Medical Necessity Guidelines: Devices for the Management of Diabetes (Continuous Glucose Monitoring Systems, Artificial Pancreas Device Systems)

Effective: July 15, 2020

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

Applies to:
COMMERCIAL Products
☒Tufts Health Plan Commercial products; Fax: 617.972.9409
☒Tufts Health Freedom Plan products; Fax: 617.972.9409
- CareLink℠ – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

TUFTS HEALTH PUBLIC PLANS Products
☒Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); Fax:888.415.9055
☒Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans; Fax: 888.415.9055
☒Tufts Health RITogether – A Rhode Island Medicaid Plan; Fax: 857.304.6404
☒Tufts Health Unify* – OneCare Plan (a dual-eligible product); Fax: 857.304.6304
*The MNG applies to Tufts Health Unify members unless a less restrictive LCD or NCD exists.

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

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.

According to the U.S. FDA, an artificial pancreas device system is a system of devices that closely mimics the glucose regulating function of a healthy pancreas. Most artificial pancreas device systems consist of three types of devices: an insulin infusion pump, a continuous glucose monitoring system (CGM), and a glucose meter used to calibrate the CGM. A computer-controlled algorithm connects the CGM and insulin infusion pump to allow continuous communication between the two devices. An artificial pancreas device system may also be referred to as a "closed-loop" system, an "automated insulin delivery" system, an "autonomous system for glycemic control", or "sensor-augmented pump therapy." Threshold suspend

device systems (also known as low glucose suspend systems) have the ability to automatically suspend the delivery of insulin when the CGM sensor detects a blood glucose level at or approaching a certain low threshold. Other devices have that same ability and can also automatically increase or decrease the basal rate of insulin delivery based on CGM readings and a preset target range.

CLINICAL COVERAGE CRITERIA

Continuous Glucose Monitoring Systems

NOTE: For **Tufts Health Together and Tufts Health RITogether**, please refer to the, Pharmacy Medical Necessity Guideline: Continuous Glucose Monitoring Systems and please fax requests to **617.673.0988**.

Tufts Health Plan covers professional, short-term continuous glucose monitoring when used for up to 72 hours as a diagnostic test without prior authorization.

Tufts Health Plan may authorize the coverage of a personal, long-term continuous glucose monitoring system (CGMS) to be used by a member when there is documentation by an endocrinologist of **ALL** of the following:

- The Member has a diagnosis of Type 1 diabetes mellitus
- The Member requires insulin injections at least three times per day or the use of an insulin pump
- The Member is performing blood sugar testing via fingerstick four or more times per day
- The Member is compliant with the prescribed insulin regimen and dietary management

AND ONE of the following is met:

1. The Member is expected to comply with a comprehensive diabetes treatment plan supervised by his or her treating provider, and is capable of recognizing the alarms and alerts of the device;
2. The Member has unawareness of hypoglycemic symptoms such as sweating, tremor, palpitations, tachycardia, confusion and lethargy;
3. The Member has recurrent episode of severe hypoglycemia defined as a glucose level of less than 50 mg/dl, which are not attributable to some type of dosing error (e.g. taking insulin too far in advance of a meal).

NOTE: For indication 2 and 3 above, the device must have an alarm feature to alert the Member of low glucose level.

Insulin Pump Therapy

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 Artificial Pancreas Device Systems.

Artificial Pancreas Device Systems

For the purposes of these guidelines, THP defines an artificial pancreas device system 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.

Tufts Health Plan may authorize the coverage of an FDA-approved artificial pancreas device system to be used by a member with Type I 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.

Replacement

Tufts Health Plan may authorize replacement of a continuous glucose monitoring system or artificial pancreas device system when documentation confirms that the device is five years old or older, or that **ALL** of the following are met:

1. The present device is deemed inoperable or ineffective due to damage resulting from events outside the control of the Member, AND
2. Documentation supports consistent compliance with use of the device and an ongoing need for it as an integral part of the Member's diabetes management program; AND

3. Replacement cannot be obtained through the supplier or manufacturer (warranty has expired); AND
4. The replacement device is similar to the previous device, without additional features or enhancements.

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 endocrinologist indicating the Member continues to use and require the device and the device continues to meet the Member's needs, and evidence of a face-to-face visit with the endocrinologist within the previous 12 months.

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

Tufts Health Plan will not cover a continuous glucose monitoring system or an artificial pancreas device system in the following circumstances:

- The Member has Type II diabetes mellitus
- The Member is pregnant and has gestational diabetes or Type II diabetes.
- Replacement or repair of units or associated equipment when lost or damaged secondary to improper care or neglect.
- Tufts Health Plan does not cover the following related items:
  - Glucowatch®

Tufts Health Plan considers the Eversense implantable CGM investigational and, therefore, not medically necessary.

