UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2024 P 1322-5
Program	Prior Authorization/Notification
Medication	Koselugo™ (selumetinib)
P&T Approval Date	8/2020, 8/2021, 8/2022, 9/2023, 9/2024
Effective Date	12/1/2024

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).

The National Comprehensive Cancer Network (NCCN) recommends Koselugo therapy in patients as a single-agent treatment for recurrent or progressive NF-1 mutated glioma, or recurrent or progressive circumscribed glioma with BRAF fusion or BRAF V600E activating mutation. NCCN also recommends Koselugo therapy in patients with Langerhans cell histiocytic neoplasms that are mitogen-activated protein (MAP) kinase pathway mutation positive or when there is no detectable mutation or testing available.

Coverage Information:

Members will be required to meet the criteria below for coverage. For members under the age of 19 years, the prescription will automatically process without a coverage review.

Some states mandate benefit coverage for off-label use of medications for some diagnoses or under some circumstances. Some states also mandate usage of other Compendium references. Where such mandates apply, they supersede language in the benefit document or in the notification criteria.

2. **Coverage Criteria[a]:**

A. <u>Patients less than 19 years of age</u>

1. **Koselugo** will be approved based on the following criterion:

   a. Patient is less than 19 years of age

Authorization will be issued for 12 months.

B. <u>Neurofibromatosis Type 1</u>

1. **<u>Initial Authorization</u>**

   a. **Koselugo** will be approved based on **<u>both</u>** of the following:

      (1) Diagnosis of neurofibromatosis type 1

-AND-

(2) Patient has plexiform neurofibromas that are **both** of the following:

(a) Inoperable
(b) Causing significant morbidity (e.g., disfigurement, motor dysfunction, pain, airway dysfunction, visual impairment, bladder/bowel dysfunction)

Authorization will be issued for 12 months.

2. **Reauthorization**

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

(1) Patient does not show evidence of progressive disease while on Koselugo therapy

Authorization will be issued for 12 months.

C. Glioma

1. **Initial Authorization**

a. **Koselugo** will be approved based on **all** of the following:

(1) One of the following:

(a) Circumscribed glioma with presence of BRAF fusion or BRAF V600E activating mutations
(b) NF-1 mutated glioma

-AND-

(2) Disease is recurrent or progressive

-AND-

(3) Used as monotherapy

Authorization will be issued for 12 months.

2. **Reauthorization**

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

(1) Patient does not show evidence of progressive disease while on Koselugo therapy

Authorization will be issued for 12 months.

D. Langerhans Cell Histiocytosis

1. **Initial Authorization**

a. **Koselugo** will be approved based on **all** of the following:

(1) Diagnosis of Langerhans cell histiocytosis

-AND-

(2) **One** of the following:

(a) Presence of MAP kinase pathway mutation
(b) No detectable mutation
(c) Genetic testing not available

-AND-

(3) Used as monotherapy

Authorization will be issued for 12 months.

2. **Reauthorization**

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

(1) Patient does not show evidence of progressive disease while on Koselugo therapy

Authorization will be issued for 12 months.

E. NCCN Recommended Regimens

The drug has been recognized for treatment of the cancer indication by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B

Authorization will be issued for 12 months.

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

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; January 2024.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at www.nccn.org. Accessed July 30, 2024.

Program	Prior Authorization/Notification – Koselugo™ (selumetinib)
Change Control	
8/2020	New program.
8/2021	Annual review. Added coverage criteria for pilocytic astrocytoma per NCCN guidelines. Updated background and references.
8/2022	Annual review. Added coverage criteria for Langerhans cell histiocytosis per NCCN guidelines. Updated background and references. Added state mandate footnote.
9/2023	Annual review. Removed criteria for pilocytic astrocytoma. Added criteria for glioma. Updated reference.
9/2024	Annual review. No changes to clinical criteria. Updated reference.