CareSource

PHARMACY POLICY STATEMENT **Indiana Medicaid**	
DRUG NAME	Koselugo (selumetinib)
BILLING CODE	Must use valid NDC code
BENEFIT TYPE	Pharmacy
SITE OF SERVICE ALLOWED	Home
COVERAGE REQUIREMENTS	Prior Authorization Required (Non-Preferred Product) QUANTITY LIMIT— see Table 1 below
LIST OF DIAGNOSES CONSIDERED **NOT** MEDICALLY NECESSARY	Click Here

Koselugo (selumetinib) is a **non-preferred** product and will only be considered for coverage under the **pharmacy** benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

NEUROFIBROMATOSIS TYPE 1 (NF1)

For **initial** authorization:

1. Member is 2 to 21 years of age; AND
2. Medication must be prescribed by or in consultation with a pediatric oncologist or a specialist with experience in treating neurofibromatosis Type 1; AND
3. Member has a confirmed diagnosis of neurofibromatosis type 1 (NF1) disease documented in chart notes; AND
4. Member has at least one measurable plexiform neurofibromas (PN) as evidenced by MRI or PET-CT scans; AND
5. The plexiform neurofibromas (PN) cannot be removed completely by surgery without substantial risks or morbidity due to reasons such as encasement of, or close proximity to, vital structures, invasiveness, or high vascularity of the PN; AND
6. Member has significant morbidity related to PN (e.g. disfigurement, motor dysfunction, pain, airway dysfunction, visual impairment, and bladder/bowel dysfunction, etc.).
7. **Dosage allowed:** 25mg/m^2 by mouth twice daily (see Table 1 below for recommended dosage based on body surface area).

If member meets all the requirements listed above, the medication will be approved for 6 months.

For **reauthorization**:

1. If the member is older than 21 years of age, therapy must be initiated prior to 21 years old in order to continue treatment; AND
2. Chart notes have been provided showing that the member has had at least a partial response (defined as ≥20% reduction in the PN volume) from baseline and no disease progression.

If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

CareSource considers Koselugo (selumenib) not medically necessary for the treatment of the diseases that are not listed in this document.

DATE	ACTION/DESCRIPTION
05/14/2020	New policy for Koselugo created.

References:

1. Koselugo [Package Insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; April 2020.
2. Gross AM, Wolters PL, Dombi E, et al. Selumetinib in children with inoperable plexiform neurofibromas. N Engl J Med 2020; 382:1430-1442.
3. Gutmann DH, Aylsworth A, Carey JC, et al. The diagnostic evaluation and multidisciplinary management of neurofibromatosis 1 and neurofibromatosis 2. JAMA 1997; 278:51.
4. Hardin AP, Hackell JM, et al. Age limit of pediatrics. Pediatrics 2017;140.
5. Miller DT, Freedenberg D, Schorry E, et al. Health supervision for children with Neurofibromatosis Type 1. Pediatrics May 2019, 143 (5) e20190660.

Effective date: 09/01/2020
Revised date: 05/14/2020

Table 1 Recommended Dosage Based on Body Suface Area

Body Surface Area*	Recommended Dosage	Quantity Limit
0.55 – 0.69 m^2	20 mg in the morning and 10 mg in the evening	90 capsules/30 days
0.70 – 0.89 m^2	20 mg twice daily	120 capsules/30 days
0.90 – 1.09 m^2	25 mg twice daily	60 capsules/30 days
1.10 – 1.29 m^2	30 mg twice daily	180 capsules/30 days
1.30 – 1.49 m^2	35 mg twice daily	120 capsules/30 days
1.50 – 1.69 m^2	40 mg twice daily	240 capsules/30 days
1.70 – 1.89 m^2	45 mg twice daily	180 capsules/30 days
≥ 1.90 m^2	50 mg twice daily	120 capsules/30 days

* The recommended dosage for patients with a BSA less than 0.55 m^2 has not been established.