# HOW TO ACCESS

Koselugo® (selumetinib) 10 mg & 25 mg capsules

## INDICATION

KOSELUGO® (selumetinib) 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).

## Koselugo Access Process

Alexion is committed to providing access education and support to healthcare providers (HCPs) and their offices for NF1 PN patients who have been prescribed Koselugo. This overview is intended to provide information to help you understand how to access Koselugo including benefits investigations, prior authorizations (PAs), navigating appeals and denials (if required), and reauthorization considerations.

**The following steps provide an overview of the access process to start patients on Koselugo:**

**1**

### Physician prescribes Koselugo

You have diagnosed a patient with NF1 who has symptomatic, inoperable PN and have prescribed Koselugo. Now what?

**2**

### Conduct benefits investigation

After you have prescribed Koselugo, Alexion's contracted specialty pharmacy, Onco360, will conduct a benefits investigation with the patient's health plan.

**3**

### Submit PA

Once the benefits investigation is complete, Onco360 will share the health plan's PA requirements with you. Each patient will have different requirements based on their unique health plan.

**4**

### PA approval

Once all PA requirements have been completed and submitted to the patient's health plan, the PA will either be approved or denied. If approved, Onco360 will ship Koselugo to the patient. If denied, what are the next steps you can take to appeal the decision?

**5**

### Reauthorization

After your patient has begun therapy on Koselugo, health plans will require a reauthorization. Reauthorization timelines and requirements will vary based on each patient's unique health plan.

This guide is intended for educational purposes only and does not represent legal advice.

1

Physician prescribes KOSELUGO® (selumetinib)

## Contact Your Regional Account Manager (RAM)

Your RAM is a key point of contact for your office. Your RAM will:

- **Review this resource with you about access to Koselugo and provide you with a guide to treatment initiation.**
- **Introduce you to the cross functional team** that will provide you and your office educational support for the Koselugo Access Process. This team consists of a OneSource™ Case Manager for Alexion patient services and Onco360—the sole contracted specialty pharmacy that dispenses Koselugo.
- **Provide you with a OneSource enrollment form** for eligible patients so they can receive ongoing support.

# Your Partners for Koselugo Access

## Meet OneSource and Onco360—Here to Educate and Support

### Send the Prescription to Onco360—The Sole Contracted Specialty Pharmacy for Koselugo[1-4]

Koselugo is distributed and available through a sole contracted specialty pharmacy that also provides ongoing, personalized support including insurance benefit validation, financial assistance sourcing, expert medication counseling, and side effect education for your patients. Once the prescription is sent to Onco360, Onco360 faxes the referral form to the prescribing physician.

- 24/7 access to certified oncology pharmacists and nurses
- Caregiver and patient counseling on administration and adherence
- Coordination with your patients' insurance companies
- Digital capabilities including refill reminders, text messaging, and a mobile application

**To contact Onco360**

Call: [XXX.XXX.XXXX]

Contact: onco360.com/about/contact-us

Order forms: onco360.com/how-to-refer/

Fax Rx: 1.978.313.6184

Visit: onco360.com/koselugo-for-nf1

e-Prescribe: NPI# 1679618151

ONESOURCE®
Personalized Patient Support from Alexion

## Onco360 and OneSource Collaborate to Provide Educational Support to Your Patient

Encourage your eligible patient to enroll in OneSource. Enrollment in OneSource enables[5,6]:

- **Insurance coverage support** (benefits verification, appeals, and more)
- **Product and disease state education**
- **Participation in the OneSource CoPay Program** for eligible patients
- **Field Reimbursement Managers/Case Managers** to provide ongoing case-specific support
- **NF1 PN community connections** through patient advocacy organizations

Eligible patients can enroll in OneSource by sending in a completed OneSource PDF Enrollment form at **AlexionOneSource.com** or calling OneSource directly at 1-888-765-4747. Enrollment can also be facilitated by Onco360.

**Get personalized support from OneSource**

Call:
1.888.765.4747

Email:
OneSource@alexion.com

Visit:
AlexionOneSource.com

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**2**

**Conduct benefits investigation**

## The Benefits Investigation Is Conducted by Onco360

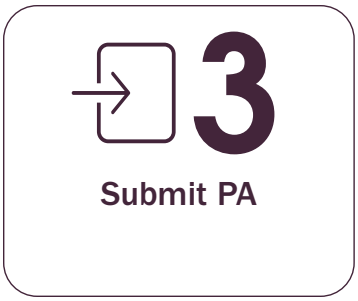
Once the KOSELUGO® (selumetinib) prescription has been sent in and verified, Onco360 will conduct a benefits investigation.[1]

Health plans can have different requirements and the benefits investigation will provide you with information that will answer key questions regarding a patient's health plan coverage and requirements[7]:

- PA requirements and specific documentation that must be submitted to obtain approval[a]
- Any additional health plan requirements or guidelines[b]
- Reauthorization criteria and time frame for continuation of therapy

Onco360 can provide this information to HCPs and their offices.[1]

**a.** For example, letter of medical necessity or prescriber information. **b.** For example, a requirement to administer as buy and bill or if the product can be obtained through a designated specialty pharmacy.




