

PRESCRIBER FORM - NF1 PN (NF1, NEUROFIBROMATOSIS TYPE 1; PN, PLEXIFORM NEUROFIBROMA)



FAX: 1.800.420.5150



MAIL: 100 College Street
New Haven, CT 06510



PHONE: 1.888.765.4747
8:30 AM to 8 PM ET Monday-Friday



EMAIL: OneSource@Alexion.com



ONESOURCE[®]
Personalized Patient Support from Alexion

OneSource™ is a complimentary, personalized patient support program offered by Alexion. It's designed to support patients' specific needs throughout treatment. For more information, visit www.AlexionOneSource.com. Contact OneSource if you have any questions while completing the forms.



INSTRUCTIONS FOR HEALTHCARE PROFESSIONALS:

To enroll your patient in OneSource, please follow these steps:

- 1 Have your patient complete all required sections and read the Authorization to Share Health Information on the **Patient Services Enrollment Form**
- 2 Complete all required sections on **PAGE 1**
- 3 Sign the Prescriber Certification on **PAGE 2**
- 4 **FAX PAGES 1-2 of the completed form and copies of the front and back of the patient's medical insurance and pharmacy coverage cards to OneSource**

Fields in red with asterisks are required.*

STEP 1: PATIENT INFORMATION

PATIENT NAME (FIRST, LAST)*	DATE OF BIRTH (MM/DD/YYYY)*	PATIENT PHONE NUMBER*	PATIENT EMAIL
LEGAL PATIENT REPRESENTATIVE* (THIS SECTION IS REQUIRED IF PATIENT IS A MINOR)			
NAME (FIRST, LAST)	PHONE NUMBER	RELATIONSHIP TO PATIENT	EMAIL

STEP 2: CLINICAL DIAGNOSIS

INDICATION (check one)*: ☐ SYMPTOMATIC INOPERABLE PN ASSOCIATED WITH NF1 ☐ OTHER - CONTACT ONESOURCE TO DETERMINE ELIGIBILITY

STEP 3: INSURANCE INFORMATION

You may complete this section OR attach copies of patient's medical and pharmacy insurance card(s).

<input type="checkbox"/> COPIES OF PATIENT'S INSURANCE CARD(S) ATTACHED <input type="checkbox"/> PATIENT DOES NOT HAVE INSURANCE	PRIMARY MEDICAL INSURANCE	SECONDARY MEDICAL INSURANCE	PHARMACY COVERAGE
INSURANCE PROVIDER			
INSURANCE PHONE #			
CARDHOLDER NAME			
CARDHOLDER DATE OF BIRTH			
MEMBER ID			
POLICY #			
GROUP #			
BIN/PCN #			

STEP 4: HEALTHCARE PRESCRIBER INFORMATION

FIRST NAME*	LAST NAME*	PROVIDER EMAIL*
ADDRESS*		PHONE NUMBER*
CITY*	STATE*	ZIP*
PRACTICE NAME	TAX ID #*	NPI #*
OFFICE CONTACT NAME	EMAIL	FAX NUMBER

Please see Indication & Important Safety Information on page 3 and accompanying full Prescribing Information for KOSELUGO, also available at www.KOSELUGO.com.

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PATIENT INFORMATION

PATIENT NAME (FIRST, LAST)*

DATE OF BIRTH (MM/DD/YYYY)*

STEP 5: PRESCRIPTION

Koselugo is available via prescription through a **sole contracted specialty pharmacy (ONC0360)**

SPECIALTY PHARMACY PROVIDER (SPP)

☐ ONC0360

☐ ON-SITE DISPENSE (prescription information does not need to be completed): _____

☐ NO PREFERENCE*

ON-SITE DISPENSE PHONE NUMBER: _____

*If you have questions, contact OneSource at 1.888.765.4747.

KOSELUGO® (selumetinib)

25-mg CAPSULES QUANTITY: _____ REFILLS: _____

10-mg CAPSULES QUANTITY: _____ REFILLS: _____

DOSE INSTRUCTIONS: _____

HEIGHT & DATE: _____

WEIGHT & DATE: _____

FREE LIMITED SUPPLY (FLS) REQUEST

FREE LIMITED SUPPLY IS AVAILABLE FOR ELIGIBLE PATIENTS WHO FACE A DELAY IN APPROVAL BY THEIR INSURANCE COMPANY FOR KOSELUGO.