Codes

The following CPT code is covered when medically necessary, without prior authorization:

Code	Description
95250	Ambulatory continuous glucose monitoring of interstitial tissue fluid via a subcutaneous sensor for up to 72 hours; sensor placement, hook-up, calibration of monitor, patient training, removal of sensor, and printout of recording

The following HCPCS codes **require prior authorization**:

Code	Description
A9276	Sensor; invasive (e.g., subcutaneous), disposable, for use with interstitial continuous glucose monitoring system, 1 unit = 1 day supply
A9277	Transmitter; external, for use with interstitial CGMS
A9278	Receiver (monitor); external, for use with interstitial continuous glucose monitoring system
K0553	Supply allowance for therapeutic continuous glucose monitor, includes all supplies and accessories, 1 month supply = 1 unit of service
K0554	Receiver (monitor), dedicated, for use with therapeutic continuous glucose monitor system
S1034	Artificial pancreas device system (e.g., low glucose suspend [LGS] feature) including continuous glucose monitor, blood glucose device, insulin pump and computer algorithm that communicates with all of the devices

Code	Description
S1035	Sensor; invasive (e.g., subcutaneous), disposable, for use with artificial pancreas device system
S1036	Transmitter; external, for use with artificial pancreas device system
S1037	Receiver (monitor); external, for use with artificial pancreas device system

The following HCPCS codes are **not covered**:

Code	Description
S1030	Continuous noninvasive glucose monitoring device, purchase (e.g. Glucowatch)
S1031	Continuous noninvasive glucose monitoring device, rental, including sensor, sensor replacement, and download to monitor (e.g. Glucowatch)

References

1. Hayes, Winifred S. Directory Report. Continuous Glucose Monitoring Systems. August 13, 2015. Annual review: October 1, 2019. Available at hayesinc.com. Last accessed July 7, 2020.
2. State of New Hampshire. Revised Statutes Annotated; RSA 415:18-f, Coverage for Diabetes Services and Supplies. August 20, 2010. Available at https://www.ncsl.org/research/health/diabetes-health-coverage-state-laws-and-programs.aspx#New Hampshire. Last accessed July 7, 2020.
3. American Diabetes Association. Classification and diagnosis of diabetes: Standards of Medical Care in Diabetes 2020. Diabetes Care 2020;43(Suppl. 1):S14–S31. Available at https://care.diabetesjournals.org/content/diacare/suppl/2019/12/20/43.Supplement_1.DC1/Standards_of_Care_2020.pdf.
4. United States Food and Drug Administration. What is the Pancreas? What is an Artificial Pancreas Device System? Available at fda.gov: https://www.fda.gov/medical-devices/artificial-pancreas-device-system/what-pancreas-what-artificial-pancreas-device-system. Last accessed July 7, 2020.
5. United States Food and Drug Administration. Types of Artificial Pancreas Device Systems. Available at fda.gov: https://www.fda.gov/medical-devices/artificial-pancreas-device-system/types-artificial-pancreas-device-systems. Last accessed July 7, 2020.
6. 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 7, 2020.

Approval History

March 14, 2018: Reviewed by the Integrated Medical Policy Advisory Committee (IMPAC), for an effective date of July 1, 2018. Two Medical Necessity Guidelines, Continuous Glucose Monitoring Systems and Artificial Pancreas Device Systems, were combined into one Medical Necessity Guideline.

Subsequent endorsement date(s) and changes made:

- September 12, 2018: Reviewed by IMPAC, note added to criteria section for continuous glucose monitoring systems, effective January 1, 2019.
- October, 2018: Template and disclaimer updated
- March 20, 2019: Reviewed by IMPAC, update to criteria for continuous glucose monitoring systems, effective July 1, 2019.
- August 14, 2019: Reviewed by IMPAC, update to "Limitations" section.
- October 16, 2019: Reviewed by IMPAC, link to Pharmacy Medical Necessity Guideline for Continuous Glucose Monitoring Systems added under Clinical Coverage Criteria, Continuous Glucose Monitoring Systems for Tufts Health Together plans effective January 1, 2020 and for Tufts Health RITogether plans effective February 1, 2020.
- July 15, 2020: Reviewed by IMPAC, update to clinical coverage criteria for continuous glucose monitoring systems, effective July 15, 2020.
- July 23, 2020: Fax number for Unify updated

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.