UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Takhzyro

Program	Prior Authorization
Medication	Takhzyro™ (lanadelumab-flyo)
Markets in Scope	Arizona, California, Hawaii, Maryland, Nevada, New Jersey, New York, New York EPP, Pennsylvania- CHIP, Rhode Island, South Carolina
Issue Date	11/2018
Pharmacy and Therapeutics Approval Date	7/2020
Effective Date	9/2020

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.

2. Coverage Criteria:

A. <u>Initial Authorization</u>

1. Takhzyro will be approved based on **<u>all</u>** of the following criteria:

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a. Diagnosis of hereditary angioedema (HAE) as confirmed by **one** of the following:

(1) C1 inhibitor (C1-INH) deficiency or dysfunction (Type I or II HAE) as documented by **one** of the following (per laboratory standard):
(a) C1-INH antigenic level below the lower limit of normal
(b) C1-INH functional level below the lower limit of normal

-OR-

(2) HAE with normal C1 inhibitor levels and **one** of the following:
(a) Confirmed presence of a FXII, angiopoietin-1 or plasminogen gene mutation
(b) Recurring angioedema attacks that are refractory to high-dose antihistamines with confirmed family history of angioedema

-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)

-AND-

c. **Both** of the following:

(1) Prescriber attests that patient has experienced attacks of a severity and/or frequency such that they would clinically benefit from prophylactic therapy with Takhzyro

-AND-

(2) Documentation of baseline HAE attack rate is greater than or equal to one attack per 4 weeks.

-AND-

d. Prescribed by **one** of the following:

(1) Immunologist
(2) Allergist

-AND-

e. **One** of the following:

(1) History of failure, contraindication, or intolerance to Haegarda

-OR-

(2) Patient is currently on Takhzyro therapy

Authorization of Takhzyro 300mg given every 2 weeks therapy will be issued for 8 months.

B. Reauthorization

1. Takhzyro will be approved based on **all** of the following criteria:

a. Documentation of positive clinical response, defined as a clinically significant reduction in the rate and/or number of HAE attacks, while on Takhzyro therapy

-AND-

b. Reduction in the utilization of on-demand therapies used for acute attacks (e.g., Berinert, Ruconest, Firazyr, Kalbitor) as determined by claims information, while on Takhzyro therapy

-AND-

c. Prescribed by **one** of the following:

(1) Immunologist
(2) Allergist

-AND-

d. **All** 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)

-AND-

e.. Documentation of the number of acute HAE attacks in the previous 6 months, while on Takhzyro therapy, therefore:

(1) Patient experienced no (zero) acute HAE attacks in the previous 6 months: **Authorization of Takhzyro 300mg given every 4 weeks for 12 months***
(2) Patient experienced one or more acute HAE attacks in the previous 6 months: **Authorization of Takhzyro 300mg given every 2 weeks for 6 months**

*Patients experiencing unexpected breakthrough HAE attacks once switched to every 4 week dosing will require additional review to allow for 2 weeks dosing.

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: Dyax Corp; November 2018.
2. Riedl MA, Bernstein JA, Craig T, et al. An open-label study to evaluate the long-term safety and efficacy of lanadelumab for prevention of attacks in hereditary angioedema: design of the HELP study extension. Clin Transl Allergy. 2017 Oct 6;7:36.
3. Maurer M, Magerl M, Ansotegui I, et al. The international WAO/EAACI guideline for the management of hereditary angioedema-The 2017 revision and update. Allergy. 2018 Jan 10.
4. Wu, E. Hereditary angioedema with normal C1 inhibitor. In: UpToDate, Saini, S (Ed), UpToDate, Waltham, MA, 2020.

Program	Prior Authorization
Change Control	
Date	Change
11/2018	New program
7/2019	Added step through Haegarda since it is the preferred prophylaxis agent for HAE. Updated references.
7/2020	Annual review. Align criteria with acute and prophylactic therapies. Removed rheumatologist as required prescriber. Added Additional Clinical Programs section. Updated references.