

Clinical Pharmacy Program Guidelines for Koselugo

Program	Prior Authorization
Medication	Koselugo™ (selumetinib)
Markets in Scope	Arizona, California, Hawaii, Nevada, Maryland, New Jersey, New York, New York EPP, Pennsylvania- CHIP, Rhode Island, South Carolina
Issue Date	8/2020
Pharmacy and Therapeutics Approval Date	8/2020
Effective Date	10/2020

1. Background:

Koselugo is a kinase inhibitor 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).

2. Coverage Criteria:

<p><u>A. Neurofibromatosis Type 1</u></p> <p>1. <u>Initial Authorization</u></p> <p style="padding-left: 40px;">a. Koselugo will be approved based on both of the following:</p> <p style="padding-left: 80px;">(1) Diagnosis of neurofibromatosis type 1</p> <p style="text-align: center; padding-left: 80px;">-AND-</p> <p style="padding-left: 80px;">(2) Patient has plexiform neurofibromas that are both of the following:</p> <p style="padding-left: 120px;">(a) Inoperable</p> <p style="padding-left: 120px;">(b) Causing significant morbidity (e.g., disfigurement, motor dysfunction, pain, airway dysfunction, visual impairment, bladder/bowel dysfunction)</p> <p>Authorization will be issued for 12 months.</p> <p>2. <u>Reauthorization</u></p> <p style="padding-left: 40px;">a. Koselugo will be approved based on the following criterion:</p>
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(1) Patient does not show evidence of progressive disease while on Koselugo therapy

Authorization will be issued for 12 months.

B. NCCN Recommended Regimens

1. Initial Authorization

a. **Koselugo** will be approved for uses not outlined above if supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium.

Authorization will be issued for 12 months.

2. Reauthorization

a. Koselugo will be approved based on the following criterion:

(1) Documentation of positive clinical response to Koselugo therapy

Authorization will be issued for 12 months.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4. References:

1. Koselugo [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; May 2020.

Program	Program type – Prior Authorization
Change Control	
8/2020	New program.