long-term “personal” systems that display readings in real time to help users build more beneficial habits. External insulin infusion pumps consist of computer-controlled pumps that deliver insulin, both at a set basal rate and at user- initiated and determined elevated “bolus doses” in response to food intake, via cannulas inserted just under the skin. Artificial pancreas device systems, also called “sensor-enhanced insulin pumps” and “sensor-augmented insulin pump therapy,” are systems in which the operation of an insulin pump is modified by the readings of a continuous glucose monitor. Systems can take the form of integrated devices or separate devices connected by third-party data transfer (either wires or wireless) and software.

Clinical Guideline Coverage Criteria

Professional short term Continuous Glucose Monitors

The Plan covers professional short term continuous glucose monitoring when used for up to 7-14 days as a diagnostic test without prior authorization.

Continuous Long-term Glucose Monitors (includes implantable CGM devices)

The Plan considers long-term continuous glucose monitoring systems as reasonable and medically necessary for diabetes when **ALL** of the following indications are met

1. The CGM is prescribed by a professional provider with an expertise in treating diabetes; **and**
2. Member is on **ONE** of the following treatment programs:
    a. Receiving intensive insulin therapy with multiple (three or more) daily insulin injections; **or**
    b. Long-acting basal insulin; **or**
    c. Continuous subcutaneous external insulin pump
3. 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. Glycosylated hemoglobin (HbA1c) > 7% on multiple consecutive readings that include a test taken in the

past three months

4. Documentation supports the need for a professional CGM device for intensive diabetes management as evidenced by **ONE** of the following:
    a. To meet individualized glycemic target goals, frequent glucose testing, and insulin adjustment is needed to promote self-management; **or**
    b. Member has participated in, or participation is ongoing in a supervised comprehensive diabetes program and Member is expected to comply with treatment plan
5. Member has demonstrated an understanding of the technology and is capable of using the device to recognize alerts and alarms or has access to a caregiver with such ability

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 experience in treating gestational diabetes. **For continued glucose monitoring post-partum, the criteria listed in the above section, titled "Continuous Long-term Glucose Monitors (includes implantable CGM devices)" would apply**.

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

Tufts Health One Care

The Plan uses guidance from the Centers for Medicare and Medicaid Services (CMS) and MassHealth for coverage determinations for its Dual Product Eligible plan members. MassHealth Medical Necessity Determinations and CMS National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), Local Coverage Articles (LCAs) and documentation included in the Medicare manuals are the basis for coverage determinations where available. For **Tufts Health One Care** the following criteria is used for:

- diabetes mellitus CMS LCD L33822
- implantable CGM LCD - Implantable Continuous Glucose Monitors (I-CGM) (L38623) (cms.gov)
- hypoglycemia due to a diagnosis other than diabetes mellitus: MassHealth Guidelines for Medical Necessity Determination for Diabetes Management

Professional short term Continuous Glucose Monitors for Tufts Health One Care

The Plan covers professional short term continuous glucose monitoring when used for up to 7-14 days as a diagnostic test without prior authorization

Continuous Long-term Glucose Monitors for Tufts Health One Care

The guidelines used to determine medical necessity for CGMs listed above include the Center for Medicaid and Medicare Services and the MassHealth Guidelines.

The Plan considers long-term continuous glucose monitoring systems as reasonable and medically necessary for diabetes when **ALL** of the following indications are met:

1. The Member has a diagnosis of diabetes mellitus (DM) type-1 or type-2; **and**
    a. The Member for whom a CGM is being prescribed, to improve glycemic control, meets at least **One** of the following:
        i. The Member is insulin- treated; **or**
        ii. The Member has a history of problematic hypoglycemia with documentation of at least **One** of the following:
            - 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**
    b. 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 the above criteria are met; **and**
    c. 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.

Tufts Health One Care members with Hypoglycemia due to a diagnosis other than Diabetes mellitus

Initial Authorization Criteria:

The Plan may cover a CGM (receiver, transmitter, sensor pack) when **ALL** of the following clinical criteria are 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.

