Koselugo®
(selumetinib)
10 mg & 25 mg capsules
5 mg & 7.5 mg oral granules

# HOW TO ACCESS KOSELUGO

## INDICATION & SELECT IMPORTANT SAFETY INFORMATION for KOSELUGO

### INDICATION

KOSELUGO is indicated for the treatment of adult and pediatric patients 1 year of age and older with neurofibromatosis type 1 (NF1) who have symptomatic, inoperable plexiform neurofibromas (PN).

### SELECT IMPORTANT SAFETY INFORMATION

**WARNINGS AND PRECAUTIONS** associated with Koselugo include Left Ventricular Dysfunction, Ocular Toxicity, Gastrointestinal Toxicity, Skin Toxicity, Increased Creatine Phosphokinase (CPK), Increased Levels of Vitamin E and Risk of Bleeding (Koselugo Capsules), and Embryo-Fetal Toxicity.

**ADVERSE REACTIONS**

**Common adverse reactions ≥40% in pediatric patients include** vomiting, diarrhea, increased CPK, dry skin, paronychia, nausea, dermatitis acneiform, and pyrexia.

**Common adverse reactions ≥40% in adult patients include** rash (all), dermatitis acneiform, and diarrhea.

**DRUG INTERACTIONS** include strong/moderate CYP3A4 inhibitors or fluconazole and strong/moderate CYP3A4 inducers.

**Please see additional Important Safety Information on pages 1 and 5-7, and the accompanying full Prescribing Information for Koselugo (selumetinib), also available by scanning the QR code.**

This document is provided for informational purposes only and is not legal advice or official guidance from payers. It is not intended to increase or maximize reimbursement by any payer. Alexion does not warrant, promise, guarantee, or make any statement that the use of this information will result in coverage or payment for KOSELUGO® (selumetinib) or that any payment received will cover providers' costs. Alexion is not responsible for any action providers take in billing for, or appealing, Koselugo claims.

Hospitals and physicians are responsible for compliance with Medicare and other payer rules and requirements and for the information submitted with all claims and appeals. Before any claims or appeals are submitted, hospitals and physicians should review official payer instructions and requirements, should confirm the accuracy of their coding or billing practices with these payers, and should use independent judgment when selecting codes that most appropriately describe the services or supplies provided to a patient.

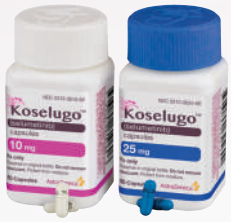
Please visit alexionaccessnavigator.com/koselugo for additional information. For inquiries regarding reimbursement, please call 1-888-765-4747 to speak with a OneSource™ patient support specialist who can connect you with your local Field Reimbursement Manager. OneSource is available Monday through Friday, 8:30 AM-8:00 PM ET.

# Product Overview[1]

Koselugo is indicated for the treatment of adult and pediatric patients 1 year of age and older with neurofibromatosis type 1 (NF1) who have symptomatic, inoperable plexiform neurofibromas (PN).

Koselugo is available in capsule and oral granule formulations; both are administered twice daily. Dosing is individualized based on the patient's body surface area.

## KOSELUGO CAPSULES PRODUCT INFORMATION[1]




| Route of Administration | Dosage Form | Strength | Package Size (Capsules per Bottle) | National Drug Code (NDC) Number |
|---|---|---|---|---|
| Oral | Capsules | 10 mg | 28 | 0310-0610-28 |
| | | | 60 | 0310-0610-60 |
| | | 25 mg | 28 | 0310-0625-28 |
| | | | 60 | 0310-0625-60 |

## KOSELUGO ORAL GRANULES PRODUCT INFORMATION[1]


| Route of Administration | Dosage Form | Strength | Package Size (Capsules per Bottle) | NDC Number |
|---|---|---|---|---|
| Oral | Oral Granules | 5 mg | 60 | 0310-0635-60 |
| | | 7.5 mg | 60 | 0310-0640-60 |

## PHARMACY BENEFIT COVERAGE[2]

Pharmacy benefits cover self-administered prescription medicines, including oral, topical, and self-injectable medications. Most insurance companies cover Koselugo under the pharmacy benefit.

