



PRIOR AUTHORIZATION REQUEST

Miplyffa and Aqneursa

Patient Information:

Name:	
Member ID:	
Address:	
City, State, Zip:	
Date of Birth:	

Prescriber Information:

Name:	
NPI:	
Phone Number:	
Fax Number:	
Address:	
City, State, Zip:	

Requested Medication

Rx Name:	
Rx Strength:	
Rx Quantity:	
Rx Frequency:	
Rx Route of Administration:	
Diagnosis and ICD Code:	

Your patient's prescription benefit requires that we review certain requests for coverage with the prescriber. You have prescribed a medication for your patient that requires Prior Authorization before benefit coverage or coverage of additional quantities can be provided. Please complete the following questions then fax this form to the toll-free number listed below. Upon receipt of the completed form, prescription benefit coverage will be determined based on the plan's rules.

SECTION A: Please note that supporting clinical documentation is required for ALL PA requests. Pharmacy prior authorization reviews can be subject to trial with additional medications that are not listed within the criteria. The policies are subject to change based on COMAR requirements, MDH transmittals and updates to treatment guidelines.

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|---|--|-----|----|
| 1 | Is the request an INITIAL or CONTINUATION of therapy?
☐ Initial (If checked, go to 6)

☐ Continuation (If checked, go to 2) | | |
| 2 | Is the patient currently receiving the requested medication?
[If no, skip to question 6.] | Yes | No |
| 3 | Has the patient been receiving medication samples of the requested medications? | Yes | No |

If you have any
questions, call:
1-888-258-8250

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[If yes, skip to question 6.]

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|----|--|-----|----|
| 4 | <p>Does the patient have a previously approved prior authorization (PA) on file with the current plan?</p> <p>[Note: If the patient does NOT have a previously approved PA on file for the requested medication with the current plan, the renewal request will be considered under initial therapy.]</p> <p>[If no, skip to question 6.]</p> | Yes | No |
| 5 | <p>Has the patient been taking the requested medication for at least 3 months and has experienced a clinically significant benefit from the medication, as documented by the prescriber? ACTION REQUIRED: Submit supporting documentation.</p> <p>[Note: Examples include disease stabilization, slowed progression, or improvement.]</p> <p>[No further questions.]</p> | Yes | No |
| 6 | <p>What is the indication?</p> <p>☐ Niemann-Pick disease type C (NPC) (If checked, go to 7)</p> <p>☐ Other (If checked, no further questions)</p> | | |
| 7 | <p>Has documentation been submitted to indicate that Niemann-Pick disease type C (NPC) has been established by a genetic test showing biallelic pathogenic variants in either the <i>NPC1</i> gene or <i>NPC2</i> gene? ACTION REQUIRED: Submit supporting documentation.</p> <p>[If no, no further questions.]</p> | Yes | No |
| 8 | <p>Has documentation been submitted to show the patient does NOT have adult-onset Niemann-Pick disease type C (NPC)? ACTION REQUIRED: Submit supporting documentation.</p> <p>[Note: Adult-onset NPC is defined as the age of the first neurological symptom occurring greater than 15 years of age.]</p> <p>[If no, no further questions.]</p> | Yes | No |
| 9 | <p>Is the requested medication prescribed by or consultation with a geneticist, endocrinologist, metabolic disorder subspecialist or a physician who specializes in the treatment of Niemann-Pick disease type C (NPC) or related disorders?</p> <p>[If no, no further questions.]</p> | Yes | No |
| 10 | <p>Has documentation been submitted to show the patient has one or more neurological symptoms of Niemann-Pick disease type C (NPC)? ACTION REQUIRED: Submit supporting documentation.</p> <p>[Note: Examples of neurologic symptoms of NPC include but not limited to hearing loss, vertical supranuclear gaze palsy, ataxia, dementia, dystonia, seizures, dysarthria, or dysphagia.]</p> <p>[If no, no further questions.]</p> | Yes | No |

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|----|--|-----|----|
| 11 | What medication is being requested?
☐ Miplyffa (If checked, go to 12)

☐ Aqneursa (If checked, go to 19) | | |
| 12 | Is the patient at least 2 years of age?
[If no, no further questions.] | Yes | No |
| 13 | Is the patient able to walk either independently or with assistance?
[If no, no further questions.] | Yes | No |
| 14 | Has documentation been submitted to show the patient does not have severe liver insufficiency? ACTION REQUIRED: Submit supporting documentation.
[Note: Defined as hepatic laboratory parameters, aspartate aminotransferase (AST) and/or alanine aminotransferase (ALT) greater than three-times the upper limit of normal for age, and gender.]
[If no, no further questions.] | Yes | No |
| 15 | Has documentation been submitted to show the patient does not have renal insufficiency? ACTION REQUIRED: Submit supporting documentation.
[Note: Defined with serum creatinine level greater than 1.5 times the upper limit of normal.]
[If no, no further questions.] | Yes | No |
| 16 | Will the requested medication be taken in combination with Miglustat?
[If no, no further questions.] | Yes | No |
| 17 | Does the provider attest that the requested medication will not be used concomitantly with Aqneursa?
[If no, no further questions.] | Yes | No |
| 18 | Does the prescribed dosing exceed Food and Drug Administration (FDA) approved indication?
[Dosing weight 8 kg to 15 kg is 47 mg three times a day, greater than 15 kg to 30 kg is 62 mg three times a day, greater than 30 kg to 55 kg is 93 mg three times a day and greater than 55 kg is 124 mg three times a day.]
[No further questions.] | Yes | No |
| 19 | Is the patient at least 4 years of age?
[If no, no further questions.] | Yes | No |
| 20 | Does the patient weigh at least 15 kg? ACTION REQUIRED: Submit supporting documentation.
[If no, no further questions.] | Yes | No |
| 21 | Has the patient been diagnosed with arthritis or other musculoskeletal disorders affecting joints, muscles, ligaments, and/or nerves?
[If yes, no further questions.] | Yes | No |

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|----|---|-----|----|
| 22 | Does the provider attest that the requested medication will not be used concurrently with Miplyffa?
[If no, no further questions.] | Yes | No |
| 23 | Does the prescribed dosing exceed Food and Drug Administration (FDA) approved indication?
[Dosing weight greater than 15 kg to less than 25 kg is 1 g morning, none in afternoon, and 1 g evening, greater than 25 kg to less than 35 kg is 1 g morning, 1 g afternoon, and 1 g evening, and greater than 35 kg is 2 g morning, 1 g afternoon, and 1 g evening.] | Yes | No |

Please document the diagnoses, symptoms, and/or any other information important to this review:

SECTION B: Physician Signature

PHYSICIAN SIGNATURE

DATE

FAX COMPLETED FORM TO: 1-833-896-0656

Disclaimer: An authorization is not a guarantee of payment. Member must be eligible at the time services are rendered. Services must be a covered Health Plan Benefit and medically necessary with prior authorization as per Plan policy and procedures.

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