CareSource Rxinnovations

PHARMACY POLICY STATEMENT
Marketplace

DRUG NAME	Personal Continuous Glucose Monitors
BILLING CODE	Must use valid NDC
BENEFIT TYPE	Pharmacy
STATUS	Prior Authorization Required

Continuous Glucose Monitors (CGMs) are compact medical systems that use a subcutaneous sensor to measure interstitial glucose levels in close to real-time (every 5 to 15 minutes, depending on the device), sending the data wirelessly to a monitor device which displays the glucose data. Self-monitoring of blood glucose (SMBG) is normally accomplished by measuring blood glucose concentration through intermittent capillary blood sampling with a reagent strip, cartridge or cuvette and a drop of capillary blood from a finger puncture. CGM offers the most benefit in patients, or patient's caregivers, that are willing to use them consistently and in patients with hypoglycemic unawareness who are at risk or have a history of severe recurrent hypoglycemia.

The following continuous glucose monitors will be considered for coverage under the pharmacy benefit when the following criteria are met:

FreeStyle Libre, FreeStyle Libre 2, Dexcom

For **initial** authorization:

1. Diagnosis of Diabetes (type 1 or type 2); AND
2. Currently utilizing 3 or more injections of insulin per day.
3. **Dosage allowed/Quantity limit:**
   Freestyle Libre: 1 reader per lifetime, 10-day sensors: 3 sensors per 30 days, 14-day sensors: 2 sensors per 28 days
   Freestyle Libre 2: 1 reader per lifetime, 2 sensors per 28 days
   Dexcom: 1 receiver per lifetime, 3 sensors per month, 1 transmitter per 90 days

If all the above requirements are met, the medication will be approved for 12 months.

For **reauthorization**:

1. Documentation showing member benefit or clinical improvement (ex. decrease in hypoglycemic events, decrease in HbA1c or glucose readings)

If all the above requirements are met, the medication will be approved for an additional 12 months.

Guardian Sensor 3

For **initial** authorization:

1. Diagnosis of Diabetes (type 1 or type 2); AND
2. Age 7 years and older; AND
3. Currently utilizing 3 or more injections of insulin per day; AND
4. One or more of the following:
   a) Recurring episodes of at least moderately severe hypoglycemia (<50mg/dl)
   b) Hypoglycemic unawareness
   c) Poor glycemic control despite at least 4 finger-sticks per day
   d) Hypoglycemia overnight
   e) Recurring diabetic ketoacidosis (DKA)

f) Insulin pump usage with poor control
g) Specific cases where CGM use led to improvement in control and the clinician feels that prolonged monitoring is needed for an insulin dependent diabetic.

5. **Dosage allowed/Quantity limit**: 5 sensors per 35 days

If all the above requirements are met, the medication will be approved for 12 months.

For **reauthorization**:

1. Documentation showing member benefit or clinical improvement (ex. decrease in hypoglycemic events, decrease in HbA1c or glucose readings)

If all the above requirements are met, the medication will be approved for an additional 12 months.

Eversense

For **initial** authorization:

1. Diagnosis of Diabetes (type 1 or type 2); AND
2. Age 18 years and older; AND
3. Currently utilizing 3 or more injections of insulin per day; AND
4. One or more of the following:
   a) Recurring episodes of at least moderately severe hypoglycemia (<50mg/dl)
   b) Hypoglycemic unawareness
   c) Poor glycemic control despite at least 4 finger-sticks per day
   d) Hypoglycemia overnight
   e) Recurring diabetic ketoacidosis (DKA)
   f) Insulin pump usage with poor control
   g) Specific cases where CGM use led to improvement in control and the clinician feels that prolonged monitoring is needed for an insulin dependent diabetic.
5. **Dosage allowed/Quantity limit**: 1 smart transmitter per year, 1 sensor per 90 days

If all the above requirements are met, the medication will be approved for 12 months.

For **reauthorization**:

1. Documentation showing member benefit or clinical improvement (ex. decrease in hypoglycemic events, decrease in HbA1c or glucose readings)

If all the above requirements are met, the medication will be approved for an additional 12 months.

CareSource considers Long Term Continuous Glucose Monitors not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
8/27/2021	New policy for Continuous Glucose Monitors created.
11/14/2022	Combined Freestyle Libre and Dexcom criteria, and updated criteria for these products to diagnosis and insulin use.
12/21/2022	Removed trial of Freestyle Libre, Freestyle Libre 2, or Dexcom from Guardian and Eversense product.

References:

1. American Diabetes Association. 7. Diabetes technology: Standards of Medical Care in Diabetes – 2021. Diabetes Care 2021;44(Suppl. 1):S85-S99.

2. Battelino T, Danne T, Bergenstal RM, et al. Clinical Targets for Continuous Glucose Monitoring Data Interpretation: Recommendations From the International Consensus on Time in Range. Diabetes Care. 2019;42(8):1593-1603. doi:10.2337/dci19-0028
3. Beck RW, Riddlesworth TD, Ruedy K, et al.; DIAMOND Study Group. Continuous glucose monitoring versus usual care in patients with type 2 diabetes receiving multiple daily insulin injections: a randomized trial. Ann Intern Med 2017;167:365-374.
4. Bolinder J, Antuna R, Geelhoed-Duijvestijn P, Kroger J, Weitgasser R. novel glucose-sensing technology and hypoglycaemia in type 1 diabetes: a multicentre, non-masked, randomized controlled trial. Lancet 2016;388:2254-2263.
5. Haak T, Hanaire H, Ajjan R, Hermanns N, Riveline J-P, Rayman G. Flash glucose-sensing technology as a replacement for blood glucose monitoring of the management of insulin-treated type 2 diabetes: a multicenter, open-label randomized controlled trial. Diabetes Ther 2017;8:55-73.
6. Evans M, Welsh Z, Ells S, Seibold A. The Impact of Flash Glucose Monitoring on Glycaemic Control as Measured by HbA1c: A Meta-analysis of Clinical Trials and Real-World Observational Studies. Diabetes Ther. 2020;11(1):83-95. doi:10.1007/s13300-019-00720-0

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