**Please see additional Important Safety Information on pages 1 and 5-7, and the accompanying full Prescribing Information for Koselugo (selumetinib), also available by scanning the QR code.**

# There Are 2 Ways to Access Koselugo:

## 1 YOUR PATIENTS CAN GET STARTED ON KOSELUGO THROUGH ONCO360®, ALEXION'S SOLE CONTRACTED SPECIALTY PHARMACY.

### STEP 1: Physician Prescribes Koselugo

You have diagnosed a patient with **NF1** who has **symptomatic, inoperable PNs** and prescribed Koselugo using the **diagnostic coding information** on pages 5 and 6. The prescription is then sent to Onco360®.

### STEP 2: Conduct Benefits Investigation

After the prescription is submitted, **Onco360** will initiate a **benefits investigation** with the patient's health plan to determine coverage and any prior authorization (PA) requirements.[3]

### STEP 3: Submit PA

After completing the benefits investigation, **Onco360 will notify you** of the health plan's PA requirements and work with the healthcare provider (HCP)'s office to submit the PA.

*Requirements will vary by health plan and may include medical records, diagnosis confirmation, and symptom documentation.*

### STEP 4: PA Approval or Denial

If the **PA is approved**, Onco360 will:

- Confirm approval with the health plan
- Verify the patient's funding and out-of-pocket responsibilities
- Coordinate the dispensing and shipment of Koselugo, regardless of OneSource™ enrollment

If the **PA is denied**, Onco360 can assist in facilitating the **appeals process**. Each health plan has its own steps and timelines, and Onco360 can help navigate the process by:

- Communicating the denial reason and outlining the payer's appeal requirements
- Gathering relevant clinical information to support the appeal
- Monitoring the appeal status and keeping you informed if anything is missing

### STEP 5: Reauthorization

Once your patient has started Koselugo, many health plans will require **periodic reauthorization** to continue therapy.

*Requirements and timelines will vary by health plan—Onco360 will guide you through the process when it's time.*

## 2 INSTITUTIONAL SPECIALTY PHARMACIES SEEKING TO DISPENSE KOSELUGO MAY PURCHASE KOSELUGO THROUGH AN AUTHORIZED SPECIALTY DISTRIBUTOR.

Non-contracted specialty pharmacies, retail pharmacies, and hospitals seeking to dispense Koselugo may purchase Koselugo through:

| | |
|---|---|
| **Cencora**[4,5] | *ASD Healthcare:* 1-800-746-6273 \| asdhealthcare.com |
| | *Oncology Supply:* 1-800-633-7555 \| oncologysupply.com |
| **Cardinal Health Specialty Pharmaceutical Distribution**[6] | 1-877-453-3972 \| specialtyonline.cardinalhealth.com |
| **CuraScript SD**[7] | 1-877-599-7748 \| curascriptsd.com |
| **McKesson Specialty Health**[8,9] | *McKesson Specialty Health (MD Offices):* 1-800-482-6700 \| mscs.mckesson.com |
| | *McKesson Plasma and Biologics (Hospitals, IDNs, VA):* 1-877-625-2566 \| mckesson.com/plasmabiologics |

Institutional specialty pharmacies can access and dispense Koselugo only if they opt in to the Koselugo Dispensing Network. To be eligible for the Koselugo Dispensing Network, an institution **must maintain a Utilization Review Accreditation Commission (URAC) or Accreditation Commission for Health Care (ACHC) accreditation and sign a letter of commitment with Asembia to opt in to the Koselugo Dispensing Network.**

# Onco360 and Alexion OneSource™ Are Resources to Support and Assist in the Entire Access Process

Onco360® ONCOLOGY PHARMACY

**Onco360**, the sole contracted specialty pharmacy for Koselugo, provides personalized support for patients and HCPs, including[3,10-12]:

