

Applicable Drugs: Koselugo (selumetinib)

Preferred: N/A

Non-preferred: N/A

Date of Origin: 6/1/2026

Date Last Reviewed / Revised: N/A

PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria I to V are met.)

- I. Documentation of one of the following FDA-approved diagnosis (A) AND must meet all criteria listed under the applicable diagnosis:

FDA-Approved Indication(s)

A. Neurofibromatosis

- i. Documentation of neurofibromatosis type I (NF1)
- ii. Documentation of symptomatic plexiform neurofibromas (PN)
- iii. Documentation that disease is not amenable to complete resection
- iv. Documentation that disease is causing significant morbidity (ex, pain, motor dysfunction, airway dysfunction, visual impairment, etc.)
- v. Koselugo will be used as monotherapy.

Other Uses With Supportive Evidence

B. Glioma

C. Langerhans Cell Histiocytosis

- II. Minimum age requirement: 1 year old and older
- III. Treatment must be prescribed by or in consultation with an oncologist, neurologist or physician specializing in NF1.
- IV. Request is for a medication with the appropriate FDA labeling, or its use is supported by current National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1 or 2A.
- V. Refer to the plan document for the list of preferred products. If the requested agent is not listed as a preferred product, must have documented treatment failure or contraindication to the preferred product(s).

EXCLUSION CRITERIA

- N/A

OTHER CRITERIA

- N/A

QUANTITY / DAYS SUPPLY RESTRICTIONS

- Quantities limited to a 30-day supply
 - Capsules and oral granules: recommended dose is 25 mg/m² orally twice daily
 - Capsules: 10 mg and 25 mg
 - Oral Granules: 5 mg and 7.5 mg
 - If request is for Koselugo oral granules, dose must be unavailable in capsules or patient must have documented inability to swallow capsules.

Recommend dosage: Koselugo capsules

Body Surface Area (BSA, m ²)	Dose (capsules)
0.55 to 0.69	20 mg in the morning and 10 mg in the evening
0.7 to 0.89	20 mg twice daily
0.9 to 1.09	25 mg twice daily
1.1 to 1.29	30 mg twice daily
1.3 to 1.49	35 mg twice daily
1.5 to 1.69	40 mg twice daily
1.7 to 1.89	45 mg twice daily
≥ 1.9	50 mg twice daily

- Recommend dosage of Koselugo capsules for patients with a BSA less than 0.55 m² has not been established

Recommend dosage: Koselugo oral granules

Body Surface Area (BSA, m ²)	Dose (capsules)
0.4 to 0.59	12.5 mg twice daily
0.6 to 0.69	15 mg twice daily
0.7 to 0.89	20 mg twice daily
0.9 to 1.09	25 mg twice daily
1.1 to 1.29	30 mg twice daily
1.3 to 1.49	35 mg twice daily
1.5 to 1.69	40 mg twice daily
1.7 to 1.89	45 mg twice daily
≥ 1.9	50 mg twice daily

- Recommend dosage of Koselugo oral granules for patients with a BSA less than 0.4 m² has not been established

APPROVAL LENGTH

- **Authorization:** 12 months
- **Re-Authorization:** 12 months. An updated letter of medical necessity or progress notes showing current medical necessity criteria are met and does not show evidence of progressive disease.

APPENDIX

N/A

REFERENCES

1. Koselugo. Prescribing Information. AstraZeneca Pharmaceuticals LP. 2025. Accessed March 20, 2026. www.accessdata.fda.gov/drugsatfda_docs/label/2025/213756s006lbl.pdf
2. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology. Central Nervous System Cancers. Version 3.2025. Updated December 5, 2025. Accessed March 20, 2026. www.nccn.org/professionals/physician_gls/pdf/cns.pdf
3. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology. Histiocytic Neoplasms. Version 2.2025. Updated November 21, 2025. Accessed March 20, 2026. www.nccn.org/professionals/physician_gls/pdf/histiocytic_neoplasms.pdf

DISCLAIMER: Medication Policies are developed to help ensure safe, effective and appropriate use of selected medications. They offer a guide to coverage and are not intended to dictate to providers how to practice medicine. Refer to Plan for individual adoption of specific Medication Policies. Providers are expected to exercise their medical judgement in providing the most appropriate care for their patients.