

AvMed

PHARMACY PRIOR AUTHORIZATION/STEP-EDIT REQUEST*

Directions: The prescribing physician must sign and clearly print name (preprinted stamps not valid) on this request. All other information may be filled in by office staff; **fax to 1-305-671-0200.** No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. **If the information provided is not complete, correct, or legible, the authorization process can be delayed.**

Drug Requested: Aqneursa™ (levacetylleucine)

MEMBER & PRESCRIBER INFORMATION: Authorization may be delayed if incomplete.

Member Name: _____

Member AvMed #: _____ Date of Birth: _____

Prescriber Name: _____

Prescriber Signature: _____ Date: _____

Office Contact Name: _____

Phone Number: _____ Fax Number: _____

NPI #: _____

DRUG INFORMATION: Authorization may be delayed if incomplete.

Drug Name/Form/Strength: _____

Dosing Schedule: _____ Length of Therapy: _____

Diagnosis: _____ ICD Code, if applicable: _____

Weight (if applicable): _____ Date weight obtained: _____

Recommended Dosing:

Patient Body Weight	Morning Dose	Afternoon Dose	Evening Dose	Required Cartons per Fill
15 to <25 kg	1 g	No Dose	1 g	2 cartons per 28 days
25 to <35 kg	1 g	1 g	1 g	3 cartons per 28 days
35 kg or more	2 g	1 g	1 g	4 cartons per 28 days

Quantity Limits: 112 packets (4 cartons) per 28 days

CLINICAL CRITERIA: Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

Initial Authorization: 12 months

(Continued on next page)

- Member is ≥ 4 years of age
- Member weighs ≥ 15 kg
- Prescribed by or in consultation with a geneticist, endocrinologist, metabolic disorder subspecialist, neurologist, or a physician who specializes in the treatment of Niemann-Pick disease type C or related disorders
- Member has a confirmed diagnosis of Niemann-Pick disease type C (NPC) as established by a genetic test showing **ONE** of the following (**submit documentation**):
 - Biallelic pathogenic variants in either the NPC1 gene or NPC2 gene
 - Mutations in only one allele of NPC1 or NPC2 plus either positive filipin staining or elevated cholestone-triol level (>2 times the upper limit of normal)
- Member has at least **ONE** neurological symptom(s) of Niemann-Pick disease type C (e.g., loss of motor function, swallowing, and speech and cognitive impairment) (**submit documentation**)
- Member can walk independently or with assistance
- Provider must submit a baseline assessment scale documenting current NPC neurologic symptom(s) (**submit documentation**)
- Requested medication will **NOT** be used in combination with Miplyffa™ (arimoclomol) for the treatment of neurological manifestations of Niemann-Pick disease type C

Reauthorization: 12 months. Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

- Member continues to meet **ALL** initial authorization criteria
- Member has derived benefit from treatment defined as disease stabilization, slowed progression, or improvement, according to the prescriber

Medication being provided by Specialty Pharmacy – Proprium Rx

*****Use of samples to initiate therapy does not meet step edit/preauthorization criteria.*****

****Previous therapies will be verified through pharmacy paid claims or submitted chart notes.****