## Prior Authorization (PA)

Health plans often require a PA (also known as a precertification or coverage determination) for use of KOSELUGO® (selumetinib) to treat pediatric patients 2 years of age and older with NF1 who have PN that cannot be completely removed by surgery. PAs are very common for orphan drugs that treat rare diseases.[7] Requirements vary by plan, and a benefits investigation is needed to understand the current health plan requirements for your NF1 PN patient needing to be prescribed Koselugo.

### 1 Step 1: Compile the PA Requirements

Onco360 will coordinate with you and your office to ensure required documentation for the PA is completed and included prior to submission to the health plan.

### 2 Step 2: Submit All PA Information

If a prescription form is submitted to Onco360 without a PA, Onco360 will initiate a PA request via CoverMyMeds, provided that the prescribing physician and the patient's health plan both use CoverMyMeds. Onco360 will share the PA key with the prescribing physician so they can submit it via CoverMyMeds. If neither the prescribing physician nor the patient's health plan is familiar with CoverMyMeds, Onco360 will help them with coordinating the PA.

Once the PA has been submitted, Onco360 will check the PA status with the health plan on a periodic basis to confirm receipt and monitor status. Payer response time will vary by health plan.

OneSource™ can communicate with enrolled patients to review: their explanation of benefits, their financial obligation, eligibility for the Alexion Koselugo CoPay Program, and out-of-pocket costs.

**Patients are eligible for the Koselugo CoPay Program if they meet ALL of the following criteria[8]:**

- Be enrolled in OneSource.
- Have commercial health insurance that covers medication costs for Koselugo, but not the full cost to the patient. The Program is not valid for beneficiaries or recipients of any federal, state, or government-funded healthcare program, including Medicaid, Medicare (including Medicare Part D), Medicare Advantage Plans, Medigap, Veterans Affairs, Department of Defense or TRICARE, or other federal or state programs (including any state prescription drug assistance programs). If the patient is enrolled in a state or federally funded prescription insurance program, they may not use this program even if they elect to be processed as an uninsured (cash-paying) patient.
- Either (i) have a valid prescription for a US Food and Drug Administration (FDA)-approved indication for Koselugo and be enrolled in OneSource, Alexion's personalized patient support program; or (ii) have received assistance from the Program in 2022 under a prior version of these Terms and Conditions *and* received assistance from the Program in the year prior to which the patient seeks copay support.
- Reside and receive treatment in the United States or its territories.
- The person who is financially responsible for the patient's copay is 18 years of age or older.

Please refer to the full **Terms and Conditions** for additional eligibility requirements.


**If the PA is approved,** Onco360 will confirm PA is approved with the health plan and will coordinate next steps for shipment. Upon approval, Onco360 will also verify a patient's funding and out-of-pocket responsibilities. Onco360 coordinates dispensing process for patients regardless of OneSource™ enrollment status.

**If a PA is denied,** you will need to determine the reason and the best course of action. Each health plan has specific options and time frames to consider if there is a denial. Contact the health plan directly to obtain information on its appeals process.

**For All Patients:**

- Onco360 can assist in facilitating the appeal for a denied PA including:
  - Communication of denial reason and payer's appeal requirements
  - Pharmacist research of supporting medical justification for the treatment decision
- Onco360 will then monitor the status of the appeal and if missing or additional information is still needed by the payer, Onco360's Care Coordinator will reach out and inform you as needed
- Once a decision is rendered by the payer, the Onco360 Care Coordinator will inform you of the outcome:
  - For appeal approvals, Onco360 will contact the patient to proceed with scheduling shipment of KOSELUGO® (selumetinib)
  - When denials occur, Onco360 will assess the patient's eligibility for OneSource support programs and warm transfer the patient to OneSource accordingly

**For Patients Enrolled in OneSource:**

- A Field Reimbursement Manager (FRM) can provide educational support to navigate the denial and appeal process.
- OneSource can communicate with your patient to educate them on their role in the process.

