UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2021 P 1322-2
Program	Prior Authorization/Notification
Medication	Koselugo™ (selumetinib)
P&T Approval Date	8/2020, 8/2021
Effective Date	11/1/2021; Oxford only: 11/1/2021

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) also recommends Koselugo therapy in patients with BRAF fusion or BRAF V600E activating mutation positive recurrent or progressive pilocytic astrocytoma.

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. <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. Pilocytic Astrocytoma

1. Initial Authorization

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

(1) Diagnosis of recurrent or progressive pilocytic astrocytoma

-AND-

(2) Presence of BRAF fusion or BRAF V600E activating mutations

-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. 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.

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.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at www.nccn.org. Accessed June 24, 2021.

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.