UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2025 P 1461-2
Program	Prior Authorization/Notification
Medication	Aqneursa™ (levacetylleucine)
P&T Approval Date	11/2024, 1/2025
Effective Date	4/1/2025

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]:

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.

![UnitedHealthcare]

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.