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

- For Reauthorization of accessories or supplies criteria, see below.

CGM Continued use for Tufts Health One Care Plan

The Plan considers continuation of a CGM device as reasonable and medically necessary when **One** of the following indications 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.

Insulin Pumps For All Plans

Insulin infusion pumps which work independently and do not communicate with or work in conjunction with a CGM device do not require prior authorization. Insulin pumps which are part of a "closed loop system" or which communicate with or work in conjunction with a CGM device do require prior authorization, please see criteria below for Hybrid Closed Loop.

Automated Insulin Dosing (AID) Device Systems, Including Paired Interoperable Insulin Pumps and Integrated Continuous Glucose Monitoring (iCGM) Systems

The Plan considers automated insulin dosing device systems as reasonable and medically necessary when **ALL** the following criteria are met:

1. Member has diabetes treated with insulin; **and**
2. Member qualifies for both an insulin pump and a long-term continuous glucose monitor; **and**
3. Member is in need of a new device due to ANY of the following:
    a. Scheduled replacement of device previously approved by the Plan, **or**
    b. New qualification, **or**
    c. Persistent insufficient glycemic control, defined as **one** of the following:
        i. Glycated hemoglobin (HbA1c) concentrations ≥ 7% on multiple consecutive readings that include a test taken in the past three months, **or**
        ii. Recurrent severe hypoglycemia (less than 50mg/dl)
4. Members are willing and able to self-monitor their long-term diabetes stability through **All** the following:
    a. Taking four blood glucose concentration observations (either through device CGM capability or fingerstick) per day; **and**
    b. Maintaining contact with their primary healthcare provider; **and**
    c. Notice warnings, signals, alerts, and alarms from the device (please see section on enhancements and accommodations for visual and auditory impairments).

The system requires interaction for post-meal bolusing and retains the functionality of both a standalone glucose monitor and insulin pump.

Note: For replacement of insulin pump or CGM systems, please refer to the replacement criteria below. In addition, the requested replacement device must, if applicable, be compatible with the remaining device.

Hybrid Closed Loop Systems (Artificial Pancreas System)

For the purposes of these guidelines, a hybrid closed loop device system is defined as an insulin pump that works in conjunction with a CGM, and the pump is able to both automatically stop and adjust the flow of insulin based on readings of the CGM.

The Plan may authorize the coverage of an FDA-approved device to be used by a member with Type 1 diabetes mellitus when the member meets all of the criteria above for a continuous glucose monitoring system, and there is documentation by an endocrinologist that the Member has been using or is a good candidate for an insulin pump.

Enhancements and Accommodations for the Visually and/or Auditorily Impaired

The Plan considers accessories to, software for, and specialized models of continuous glucose monitoring systems designed to accommodate visual or auditory impairments as reasonable and medically necessary when **ALL** the following criteria are met:

1. Member has a visual or auditory impairment that precludes the successful use of a standard model without assistance beyond initial setup and instruction; **and**
2. The standard model does not come with accommodations sufficient to allow successful independent use; **and**
3. The accommodation feature being requested is appropriate for the needs of the member.

Replacement

The Plan considers the replacement of a synonymous continuous glucose monitoring system, insulin pump, or AID system as reasonable and medically necessary when documentation confirms **ALL** the following indications are met:

1. Documentation is in the form of clinical notes or letters generated by a clinician overseeing the member's diabetic condition; **and**
2. The present monitor has been rendered ineffective or inoperable due to either:
    a. A change in member condition that the current monitor is unable to accommodate, **or**
    b. Being damaged by events outside the control of the user; **and**
3. Device has been used according to treatment plan; **and**
4. Continued use of the device is supported; **and**
5. Device replacement cannot be obtained from the manufacturer or supplier due to the expiration of device warranty; **and**
6. Loss/damage is not attributable to abuse, sabotage, or neglect on the part of the user; **and**
7. The cost of replacement rather than repair is justified by the nature of damage and useful lifetime of the device; **and**
8. The replacement is not an additional/backup monitor; **and**
9. The replacement device is similar to the device being replaced unless replacement has been necessitated by a change in member condition that the old device is unable to accommodate.