- 24/7 access to certified oncology pharmacists and nurses for medication-related questions
- Counseling for caregivers and patients on medication administration and adherence
- Coordination with insurance companies for benefits verification and coverage support
- Digital tools like refill reminders, text alerts, and a mobile app for convenience

**To contact Onco360**

Call: 1.877.662.6633

Fax Rx: 1.877.662.6355

Visit: onco360.com/koselugo-for-nf1/

e-Prescribe: NPI# 1679618151

ONESOURCE® Personalized Patient Support from Alexion

**OneSource**, a personalized patient support program offered by Alexion, provides additional support for eligible patients, including[13]:

- Product and disease state education tailored to patient needs
- Enrollment in the OneSource CoPay Program[14] and other available access programs for eligible patients
- Ongoing support from Patient Education Managers, Case Managers, and Field Reimbursement Managers
- Connections to the NF1 PN community through patient advocacy groups

**Eligible patients can enroll in OneSource by:**

Calling 1.888.765.4747

Emailing OneSource@alexion.com

Completing the OneSource Enrollment Form at AlexionOneSource.com/kos

**Please see additional Important Safety Information on pages 1 and 5-7, and the accompanying full Prescribing Information for Koselugo (selumetinib), also available by scanning the QR code.**

# Koselugo Coding and Billing Information

The coding and billing information for Koselugo provided in this overview is intended to offer objective and publicly available guidance for specialty pharmacies, retail pharmacies, hospitals, and outpatient clinics seeking to dispense Koselugo.

## NATIONAL DRUG CODE (NDC)

Some payers may require drugs like Koselugo to be billed on pharmacy claims with the product's NDC. The following NDCs are used to identify Koselugo when submitting a pharmacy claim:

### *Capsules*[1,15]

| Strength | Bottle Count | 10-Digit NDC | 11-Digit NDC (Billing Format) |
|---|---|---|---|
| 10 mg | 28 | 0310-0610-28 | 00310-0610-28 |
| 25 mg | 28 | 0310-0625-28 | 00310-0625-28 |
| 10 mg | 60 | 0310-0610-60 | 00310-0610-60 |
| 25 mg | 60 | 0310-0625-60 | 00310-0625-60 |

### *Oral granules*[1,15]

| Strength | Bottle Count | 10-Digit NDC | 11-Digit NDC (Billing Format) |
|---|---|---|---|
| 5 mg | 60 | 0310-0635-60 | 00310-0635-60 |
| 7.5 mg | 60 | 0310-0640-60 | 00310-0640-60 |

Payers typically require HCPs to use the Health Insurance Portability and Accountability Act (HIPAA)-compliant, 11-digit NDC format. Please note that payers have different guidance for placement of the NDC on pharmacy claims. Typically, the 11-digit NDC is reported without any dashes or other punctuation.[14]

## HEALTHCARE COMMON PROCEDURE CODING SYSTEM (HCPCS)[16]

The following drug-specific HCPCS billing code can be reported on medical claims forms to payers:

| HCPCS Code[a] | Code Descriptor |
|---|---|
| **J8499** | Prescription drug, oral, non-chemotherapeutic, NOS |

**a.** Other HCPCS codes may be applicable.

## IMPORTANT SAFETY INFORMATION for KOSELUGO
## WARNINGS AND PRECAUTIONS

**Left Ventricular Dysfunction.** Koselugo can cause cardiomyopathy, defined as a decrease in left ventricular ejection fraction (LVEF) ≥10% below baseline. In the pediatric safety pool, Grade 2 LVEF decrease occurred, as well as decreased LVEF of ≥20% resulting in dose interruption and dose reduction. The median time to first occurrence of LVEF decrease was approximately 12 months. In the adult population, Grade 2 LVEF decrease occurred, with decreased LVEF resulting in dose interruption. The median time to first occurrence of LVEF decrease was approximately 4 months. 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 until resolution. Upon resolution of decreased LVEF, obtain an echocardiogram or a cardiac MRI every 2 to 3 months.

