



UnitedHealthcare Pharmacy  
Clinical Pharmacy Programs

Program Number	2023 P 1263-6
Program	Prior Authorization/Notification
Medication	Takhzyro <sup>®</sup> (lanadelumab-flyo)
P&T Approval Date	11/10218, 11/2019, 11/2020, 11/2021, 11/2022, 3/2023
Effective Date	6/1/2023; 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 adult and pediatric patients 2 years and older.<sup>1</sup>

**2. Coverage Criteria<sup>a</sup>:**

**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.**

<sup>a</sup> 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 <sup>®</sup> (lanadelumab-flyo)
<b>Change Control</b>	
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.