Lanadelumab

Included Products: Takhzyro (lanadelumab-flyo)

Created: 01/10/2019 *Revised:* 03/11/2021 *Reviewed:* 03/09/2023 *Updated:* 04/01/2023

All Diagnoses			
Initial Criteria		**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 at least two attacks per month which 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.	All approvals subject to medical director review.		
Renewal Criteria		**If yes**	**If no**
1.	Has the patient been attack free for greater than 6 months?	Continue to #2.	Continue to #3.

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2.	Is the request for the extended dosing interval of 300 mg every 4 weeks or is there a statement explaining why they wish to keep the dosing interval every 2 weeks?	Approve for 12 months.	Pend for documentation of why 4-week interval would not be appropriate.
3.	Has there been at least a 50% reduction in the number of angioedema attacks, significant improvement in the severity of attacks, and clinical documentation of functional improvement?	Approve for 6 months.	Do not approve.