UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2024 P 2278-4
Program	Prior Authorization/Medical Necessity
Medication	Omnipod® 5
P&T Approval Date	5/2022, 9/2022, 11/2023, 11/2024
Effective Date	2/1/2025

1. Background:

External insulin pumps are used for managing individuals with type 1 or type 2 diabetes and deliver insulin by continuous subcutaneous infusion. Members will be required to meet the following coverage criteria.

2. Coverage Criteria[a]:

A. Initial Authorization

1. **Omnipod 5** will be approved based on **one** of the following criteria:

   a. **All** of the following:

      (1) Diagnosis of diabetes

      -AND-

      (2) **All** of the following[b:]

      (a) Patient regularly tests blood glucose ≥ 4 times/day or utilizes a continuous glucose monitor (CGM) for ≥ 8 weeks
      (b) Patient has completed a diabetes management program
      (c) Patient injects insulin ≥ 3 times/day

      -AND-

      (3) **One** of the following[b]:

      (a) Unexplained, nocturnal, or severe hypoglycemia
      (b) Hypoglycemia unawareness
      (c) Dawn phenomenon blood glucose >200 mg/dL
      (d) Wide and unpredictable (erratic) swings in blood glucose levels
      (e) Glycemic targets within individualized range but lifestyle requires increased flexibility of insulin pump use
      (f) HbA1C > 7% or outside individualized targets

      -AND-

      (4) **Both** of the following:

(a) Patient or caregiver is motivated to assume responsibility for self-care and insulin management
(b) Patient or caregiver demonstrates knowledge of importance of nutrition including carbohydrate counting and meal planning.

-OR-

b. For continuation of therapy

Authorization will be issued for 12 months.

B. <u>Reauthorization</u>

1. **Omnipod 5** will be approved for continuation of therapy based on the following criteria[b]:

   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. Diabetes Technology: Standards of Care in Diabetes - 2024. Diabetes Care 2024; 47S126-S144.
2. Blonde L, Umpierrez G, Reddy S, et al.; American Association of Clinical Endocrinology Clinical Practice Guideline: Developing a Diabetes Mellitus Comprehensive Care Plan- 2022 Update. Endocrine Practice 28(2022)923-1049.

Program	Prior Authorization/Medical Necessity – Omnipod 5
Change Control	
5/2022	New program.
9/2022	Added continuation of therapy. Clarified that CGM could be used to monitor blood glucoses.
11/2023	Annual review. Updated references.
11/2024	Annual review. Updated references.