Note: In cases where neither the make/model nor comparable make/model from other brands are available for replacement, selection of a new device must be based on compatibility with member's remaining device and member's clinical condition.

Reauthorization of Accessories/Supplies

The initial authorization for a continuous glucose monitoring system or artificial pancreas device system will include one year's worth of supplies (e.g., transmitter or sensors). Subsequent authorizations for accessories/supplies will require updated documentation from the treating professional provider indicating the Member continues to use and require the device and the device continues to meet the Member's needs.

Note: For requests for accessories/supplies, the request must indicate what device the supplies will be used for, including name and type of device. Requests for accessories/supplies will not be authorized unless The Plan has approved the associated device, except for members who are new to The Plan and have been successfully using the device prior to becoming a member (supporting documentation required).

Limitations

The Plan considers continuous glucose monitoring, insulin pump, and AID systems as not medically necessary for all other indications. In addition, the Plan does not cover:

1. CGMS for gastric bypass surgery without the diagnosis of diabetes for long-term use
2. CGMS for nesidioblastosis for long-term use; short-term use (7-14 days) for diagnostic purposes may be medically necessary
3. Noninvasive continuous glucose monitors
4. Remote wireless glucose monitors (e.g., mySentry)
5. Hypoglycemic Wristband Alarm (e.g., Sleep Sentry)

6. Nonprogrammable transdermal insulin delivery systems
7. Accessories, such as shower covers, belt clips, and additional software or hardware for data transfer unless necessitated by a documented disability
8. Lasette laser blood glucose monitoring devices
9. Insulin infuser ports

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.

Codes

The following code(s) require prior authorization:

Table 1: CPT/HCPCS Codes

Code	Description
0446T	Creation of subcutaneous pocket with insertion of implantable interstitial glucose sensor, including system activation and patient training
0447T	Removal of implantable interstitial glucose sensor from subcutaneous pocket via incision
0448T	Removal of implantable interstitial glucose sensor with creation of subcutaneous pocket at different anatomic site and insertion of new implantable sensor, including system activation
A4239	Supply allowance for nonadjunctive, nonimplanted continuous glucose monitor (CGM), includes all supplies and accessories, 1 month supply = 1 unit of service
A9274	External ambulatory insulin delivery system, disposable, each, includes all supplies and accessories
A9276	Sensor; invasive (e.g., subcutaneous), disposable, for use with nondurable medical equipment interstitial continuous glucose monitoring system (CGM), one unit = 1 day supply
A9277	Transmitter; external, for use with nondurable medical equipment interstitial continuous glucose monitoring system (CGM)
A9278	Receiver (monitor); external, for use with nondurable medical equipment interstitial continuous glucose monitoring system (CGM)
E2103	Nonadjunctive, nonimplanted continuous glucose monitor (CGM) or receiver

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Approval And Revision History

November 16, 2022: Reviewed by the Medical Policy Approval Committee (MPAC) for integration between Harvard Pilgrim Health Care (HPHC) and Tufts Health Plan (THP)

Subsequent endorsements date(s) and changes:

- June 21, 2023: Reviewed by MPAC; language added clarifying CGM access via DME providers or pharmacy. Prior authorization will no longer be required for 95249 and 95250, effective August 1, 2023
- October 18, 2023: Reviewed by MPAC, renewed without changes
- November 2023: Rebranded Unify to One Care and updated One Care criteria effective January 1, 2024
- June 13, 2024: Reviewed by UM Committee, renewed without changes
- June 20, 2024: Reviewed by MPAC, renewed without changes, effective August 1, 2024
- July 22, 2024: Reviewed at MPAC, added coverage for long acting basal insulin, added coverage for implantable CGM (0446T, 0447T, 0448T), revised gestational diabetes criteria, coding clarified for RITogether and Tufts Health One Care effective December 1, 2024
- September 19, 2024: Reviewed at MPAC, minor clarifications made to overview effective November 1, 2024

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.