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Prior Authorization Guideline

Guideline Name	Orladeyo (berotralstat)

Guideline Note:

Effective Date:	7/1/2026

1 . Criteria

Product Name:Orladeyo	
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - 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

AND

2 - Patient has 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

AND

3 - Patient has 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)

AND

4 - Treatment with acute, abortive therapy is not an option for the patient (Firazyr, Berinert)

AND

5 - Patient has tried and failed Cinryze IV, Haegarda, and Takhzyro

Product Name:Orladeyo	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - There has 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