UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2022 P 2170-6
Program	Prior Authorization/Medical Necessity
Medication	Guardian Connect Sensor and Transmitter for Continuous Glucose Monitoring
P&T Approval Date	7/2019, 10/2019, 11/2019, 3/2020, 6/2021, 2/2022
Effective Date	5/1/2022; Oxford only: 5/1/2022

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 Continuous Glucose sensors and transmitters** will be approved for initial therapy based on **all** of the following criteria:

   a. Diagnosis of diabetes
   b. Patient is motivated and knowledgeable about use of continuous glucose monitoring, is adherent to diabetic treatment plan, and participates in ongoing education and support[b]
   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 G4, Dexcom G5 and Dexcom G6 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.

B. Reauthorization[b]

1. **Guardian Connect Continuous Glucose 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, diabetes medications may be approved based on both of the following: 1) Provider attests use of this product is medically necessary; 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. Standards of medical care in diabetes - 2021. Available at: https://care.diabetesjournals.org/content/44/Supplement_1Accessed May 5, 2021.
2. Handelsman Y, Bloomgarden ZT, Grunberger G, et al.; American Association of Clinical Endocrinologists and American College of Endocrinology. Clinical practice guidelines for developing a diabetes mellitus comprehensive care plan -2015. Endocr Pract. 2015 Apr;21 Suppl 1:1-87.

Program	Prior Authorization/Medical Necessity – Guardian Connect Continuous Glucose Monitor, sensor and transmitter
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.