

Omaveloxolone (SKYCLARYS™)

Goal(s):

Promote use that is consistent with medical evidence and product labeling in patients with Friedreich's ataxia.

Length of Authorization:

- Up to 12 months

Requires PA:

- Omaveloxolone oral capsules (pharmacy claims)

Covered Alternatives:

- Current PMPDP preferred drug list per OAR 410-121-0030 at www.orpdl.org
- Searchable site for Oregon FFS Drug Class listed at www.orpdl.org/drugs/

Table 1. Recommended Dosage of Omaveloxolone with Concomitant use of CYP3A4 Inhibitors or Inducers

| Concomitant Drug Class | Dosage |
|---|---|
| Strong CYP3A4 Inhibitor (such as, but not limited to: ketoconazole, nefazodone, voriconazole) | Recommended to avoid concomitant use. If co-administration cannot be avoided: <ul style="list-style-type: none"> • Reduce omaveloxolone dose to 50 mg once daily with close monitoring to detect adverse effects • If adverse effects emerge, coadministration with strong CYP3A4 inhibitor should be discontinued |
| Moderate CYP3A4 Inhibitor (such as, but not limited to: erythromycin, verapamil, diltiazem, cyclosporine) | Recommended to avoid concomitant use. If co-administration cannot be avoided: <ul style="list-style-type: none"> • Reduce omaveloxolone dose to 100 mg once daily with close monitoring to detect adverse effects • If adverse effects emerge, further reduce omaveloxolone dose to 50 mg once daily |
| Strong or Moderate CYP3A4 Inducer (such as, but not limited to: phenytoin, carbamazepine, rifampin) | Recommended to avoid concomitant use. |

| Approval Criteria | | |
|---|---|---|
| 1. What diagnosis is being treated? | Record ICD10 code. | |
| 2. Is the request for continuation of therapy previously approved by the FFS program? | Yes: Go to Renewal Criteria | No: Go to #3 |
| 3. Is the medication prescribed by or in consultation with a neurologist? | Yes: Go to #4 | No: Pass to RPh. Deny; medical appropriateness |

Approval Criteria

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|--|--|---|
| <p>4. Is the request for a patient who has had a trinucleotide repeat expansion assay genetic test confirming the diagnosis of Friedreich's ataxia in a patient 16 years of age and older?</p> | <p>Yes: Go to #5</p> | <p>No: Pass to RPh. Deny; medical appropriateness</p> |
| <p>5. Is the patient able to swallow whole capsules or capsule contents mixed into an appropriate amount of applesauce?</p> <p>Note: Capsules should be swallowed whole or mixed into 30 mL of applesauce. Capsule contents should not be mixed with milk, orange juice, or given via enteral feeding tube. Capsules may not be crushed or chewed.</p> | <p>Yes: Go to #6</p> | <p>No: Pass to RPh. Deny; medical appropriateness.</p> |
| <p>6. Have baseline labs (alanine transaminase [ALT], aspartate aminotransferase [AST], bilirubin, b-type natriuretic peptide [BNP] and lipid parameters) been obtained prior to initiating therapy?</p> | <p>Yes: Document date and results: Go to #7</p> | <p>No: Pass to RPh. Deny; medical appropriateness</p> |
| <p>7. Is baseline BNP > 200 pg/mL?</p> | <p>Yes: Pass to RPh. Deny; medical appropriateness.</p> | <p>No: Go to #8</p> |
| <p>8. Has the provider documented the patient does not have severe hepatic impairment (Child-Pugh Class C)?</p> | <p>Yes: Go to #9</p> | <p>No: Pass to RPh. Deny; medical appropriateness</p> |
| <p>9. If patient has moderate liver impairment (Child-Pugh Class B) has the dose been modified to 100 mg once daily?</p> | <p>Yes: Go to #10</p> | <p>No: Pass to RPh. Deny; medical appropriateness</p> |
| <p>10. If patient is taking other medications, are they CYP3A4 inhibitors or inducers that require omaveloxolone dosing adjustments as outlined in Table 1 and has the omaveloxolone dose been adjusted?</p> | <p>Yes: Approve for up to 6 months.</p> | <p>No: Pass to RPh. Deny; medical appropriateness</p> |

Renewal Criteria

1. Has the patient's condition progressed slower than expected, stabilized, or improved as assessed by the prescribing provider and provider attests to patient's current status.

Yes: Approve for 12 months.
Document baseline assessment and provider attestation received.

No: Pass to RPh; Deny; medical appropriateness.

*P&T/DUR Review: 2/25 (DM); 6/23 (DM)
Implementation: 3/10/25; 7/1/23*