Clinical Policy: Selumetinib (Koselugo)

Reference Number: CP.PHAR.464
Effective Date: 04.10.20
Last Review Date: 05.20
Line of Business: Commercial, HIM, Medicaid

Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

Selumetinib (Koselugo™) is a mitogen-activated protein kinase enzyme 1/2 inhibitor.

FDA Approved Indication(s)

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).

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation® that Koselugo is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Neurofibromatosis Type 1 (must meet all)**:**

1. Diagnosis of NF1;
2. Prescribed by or in consultation with an oncologist or neurologist;
3. Age between 2 and 18 years at start of therapy;
4. Member has body surface area ≥ 0.55 m^2;
5. Member has at least one measurable PN, defined as a lesion ≥ 3 cm measured in one dimension;
6. Member meets one of the following (a or b):
   a. Positive genetic testing for NF1;
   b. Member has at least one other diagnostic criterion for NF1 (*see Appendix D*);
7. Complete resection of PN is not considered to be feasible without substantial risk or morbidity (e.g., due to encasement of, or close proximity to, vital structures, invasiveness, or high vascularity of the PN);
8. Dose does not exceed 100 mg (4 capsules) per day.

Approval duration: 6 months

B. Other diagnoses/indications

1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial, HIM.PHAR.21 for health insurance marketplace, and CP.PMN.53 for Medicaid.

II. Continued Therapy

A. Neurofibromatosis Type 1 (must meet all)**:**

1. Currently receiving medication via Centene benefit, or documentation supports that member is currently receiving Koselugo for a covered indication and has received this medication for at least 30 days;
2. Member is responding positively to therapy as evidenced by decreased or maintained volume of PN(s) from baseline;
3. If request is for a dose increase, new dose does not exceed 100 mg (4 capsules) per day.

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.
   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial, HIM.PHAR.21 for health insurance marketplace, and CP.PMN.53 for Medicaid.

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – CP.CPA.09 for commercial, HIM.PHAR.21 for health insurance marketplace, and CP.PMN.53 for Medicaid or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
FDA: Food and Drug Administration
NF1: neurofibromatosis type 1
PN: plexiform neurofibroma

Appendix B: Therapeutic Alternatives
Not applicable

Appendix C: Contraindications/Boxed Warnings
None reported

Appendix D: National Institutes of Health: Neurofibromatosis 1 Diagnostic Criterion

- Six or more café-au-lait macules (greater than or equal to 0.5 cm in prepubertal subjects or greater than or equal to 1.5 cm in post pubertal subjects)
- Freckling in axilla or groin
- Optic glioma
- Two or more Lisch nodules

- A distinctive bony lesion (dysplasia of the sphenoid bone or dysplasia or thinning of long bone cortex)
- A first-degree relative with NF1

Appendix E: Recommended Dosage Based on Body Surface Area

Body Surface Area	Recommended Dosage
0.55 – 0.69 m^2	20 mg in the morning and 10 mg in the evening
0.70 – 0.89 m^2	20 mg twice daily
0.90 – 1.09 m^2	25 mg twice daily
1.10 – 1.29 m^2	30 mg twice daily
1.30 – 1.49 m^2	35 mg twice daily
1.50 – 1.69 m^2	40 mg twice daily
1.70 – 1.89 m^2	45 mg twice daily
≥ 1.90 m^2	50 mg twice daily

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
NF1	25 mg/m^2 PO BID	100 mg/day

VI. Product Availability

Capsules: 10 mg, 25 mg

VII. References

1. Koselugo Prescribing Information. Wilmington, DE: AstraZeneca Pharmaceuticals LP; April 2020. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/213756s000lbl.pdf. Accessed April 13, 2020.
2. Dombi E, Baldwin A, Marcus L, et al. Activity of selumetinib in neurofibromatosis type-1 related plexiform neurofibromas. N Engl J Med. 2016; 375(26): 2550-2560.
3. Gross AM, Wolters P, Baldwin A et al. SPRINT: Phase II study of the MEK ½ inhibitor selumetinib (AZD6244, ARRY142886) in children with neurofibromatosis type 1 (NF1) and inoperable plexiform neurofibromas (PN). Journal of Clinical Oncology. 2018; 36(15): 10503. Available from: http://ascopubs.org/doi/abs/10.1200/JCO.2018.36.15_suppl.10503. Accessed January 9, 2020.
4. National Institutes of Health Consensus Development Conference Statement: neurofibromatosis. Bethesda, Md., USA, July 13-15, 1987. Neurofibromatosis 1:172-178, 1988
5. Miller DT, Freedenberg D, Schorry E, et al. Health Supervision for Children With Neurofibromatosis Type 1. Pediatrics. 2019;143(5):e20190660

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created pre-emptively	01.09.20	02.20
Drug is now FDA approved - criteria updated per FDA labeling; modified prescriber restriction to indicate that Koselugo can be	04.21.20	05.20

Reviews, Revisions, and Approvals	Date	P&T Approval Date
prescribed by neurologist and oncologist; expanded age restriction; added Appendix E: Recommended Dosage Based on Body Surface Area; references reviewed and updated.		

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

Note:
For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.