LANADELUMAB

Generic	Brand	HICL	GCN	Exception/Other
LANADELUMAB-FLYO	TAKHZYRO	45177		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of hereditary angioedema (HAE) and meet **ALL** of the following criteria?
   - Diagnosis of HAE is confirmed via complement testing
   - The medication is being used for prophylaxis to prevent HAE attacks
   - The patient is 12 years of age or older
   - The medication is prescribed by or in consultation with an allergist/immunologist or hematologist

   If yes, **approve for 12 months by HICL with a quantity limit of #4mL per 28 days.**
   APPROVAL TEXT: Renewal requires physician attestation of improvement (i.e., reductions in attack frequency or attack severity) compared to baseline in HAE attacks with routine prophylaxis.

   If no, do not approve.
   INITIAL DENIAL TEXT: The guideline named **LANADELUMAB (Takhzyro)** requires a diagnosis of hereditary angioedema (HAE). Additionally, the following criteria must be met:
   - Diagnosis of HAE is confirmed via complement testing
   - The medication is being used for prophylaxis to prevent HAE attacks
   - The patient is 12 years of age or older
   - The medication is prescribed by or in consultation with an allergist/immunologist or hematologist

RENEWAL CRITERIA

1. Does the patient have a diagnosis of hereditary angioedema (HAE) and meet the following criteria?
   - Physician attestation of improvement (i.e., reductions in attack frequency or attack severity) compared to baseline in HAE attacks with routine prophylaxis

   If yes, **approve for 12 months by HICL with a quantity limit of #4mL per 28 days.**
   If no, do not approve.
   RENEWAL DENIAL TEXT: The guideline named **LANADELUMAB (Takhzyro)** requires a diagnosis of hereditary angioedema (HAE) for renewal. The following criteria must also be met:
   - Physician attestation of improvement (i.e., reductions in attack frequency or attack severity) compared to baseline in HAE attacks with routine prophylaxis

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RATIONALE
Ensure appropriate utilization of LANADELUMAB (Takhzyro) based on FDA-approved indication and clinical trial design.

FDA APPROVED INDICATIONS
Takhzyro is a plasma kallikrein inhibitor (monoclonal antibody) indicated for prophylaxis to prevent attacks of hereditary angioedema (HAE) in patients 12 years and older.

DOSING AND ADMINISTRATION
The recommended starting dosage of Takhzyro is 300 mg given subcutaneously every 2 weeks. A dosing interval of 300 mg every 4 weeks is also effective and may be considered if the patient is well-controlled (e.g., attack-free) for more than 6 months.

Takhzyro should be administered subcutaneously into the abdomen, thigh, or upper arm and is provided as a ready-to-use solution in a single-dose vial that does not require additional reconstitution or dilution for administration. Takhzyro is intended for self-administration or administration by a caregiver, following training by a healthcare professional. In clinical studies, the majority of patients self-administered Takhzyro over 10 to 60 seconds.

REFERENCES

- Takhzyro [Prescribing Information]. Lexington, MA: Dyax Corp.; August 2018.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 09/24/18
Created: 09/18
Client Approval: 09/18
P&T Approval: 07/18