HIGHMARK WHOLECARE

Updated: 9/2026
PARP Approved: 10/2026

Prior Authorization Criteria

Zanvastro (zilganersen)

All requests for Zanvastro (zilganersen) require a prior authorization and will be screened for medical necessity and appropriateness using the criteria listed below.

For all requests for Zanvastro (zilganersen), the following criteria must be met:

- Member has a diagnosis of Alexander disease confirmed by documentation including all of the following:
  - A clinical assessment of neurological and physical symptoms
  - MRI brain imaging
  - Genetic testing confirming the disease-causing/pathogenic GFAP gene variant consistent with Alexander disease
- Prescribed by, or in consultation with, a neurologist or other physician experienced in the diagnosis and management of Alexander disease.
- Documentation of the member's current clinical manifestations and gross motor skill level is provided including:
  - A baseline assessment appropriate to the member's age and functional ability or gross motor skill level (e.g. 10 meter walk test or Gross Motor Function Measure-88 (GMFM-88)) is documented to permit evaluation of disease course and treatment response.
- Zanvastro will be administered intrathecally by an appropriately trained healthcare professional in a setting capable of performing and monitoring lumbar puncture/intrathecal administration.
- Is age-appropriate according to FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature.
- The requested dose and frequency is in accordance with FDA-approved labeling, nationally recognized compendia, and/or evidence-based practice guidelines.
- Zanvastro will not be used concurrently with another disease-modifying therapy directed at the underlying GFAP-mediated mechanism of Alexander disease.
- **Initial Duration of Approval**: 6 months
- **Reauthorization Criteria:**
  - The member continues to have a diagnosis of Alexander disease
  - The provider documents that continued treatment remains clinically appropriate
  - Documented clinical assessments demonstrate clinical benefit or stabilization of disease, as appropriate for the member's age, gross motor function or baseline function, and manifestations
  - The member has not experienced toxicity or another safety issue that, in the treating provider's judgment, makes continued treatment inappropriate
  - The requested dose and remain consistent with FDA-approved prescribing information.
- **Reauthorization Duration of Approval**: 12 months

Coverage may be provided for any non-FDA labeled indication if it is determined that the use is a medically accepted indication supported by nationally recognized pharmacy compendia or

peer-reviewed medical literature for treatment of the diagnosis(es) for which it is prescribed. These requests will be reviewed on a case by case basis to determine medical necessity.

When criteria are not met, the request will be forwarded to a Medical Director for review. The physician reviewer must override criteria when, in their professional judgment, the requested medication is medically necessary.

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ZANVASTRO (ZILGANERSEN) PRIOR AUTHORIZATION FORM

Please complete and fax all requested information below including any progress notes, laboratory test results, or chart documentation as applicable to Highmark Wholecare Pharmacy Services. **FAX:** (888) 245-2049
If needed, you may call to speak to a Pharmacy Services Representative. **PHONE**: (800) 392-1147 Mon – Fri 8:30am to 5:00pm

PROVIDER INFORMATION

Requesting Provider:	Provider NPI:
Provider Specialty:	Office Contact:
State license #:	Office NPI:
Office Address:	Office Phone:
	Office Fax:

MEMBER INFORMATION

Member Name:	DOB:	
Member ID:	Member weight:	Height:

REQUESTED DRUG INFORMATION

Medication:	Strength:	
Directions:	Quantity:	Refills:
Is the member currently receiving requested medication? ☐ Yes ☐ No	Date Medication Initiated:	

Billing Information

This medication will be billed: ☐ at a pharmacy **OR** ☐ medically, JCODE:_____

Place of Service: ☐ Hospital ☐ Provider's office ☐ Member's home ☐ Other

Place of Service Information

Name:	NPI:
Address:	Phone:

MEDICAL HISTORY (Complete for ALL requests)

Diagnosis:	ICD Code:

Is there documentation of the following to support a diagnosis of Alexander disease? ☐ Yes ☐ No

- A clinical assessment of neurological and physical symptoms
- MRI brain imaging
- Genetic testing confirming the disease-causing/pathogenic GFAP gene variant consistent with Alexander disease

Is there documentation of the member's current clinical manifestations and gross motor skill level including a baseline assessment appropriate to the member's age and functional ability or gross motor skill level (e.g. 10 meter walk test or Gross Motor Function Measure-88 (GMFM-88))? ☐ Yes ☐ No

Will the medication be administered intrathecally by an appropriately trained healthcare professional in a setting capable of performing and monitoring lumbar puncture/intrathecal administration? ☐ Yes ☐ No

Will Zanvastro be used concurrently with another disease-modifying therapy directed at the underlying GFAP-mediated mechanism of Alexander disease? ☐ Yes ☐ No

CURRENT or PREVIOUS THERAPY

Medication Name	Strength/ Frequency	Dates of Therapy	Status (Discontinued & Why/Current)

REAUTHORIZATION

Is there documentation from the provider that continued treatment remains clinically appropriate? ☐ Yes ☐ No

Is there a documented clinical assessment demonstrating a clinical benefit or stabilization of disease, as appropriate for the member's age, gross motor function or baseline function, and manifestations? ☐ Yes ☐ No

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ZANVASTRO (ZILGANERSEN)
PRIOR AUTHORIZATION FORM (CONTINUED)– PAGE 2 of 2

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MEMBER INFORMATION

Member Name:	DOB:	
Member ID:	Member weight:	Height:

Has the member experienced toxicity or another safety issue that, in the treating provider's judgment, making continued treatment inappropriate? ☐ Yes ☐ No

Has the member experienced an improvement with treatment? ☐ Yes ☐ No

SUPPORTING INFORMATION or CLINICAL RATIONALE

Prescribing Provider Signature	Date