

UnitedHealthcare Pharmacy  
Clinical Pharmacy Programs

Program Number	2025 P 1460-2
Program	Prior Authorization/Notification
Medication	Miplyffa™ (arimoclomol)
P&T Approval Date	11/2024, 1/2025
Effective Date	4/1/2025

**1. Background:**

Miplyffa (arimoclomol) is indicated for use in combination with miglustat for the treatment of neurological manifestations of Niemann-Pick disease type C (NPC) in adult and pediatric patients 2 years of age and older.

**2. Coverage Criteria<sup>a</sup>:****A. Initial Authorization**

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

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

**-AND-**

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

**-AND-**

c. Miplyffa is prescribed in combination with miglustat

**-AND-**

d. Patient is not receiving Miplyffa in combination with Aqneursa (levacetylleucine)

**Authorization will be issued for 12 months.**

**B. Reauthorization**

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

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

**-AND-**

b. Miplyffa continues to be prescribed in combination with miglustat

**-AND-**

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

**Authorization will be issued for 12 months.**

<sup>a</sup> 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. Miplyffa [package insert]. Celebration, FL: Zevra Therapeutics Inc.; September 2024.

Program	Prior Authorization/Notification - Miplyffa (arimoclomol)
<b>Change Control</b>	
Date	Change
11/2024	New program.
1/2025	Added criteria that Miplyffa not taken in combination with Aqneursa.