



STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

LANADELUMAB-FLYO

| Generic | Brand | HICL | GCN | Medi-Span | Exception/Other |
|------------------|----------|-------|-----|---------------------|-----------------|
| LANADELUMAB-FLYO | TAKHZYRO | 45177 | | GPI-10 (8584204020) | |

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?
 - The patient is 2 years of age or older
 - Therapy is prescribed by or in consultation with an allergist, immunologist or hematologist
 - The patient's diagnosis of HAE is confirmed via documentation (e.g., chart note, lab result, diagnostic test result, etc.) of complement testing
 - Takhzyro is being used for prophylaxis against HAE attacks
 - The patient is NOT on concurrent treatment with alternative prophylactic agent for HAE (e.g., Cinryze, Haegarda, danazol, berotralstat)

If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #4mL per 28 days.**
APPROVAL TEXT: Prescriber may consider a dosing interval of every 4 weeks if the patient is well-controlled for more than six months.

If no, do not approve.

INITIAL DENIAL TEXT: ***Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.**

Our guideline named **LANADELUMAB-FLYO (Takhzyro)** requires the following rule(s) be met for approval:

- A. You have hereditary angioedema (HAE: a type of gene condition with severe body swelling)
- B. You are 2 years of age or older
- C. Therapy is prescribed by or in consultation with an allergist, immunologist (allergy or immune system doctor) or hematologist (blood doctor)
- D. Your diagnosis is confirmed by documentation (such as chart note, lab result, diagnostic test result) of complement testing (a type of blood test)
- E. Takhzyro is being used for prevention of hereditary angioedema attacks
- F. You will NOT be using Takhzyro concurrently (at the same time) with an alternative preventive agent for HAE (such as Cinryze, Haegarda, danazol, berotralstat)

Your doctor told us **[INSERT PT SPECIFIC INFO PROVIDED]**. We do not have information showing you **[INSERT UNMET CRITERIA]**. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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LANADELUMAB-FLYO

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of hereditary angioedema (HAE) and meet **ALL** of the following criteria?

- The patient has experienced improvement (i.e., reductions in attack frequency or attack severity) compared to baseline in HAE attacks
- The patient is NOT on concurrent treatment with alternative prophylactic agent for HAE (e.g., Cinryze, Haegarda, danazol, berotralstat)

If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #4mL per 28 days.**

APPROVAL TEXT: Prescriber may consider a dosing interval of every 4 weeks if the patient is well-controlled for more than six months.

If no, do not approve.

RENEWAL DENIAL TEXT: ***Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.**

Our guideline named **LANADELUMAB-FLYO (Takhzyro)** requires the following rule(s) be met for renewal:

- A. You have hereditary angioedema (HAE: a type of gene condition with severe body swelling)
- B. You have experienced improvement (reductions in attack frequency or attack severity) compared to baseline in hereditary angioedema attacks
- C. You will NOT be using Takhzyro concurrently (at the same time) with an alternative preventive agent for HAE (such as Cinryze, Haegarda, danazol, berotralstat)

Your doctor told us **[INSERT PT SPECIFIC INFO PROVIDED]**. We do not have information showing you **[INSERT UNMET CRITERIA]**. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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LANADELUMAB-FLYO

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Takhzyro.

REFERENCES

- Takhzyro [Prescribing Information]. Lexington, MA: Dyax Corp.; February 2023.

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|---------|------------|-----|
| Library | Commercial | NSA |
| Yes | Yes | No |

Part D Effective: N/A

Commercial Effective: 04/10/23

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P&T Approval: 04/23