SENTARA HEALTH PLANS

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 1-800-750-9692.** No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. **If information provided is not complete, correct, or legible, authorization may be delayed.**

Drug Requested: Skyclarys® (omaveloxolone)

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

Member Name: _____

Member Sentara #: _____ **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 ≥ 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)
- ❑ Member does **NOT** have any of the following **(submit chart notes and/or lab documentation)**:
  - Severe hepatic impairment (i.e., Child-Pugh Class C)

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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.*