

Skyclarys (omaveloxolone)
Effective 09/01/2023

Plan	<input type="checkbox"/> MassHealth UPPL <input checked="" type="checkbox"/> Commercial/Exchange	Program Type	<input checked="" type="checkbox"/> Prior Authorization <input type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy
Benefit	<input checked="" type="checkbox"/> Pharmacy Benefit <input type="checkbox"/> Medical Benefit		
Specialty Limitations	This medication has been designated specialty and must be filled at a contracted specialty pharmacy.		
Contact Information	Medical Benefit	Phone: 833-895-2611	Fax: 888-656-6671
	Pharmacy Benefit	Phone: 800-711-4555	Fax: 844-403-1029
Exceptions	N/A		

Overview

Skyclarys is indicated for the treatment of Friedreich's ataxia in adults and adolescents aged 16 years and older.

Coverage Guidelines

Authorization may be granted for members new to General Brigham Health Plan who are currently receiving treatment with Skyclarys excluding when the product is obtained as samples or via manufacturer's patient assistance programs.

OR

Authorization may be granted for members meeting ALL the following criteria:

1. Member has a diagnosis of Friedreich's ataxia
2. Medical records confirming a mutation of the FXN gene
3. Medical record documentation confirming the member demonstrates clinical manifestations of disease (e.g., muscle weakness, decline in coordination, frequent falling)
4. Member is 16 years of age or older

Continuation of Therapy

Authorization of 12 months may be granted for continued treatment of Friedreich's ataxia when the disease has improved or stabilized (e.g., improvement in speech or swallowing, upper/lower limb coordination, upright stability).

Limitations

1. Initial approvals and reauthorizations will be granted for 12 months.
2. The following quantity limits apply:

Skyclarys 50mg	90 capsules per 30 days
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References

1. Skyclarys [package insert]. Plano, TX: Reata Pharmaceuticals, Inc.; February 2023.
2. Bidichandani SI, Duncan CG. Friedreich's ataxia - symptoms, causes, treatment: NORD. National Organization for Rare Disorders. <https://rarediseases.org/rare-diseases/friedreichs-ataxia/>. Published January 25, 2023. Accessed March 9, 2023.

Review History

07/12/2023 - Reviewed at July P&T, Effective 9/1/23

