

UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

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| Program Number | 2025 P 2170-12 |
| 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, 7/2024, 9/2025, 12/2025 |
| Effective Date | 3/1/2026 |

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, Guardian 3, Guardian 4, MiniMed Instinct, Simplera* and Simplera Sync when the Dexcom or Freestyle Libre monitors are not appropriate for the patient.

Section Overview

Section 2: Medical Necessity Coverage Criteria for Book of Business

Section 3: Medical Necessity Coverage Criteria for State of Illinois

2. Coverage Criteria^a:

A. Initial Authorization

1. **Guardian Connect, Guardian 3, and Guardian 4, MiniMed Instinct, Simplera* and Simplera Sync continuous glucose sensors and transmitters** will be approved for initial therapy based on **all** of the following criteria:

a. Diagnosis of diabetes

-AND-

b. **All** of the following:

(1) Patient is motivated and knowledgeable about use of continuous glucose monitoring

-AND-

(2) Patient is adherent to diabetic treatment plan

-AND-

(3) Patient participates in ongoing education and support

-AND-

c. **One** of the following:

- (1) Patient is on an intensive insulin regimen (3 or more insulin injections per day or uses continuous subcutaneous insulin infusion pump)^b

-OR-

(2) One of the following:

- (a) Patient has a history of a 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
- (b) Patient has a history of more than one level 2 hypoglycemia events [(glucose <54mg/dL (3.0mmol/L))] that persist despite multiple attempts to adjust medication(s) or modify diabetes treatment plan

-AND-

d. Patient regularly monitors blood glucose 4 or more times per day^b

-AND-

e. **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)

-OR-

- (2) Patient has a physical or mental limitation that makes utilization of Freestyle Libre 2, Libre 2 Plus, Libre 3 and Libre 3 Plus 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

-AND-

b. **All** of the following:

- (1) Patient is motivated and knowledgeable about use of continuous glucose monitoring

-AND-

(2) Patient is adherent to diabetic treatment plan

-AND-

(3) Patient participates in ongoing education and support

-AND-

c. **One** of the following:

(1) Patient is on an intensive insulin regimen (3 or more insulin injections per day or uses continuous subcutaneous insulin infusion pump)^b

-OR-

(2) One of the following:

(a) Patient has a history of a 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

(b) Patient has a history of more than one level 2 hypoglycemia events [(glucose <54mg/dL (3.0mmol/L))] that persist despite multiple attempts to adjust medication(s) or modify diabetes treatment plan

-AND-

d. 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. Coverage Criteria for the State of Illinois:

A. Initial Authorization

1. **All continuous glucose monitors, sensors and transmitters** will be approved for initial therapy based on **all** of the following criteria:
 - a. Diagnosis of diabetes

-AND-
 - b. Provider attests the patient or caregiver has been provided sufficient training in using the continuous glucose monitor

-AND-
 - c. **One** of the following:
 - (1) Patient uses insulin for treatment

-OR-
 - (2) Patient has a history of hypoglycemia as documented by one of the following:
 - (a) Recurrent hypoglycemic events characterized by an altered mental or physical state, despite multiple attempts to adjust medications or modify treatment plan
 - (b) At least one hypoglycemia event characterized by an altered mental or physical state requiring third-party assistance for treatment of hypoglycemia

-AND-
 - d. Patient has had an in-person or telehealth visit to evaluate diabetes control within the past 6 months

Authorization will be issued indefinitely.

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. (2024). 7. Diabetes technology: Standards of care in diabetes 2024. *Diabetes Care*, 47(Supplement_1), S126–S144. <https://doi.org/10.2337/dc24-S007>
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.

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| 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. |
| 7/2024 | Removed requirement for inadequate glycemic control. Added criteria for hypoglycemia. |
| 9/2025 | Added Simplera to program. Added definitions to hypoglycemia criteria. Added section for State of Illinois. |
| 12/2025 | Added MiniMed Instinct to program. |