

SmartPA Criteria Proposal

Drug/Drug Class:	Koselugo™ Clinical Edit
First Implementation Date:	TBD
Proposed Date:	June 18, 2020
Prepared for:	MO HealthNet
Prepared by:	MO HealthNet/Conduent
Criteria Status:	<input type="checkbox"/> Existing Criteria <input type="checkbox"/> Revision of Existing Criteria <input checked="" type="checkbox"/> New Criteria

Executive Summary

Purpose: Ensure appropriate utilization and control of Koselugo™ (selumetinib)

Why Issue Selected: Koselugo™ (selumetinib), FDA approved on April 10, 2020, is the first treatment approved for pediatric patients aged 2 years and older with neurofibromatosis type 1 (NF1) who have symptomatic, inoperable plexiform neurofibromas (PN). NF1 is a rare, multisystem disorder, primarily involving the skin and peripheral nervous system, caused by a pathogenic variant in the *NF1* gene. Approximately 10,000 to 20,000 children in the United States are estimated to have NF1 or 1 in 2,600-3,000 infants. PN are benign tumors that grow along the length of a nerve and typically change the color and/or texture of overlying skin. The tumors can be found in any part of the body and are often difficult to remove due to their intertwining with normal tissues and peripheral nerves. PN are present in approximately 50% of patients with NF1; however, less than 20% will require any intervention for PN during childhood. Koselugo is an inhibitor of mitogen-activated protein kinase 1 and 2 (MEK1/2). MEK1/2 proteins are upstream regulators of the extracellular signal-related kinase (ERK) pathway. MEK and ERK are critical components of the RAS-regulated RAF-MEK-ERK pathway, which is often activated in different types of cancer. Koselugo is dosed per body surface area and may cause serious side effects including cardiomyopathy, ocular toxicity, gastrointestinal toxicity, skin toxicity and increases in creatinine phosphokinase.

Program-Specific Information:	Drug	Cost per capsule	Cost per month
	KOSELUGO 10 MG CAPSULE	\$72.70 WAC	\$12,500 estimated for the average patient
	KOSELUGO 25 MG CAPSULE	\$181.75 WAC	

Type of Criteria: Increased risk of ADE Preferred Drug List
 Appropriate Indications Clinical Edit

Data Sources: Only Administrative Databases Databases + Prescriber-Supplied

Setting & Population

- Drug class for review: Koselugo™ (selumetinib)

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- Age range: All appropriate MO HealthNet participants aged 2 years or older

Approval Criteria

Initial Therapy:

- Participant aged 2 years or older **AND**
- Documented diagnosis of neurofibromatosis type 1 **AND**
- Documentation of inoperable plexiform neurofibromas (PN) defined as a PN that cannot be completely removed without risk for substantial morbidity due to encasement of or close proximity to vital structures, invasiveness, or high vascularity of the PN **AND**
- Prescribed by or in consultation with an oncologist, neurologist, or other specialist familiar with the treated disease state **AND**
- Documentation of baseline left ventricular ejection fraction (LVEF) **AND**
- Documentation of baseline ophthalmic assessment **AND**
- Documentation of baseline CPK level **AND**
- Participant is not currently pregnant **AND**
- Participant (male or female of appropriate age) is utilizing concurrent birth control methods

Continuation of Therapy:

- Initial approval is for 1 year, renewal of prior authorization may be given following documentation of the following:
 - Ophthalmic examinations for ocular toxicities at least once annually **AND**
 - LVEF assessed every 3 months during the first year of treatment and then every 6 months thereafter **AND**
 - Recent CPK level **AND**
 - Documentation of benefit of therapy, examples include:
 - stabilization or reduction in PN size or number of PN
 - improved quality of life

Denial Criteria

- Therapy will be denied if no approval criteria are met
- Documented severe hepatic impairment (Child-Pugh Class C)

Required Documentation

Laboratory Results:	<input checked="" type="checkbox"/>	Progress Notes:	<input checked="" type="checkbox"/>
MedWatch Form:	<input type="checkbox"/>	Other:	<input checked="" type="checkbox"/>

Disposition of Edit

Denial: Exception code "0682" (Clinical Edit)
 Rule Type: CE

Default Approval Period

1 year

References

- Koselugo – selumetinib capsule [package insert]. Wilmington, DE: AstraZeneca; 2020.
- NIH: U.S. National Library of Medicine. “AZD6244 Hydrogen Sulfate for Children with Nervous System Tumors.”
<https://clinicaltrials.gov/ct2/show/NCT01362803?term=NCT01362803&draw=2&rank=1>. Accessed 22 April 2020.
- IPD Analytics: New Drug Review. “Koselugo (Selumetinib)”. Accessed 22 April 2020.
- American Academy of Pediatrics. “Health Supervision for Children with Neurofibromatosis Type 1.”
<https://pediatrics.aappublications.org/content/pediatrics/143/5/e20190660.full.pdf>. Accessed 22 April 2020.

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