Reference number(s)
3770-A

Specialty Guideline Management
Koselugo

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
Koselugo	selumetinib

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]

Koselugo is indicated for the treatment of pediatric patients 2 years of age and older with neurofibromatosis type 1 (NF1) who have symptomatic, inoperable plexiform neurofibromas (PN).

Compendial Uses[2]

- Circumscribed glioma, pleomorphic xanthoastrocytoma (PXA)
- Langerhans cell histiocytosis

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

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3770-A

Documentation

Submission of the following information is necessary to initiate the prior authorization review: Documentation of BRAF mutation status, where applicable.

Coverage Criteria

Neurofibromatosis type 1[1]

Authorization of 12 months may be granted for treatment of neurofibromatosis type 1 (NF1) when the member has symptomatic, inoperable plexiform neurofibromas (PN).

Circumscribed Glioma, Pleomorphic Xanthoastrocytoma (PXA)[2]

Authorization of 12 months may be granted as a single agent for treatment of recurrent or progressive disease when any of the following criteria are met:

- Member has a circumscribed glioma and either of the following are met:
  - BRAF fusion or BRAF V600E activating mutation positive disease or
  - Disease is WHO grade 1
- Member has a NF-1 mutated glioma
- Member has WHO grade 2 pleomorphic xanthoastrocytoma (PXA)

Langerhans Cell Histiocytosis[2]

Authorization of 12 months may be granted as a single agent for treatment of Langerhans cell histiocytosis.

Continuation of Therapy

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in the coverage criteria section when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

References

1. Koselugo [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; January 2024.
2. The NCCN Drugs & Biologics Compendium® © 2025 National Comprehensive Cancer Network, Inc. https://www.nccn.org. Accessed February 26, 2025.