

Clinical Policy Title:	berotralstat
Policy Number:	RxA.861
Drug(s) Applied:	Orladeyo®
Original Policy Date:	10/11/2024
Last Review Date:	12/11/2025
Line of Business Policy Applies to:	All lines of business (except Medicare)

Criteria

I. Initial Approval Criteria

A. Hereditary Angioedema (must meet all):

1. Diagnosis of HAE confirmed by one of the following (a or b):
 - a. Low C1-INH antigenic or functional level
 - b. Normal C1-INH levels, and at least one of the following (i or ii):
 - i. Presence of a mutation associated with the disease;
 - ii. Recurring angioedema attacks that are refractory to high-dose antihistamine therapy (i.e., cetirizine 40 mg/day or equivalent) for at least 1 month.
2. Prescribed for the prophylaxis of HAE attacks.

Approval Duration

All Lines of Business (except Medicare): 12 months

II. Continued Therapy Approval

A. Hereditary Angioedema (must meet all):

1. Auto-approval based on lookback functionality within the past 120 days as a proxy for member responding positively to therapy

Approval Duration

All Lines of Business (except Medicare): 12 months

References

1. Orladeyo Prescribing Information. Durham, NC: BioCryst Pharmaceuticals, Inc.; November 2023. Available at: <https://orladeyo.com/>. Accessed October 11, 2024.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	10/11/2024	12/05/2024
Policy reviewed	12/11/2025	12/11/2025

This clinical policy has been developed to authorize, modify, or determine coverage for individuals with similar conditions. Specific care and treatment may vary depending on individual need and benefits covered by the plan. This policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. This document may contain prescription brand name drugs that are trademarks of pharmaceutical manufacturers that are not affiliated with RxAdvance.