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AETNA BETTER HEALTH® OF VIRGINIA REQUEST FORM

DUR MEDICATION SKYCLARYS™ (omaveloxolone)

Fax back to: 1-855-799-2553

If the following information is not complete, correct, or legible, the PA process can be delayed. Please use one form per member.

MEMBER INFORMATION

Last Name: _____

First Name: _____

Medicaid ID Number: _____

Date of Birth: _____

Weight in Kilograms: _____

PRESCRIBER INFORMATION

Last Name: _____

First Name: _____

NPI Number: _____

Phone Number: _____

Fax Number: _____

DRUG INFORMATION

Drug Name/Form: _____

Strength: _____

Dosing Frequency: _____

Length of Therapy: _____

Quantity per Day: _____

DIAGNOSIS AND MEDICAL INFORMATION

For initial approval, complete the following questions to receive a 6-months approval:

1. Is Skyclarys prescribed by or in consultation with a neurologist?
   ☐ Yes ☐ No

2. Is the member 16 years of age or older?
   ☐ Yes ☐ No

(Form continued on next page).

Member's Last Name: **Member's First Name:**

3. Does the member have a diagnosis of Friedreich's ataxia as confirmed by molecular genetic testing and detection of biallelic pathogenic variant in the *FXN* gene and clinical signs and symptoms (e.g., ataxia, speech disturbance, sensory dysfunction, etc.) that is consistent with Friedreich's ataxia?
   ☐ Yes ☐ No

4. Does the member retain meaningful voluntary motor function (e.g., manipulate objects using upper extremities, ambulates)?
   ☐ Yes ☐ No

5. Does the member have a 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)
   ☐ Yes ☐ No

6. Does the member have signs of very advanced disease (e.g., cardiomyopathy by transthoracic echocardiogram)?
   ☐ Yes ☐ No

7. Is the member B-Type Natriuretic Peptide (BNP) ≤ 200 pg/mL prior to initiating therapy and will be monitored periodically during treatment?
   ☐ Yes ☐ No

8. Will the prescriber assess the following prior to therapy initiation and periodically during therapy as recommended in the product label:
   - Liver function (alanine transaminase [ALT], aspartate transaminase [AST], bilirubin); **AND**
   - Lipid parameters?

   ☐ Yes ☐ No

9. Does the member have severe hepatic impairment (Child-Pugh C)?
   ☐ Yes ☐ No

(Form continued on next page).

Member's Last Name: **Member's First Name:**

10. Will the member avoid concomitant therapy with all of the following:
    - Moderate or strong CYP3A4 inhibitors (e.g., fluconazole, itraconazole); if therapy is unavoidable, the member will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
    - Moderate or strong CYP3A4 inducers (e.g., rifampin, carbamazepine, St. John's wort)?

    ☐ Yes ☐ No

11. Have members of reproductive potential been advised to use non-hormonal contraceptive method (e.g., non-hormonal intrauterine system, condoms) during omaveloxolone therapy and for 28 days after discontinuation?
    ☐ Yes ☐ No

For renewal, complete the following questions to receive a 6-months approval:

12. Does the member continue to meet the above criteria?
    ☐ Yes ☐ No

13. Does the member have disease improvement as defined by stabilization **or** slowed progression of disease signs and symptoms (e.g., bulbar function, upper/lower limb coordination, upright stability) from pretreatment baseline*****?
    **Note: Stabilization or slowed progression is evidenced by assessment of activities of daily living, such as dressing, grooming, walking, pointing, swallowing, and speaking*
    ☐ Yes ☐ No

14. Has the member been assessed for adverse effects (e.g., fluid overload, heart failure; ALT or AST > 5x the ULN or > 3x the ULN with signs of liver dysfunction)?
    ☐ Yes ☐ No

Prescriber Signature (Required) **Date**

By signature, the Physician confirms the above information is accurate and verifiable by member records.

Please include ALL requested information; Incomplete forms will delay the PA process.
Submission of documentation does NOT guarantee coverage.