

BEROTRALSTAT



Included Products: ORLADEYO (BEROTRALSTAT)

Created: 03/11/2021

Revised: 03/13/2025

Reviewed: 03/13/2025

Updated: 04/01/2025

All Diagnoses

Initial Criteria: All Diagnoses		If yes	If no
1.	Does the member have a diagnosis of hereditary angioedema (HAE) confirmed by genetic testing or normal C1q lab levels with levels below the lab's normal reference range for both C4 and C1INH?	Continue to #2.	Do not approve.
2.	Does the member have a history of attacks that are considered severe with swelling of the face, throat or gastrointestinal tract that significantly interrupts usual daily activity despite short-term symptomatic treatment?	Continue to #3.	Do not approve.
3.	Has the member been evaluated for triggers of HAE attacks and is maximally managed for avoidance of those triggers (such as stress, hormonal changes, dental surgery, trauma, medications including ACE inhibitors and estrogen)?	Continue to #4.	Do not approve.
4.	Is treatment with acute, abortive therapy an option for this member (Firazyr, Berinert)?	Do not approve.	Continue to #5.
5.	Has the member tried and failed Cinryze IV, Haegarda, and Takhzyro?	Continue to #6.	Do not approve.
6.	All approvals subject to medical director review. Initial approval duration of 6 months.		
Renewal Criteria		If yes	If no
1.	Has there been at least a 50% reduction in the number of angioedema attacks, significant improvement in the severity and duration of attacks, and clinical documentation of functional improvement?	Continue to #2.	Do not approve.
2.	Approve for 12 months.		