CarePartners of Connecticut MEDICARE ADVANTAGE

Medical Necessity Guidelines

Medical Benefit Drugs

Continuous Glucose Monitoring Systems: Freestyle and Dexcom Products

Effective: January 1, 2024

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

Applies to:

☒ CarePartners of Connecticut Medicare Advantage HMO plans, Fax 617-673-0956

☒ CarePartners of Connecticut Medicare Advantage PPO plans, 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.

CarePartners of Connecticut uses guidance from the Centers for Medicare and Medicaid Services (CMS) for coverage determinations 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 are the basis for coverage determinations where available. For CarePartners of Connecticut Medicare Advantage plan members, the following criteria is used: LCD- Glucose Monitors L333822

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 products.

Clinical Guideline Coverage Criteria

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: In addition to the above criteria, the Plan may cover Dexcom G6 (or 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).
- 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.

Codes

The following code(s) require prior authorization:

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. Glucose Monitors Local Coverage Determination (L33822). Centers for Medicare and Medicaid Services. Last updated April 16, 2023. https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=33822.
2. Glucose Monitor- Policy Article (A52464). Centers for Medicare and Medicaid Services. Last Updated April 16, 2023. https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleId=52464
2. 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.
3. American Diabetes Association. Standards of Medical Care in Diabetes-2022. Diabetes Technology. Diabetes Care. 2022;45(Suppl 1):S97-S112.
4. United States Food and Drug Administration. What is an Artificial Pancreas Device System? Available at fda.gov. Last accessed May 31, 2017.
5. United States Food and Drug Administration. Types of Artificial Pancreas Device Systems. Available at fda.gov. Last accessed May 31, 2017.
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 June 6, 2017.

Approval And Revision History

March 15, 2023: Reviewed by the Medical Policy Approval Committee (MPAC)

Subsequent changes:

- 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 CPCT logo
- March 2023 updated criteria to be in alignment with LCD L33822 and added NCA A52464 to references effective April 16, 2023
- October 18, 2023: updated preferred products, added clarifying LCD language, and removed NDC grid effective January 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.

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.