

AvMed

PHARMACY PRIOR AUTHORIZATION/STEP-EDIT REQUEST*

Directions: The prescribing physician must sign and clearly print name (preprinted stamps not valid) on this request. All other information may be filled in by office staff; **fax to 1-305-671-0200.** No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. **If the information provided is not complete, correct, or legible, the authorization process can be delayed.**

Drug Requested: Koselugo™ (selumetinib)

MEMBER & PRESCRIBER INFORMATION: Authorization may be delayed if incomplete.

Member Name: _____

Member AvMed #: _____ Date of Birth: _____

Prescriber Name: _____

Prescriber Signature: _____ Date: _____

Office Contact Name: _____

Phone Number: _____ Fax Number: _____

DEA OR NPI #: _____

DRUG INFORMATION: Authorization may be delayed if incomplete.

Drug Form/Strength: _____

Dosing Schedule: _____ Length of Therapy: _____

Diagnosis: _____ ICD Code, if applicable: _____

Weight: _____ Date: _____

Recommended dosage based on body surface area:

Body Surface Area	Recommended Dosage Based on a dose of 25 mg/m ² /dose
0.55 – 0.69 m ²	20 mg in the morning and 10 mg in the evening
0.7 – 0.89 m ²	20 mg twice daily
0.9 – 1.09 m ²	25 mg twice daily
1.1 – 1.29 m ²	30 mg twice daily
1.3 – 1.49 m ²	35 mg twice daily
1.5 – 1.69 m ²	40 mg twice daily
1.7 – 1.89 m ²	45 mg twice daily
≥1.9m ²	50 mg twice daily

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CLINICAL CRITERIA: Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

Initial Authorization Approval: 6 months

- Provider is an oncologist, a neurologist, or specialized in treating Neurofibromatosis Type 1

AND

- The patient is between 2 and 18 years of age at start of therapy

AND

- Patient has a confirmed diagnosis for Neurofibromatosis, Type 1 (NF1) by meeting **TWO or more** of the following findings:
 - Six or more café au lait macules (CALMs) over 5 mm in greatest diameter in prepubertal individuals and over 15 mm in greatest diameter in postpubertal individuals
 - Two or more neurofibromas of any type or 1 plexiform neurofibromas (PN)
 - Freckling in the axillary or inguinal region
 - Optic glioma
 - Two or more Lisch nodules (iris hamartomas)
 - A distinctive osseous lesion such as sphenoid dysplasia or thinning of long bone cortex with or without pseudarthrosis
 - A first-degree relative (parent, sibling, or offspring) with NF1 by the above criteria

OR

- Diagnosis can be confirmed with a positive genetic test for NF1

AND

- The patient has confirmed formations of plexiform neurofibromas (PN), able to be measured, and resection or operation is not considered to be feasible without substantial risk or morbidity (i.e. extensive interdigitation into vital structures, invasiveness, or high risk of nerve injury and/or hemorrhage)

AND

- A baseline tumor volumetric MRI assessment was completed and submitted with this request [Please submit MRI data and results]

AND

- Body Surface area ≥ 0.55 m², dosing will follow recommendations in the table above, and will not exceed 100mg (4 capsules) per day

ENTER CALCULATED BSA: _____ m² ENTER DOSE PRESCRIBED: _____

AND

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- The following safety monitoring parameters have been obtained prior to initiating therapy, and will continue to be assessed accordingly (**please submit current laboratory/clinical documentation as recent as this request**)
 - Liver Function Tests
 - Creatine Phosphokinase Level
 - Ejection Fraction
 - R or PTT, **if receiving vitamin-K antagonists or antiplatelet agents**

Reauthorization Approval: 12 months. Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

- The patient has is not experiencing progressing plexiform neurofibromas as confirmed by MRI volumetric assessment compared to pretreatment [**Please submit MRI data and results**]
- The patient is being monitored for, and not experiencing any signs or symptoms of increased bleeding, cardiotoxicity, liver injury, or ocular toxicity.
- Dose does not exceed 100 mg (4 capsules) per day

Medication being provided by a Specialty Pharmacy - PropriumRx

Not all drugs may be covered under every Plan

If a drug is non-formulary on a Plan, documentation of medical necessity will be required.

Use of samples to initiate therapy does not meet step edit/ preauthorization criteria.

**Previous therapies will be verified through pharmacy paid claims or submitted chart notes.*