

UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2025 P 1386-4
Program	Prior Authorization/Notification
Medication	Omnipod® 5, Twiist™
P&T Approval Date	5/2022, 6/2023, 6/2024, 3/2025
Effective Date	6/1/2025

1. Background:

External insulin pumps are used for managing individuals with diabetes and deliver insulin by continuous subcutaneous infusion. OmniPod 5 is indicated for management of type 1 diabetes in persons aged 2 and older and in persons with type 2 diabetes aged 18 and older. Twiist is indicated in persons aged 6 and older with type 1 diabetes. Members will be required to meet the following coverage criteria.

2. Coverage Criteria^a:**A. Initial Authorization**

1. **Omnipod 5** or **Twiist** will be approved for initial therapy based on **both** of the following criteria:

- a. **One** of the following:

- (1) For Omnipod 5: Diagnosis of diabetes
- (2) For Twiist: Diagnosis of Type 1 diabetes

-AND-

- b. **Both** of the following:

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

Authorization will be issued for 12 months.

B. Reauthorization

1. **Omnipod 5** or **Twiist** will be approved for continuation of therapy based on the following criteria:

- 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.

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: Standard of Medical Care in Diabetes - 2024. Diabetes Care 2024;47(supplement 1):S126-S144.
2. American College Of Clinical Endocrinology Consensus Statement: Comprehensive Type 2 Diabetes Management Algorithm- 2023 Update. Endocrine Practice 29(2023)305-340.

Program	Prior Authorization/Notification – Omnipod 5
Change Control	
5/2022	New program.
6/2023	Annual review. Updated references.
6/2024	Annual review. Updated references.
3/2025	Added Twiist to criteria.