

UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2021 P 1263-4
Program	Prior Authorization/Notification
Medication	Takhzyro™ (lanadelumab-flyo)
P&T Approval Date	11/10218, 11/2019, 11/2020, 11/2021
Effective Date	2/1/2022; Oxford only: N/A

1. Background:

Takhzyro is a plasma kallikrein inhibitor (monoclonal antibody) indicated for prophylaxis to prevent attacks of hereditary angioedema (HAE) in patients 12 years and older.¹

2. Coverage Criteria:

A. Hereditary Angioedema

1. Initial Authorization

a. Takhzyro will be approved based on **both** of the following criteria:

(1) Diagnosis of hereditary angioedema (HAE)

-AND-

(2) **Both** of the following:

(a) For prophylaxis against HAE attacks

-AND-

(b) Not used in combination with other approved agents for prophylaxis against HAE attacks (e.g. Cinryze, Haegarda, Orladeyo)

Authorization of therapy will be issued for 12 months.

2. Reauthorization

a. Takhzyro will be approved based on **both** of the following criteria:

(1) Documentation of positive clinical response while on Takhzyro therapy

-AND-

b. **Both** of the following:

(1) For prophylaxis against HAE attacks

-AND-

(2) Not used in combination with other approved agents for prophylaxis against HAE attacks (e.g. Cinryze, Haegarda, Orladeyo)

Authorization of therapy will be issued for 12 months.

3. Additional Clinical Programs:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4. References:

1. Takhzyro [package insert]. Lexington, MA: Shire; November 2018.

Program	Takhzyro™ (lanadelumab-flyo)
Change Control	
11/2018	New program
11/2019	Annual review. Updated references.
11/2020	Annual review. No changes.
11/2021	Annual review. Updated combination examples to include Orladeyo with no change in clinical intent.