**Navigating the Denial and Appeal Process:**

1. Obtain the denial letter and determine the denial reason
2. Determine the best course of action
3. Keep mindful of timelines and specific health plan requirements
4. Follow up: Onco360 will follow up with your office and the patient's health plan to coordinate next steps

5

Reauthorization

## Reauthorization

After a patient has received a PA, the patient may need a reauthorization (also known as a renewal of authorization) after a specified time period.[7] This is often required to confirm that a therapy continues to be medically necessary for a patient and that they have responded to therapy.

Information about reauthorization criteria, timing, and requirements can be found in a patient's medical policy or during the PA process. The process and specific requirements for requesting reauthorization will vary depending on the patient's health plan, Pharmacy Benefits Manager benefits, or the medical/clinical policy.

For OneSource™ enrolled patients, your FRM and OneSource Case Manager can provide educational support to you and your office around the reauthorization process. Onco360 can provide educational support for the reauthorization process for all patients, regardless of OneSource enrollment status.

# Get to Know Your Cross-Functional Support Team

who can help with reimbursement, provide clinical resources, and more

### ALEXION MAIN POINT OF CONTACT

**Regional Account Manager (RAM)**

Facilitates clinical discussions with HCPs based on approved FDA prescribing information for Alexion medications and promotes these products to serve patients.

Name _____

Phone _____

Email _____

### HCP ACCESS SUPPORT

**Field Reimbursement Manager (FRM)**

Can provide access and reimbursement education; educational support for coding, billing, and appropriate claims submission; and PA and appeal assistance.

Name _____

Phone _____

Email _____

### PATIENT ACCESS SUPPORT

**Onboarding: OneSource Case Manager (CM)**

For eligible patients, OneSource CM works with patients and assigned provider offices to help patients overcome insurance, financial, educational, and logistical barriers from program enrollment to the first prescription.

Name _____

Phone _____

Email _____

**Explore Alexion Access Navigator**

ALEXION ACCESS NAVIGATOR

Alexion Access Navigator is a dedicated resource website for US HCPs and their offices that contains downloadable access and reimbursement materials for KOSELUGO® (selumetinib).

Online: https://alexionaccessnavigator.com/koselugo

# IMPORTANT SAFETY INFORMATION FOR KOSELUGO® (selumetinib)

## WARNINGS AND PRECAUTIONS

**Cardiomyopathy.** A decrease in left ventricular ejection fraction (LVEF) ≥10% below baseline occurred in pediatric patients who received Koselugo in SPRINT with some experiencing decreased LVEF below the institutional lower limit of normal (LLN), including one patient with Grade 3. All patients with decreased LVEF were asymptomatic and identified during routine echocardiography. The safety of Koselugo has not been established in patients with a history of impaired LVEF or a baseline ejection fraction that is below the institutional LLN. Assess ejection fraction by echocardiogram prior to initiating treatment, every 3 months during the first year of treatment, every 6 months thereafter, and as clinically indicated. Withhold, reduce dose, or permanently discontinue Koselugo based on severity of adverse reaction. In patients who interrupt Koselugo for decreased LVEF, obtain an echocardiogram or a cardiac MRI every 3 to 6 weeks. Upon resolution of decreased LVEF, obtain an echocardiogram or a cardiac MRI every 2 to 3 months.

**Ocular Toxicity.** Blurred vision, photophobia, cataracts, and ocular hypertension occurred. Retinal pigment epithelial detachment (RPED) occurred in the pediatric population during treatment with single agent Koselugo and resulted in permanent discontinuation. Conduct ophthalmic assessments prior to initiating Koselugo, at regular intervals during treatment, and for new or worsening visual changes. Permanently discontinue Koselugo in patients with retinal vein occlusion (RVO). Withhold Koselugo in patients with RPED, conduct ophthalmic assessments every 3 weeks until resolution, and resume Koselugo at a reduced dose.

**Gastrointestinal Toxicity.** Diarrhea occurred, including Grade 3. Diarrhea resulting in permanent discontinuation, dose interruption or dose reduction occurred. Advise patients to start an anti-diarrheal agent (eg, loperamide) and to increase fluid intake immediately after the first episode of diarrhea. Withhold, reduce dose, or permanently discontinue Koselugo based on severity of adverse reaction.

**Skin Toxicity.** Rash occurred in 91% of 74 pediatric patients. The most frequent rashes included dermatitis acneiform (54%), maculopapular rash (39%), and eczema (28%). Grade 3 rash occurred, in addition to rash resulting in dose interruption or dose reduction. Monitor for severe skin rashes. Withhold, reduce dose, or permanently discontinue Koselugo based on severity of adverse reaction.

