

Koselugo (selumetinib)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	1 year

Medications	Quantity Limit
Koselugo (selumetinib)	May be subject to quantity limit

APPROVAL CRITERIA

Requests for Koselugo (selumetinib) may be approved if the following criteria are met:

- I. Individual is 2 years of age or older; **AND**
- II. Individual has a diagnosis neurofibromatosis type 1 (NF1); **AND**
- III. Individual has symptomatic, inoperable plexiform neurofibromas (PN);

OR

- IV. Individual has a diagnosis of recurrent, refractory or progressive WHO grade 1 pilocytic astrocytoma (NCCN 2A); **AND**
- V. Individual is 3 to 21 years of age; **AND**
- VI. Individual has a BRAF fusion or BRAF V600E mutation; **AND**
- VII. Using as a single agent.

Requests for Koselugo (selumetinib) may not be approved for the following:

- I. Individual has retinal vein occlusion (RVO) or retinal pigment epithelial detachment (RPED); **OR**
- II. Individual has rhabdomyolysis.

Key References:

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2021. URL: <http://www.clinicalpharmacology.com>. Updated periodically.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: July 13, 2021
3. Dombi E, Baldwin A, Marcus LJ, et al. Activity of Selumetinib in Neurofibromatosis Type 1-Related Plexiform Neurofibromas. N Engl J Med. 2016;375(26):2550–2560. doi:10.1056/NEJMoa1605943.
4. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
5. Gross AM, Wolters PL, Dombi E, et al. Selumetinib in Children with Inoperable Plexiform Neurofibromas. N Engl J Med. 2020;382(15):1430–1442. doi:10.1056/NEJMoa1912735.
6. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2021; Updated periodically.

7. NCCN Clinical Practice Guidelines in Oncology™. © 2019 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: <http://www.nccn.org/index.asp>. Accessed on July 13, 2021.
 - a. Central Nervous System Cancers. V1.2021. Revised June 4, 2021.

Federal and state laws or requirements, contract language, and Plan utilization management programs or policies may take precedence over the application of this clinical criteria.

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