

UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2026 P 1461-3
Program	Prior Authorization/Notification
Medication	Aqneursa™ (levacetylleucine)
P&T Approval Date	11/2024, 1/2025, 1/2026
Effective Date	4/1/2026

1. Background:

Aqneursa (levacetylleucine) is indicated for the treatment of neurological manifestations of Niemann-Pick disease type C (NPC) in adults and pediatric patients weighing ≥ 15 kg.

2. Coverage Criteria^a:

A. Initial Authorization

1. **Aqneursa** will be approved based on **all** of the following criteria:

a. Diagnosis of Niemann-Pick disease type C (NPC)

-AND-

b. Aqneursa is being used to treat neurological manifestations of NPC

-AND-

c. Patient is not receiving Aqneursa in combination with Miplyffa (arimoclomol)

Authorization will be issued for 12 months.

B. Reauthorization

1. **Aqneursa** will be approved based on **both** the following criteria:

a. Documentation of positive clinical response to Aqneursa (e.g., slowed disease progression from baseline based on assessment with NPC-specific scales)

-AND-

b. Patient is not receiving Aqneursa in combination with Miplyffa (arimoclomol)

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.

4. References:

1. Aqneursa [package insert]. Austin TX: IntraBio Inc.; September 2024.

Program	Prior Authorization/Notification - Aqneursa (levacetylleucine)
Change Control	
Date	Change
11/2024	New program.
1/2025	Added criteria that Aqneursa not taken in combination with Miplyffa.
1/2026	Annual review without changes to coverage criteria.