



# Skyclarys Prior Authorization with Quantity Limit Program Summary

## POLICY REVIEW CYCLE

**Effective Date**  
11-01-2025

**Date of Origin**  
05-18-2023

## POLICY AGENT SUMMARY PRIOR AUTHORIZATION

| Target Brand Agent(s) | Target Generic Agent(s) | Strength | Targeted MSC  | Available MSC | Final Age Limit | Preferred Status |
|-----------------------|-------------------------|----------|---------------|---------------|-----------------|------------------|
| Skyclarys             | omaveloxolone cap       | 50 MG    | M ; N ; O ; Y | N             |                 |                  |

## POLICY AGENT SUMMARY QUANTITY LIMIT

| Target Brand Agent Name(s) | Target Generic Agent Name(s) | Strength | QL Amount | Dose Form | Day Supply | Duration | Addtl QL Info | Allowed Exceptions | Targeted NDCs When Exclusions Exist |
|----------------------------|------------------------------|----------|-----------|-----------|------------|----------|---------------|--------------------|-------------------------------------|
| Skyclarys                  | omaveloxolone cap            | 50 MG    | 90        | Capsules  | 30         | DAYS     |               |                    |                                     |

## CLIENT SUMMARY – PRIOR AUTHORIZATION

| Target Brand Agent Name(s) | Target Generic Agent Name(s) | Strength | Client Formulary  |
|----------------------------|------------------------------|----------|---|
| Skyclarys                  | omaveloxolone cap            | 50 MG    | IL HMO Performance Annual ; Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Annual 2024 ; HIM Quarterly 2024 ; HIM Quarterly 2025 ; HIM Quarterly 2026 ; IL HIM Annual 2025 ; IL HIM Annual 2026 ; IL non-HMO Performance Full ; Jade ; MT Performance Full ; OK Performance Full ; Performance ; Performance Annual ; Performance Biosimilar ; Performance Select ; Performance Select Biosimilar ; TX HIM Annual 2025 ; TX HIM Annual 2026 ; Topaz ; Whole Foods |

## CLIENT SUMMARY – QUANTITY LIMITS

| Target Brand Agent Name(s) | Target Generic Agent Name(s) | Strength | Client Formulary   |
|----------------------------|------------------------------|----------|--|
| Skyclarys                  | omaveloxolone cap            | 50 MG    | IL HMO Performance Annual ; Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Annual 2024 ; HIM Quarterly 2024 ; HIM Quarterly 2025 ; HIM Quarterly 2026 ; IL HIM Annual 2025 ; IL HIM Annual 2026 ; IL non-HMO Performance Full ; Jade ; MT Performance Full ; NM HIM Annual 2024 ; NM HIM Annual 2025 ; NM HIM Annual 2026 ; NM Performance Full ; OK Performance Full ; Performance ; Performance Annual ; Performance Biosimilar ; Performance Select ; Performance Select Biosimilar ; TX HIM Annual 2025 ; TX HIM Annual 2026 ; Topaz ; Whole Foods |

## PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

| Module | Clinical Criteria for Approval   |
|--------|--|
|        | <p><b>Initial Evaluation</b></p> <p><b>Target Agent(s)</b> will be approved when ALL of the following are met:</p> <ol style="list-style-type: none"> <li>1. BOTH of the following: <ol style="list-style-type: none"> <li>A. The patient has a diagnosis of Friedreich ataxia (FA, FRDA) with genetic analysis confirming mutation in the frataxin (FXN) gene [chart notes required] <b>AND</b></li> <li>B. If the patient has an FDA labeled indication, then ONE of the following: <ol style="list-style-type: none"> <li>1. The patient’s age is within FDA labeling for the requested indication for the requested agent <b>OR</b></li> <li>2. There is support for using the requested agent for the patient’s age for the requested indication <b>AND</b></li> </ol> </li> </ol> </li> <li>2. The prescriber is a specialist in the area of the patient’s diagnosis (e.g., cardiologist, geneticist, neurologist), or the prescriber has consulted with a specialist in the area of the patient’s diagnosis <b>AND</b></li> <li>3. The patient does NOT have any FDA labeled contraindications to the requested agent</li> </ol> <p><b>Length of Approval:</b></p> <p>BCBSOK: 36 months</p> <p>ALL other plans: 12 months</p> <p>NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.</p> <p><b>The requested agent will also be approved when the following are met:</b></p> <ol style="list-style-type: none"> <li>1. The member resides in Ohio <b>AND</b></li> <li>2. The plan is Fully Insured or HIM Shop (SG) <b>AND</b> BOTH of the following</li> </ol> |

