



Commercial & HealthCare Exchange PA Criteria *Effective: September 2nd, 2020*

Prior Authorization: Koselugo

Products Affected: Koselugo (selumetinib) oral capsules

Medication Description: Selumetinib is a selective mitogen-activated extracellular kinase (MEK) inhibitor which inhibits MEK protein kinases 1 and 2. MEK1/2 proteins are upstream regulators of the extracellular signal-related kinase (ERK) pathway. Both MEK and ERK are critical components of the RAS-regulated RAF-MEK-ERK pathway, which is often activated in different cancer types. In mouse neurofibromatosis type 1 (NF1) models genetically modified to mirror human NF1 genotype and phenotype, selumetinib inhibited ERK phosphorylation, and reduced neurofibroma numbers, volume, and proliferation.

Covered Uses: 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).

Exclusion Criteria: N/A

Required Medical Information: Diagnosis

Age Restrictions: 2 years of age and older

Prescriber Restrictions: Prescribed by or in consultation with an oncologist or neurologist.

Coverage Duration: 12 months

Other Criteria:

Neurofibromatosis type 1

- A. Patient must have a confirmed diagnosis of Neurofibromatosis type 1 (NF1); **AND**
- B. Patient has at least one measurable PN, defined as a lesion ≥ 3 cm measured in one dimension; **AND**
- C. Patient meets one of the following (i or ii):
 - i. Positive genetic testing for NF1; **OR**
 - ii. Patient has at least one other diagnostic criterion for NF1 (e.g. six or more face-au-lait macules, freckling in axilla or groin, optic glioma, two or more lisch nodules, a distinctive bony lesion, a first-degree relative with NF1)
- D. Patient is not a candidate for complete resection of PN.

References:

1. Koselugo™ capsules [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals; April 2020.
2. Koselugp, Lexi-Drugs. Lexicomp. Wolters Kluwer Health, Inc. Riverwoods, IL. Available at: <http://online.lexi.com>. Accessed 8/11/2020
3. Micromedex® Healthcare Series; Thomson Micromedex, Greenwood Village, Co. 2019

September 2020



Confidential Information

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4. Drug Trials Snapshots: KOSELUGO, <https://www.fda.gov/drugs/resources-information-approved-drugs/drug-trials-snapshots-koselugo> , Accessed 8/11/20
5. Cimino PJ, Gutmann DH. Neurofibromatosis type 1. Handb Clin Neurol. 2018; 148:799-811.
6. Neurofibromatosis Type 1 (NF1), https://www.hopkinsmedicine.org/neurology_neurosurgery/centers_clinics/neurofibromatosis/nf1/index.html , Accessed 8/11/20
7. Neurofibromatosis Type 1 (NF1) , <https://www.mskcc.org/cancer-care/types/neurofibromatosis/neurofibromatosis-type-1-nf1> , Accessed 8/11/20

Policy Revision history

Rev #	Type of Change	Summary of Change	Sections Affected	Date
1	New Policy	New Policy	All	9/2020