Medical Necessity Guidelines: Continuous Glucose Monitoring and Diabetes Management Devices for Tufts Health Together

Effective: August 1, 2023

Prior Authorization Required
If REQUIRED, submit supporting clinical documentation pertinent to service request.

<table>
<thead>
<tr>
<th>Applies to:</th>
<th>Yes ☒</th>
<th>No ☐</th>
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<tbody>
<tr>
<td>COMMERCIAL Products</td>
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<tr>
<td>○ Tufts Health Plan Commercial products; Fax: 617.972.9409</td>
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<tr>
<td>□ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); Fax: 888.415.9055</td>
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<tr>
<td>▒ Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans; Fax: 888.415.9055</td>
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<td>□ Tufts Health RITogether – A Rhode Island Medicaid Plan; Fax: 857.304.6404</td>
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<tr>
<td>□ Tufts Health Unify* – OneCare Plan (a dual-eligible product); Fax: 857.304.6304</td>
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<tr>
<td>☒ Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans; Fax: 888.415.9055</td>
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SENIOR Products
- Tufts Health Plan Senior Care Options (SCO), (a dual-eligible product) – Refer to the Tufts Health Plan SCO Prior Authorization List
- Tufts Medicare Preferred HMO, (a Medicare Advantage product) – Refer to the Tufts Medicare Preferred HMO Prior Authorization and Inpatient Notification List

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

OVERVIEW

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, that 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.
Note:
- Continuous Glucose devices (CGMs) for Tufts Health Together may only be obtained through a network pharmacy. Exception: if member is receiving an artificial pancreas device from a DME Provider.
- Subcutaneous Insulin Delivery Devices for Tufts Health Together are available through the pharmacy; fax request to RXUM 617-673-0988; or devices can be obtained through a DME provider.

**CLINICAL 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**
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 insulin-dependent diabetes; **and**
4. The member requires multiple daily insulin administrations or an insulin pump is being used (Note: this does **NOT** apply to members who are not receiving insulin due to a physical disability, visual impairment, cognitive impairment, or age < 18 years); **and**
2. The member meets **One** of the following:
   a. HbA1c ≥ 7% or at a value that does not meet documented target treatment; **or**
   b. Frequent hypoglycemia or nocturnal hypoglycemia; **or**
   c. History of hypoglycemic unawareness; **or**
   d. Dawn phenomenon with fasting blood sugars frequently exceeding 200mg/dL; **or**
   e. History of emergency room visit or hospitalization related to ketoacidosis or hypoglycemia; **or**
   f. Use of a compatible insulin pump to achieve glycemic control; **or**
   g. Pregnancy

**Hypoglycemia Due to a Diagnosis other than Diabetes Mellitus**
When the Member has another non-diabetes-based condition causing a disorder of glucose metabolism or improper endogenous insulin secretion resulting in frequent hypoglycemia or nocturnal hypoglycemia or hypoglycemic unawareness, the use of a continuous long-term glucose monitor may be medically necessary when the following criteria are met:
1. Member has a diagnosis of Hypoglycemia due to a diagnosis other than Diabetes mellitus; and
2. Member has clinical rationale for use of CGM instead of capillary blood glucose monitoring using test strips and a blood glucose meter

**Note:** Disorders 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.

**Insulin Delivery Device:**
The plan may authorization coverage of Omnipod Classic, Omnipod 5, Omnipod Dash, and V-Go when **ALL** of the following criteria are met, and limitations do not apply:
1. Diagnosis of diabetes mellitus; **and**
2. **If the request is for V-Go:** The member is 18 years of age or older; **and**

3. **One** of the following:
   a. The Member’s current treatment plan involves testing blood glucose at least 4 times per day. If member is nonadherent to testing, documentation that testing is recommended or prescribed at least four times daily; **or**
   b. Use of continuous glucose monitoring

4. The Member is currently receiving multiple daily insulin injections (at least three) or is on an insulin pump (**Note:** this does **NOT** apply to members who are not receiving insulin due to a physical disability, visual impairment, cognitive impairment, or age < 18 years); **and**

5. The Member meets **One** of the following:
   a. The Member’s A1C is > 7% or does not meet documented target treatment
   b. Frequent hypoglycemia
   c. Fluctuations of more than 100 mg/dL in blood glucose before mealtime
   d. Dawn phenomenon with fasting blood sugars frequently exceeding 200 mg/dL
   e. History of severe glycemic excursions

**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 that **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 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**
Documentation that the Member has had an improvement in diabetic control/relative stability (e.g., provider attestation or A1C improvement or improvement in hypoglycemia or hyperglycemia can be considered to meet this requirement)

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 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 Tufts Health Plan has approved the associated device, except for members who are new to Tufts Health Plan and have been successfully using the device prior to becoming a member (supporting documentation required).
LIMITATIONS

1. Initial and reauthorization requests will be approved for 1 year.
2. The following are considered not medically necessary:
   a. Non FDA-approved devices
   b. Remote continuous glucose monitoring devices, accessories, and additional hardware or software that are ancillary to CGMs (e.g., complementary watches.)
   c. Replacement of an existing CGM with another CGM for additional features which are not medically necessary
   d. Noninvasive continuous glucose monitors
   e. Remote wireless glucose monitors (e.g., mySentry)
   f. Hypoglycemic Wristband Alarm (e.g., Sleep Sentry)
   g. Nonprogrammable transdermal insulin delivery systems

CODES

The following HCPCS code(s) require prior authorization:

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<thead>
<tr>
<th>HCPCS® Codes</th>
<th>Description</th>
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<tr>
<td>A4239</td>
<td>Supply allowance for nonadjunctive, nonimplanted continuous glucose monitor (CGM), includes all supplies and accessories, 1 month supply = 1 unit of service</td>
</tr>
<tr>
<td>A9274</td>
<td>External ambulatory insulin delivery system, disposable, each, includes all supplies and accessories</td>
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<tr>
<td>A9276</td>
<td>Sensor; invasive (e.g., subcutaneous), disposable, for use with nondurable medical equipment interstitial continuous glucose monitoring system (CGM), one unit = 1 day supply</td>
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<tr>
<td>A9277</td>
<td>Transmitter; external, for use with nondurable medical equipment interstitial continuous glucose monitoring system (CGM)</td>
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<tr>
<td>A9278</td>
<td>Receiver (monitor); external, for use with nondurable medical equipment interstitial continuous glucose monitoring system (CGM)</td>
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<tr>
<td>E2103</td>
<td>Nonadjunctive, nonimplanted continuous glucose monitor (CGM) or receiver</td>
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REFERENCES


References:


**APPROVAL HISTORY**

Subsequent Endorsement date(s) and changes made:
- April 5, 2022: Template updated
- June 15, 2022: Reviewed by Medical Policy Approval Committee (MPAC), renewed without changes

**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.

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.