**Increased Creatine Phosphokinase (CPK).** Increased CPK occurred, including Grade 3 or 4 resulting in dose reduction. Increased CPK concurrent with myalgia occurred, including one patient who permanently discontinued Koselugo for myalgia. Obtain serum CPK prior to initiating Koselugo, periodically during treatment, and as clinically indicated. If increased CPK occurs, evaluate for rhabdomyolysis or other causes. Withhold, reduce dose, or permanently discontinue Koselugo based on severity of adverse reaction.

**Increased Levels of Vitamin E and Risk of Bleeding.** Koselugo capsules contain vitamin E which can inhibit platelet aggregation and antagonize vitamin K-dependent clotting factors. Supplemental vitamin E is not recommended if daily vitamin E intake (including the amount of vitamin E in Koselugo and supplement) will exceed the recommended or safe limits due to increased risk of bleeding. An increased risk of bleeding may occur in patients who are coadministered vitamin-K antagonists or anti-platelet antagonists with Koselugo. Monitor for bleeding in these patients and increase international normalized ratio (INR) in patients taking a vitamin-K antagonist. Perform anticoagulant assessments more frequently and adjust the dose of vitamin K antagonists or anti-platelet agents as appropriate.

**Embryo-Fetal Toxicity.** Based on findings from animal studies, Koselugo can cause fetal harm when administered during pregnancy. In animal studies, administration of selumetinib to mice during organogenesis caused reduced fetal weight, adverse structural defects, and effects on embryo-fetal survival at approximate exposures >5 times the human exposure at the clinical dose of 25 mg/m$^2$ twice daily. Advise patients of reproductive potential of the potential risk to a fetus and to use effective contraception during treatment with Koselugo and for 1 week after the last dose.

**Please see Important Safety Information on pages 7-8 and the accompanying full Prescribing Information for Koselugo® (selumetinib).**

# IMPORTANT SAFETY INFORMATION FOR KOSELUGO® (selumetinib) (cont'd)

## ADVERSE REACTIONS

**Common adverse reactions ≥40% include** vomiting, rash (all), abdominal pain, diarrhea, nausea, dry skin, musculoskeletal pain, fatigue, pyrexia, acneiform rash, stomatitis, headache, paronychia, and pruritus.

## DRUG INTERACTIONS

**Effect of Other Drugs on Koselugo**

**Concomitant use of Koselugo with a strong or moderate CYP3A4 inhibitor or fluconazole** increased selumetinib plasma concentrations, which may increase the risk of adverse reactions. Avoid coadministration with Koselugo. If coadministration cannot be avoided, reduce Koselugo dosage.

**Concomitant use of Koselugo with a strong or moderate CYP3A4 inducer** decreased selumetinib plasma concentrations, which may reduce Koselugo efficacy. Avoid concomitant use with Koselugo.

## SPECIAL POPULATIONS

**Pregnancy & Lactation.** Verify the pregnancy status of patients of reproductive potential prior to initiating Koselugo. Due to the potential for adverse reactions in a breastfed child, advise patients not to breastfeed during treatment with Koselugo and for 1 week after the last dose.

**To report SUSPECTED ADVERSE REACTIONS, contact AstraZeneca 1-800-236-9933 or at https://us-aereporting.astrazeneca.com or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.**

**Please see accompanying full Prescribing Information for Koselugo (selumetinib).**

**REFERENCES: 1.** Patient journey. Onco360 Oncology Pharmacy. Accessed August 15, 2022. https://onco360.com/patient-journey/ **2.** Koselugo for NF1. Onco360 Oncology Pharmacy. Accessed September 8, 2023. https://onco360.com/koselugo-for-nf1/ **3.** How to refer. Onco360 Oncology Pharmacy. Accessed September 8, 2023. https://onco360.com/how-to-refer/ **4.** About. Contact us. Onco360 Oncology Pharmacy. Accessed September 8, 2023. https://onco360.com/about/contact-us/ **5.** Always here to help. Alexion Pharmaceuticals. Accessed September 8, 2023. https://alexion.com/our-inspiration/support-services **6.** Alexion Pharmaceuticals. About OneSource™. Accessed September 8, 2023. https://alexiononesource.com/kos/about **7.** Drella M. Frequently asked questions about pharmacy prior authorization [blog]. Outsource Strategies International. December 2, 2019. Accessed September 8, 2023. https://www.outsourcestrategies.com/blog/frequently-asked-questions-about-pharmacy-prior-authorization.html **8.** Alexion Koselugo CoPay Program Terms and Conditions. Alexion OneSource. June 2023. Accessed September 8, 2023. https://alexiononesource.com/koscopay

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ALEXION®
AstraZeneca Rare Disease

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