KOSELUGO® (selumetinib)

25-mg CAPSULES QUANTITY: _____

10-mg CAPSULES QUANTITY: _____

DOSE INSTRUCTIONS: _____

STEP 6: PRESCRIBER CERTIFICATION

By signing below, I attest that: (i) based on my clinical judgment, Koselugo is medically necessary for the patient and diagnosis identified on this form and I will be supervising the patient's treatment; (ii) I am authorized under applicable law to prescribe Koselugo and I have verified and complied with all applicable prescription requirements; (iii) I am authorizing Alexion to forward the patient's prescription to a pharmacy by any means under applicable law; (iv) I am under no obligation to prescribe Koselugo and I have not received, nor will I receive, any benefit from Alexion for prescribing Koselugo; and (v) the information provided on this form is complete, current, and accurate to the best of my knowledge. I also acknowledge that Alexion will use and share the personal data collected about me (as the prescriber) in accordance with the Privacy Notice on the Alexion website at <https://alexion.com/Legal#privacy>.

SIGN ONE*

PRESCRIBER'S SIGNATURE (NO STAMPS) - **DISPENSE AS WRITTEN**

DATE (MM/DD/YYYY)

PRESCRIBER'S SIGNATURE (NO STAMPS) - **MAY SUBSTITUTE**

DATE (MM/DD/YYYY)

Please verify your local prescribing requirements (eg, New York prescribers must provide a separate prescription).

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IMPORTANT SAFETY INFORMATION WARNINGS AND PRECAUTIONS

Cardiomyopathy. A decrease in left ventricular ejection fraction (LVEF) $\geq 10\%$ 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/m² 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.

ADVERSE REACTIONS

Common adverse reactions $\geq 40\%$ 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 FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

INDICATION

KOSELUGO 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).

Please see accompanying full Prescribing Information for Koselugo (selumetinib), also available at https://alexion.com/Documents/koselugo_uspi.pdf.

This material is intended only for residents of the United States.

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- 1 Complete all the required information (in red) on **this page** and read the Authorization to Share Health Information on **the next page**
- 2 Sign the Authorization to Share Health Information section on **this page**
- 3 Email or fax **this page** and **copies of the front and back of your medical insurance and pharmacy coverage cards** to OneSource (see the email address and fax number above)

Be sure to complete all required fields and sign and date the form. If information is incomplete, it could delay our ability to enroll you in OneSource. OneSource can start offering you personalized support once you submit this form fully and correctly completed.

Fields in red with asterisks are required.* **Contact OneSource if you have any questions while completing the form.**

PATIENT INFORMATION

PATIENT NAME (FIRST, MIDDLE INITIAL, LAST)*		DATE OF BIRTH (MM/DD/YYYY)*	GENDER: <input type="checkbox"/> MALE <input type="checkbox"/> FEMALE <input type="checkbox"/> NON-BINARY PREFER TO SELF-DESCRIBE:	
ADDRESS*				
CITY*		STATE*	ZIP*	
PRIMARY PHONE NUMBER* <input type="checkbox"/> MOBILE <input type="checkbox"/> HOME		OK TO SEND A TEXT MESSAGE? <input type="checkbox"/> YES <input type="checkbox"/> NO OK TO LEAVE A PHONE MESSAGE? <input type="checkbox"/> YES <input type="checkbox"/> NO		
PATIENT DIAGNOSIS				
PREFERRED LANGUAGE <input type="checkbox"/> ENGLISH <input type="checkbox"/> SPANISH <input type="checkbox"/> OTHER _____		PATIENT EMAIL <input type="checkbox"/> NONE		
LEGAL PATIENT REPRESENTATIVE* (REQUIRED IF A PATIENT IS A MINOR)		RELATIONSHIP TO PATIENT	EMAIL	
NAME:		PHONE:		
DESIGNATED CARE PARTNER		RELATIONSHIP TO PATIENT	EMAIL	
NAME:		PHONE:		

PRESCRIBING PHYSICIAN'S INFORMATION

PROVIDER NAME	PROVIDER PHONE NUMBER	PROVIDER EMAIL
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AUTHORIZATION TO SHARE HEALTH INFORMATION

By signing below, I acknowledge that I have read and agree to the Authorization to Share Health Information terms on the next page.

