UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

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

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[a]:

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

Authorization will be issued for 12 months.

B. Reauthorization

1. **Miplyffa** will be approved based on **both** 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

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. Miplyffa [package insert]. Celebration, FL: Zevra Therapeutics Inc.; September 2024.

Program	Prior Authorization/Notification - Miplyffa (arimoclomol)
Change Control	
Date	Change
11/2024	New program.