Diabetes Testing Supplies – Continuous Glucose Monitoring (CGM) Systems

Prior Authorization and Quantity Limit Criteria - Medicare Part B

PRIOR AUTHORIZATION AND QUANTITY LIMIT CRITERIA FOR APPROVAL

Preferred therapeutic CGMs: Dexcom and Freestyle Libre
PA applies to non-preferred products only
QL applies to ALL products

Non-preferred continuous glucose monitoring (CGM) systems will be approved when ALL of the following are met:

1. The patient has diabetes mellitus
   AND
2. ONE of the following:
   A. The beneficiary is insulin treated
      OR
   B. The beneficiary has non-insulin treated diabetes AND ONE of the following:
      i. A history of recurrent (more than one) level 2 hypoglycemic events AND documentation of BOTH of the following:
         a At least ONE of the following:
            1. The glucose values for the qualifying event(s) [glucose less than 54 mg/dL (3.0 mmol/L)]
               OR
            2. Classification of the hypoglycemic episode(s) as level 2 event(s)
               OR
            3. Incorporate a copy of the beneficiary's BGM testing log into the medical record reflecting the specific qualifying events [glucose less than 54 mg/dL (3.0 mmol/L)]

         AND
         b Documentation of more than one previous medication adjustment and/or modification to the treatment plan (such as raising A1c targets) prior to the most recent level two event

      OR
      ii. A history of at least one level 3 hypoglycemic events characterized by altered mental and/or physical state AND documentation of BOTH of the following:
         a At least ONE of the following:
            1. The glucose values for the qualifying event(s) [glucose less than 54 mg/dL (3.0 mmol/L)]
               OR
            2. Classification of the hypoglycemic episode(s) as level 3 event(s)
               OR
            3. Incorporate a copy of the beneficiary's BGM testing log into the medical record reflecting the specific qualifying event [glucose less than 54 mg/dL (3.0 mmol/L)]

         AND
         b An indication that the beneficiary required third party assistance for treatment of hypoglycemia

   AND
3. ONE of the following:
   A. The prescriber has indicated that the patient had an in-person visit or telehealth visit to evaluate their diabetes condition within six (6) months prior to ordering the CGM to determine that criteria 1-2 above are met

OR

B. If previously approved through the plan's Prior Authorization criteria, the prescriber has indicated that the patient has had an in-person or telehealth visit to assess adherence to their diabetes treatment regimen and use of the CGM device

AND

4. The prescriber has indicated the patient has failed or has limitations of use to the preferred CGMs

AND

5. ONE of the following:
   A. The requested quantity does NOT exceed the program benefit limit
      OR
   B. BOTH of the following:
      i. The requested quantity is greater than the program benefit limit
         AND
      ii. The prescriber has provided information in support of therapy with a higher amount for the requested indication

Length of approval: 12 months

NOTES:

- Criteria above are reflective of LCD L33822

CGM Quantity Limits	
Product	**Quantity Limit**
FreeStyle Libre reader	1 reader / 365 days
FreeStyle Libre 14 day sensor	2 sensors / 28 days
FreeStyle Libre reader	1 reader / 365 days
FreeStyle Libre 2 Sensor	2 sensors / 28 days
FreeStyle Libre 2 Reader	1 reader / 365 days
FreeStyle Libre 3 Sensor	2 sensors / 28 days
FreeStyle Libre 3 Reader	1 reader / 365 days
FreeStyle Libre 2 Plus Sensor	2 sensors / 30 days
FreeStyle Libre 3 Plus Sensor	2 sensors / 30 days
Dexcom G6 transmitter	1 transmitter / 90 days
Dexcom G6 sensor	4 sensors / 28 days
Dexcom G7 sensor	3 sensors / 30 days
Dexcom G7 receiver	1 receiver / 365 days
Dexcom G6 receiver	1 receiver / 365 days
Guardian Link 3 Transmitter	1 transmitter / 365 days
Guardian Real-Time Replacement Monitor	1 monitor / 365 days
Guardian Real-Time Replacement Monitor Pediatric	1 monitor / 365 days
Guardian Sensor 3	4 sensors / 28 days
Minilink Real Time Transmitter	1 transmitter / 365 days
Minimed 630G Guardian Press Starter Transmitter kit	1 kit / 365 days
Paradigm Real-Time Transmitter	1 transmitter / 365 days
Guardian 4 Sensor	4 sensors / 28 days
Guardian 4 Transmitter Kit	1 transmitter / 365 days