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Prior Authorization Guideline

Guideline Name	Takhzyro (lanadelumab-flyo)

Guideline Note:

Effective Date:	7/1/2026

1 . Criteria

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

Approval Criteria

1 - Diagnosis of hereditary angioedema (HAE) confirmed by one of the following:

- genetic testing
- normal C1q lab levels with levels below the lab's normal reference range for both C4 and C1INH

AND

2 - 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 (e.g., Firazyr, Berinert) is NOT an option for the patient

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

Approval Criteria

1 - Both of the following:

1.1 Patient has been attack free for greater than 6 months

AND

1.2 One of the following:

- Request is for the extended dosing interval of 300mg every 4 weeks
- Submission of medical records (e.g., chart notes) documenting clinical rationale for keeping the dosing interval at every 2 weeks

OR

2 - Submission of medical records (e.g., chart notes) demonstrating at least a 50% reduction in the number of angioedema attacks, significant improvement in the severity of attacks, and clinical documentation of functional improvement