Koselugo (selumetinib)

NOTICE

This policy contains information which is clinical in nature. The policy is not medical advice. The information in this policy is used by Wellmark to make determinations whether medical treatment is covered under the terms of a Wellmark member's health benefit plan. Physicians and other health care providers are responsible for medical advice and treatment. If you have specific health care needs, you should consult an appropriate health care professional. If you would like to request an accessible version of this document, please contact customer service at 800-524-9242.

BENEFIT APPLICATION

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This medical policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

DESCRIPTION

The intent of the Koselugo (selumetinib) policy is to ensure appropriate selection of patients for therapy based on product labeling, clinical guidelines, and clinical studies. The indications below including FDA-approved indications and compendial uses are considered covered benefits provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications

Treatment of pediatric patients 2 years of age and older with neurofibromatosis type 1 (NF1) who have symptomatic, inoperable plexiform neurofibromas (PNs).

Compendial Uses

1. Pilocytic astrocytoma
2. Langerhans cell histiocytosis

POLICY

Documentation

Submission of the following information is necessary to initiate the prior authorization review: Documentation of BRAF mutation status, where applicale.

Criteria for Initial Approval

A. Koselugo (selumetinib) may be considered **medically necessary** for the treatment of pediatric members 2 years of age and older with neurofibromatosis type 1 (NF1) who have symptomatic, inoperable plexiform neurofibromas (PN).

Approval will be for **12 months.**

B. Koselugo (selumetinib) may be considered **medically necessary** for the treatment of recurrent or progressive pilocytic astrocytoma with BRAF fusion or BRAF V600E activating mutation, as a single agent.

Approval will be for **12 months.**

C. Koselugo (selumetinib) may be considered **medically necessary** as a single agent for treatment of Langerhans cell histiocytosis.

Approval will be for **12 months.**

Continuation of Therapy

A. The continued treatment of Koselugo (selumetinib) may be considered **medically necessary** for members requesting reauthorization for an indication listed in the Criteria for Initial Approval section when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

Approval will be for **12 months.**

Dosing and Administration

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

Quantity Limits

Koselugo 10 mg – 8 capsules per day
Koselugo 25 mg – 4 capsules per day

PROCEDURES AND BILLING CODES

To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnostic codes.

- N/A

REFERENCES

- Food and Drug Administration (FDA). Drugs@FDA. URL: http://www.accessdata.fda.gov/scripts/cder/drugsatfda. Available from Internet. Accessed 2020 July 31.
- Gross AM, Wolters PL, Dombi E et al. Selumetinib in children with inoperable plexiform neurofibromas. N Engl J Med. 2020; 382(15):1430-42.
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- Miller D, Freedenberg D, Schorry E et al. Health supervision for children with neurofibromatosis type 1. Pediatrics. 2019; 143(5):e20190660.
- Stewart D, Korf B, Nathanson K et al. Care of adults with neurofibromatosis type 1: a clinical practice resource of the American College of Medical Genetics and Genomics (ACMG). Genet Med. 2018; 20(7):671-82.
- Wise J, Cryer J, Belasco J, et al. Management of head and neck plexiform neurofibromas in pediatric patients with neurofibromatosis type 1. Arch Otolaryngol Head Neck Surg. 2005; 131(8):712-18.
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*Some content reprinted from CVSHeatlh

POLICY HISTORY

Policy #: 05.04.13
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