Reference number(s)
7614-A

Specialty Guideline Management
Zanvastro

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Zanvastro	zilganersen

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-approved Indications[1]

Zanvastro is a glial fibrillary acidic protein (GFAP)-directed antisense oligonucleotide indicated for the treatment of Alexander disease in pediatric and adult patients.

All other indications are considered experimental/investigational and not medically necessary.

Documentation

Submission of the following information is necessary to initiate the prior authorization review:

Initial Requests:

- Medical records (e.g., chart notes and/or laboratory reports) documenting all of the following:
  - Genetic testing results demonstrating a pathogenic variant in the glial fibrillary acidic protein (GFAP) gene.

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- Clinical phenotype consistent with Alexander disease (e.g., seizures, developmental delay, failure to thrive, ocular movement abnormalities, bulbar symptoms).
- Brain magnetic resonance imaging (MRI) findings consistent with a diagnosis of Alexander disease.
- Baseline functional assessment, as applicable:
    - Gross Motor Function Measure-88 (GMFM-88) standing (Dimension D) and walking/running/jumping (Dimension E) subscale scores for member ≥ 2 years and < 5 years of age; or
    - 10 Meter Walk Test (10MWT) results for member ≥ 5 years of age.

Continuation Requests:

- Medical records (e.g., chart notes and/or laboratory reports) documenting a clinically positive response to therapy (e.g., stabilization or improvement in GMFM-88 subscale scores, 10MWT results, as applicable).

Prescriber Specialties

This medication must be prescribed by or in consultation with a neurologist or a physician who specializes in the treatment of Alexander disease.

Coverage Criteria

Alexander Disease[1-3]

Authorization of 12 months may be granted for treatment of Alexander disease when all of the following criteria are met:

- Member is 2 years to less than 65 years of age.
- Member has a genetically confirmed diagnosis of Alexander disease, with documentation of pathogenic variant in the glial fibrillary acidic protein (GFAP) gene.
- Member exhibits documented clinical phenotype consistent with Alexander disease (e.g., seizures, developmental delay, failure to thrive, ocular movement abnormalities, bulbar symptoms).
- Member has documented brain MRI consistent with a diagnosis of Alexander disease.
- Gross Motor Function Mesaure-88 (GMFM-88) standing (Dimension D) and walking/running/jumping (Dimension E) subscale scores for member ≥ 2 years and < 5 years of age or 10 Meter Walk Test (10MWT) results for member ≥ 5 years of age have been assessed at baseline and will be monitored as clinically appropriate.
- Member does not have moderate or severe renal impairment, end-stage renal disease, or moderate or severe hepatic impairment.

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- Member has not received gene therapy, cell transplantation, or any other experimental brain surgery previously.
- Member does not have obstructive hydrocephalus.
- Member does not have a functional ventriculoperitoneal shunt for the drainage of cerebrospinal fluid (CSF) or an implanted central nervous system (CNS) catheter.
- Member has been evaluated prior to intrathecal administration for factors that increase risks associated with lumbar puncture.
- Member does not have brain or spinal disease that would interfere with lumbar puncture or cerebrospinal fluid circulation.

Continuation of Therapy[1-2]

Authorization of 12 months may be granted for members requesting continuation of therapy when the member demonstrates a clinically positive response to therapy (e.g., stabilization or improvement in GMFM-88 subscale scores, 10MWT results, as applicable).

References

1. Zanvastro [package insert]. Carlsbad, CA: Ionis Pharmaceuticals, Inc.; September 2026.
2. ClinicalTrials.gov. A Study to Evaluate Efficacy and Safety of ION373 in Participants With Alexander Disease (NCT04849741). https://clinicaltrials.gov/study/NCT04849741. Accessed September 10, 2026.
3. Prust M, Wang J, Morizono H, et al. GFAP mutations, age at onset, and clinical subtypes in Alexander disease. *Neurology*. 2011;77(13):1287-1294. doi:10.1212/WNL.0b013e3182309f72.

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