

UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2024 P 1461-1
Program	Prior Authorization/Notification
Medication	Aqneursa™ (levacetylleucine)
P&T Approval Date	11/2024
Effective Date	2/1/2025

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:

<p>A. <u>Initial Authorization</u></p> <p>1. Aqneursa will be approved based on both of the following criteria:</p> <p style="margin-left: 40px;">a. Diagnosis of Niemann-Pick disease type C (NPC)</p> <p style="text-align: center;">-AND-</p> <p style="margin-left: 40px;">b. Aqneursa is being used to treat neurological manifestations of NPC</p> <p>Authorization will be issued for 12 months.</p> <p>B. <u>Reauthorization</u></p> <p>1. Aqneursa will be approved based on the following criterion:</p> <p style="margin-left: 40px;">a. Documentation of positive clinical response to Aqneursa (e.g., slowed disease progression from baseline based on assessment with NPC-specific scales)</p> <p>Authorization will be issued for 12 months.</p> <p>^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.</p>

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.