

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: Skyclarys® (omaveloxolone)

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: _____

Weight: _____ Date: _____

Quantity Limit: 3 capsules per day

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: 12 months

- Member is 16 years of age or older
- Member has a diagnosis of Friedreich's ataxia as established by molecular genetic testing and detection of biallelic pathogenic variants in the FXN gene (**submit documentation**)
- Prescribed by or in consultation with a Neurologist, Geneticist or Physician who specializes in the treatment of Friedreich's ataxia
- Member exhibits clinical signs and symptoms of disease (e.g., ataxia, speech disturbance, sensory dysfunction muscle weakness, decline in coordination, frequent falling) that are consistent with Friedreich's ataxia

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- Member has a baseline modified Friedreich Ataxia Rating Scale (mFARS) score between 20-80 (if score is below 20 please send genetic test to document member is **NOT** a carrier): _____ (submit score)
- Provider must submit member's current Activities of Daily Living (FA-ADL) scale score: _____
- Member's B- Type natriuretic Peptide (BNP) is ≤ 200 pg/mL prior to initiating therapy and will be monitored periodically during treatment
- Member must **NOT** have uncontrolled diabetes (i.e., HbA1c $\geq 11\%$)
- Member will avoid concomitant therapy with the following:
 - Strong or moderate CYP3A4 inhibitors (e.g., fluconazole, itraconazole) [**NOTE: If therapy is unavoidable, members will be monitored closely for adverse reaction and/or dose modifications will be implemented**]
 - Strong and moderate CYP3A4 inducers (e.g., rifampin, carbamazepine, St. John's Wort)
- Member does **NOT** have any of the following (submit chart notes and/or lab documentation):
 - Severe hepatic impairment (i.e., Child-Pugh Class C)
 - Signs of very advanced disease (i.e., cardiomyopathy by transthoracic echocardiogram)
 - Pes cavus defined as having a loss of lateral support and was determined if light from a flashlight could be seen under the patient's arch when barefoot and weight bearing
 - History of clinically significant left-sided heart disease and/or clinically significant cardiac disease (**NOTE: Excludes mild to moderate cardiomyopathy associated with Friedreich's ataxia**)
- Member retains meaningful voluntary motor function (e.g., manipulate objects using upper extremities, ambulates)

Reauthorization: 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.

- Member's modified Friedreichs Ataxia Rating scale (mFARS) score has improved from baseline (e.g., bulbar function, upper/lower limb coordination, upright stability): _____ (submit score obtained within the last 30 days)
- Provider must submit member's current Activities of Daily Living (FA-ADL) scale score obtained within the last 30 days: _____
- Member continues to avoid concomitant therapy with strong or moderate CYP3A4 inhibitors s (e.g., fluconazole, itraconazole) **AND** strong and moderate CYP3A4 inducers (e.g., rifampin, carbamazepine, St. John's Wort)

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- ❑ Member does **NOT** have any of the following (**submit chart notes and/or lab documentation**):
 - Severe hepatic impairment (i.e., Child-Pugh Class C)
 - Signs of very advanced disease (i.e., cardiomyopathy by transthoracic echocardiogram)
 - Pes cavus defined as having a loss of lateral support and was determined if light from a flashlight could be seen under the patient's arch when barefoot and weight bearing
 - History of clinically significant left-sided heart disease and/or clinically significant cardiac disease (**NOTE**: Excludes mild to moderate cardiomyopathy associated with Friedreich's ataxia)
- ❑ Member retains meaningful voluntary motor function (e.g., manipulate objects using upper extremities, ambulates)

Medication being provided by a Specialty Pharmacy – Proprium Rx

*****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.****