UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2023 P 2170-9
Program	Prior Authorization/Medical Necessity
Medication	Continuous glucose monitors, sensors and transmitters (all brands)
P&T Approval Date	7/2019, 10/2019, 11/2019, 3/2020, 6/2021, 2/2022, 6/2022, 2/2023, 8/2023
Effective Date	11/1/2023

1. Background:

Continuous glucose monitors may be used by patients with diabetes who require glucose monitoring beyond what can be achieved with a standard blood glucose monitor. Coverage will be provided for the Guardian Connect sensor and transmitter when the Dexcom or Freestyle Libre monitors are not appropriate for the patient.

2. Coverage Criteria[a]:

A. Initial Authorization

1. **Guardian Connect and Guardian 4 continuous glucose sensors and transmitters** will be approved for initial therapy based on **all** of the following criteria:

   a. Diagnosis of diabetes
   b. **All** of the following:
      (1) Patient is motivated and knowledgeable about use of continuous glucose monitoring
      (2) Patient is adherent to diabetic treatment plan
      (3) Patient participates in ongoing education and support
   c. Patient is on an intensive insulin regimen (3 or more insulin injections per day or uses continuous subcutaneous insulin infusion pump)[b]
   d. Patient has inadequate glycemic control despite intensive diabetes management[b]
   e. Patient regularly monitors blood glucose 4 or more times per day[b]

   -AND-

   f. **One** of the following[b]:
      (1) Patient has a physical or mental limitation that makes utilization of Dexcom G6 and Dexcom G7 unsafe, inaccurate or otherwise not feasible (e.g. manual dexterity; document limitation)
      (2) Patient has a physical or mental limitation that makes utilization of Freestyle Libre unsafe, inaccurate or otherwise not feasible (e.g. manual dexterity; document limitation)

   Authorization will be issued for 12 months.

2. **All other continuous glucose monitors, sensors and transmitters** will be approved for initial therapy based on **all** of the following criteria:

   a. Diagnosis of diabetes

b. **All** of the following:
(1) Patient is motivated and knowledgeable about use of continuous glucose monitoring
(2) Patient is adherent to diabetic treatment plan
(3) Patient participates in ongoing education and support
c. Patient is on an intensive insulin regimen (3 or more insulin injections per day or uses continuous subcutaneous insulin infusion pump)[b]
d. Patient has inadequate glycemic control despite intensive diabetes management[b]
e. Patient regularly monitors blood glucose 4 or more times per day[b]

Authorization will be issued for 12 months.

B. Reauthorization[b]

1. **Continuous glucose monitors, sensors and transmitters** will be approved for continuation of therapy based on the following criterion:

a. Documentation of positive clinical response

Authorization will be issued for 12 months.

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.
[b] In Florida, Maine, Tennessee, and Texas only, medications prescribed for diabetes may be approved based on both of the following: 1) Provider attests use of this product is medically necessary for the treatment of diabetes; and- 2) If applicable, clinical characteristics exist that preclude the use of the covered preferred alternative(s) and use of the covered preferred alternative(s) could result in worsening of patient's condition or inadequate treatment (document alternatives and clinical information related to worsening/inadequate treatment).

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.
- Coverage is not provided for indications unproven per medical benefit drug policy.

4. References:

1. American Diabetes Association. Diabetes Technology: Standards of Care in Diabetes - 2023. Diabetes Care December 2022, Vol.46, S111-S127
2. Lane AS, Mlynarczyk MA, de Veciana M, et al. Real-time continuous glucose monitoring in gestational diabetes: a randomized controlled trial. Am J Perinatol. 2019 Jul;36(9):891-897.
3. LeRoith D, Biessels GJ, Braithwaite SS, et al. Treatment of diabetes in older adults: an Endocrine Society clinical practice guideline. J Clin Endocrinol Metab. 2019 May 1;104(5):1520-1574.

Program	Prior Authorization/Medical Necessity –Continuous glucose monitors, sensors and transmitters
Change Control	
7/2019	New Medical Necessity program.
10/2019	Removed monitor from criteria.
11/2019	Modified criteria to allow coverage for any type of diabetes.
3/2020	Added requirement that patient is knowledgeable about continuous glucose monitors, participates in education and support, and monitors blood glucose 3 or more times per day.
6/2021	Modified criteria to monitor blood glucose 4 or more times per day and added criteria that patient has inadequate glycemic control despite an intensive diabetes management.
2/2022	Added Florida, Maine, Tennessee, and Texas mandate language.
6/2022	Added criteria for all continuous glucose monitors.
2/2023	Removed Dexcom G4 and G5 since they are no longer on the market. Added the new product Dexcom G7.
8/2023	Added Guardian 4 to criteria. Updated diabetes mandate language. Updated references.