| Module | Clinical Criteria for Approval   |
|--------|--|
|        | <p>A. The patient does NOT have any FDA labeled contraindications to the requested agent <b>AND</b></p> <p>B. ONE of the following:</p> <ol style="list-style-type: none"> <li>1. The patient has another FDA labeled indication for the requested agent and route of administration <b>OR</b></li> <li>2. The patient has another indication that is supported in compendia for the requested agent and route of administration <b>OR</b></li> <li>3. The prescriber has submitted TWO articles from major peer-reviewed professional medical journals [e.g., Journal of American Medical Association (JAMA), New England Journal of Medicine (NEJM), Lancet] supporting the proposed use(s) as generally safe and effective. Accepted study designs may include, but are not limited to, randomized, double blind, placebo controlled clinical trials. NOTE: Case studies are not acceptable [journal articles required]</li> </ol> <p><b>Non-oncology compendia allowed:</b> DrugDex level 1, 2A or 2B, AHFS-DI (narrative text must be supportive)</p> <p><b>Oncology compendia allowed:</b> NCCN 1 or 2A, AHFS-DI (narrative text must be supportive), DrugDex level 1, 2A, or 2B, or Clinical Pharmacology (narrative text must be supportive), Lexi-Drugs evidence level A, peer-reviewed medical literature</p> <p><b>Length of Approval:</b></p> <p>BCBSOK: 36 months</p> <p>ALL other plans: 12 months</p> <p>NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria</p> <p><b>Renewal Evaluation</b></p> <p><b>Target Agent(s)</b> will be approved when ALL of the following are met:</p> <ol style="list-style-type: none"> <li>1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process [Note: patients not previously approved for the requested agent will require initial evaluation review] <b>AND</b></li> <li>2. The patient has had clinical benefit with the requested agent <b>AND</b></li> <li>3. The prescriber is a specialist in the area of the patient's diagnosis (e.g., cardiologist, geneticist, neurologist), or the prescriber has consulted with a specialist in the area of the patient's diagnosis <b>AND</b></li> <li>4. The patient does NOT have any FDA labeled contraindications to the requested agent</li> </ol> <p><b>Length of Approval:</b></p> <p>BCBSOK: 36 months</p> <p>ALL other plans: 12 months</p> <p>NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.</p> |

## QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

| Module | Clinical Criteria for Approval  |
|--------|---|
|        | <p><b>Quantity Limit for the Target Agent(s)</b> will be approved when ONE of the following is met:</p> |

| Module | Clinical Criteria for Approval  |
|--------|---|
|        | <ol style="list-style-type: none"> <li>1. The requested quantity (dose) does NOT exceed the program quantity limit <b>OR</b></li> <li>2. The requested quantity (dose) exceeds the program quantity limit AND ONE of the following: <ol style="list-style-type: none"> <li>A. BOTH of the following: <ol style="list-style-type: none"> <li>1. The requested agent does NOT have a maximum FDA labeled dose for the requested indication <b>AND</b></li> <li>2. There is support for therapy with a higher dose for the requested indication <b>OR</b></li> </ol> </li> <li>B. BOTH of the following: <ol style="list-style-type: none"> <li>1. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication <b>AND</b></li> <li>2. There is support for why the requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does NOT exceed the program quantity limit <b>OR</b></li> </ol> </li> <li>C. BOTH of the following: <ol style="list-style-type: none"> <li>1. The requested quantity (dose) exceeds the maximum FDA labeled dose for the requested indication <b>AND</b></li> <li>2. There is support for therapy with a higher dose for the requested indication</li> </ol> </li> </ol> </li> </ol> <p><b>Length of Approval:</b> 12 months</p> |