SIGN HERE*

SIGNATURE OF PATIENT OR LEGALLY AUTHORIZED REPRESENTATIVE

DATE (MM/DD/YYYY)

CONSENT FOR COPAY PROGRAM (OPTIONAL)

By signing below, I acknowledge that I have read and agree to the Alexion OneSource CoPay Program eligibility terms and conditions available at <https://alexiononesource.com/> CoPay or on request by contacting OneSource at 1.888.765.4747.

SIGNATURE OF PATIENT OR LEGALLY AUTHORIZED REPRESENTATIVE

DATE (MM/DD/YYYY)

CONSENT FOR AUTOMATED TEXT COMMUNICATIONS (OPTIONAL)

By signing below, I give Alexion and companies working at Alexion's direction permission to use automated text (SMS) messages to provide patient support services and to provide information to me about Alexion products, services, programs, or other topics that Alexion thinks may interest me. I understand that (i) I am not required to consent to receiving text messages as a condition of any purchase of Alexion products or enrollment in these programs; (ii) my telecommunication services provider may charge me for any text messages that I receive from Alexion; and (iii) I may opt out of receiving automated text messages from Alexion at any time without affecting my enrollment in these programs.

SIGNATURE OF PATIENT OR LEGALLY AUTHORIZED REPRESENTATIVE

DATE (MM/DD/YYYY)

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AUTHORIZATION TO SHARE HEALTH INFORMATION

Alexion Pharmaceuticals, Inc. (“Alexion”) offers patient services including educational resources, case management support, and financial assistance for eligible patients.

By signing the prior page, I give permission for my healthcare providers, health plans, other insurance programs, pharmacies, and other healthcare service providers (“My Healthcare Entities”) to share information, including protected health information relating to my medical condition, treatment, and health insurance coverage (collectively “My Information”) with Alexion and companies working at its direction so that Alexion may use and disclose My Information to:

- review my insurance coverage and eligibility for benefits for treatment with an Alexion product;
- coordinate treatment with an Alexion product, as well as related services, such as arranging home infusion services or vaccination services;
- provide me with educational and promotional materials, contact me about market research or clinical studies, or otherwise contact me about Alexion products, services, programs, or other topics that Alexion thinks may interest me
- remove identifiers from My Information and combine such resulting information with other information for research, regulatory submissions, business improvement projects, and publication purposes; and
- (as applicable to my Alexion product) review my vaccination and prophylaxis history and provide corresponding patient support, such as sending reminders about potential upcoming vaccinations.

I understand that My Healthcare Entities may receive payment from Alexion in exchange for sharing My Information.

I understand that My Information is also subject to the Alexion Privacy Notice available at <https://alexion.com/Legal#privacy>, and that the Alexion Privacy Notice provides additional information about Alexion’s privacy practices and the rights that may be available to me. Although Alexion has implemented privacy and security controls designed to help protect My Information, I understand that once My Information has been disclosed to Alexion, the Health Insurance Portability and Affordability Act (“HIPAA”) may not apply and may be subject to redisclosure.

I understand that I may refuse to sign this Authorization and that My Healthcare Entities may not condition treatment, payment, enrollment, or eligibility for benefits on whether I sign this Authorization. I also understand that if I do not sign this Authorization, I will not be able to receive support through the Alexion OneSource™ Patient Support Program.

This Authorization expires ten (10) years from the date next to my signature, unless I cancel/revoke it sooner, or unless a shorter time frame is required by applicable law.

I understand that I may revoke my authorization, or unsubscribe or modify the services I receive, at any time by mailing a letter to Alexion OneSource Patient Support Program, 100 College Street, New Haven, CT 06510 or by emailing OneSource@Alexion.com. I also understand that modifying my authorization will not affect any use or disclosure of My Information that occurred before Alexion received notice of my cancellation. I also understand I have a right to receive a copy of this Authorization after it is signed and can request a copy at any time by contacting OneSource at 1.888.765.4747.

OneSource Services

Alexion services and support are subject to change. Participation is voluntary, and person(s) may be removed from Alexion services for code of conduct violations.

This material is intended only for residents of the United States.