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## DIAGNOSIS CODES[17]

The following International Classification of Diseases, 10th Revision, Clinical Modification (ICD-10-CM) codes may be appropriate to describe patients diagnosed with NF1 who have symptomatic, inoperable PN, as documented:

| ICD-10-CM | Description |
|---|---|
| **Q85.01** | Neurofibromatosis, type 1 |
| **AND one of the following:** | |
| D33.3 | Benign neoplasm of cranial nerves |
| D36.10 | Benign neoplasm of peripheral nerves and autonomic nervous system, unspecified |
| D36.11 | Benign neoplasm of peripheral nerves and autonomic nervous system of face, head, and neck |
| D36.12 | Benign neoplasm of peripheral nerves and autonomic nervous system, upper limb, including shoulder |
| D36.13 | Benign neoplasm of peripheral nerves and autonomic nervous system of lower limb, including hip |
| D36.14 | Benign neoplasm of peripheral nerves and autonomic nervous system of thorax |
| D36.15 | Benign neoplasm of peripheral nerves and autonomic nervous system of abdomen |
| D36.16 | Benign neoplasm of peripheral nerves and autonomic nervous system of pelvis |
| D36.17 | Benign neoplasm of peripheral nerves and autonomic nervous system of trunk, unspecified |

# Additional Access Resources Are Available on Access Navigator

**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 (Cont'd)
## WARNINGS AND PRECAUTIONS (Cont'd)

**Ocular Toxicity.** Koselugo can cause ocular toxicity, including retinal vein occlusion (RVO), retinal pigment epithelial detachment (RPED), and blurred vision. In the pediatric safety pool, blurred vision, photophobia, cataracts, ocular hypertension, and retinal tear occurred. Blurred vision resulted in dose interruption. RPED occurred in the pediatric population during treatment with Koselugo and resulted in permanent discontinuation. In the adult population, blurred vision and vitreous floaters occurred in patients receiving Koselugo. 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 RVO. Withhold Koselugo in patients with RPED, conduct ophthalmic assessments every 3 weeks until resolution, and resume Koselugo at a reduced dose.

**Gastrointestinal Toxicity.** Koselugo can cause gastrointestinal toxicities, including diarrhea and colitis. In the pediatric safety pool (N=134), diarrhea occurred in 59% of patients, in addition to diarrhea resulting in permanent discontinuation and dose interruption. In the adult population (N=71), diarrhea occurred in 42% of patients who received Koselugo, in addition to diarrhea resulting in dose interruption. The median time to first onset of diarrhea was approximately 2 months in the pediatric safety pool and 1 month in the adult population. 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.

## IMPORTANT SAFETY INFORMATION (Cont'd)

## WARNINGS AND PRECAUTIONS (Cont'd)

**Skin Toxicity.** Koselugo can cause severe rashes, including dermatitis acneiform. In the pediatric safety pool (N=134), rash occurred in 68% of patients. The most frequent rashes included dermatitis acneiform (47%) and maculopapular rash (31%). Pruritus, alopecia, and eczema occurred. In the adult population (N=71), rash occurred in 85% of patients who received Koselugo. The most frequent rash included dermatitis acneiform (66%). Alopecia and pruritus occurred in patients who received Koselugo. Grade 3 rash and rash resulting in dose interruption and dose reduction occurred in both the pediatric safety pool and the adult population. Permanent discontinuation also occurred in the adult population. Monitor for severe skin rashes. Withhold, reduce dose, or permanently discontinue Koselugo based on severity of adverse reaction.

