UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2024 P 1263-7
Program	Prior Authorization/Notification
Medication	Takhzyro® (lanadelumab-flyo)
P&T Approval Date	11/10218, 11/2019, 11/2020, 11/2021, 11/2022, 3/2023, 3/2024
Effective Date	6/1/2024

1. Background:
Takhzyro is a plasma kallikrein inhibitor (monoclonal antibody) indicated for prophylaxis to prevent attacks of hereditary angioedema (HAE) in adult and pediatric patients 2 years and older.[1]

2. Coverage Criteria[a]:

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 products indicated 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 products indicated for prophylaxis against HAE attacks (e.g., Cinryze, Haegarda, Orladeyo)

Authorization of therapy will be issued for 12 months.

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

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; February 2023.

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.
11/2022	Annual review with no change to criteria. Added state mandate footnote. Updated reference.
3/2023	Updated background with expanded FDA indication in patients aged 2 years and older. Updated combination use language with prophylactic therapies without change to clinical intent. Updated reference.
3/2024	Annual review. No changes to coverage criteria.