

SPECIALTY GUIDELINE MANAGEMENT

KOSELUGO (selumetinib)

POLICY

I. 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.

A. FDA-Approved Indication

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).

B. Compendial Uses

1. Circumscribed glioma
2. Langerhans cell histiocytosis

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

II. DOCUMENTATION

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

III. CRITERIA FOR INITIAL APPROVAL

A. **Neurofibromatosis type 1**

Authorization of 12 months may be granted for treatment of neurofibromatosis type 1 (NF1) when either of the following criteria are met:

1. Member is 2 years of age or older with symptomatic, inoperable plexiform neurofibromas (PN), or
2. The requested medication will be used as a single agent in members with recurrent or progressive NF-1 mutated glioma

B. **Circumscribed Glioma**

Authorization of 12 months may be granted as a single agent for treatment of recurrent or progressive circumscribed glioma with a BRAF fusion or BRAF V600E activating mutation.

C. **Langerhans Cell Histiocytosis**

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

IV. CONTINUATION OF THERAPY

Reference number(s)
3770-A

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

V. REFERENCES

1. Koselugo [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; January 2024.
2. The NCCN Drugs & Biologics Compendium® © 2024 National Comprehensive Cancer Network, Inc. <https://www.nccn.org>. Accessed February 28, 2024.