**Increased Creatine Phosphokinase (CPK).** Koselugo can cause increased CPK, myalgia, and rhabdomyolysis. In the pediatric safety pool (N=134), increased CPK, based on laboratory data, occurred in 73% of patients, including Grade 3 or 4. In the adult population (N=71), increased CPK, based on laboratory data, occurred in 70% of patients who received Koselugo, including Grade 3 or 4. Increased CPK resulted in dose interruption and dose reduction in both the pediatric safety pool and adult population. Increased CPK concurrent with myalgia occurred in both populations, including one patient who permanently discontinued Koselugo for myalgia in the pediatric safety pool. 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).** 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 co-administered vitamin-K antagonists or anti-platelet antagonists with Koselugo capsules. Monitor for bleeding in these patients and increase international normalized ratio (INR) monitoring 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. Koselugo oral granules do not contain vitamin E.

**Embryo-Fetal Toxicity.** 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 pregnant women of the potential risk to a fetus. Advise females of reproductive potential and males with female partners of reproductive potential to use effective contraception during treatment with Koselugo and for 1 week after the last dose.

## ADVERSE REACTIONS

**Common adverse reactions ≥40% in pediatric patients include** vomiting, diarrhea, increased CPK, dry skin, paronychia, nausea, dermatitis acneiform, and pyrexia. **Common adverse reactions ≥40% in adult patients include** rash (all), dermatitis acneiform, and diarrhea.

## 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 at 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 the accompanying full Prescribing Information for Koselugo (selumetinib), also available by scanning the QR code.**

**References: 1.** KOSELUGO. Prescribing Information. AstraZeneca Pharmaceuticals LP. **2.** McCain J. The importance of a thorough benefits investigation to help navigate medical vs pharmacy benefit. National Association of Medication Access & Patient Advocacy, Inc. Accessed November 2, 2025. https://namapa.org/medical-vs-pharmacy-benefit **3.** Onco360 Oncology Pharmacy. Patient journey. Accessed November 2, 2025. https://onco360.com/patient-journey **4.** Cencora ASD Healthcare. Contact us. Accessed November 2, 2025. https://www.asdhealthcare.com/contact-us **5.** Cencora Oncology Supply. Contact us. Accessed November 2, 2025. https://www.oncologysupply.com/contact-us **6.** Cardinal Health Specialty Distribution Services. Specialty pharmaceutical distribution services. Accessed November 2, 2025. https://www.cardinalhealth.com/en/solutions/specialty-distribution-services.html **7.** CuraScript SD. Corporate information. Accessed November 2, 2025. https://www.curascriptsd.com/Contact-Us **8.** McKesson. Customer center. Accessed November 2, 2025. https://mscs.mckesson.com/CustomerCenter/MckessonWebStore.html?customerType=ONCL **9.** McKesson Plasma and Biologics. Business overview. Accessed November 2, 2025. https://www.mckesson.com/business-solutions/our-businesses/mckesson-plasma-biologics/ **10.** Onco360 Oncology Pharmacy. Koselugo for NF1. Accessed November 2, 2025. https://onco360.com/koselugo-for-nf1 **11.** Onco360 Oncology Pharmacy. How to refer. Accessed November 2, 2025. https://onco360.com/how-to-refer **12.** Onco360 Oncology Pharmacy. About. Contact us. Accessed November 2, 2025. https://onco360.com/about/contact-us **13.** Alexion Pharmaceuticals. About OneSource™. Accessed November 2, 2025. https://alexiononesource.com/kos/about **14.** Alexion Koselugo CoPay Program Terms and Conditions. Alexion OneSource. Updated December 17, 2024. Accessed November 2, 2025. https://alexiononesource.com/koscopay **15.** Drugs.com. National drug codes explained. Updated March 20, 2025. Accessed November 2, 2025. https://www.drugs.com/ndc.html **16.** Centers for Medicare & Medicaid Services. October 2025 alpha-numeric HCPCS file. Accessed November 2, 2025. https://www.cms.gov/medicare/coding-billing/healthcare-common-procedure-system/quarterly-update **17.** Centers for Medicare & Medicaid Services. 2026 ICD-10-CM. Updated October 1, 2025. Accessed November 2, 2025. https://www.cms.gov/files/zip/2026-code-tables-tabular-and-index.zip


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ALEXION®
AstraZeneca Rare Disease