UnitedHealthcare

UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2024 P 1339-5
Program	Prior Authorization/Non-Formulary
Medications	Envarsus XR™ (tacrolimus extended-release tablets)*
P&T Approval Date	12/2020, 12/2021, 12/2022, 12/2023, 12/2024
Effective Date	3/1/2025

1. Background:

This program requires the provider to validate that the member is not an appropriate candidate for immediate-release tacrolimus for prophylaxis of organ rejection in kidney transplant patients.

Envarsus XR is indicated for prophylaxis of organ rejection in de novo kidney transplant patients in combination with other immunosuppressants and prophylaxis of organ rejection in kidney transplant patients converted from tacrolimus immediate-release formulations in combination with other immunosuppressants.

2. Coverage Criteria[a]:

A. Prophylaxis of organ rejection in kidney transplant

1. **Envarsus XR** will be approved based on **all** of the following:

    a. Patient is the recipient of a kidney transplant

    -AND-

    b. **One** of the following:

    (1) Provider attests that the patient is not an appropriate candidate for immediate-release tacrolimus based on **one** of the following:

    i. Unable to achieve or maintain an appropriate therapeutic drug level with immediate-release tacrolimus
    ii. In the provider's expert opinion, the patient would be unable to achieve or maintain an appropriate therapeutic drug level with immediate-release tacrolimus

    -OR-

    (2) Patient is currently on Envarsus XR therapy and the provider attests that switching therapy would be clinically inappropriate

    -AND-

    c. Envarsus XR will be used in combination with other immunosuppressant medications (e.g., mycophenolate, azathioprine, corticosteroids) to prevent organ

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rejection in kidney transplant recipients

-AND-

d. Prescribed by or in consultation with a nephrologist or transplant specialist

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.

* Envarsus XR is typically excluded from coverage. Tried/Failed criteria may be in place. Please refer to plan specifics to determine exclusion status.

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.

4. References:

1. Envarsus XR [package insert]. Cary, NC: Veloxis Pharmaceuticals, Inc; April 2024.

Program	Prior Authorization/Non-Formulary – Envarsus XR
Change Control	
12/2020	New program
12/2021	Annual review with no changes to clinical criteria.
12/2022	Annual review with no changes to clinical criteria. Updated exclusion statement.
12/2023	Annual review. Updated formatting and wording of criteria with no change to clinical content. Updated reference.
12/2024	Annual review with no changes to coverage criteria. Updated reference.

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