Pharmacy Medical Necessity Guidelines:
Continuous Glucose Monitoring Systems – Dexcom G6 Systems Only

Effective: January 1, 2021

Prior Authorization Required	√	Type of Review – Care Management	
Not Covered		Type of Review – Clinical Review	√
Pharmacy (RX) or Medical (MED) Benefit	MED	Department to Review	RxUM

These pharmacy medical necessity guidelines apply to the following:

Commercial Products

☐ Tufts Health Plan Commercial products – large group plans
☐ Tufts Health Plan Commercial products – small group and individual plans
☐ Tufts Health Freedom Plan products – large group plans
☐ Tufts Health Freedom Plan products – small group plans
- 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)
☒ Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans
☒ Tufts Health RITogether – A Rhode Island Medicaid Plan

Fax Numbers:
RXUM: 617.673.0988

Note: This guideline does not apply to Medicare Members (includes dual eligible Members).

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.

NOTE: For Tufts Health Commercial, please refer to the Medical Necessity Guidelines: Devices for the Management of Diabetes (Continuous Glucose Monitoring Systems, Artificial Pancreas Device Systems) and please fax requests to 617.972.9409.

COVERAGE GUIDELINES

Continuous Glucose Monitoring Systems

Tufts Health Plan may authorize the coverage of a personal, long-term continuous glucose monitoring system (CGMS) to be used by a member when **ALL** of the following criteria are met:

1) The request is initiated by an endocrinologist

AND

2) The Member has a diagnosis of Type 1 diabetes mellitus

AND

3) The Member requires insulin injections at least three times per day or the use of an insulin pump

AND

4) The Member is performing blood sugar testing via fingerstick four or more times per day

AND

5) The Member is compliant with the prescribed insulin regimen and dietary management

AND

6) **ONE** of the following is met (a,b, or c):
   a) The Member has unawareness of hypoglycemic symptoms such as sweating, tremor, palpitations, tachycardia, confusion and lethargy
   b) 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).
   c) 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

Replacement

Tufts Health Plan may authorize replacement of a continuous glucose monitoring 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.

LIMITATIONS

- Any requests for non-covered Continuous Glucose Monitors and related supplies, such as Freestyle Libre, Medtronic Guardian, Dexcom 4 and Dexcom 5, will require detailed clinical documentation of need for alternative treatment and will be considered on a case by case basis. Refer to the Pharmacy Medical Necessity Guidelines for Noncovered Drugs with Suggested Alternatives and submit a formulary exception request to Tufts Health Plan, as indicated.
  - Tufts Health Plan will not cover a continuous glucose monitoring 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 will only allow access the following continuous glucose monitoring system at retail pharmacies under the medical benefit:
    - Dexcom G6 system and related products
      - All other continuous glucose monitoring systems should be reviewed by Precertification/Medical Management and may be covered under the medical benefit if approved
  - The initial authorization for a continuous glucose monitoring 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.
  - Limitations on approvals are as follows:

Description	NDC	Refills
Dexcom G6 Receiver (Retail)	08627-0091-11	Refill once a Year
Dexcom G6 Transmitter (Retail)	08627-0016-01	Refill every three months
Dexcom G6 Sensor Pack (Retail)	08627-0053-03	Refill every 30 days

- The following quantity limitations apply:

Dexcom G6 Receiver (Retail)	1 receiver per 365 days
Dexcom G6 Transmitter (Retail)	1 transmitter every 90 days
Dexcom G6 Sensor Pack (Retail)	1 sensor pack every 30 days

CODES

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

REFERENCES

1. Hayes, Winifred S. Directory Report. Continuous Glucose Monitoring Systems. August 13, 2015. Annual review: July 26, 2017. Available at hayesinc.com. Last accessed February 8, 2018.
2. State of New Hampshire, Revised Statutes Annotated; RSA 415:18-f, Coverage for Diabetes Services and Supplies.
3. American Diabetes Association. Standards of Medical Care in Diabetes-2017. Available at diabetes.org. Last accessed June 1, 2017.
4. American Diabetes Association. Diabetes Basics. Available at diabetes.org. Last accessed June 5, 2017.
5. United States Food and Drug Administration. What is an Artificial Pancreas Device System? Available at fda.gov. Last accessed May 31, 2017.
6. United States Food and Drug Administration. Types of Artificial Pancreas Device Systems. Available at fda.gov. Last accessed May 31, 2017.
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 June 6, 2017.

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 and Tufts Health RITogether plans, effective January 1, 2020
- July 15, 2020: Reviewed by IMPAC, update to clinical coverage criteria for continuous glucose monitoring systems, effective July 15, 2020.
- September 15, 2020: Effective January 1, 20201, added Tufts Health Direct to Pharmacy MNG. Pharmacy benefit and access for Direct members is effective January 1, 2021. Added the name and link to Medical Necessity Guideline for Commercial and updated title to: Continuous Glucose Monitoring Systems – Dexcom G6 Systems Only.

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.