

Clinical Oversight Review Board (CORB) Criteria for Prescribing/ Criteria-Based Consultation (CBC) Criteria for Coverage

Arimoclomol (Miplyffa)

Notes:

- Quantity Limits: Yes
- * Adult-onset NPC is defined as the first neurologic symptom occurring after age 15 years
- ^ Examples of neurologic symptoms of Niemann-Pick disease type C include loss of coordination (ataxia), difficulty swallowing (dysphagia), and speech difficulties (dysarthria), abnormal eye movements (vertical supranuclear ophthalmoplegia) and cognitive impairment

Non-Formulary **arimoclomol (Miplyffa)** requires a clinical review. Appropriateness of therapy will be based on the following criteria:

Initiation (new start) criteria, criteria for current Kaiser Permanente members already taking the medication who have not been reviewed previously, and criteria for new members entering Kaiser Permanente already taking the medication who have not been reviewed previously: Non-Formulary **arimoclomol (Miplyffa)** will be covered on the prescription drug benefit for 12 months when the following criteria are met:

- Prescribed by a neurologist or geneticist
- Patient has a diagnosis of Niemann-Pick disease type C (NPC) that is confirmed by a genetic test showing biallelic pathogenic variants in either the NPC1 gene or NPC2 gene
- Patient does NOT have adult onset of NPC*
- Patient is 2 years of age or older
- Patient has one or more neurologic symptom^ of NPC
- Patient can walk independently or with assistance
- Patient is taking miglustat
- Patient is NOT taking Aqneursa (levacetylleucine)

Continued use criteria for patients previously approved per the above criteria who are currently stable on the medication: Non-Formulary **arimoclomol (Miplyffa)** will continue to be covered on the prescription drug benefit for 12 months when the following criteria are met:

- Prescribed by a neurologist or geneticist
- Patient is taking miglustat
- Patient is NOT taking Aqneursa (levacetylleucine)

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- Patient demonstrates positive clinical response to therapy (e.g., slowing of disease progression, improvement in neurological symptoms of the disease), as documented by prescriber

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