Takhzyro (lanadelumab-flyo)
Effective 01/01/2021

Plan	☒ MassHealth ☐Commercial/Exchange	**Program Type**	☒ Prior Authorization ☒ Quantity Limit ☐ Step Therapy
Benefit	☒ Pharmacy Benefit ☐ Medical Benefit (NLX)		
Specialty Limitations	This medication has been designated specialty and must be filled at a contracted specialty pharmacy.		
Contact Information	**Specialty Medications**		
	All Plans	Phone: 866-814-5506	Fax: 866-249-6155
	Non-Specialty Medications		
	MassHealth	Phone: 877-433-7643	Fax: 866-255-7569
	Commercial	Phone: 800-294-5979	Fax: 888-836-0730
	Exchange	Phone: 855-582-2022	Fax: 855-245-2134
	Medical Specialty Medications (NLX)		
	All Plans	Phone: 844-345-2803	Fax: 844-851-0882
Exceptions	N/A		

Overview
Takhzyro (lanadelumab-flyo) is used to prevent attacks of hereditary angioedema (HAE) in adults and pediatric patients 12 years and older.

Coverage Guidelines
Authorization may be granted for members new to the plan who are currently receiving treatment with Takhzyro, excluding when the product is obtained as samples or via manufacturer's patient assistance programs.

OR

Authorization may be granted for members when ALL the following criteria are met, and documentation is provided:

1. The member will be using Takhzyro for the prevention of hereditary angioedema attacks
2. Takhzyro will not be used in combination with any medication used for the prophylaxis of HAE attacks.
3. Member meets ONE of the following:
    a. Member has C1 inhibitor deficiency or dysfunction as confirmed by laboratory testing and meets BOTH of the following criteria:
        i. Member has a C4 level below the lower limit of normal as defined by the laboratory performing the test
        ii. Member meets ONE of the following criteria:
            (a) C1 inhibitor (C1-INH) antigenic level below the lower limit of normal as defined by the laboratory performing the test
            (b) Normal C1-INH antigenic level and a low C1-INH functional level (functional C1-INH less than 50% or C1-INH functional level below the lower limit of normal as defined by the laboratory performing the test).

b. Member has normal C1 inhibitor as confirmed by laboratory testing and meets ONE of the following criteria:
    i. Member has an F12, angiopoietin-1, plasminogen, or kininogen-1 (KNG1) gene mutation as confirmed by genetic testing
    ii. Member has a documented family history of angioedema and the angioedema was refractory to a trial of high-dose antihistamine (e.g., cetirizine) for at least one month.

Continuation of Therapy

Reauthorization may be granted for members when ALL of the following are met, and documentation is provided:

1. Member meets all initial approval criteria.
2. Member has experienced a significant reduction in frequency of attacks (e.g. ≥ 50%) since starting treatment.
3. Member has reduced the use of medications to treat acute attacks.

Limitations

1. Initial approvals and reauthorizations will be for 6 months.
2. The following quantity limits apply:

References

1. Takhzyro [package insert]. Lexington, MA: Dyax Corp.; November 2018.
2. 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;73(8)1575-1596.
3. Henao MP, Kraschnewski J, Kelbel T, Craig T. Diagnosis and screening of patients with hereditary angioedema in primary care. *Therapeutics and Clin Risk Management.* 2016; 12: 701-711.
4. Bernstein, J. Severity of Hereditary Angioedema, Prevalence, and Diagnostic Considerations. *Am J Med.* 2018:24;292-298.
5. Busse PJ, Christiansen, SC, Riedl MA, et al. US HAEA Medical Advisory Board 2020 Guidelines for the Management of Hereditary Angioedema. *J Allergy Clin Immunol: In Practice.* 2021 Jan;9(1):132-150.e3.
6. Sharma J, Jindal AK, Banday AZ, et al. Pathophysiology of Hereditary Angioedema (HAE) Beyond the SERPING1 Gene [published online ahead of print, 2021 Jan 14] [published correction appears in Clin Rev Allergy Immunol. 2021 Feb 17]. *Clin Rev Allergy Immunol*. 2021;10.1007/s12016-021-08835-8. Doi:10.1007/s12016-021-08835-8.
7. Kanani, A., Schellenberg, R. & Warrington, R. Urticaria and angioedema. *All Asth Clin Immun* 7, S9 (2011), Table 2.

Review History

9/21/2022 – Created and Reviewed for Sept P&T; switched from SGM to custom. Separated out MH vs. Comm/Exch. Effective 1/1/2023

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