Reference number(s)
2671-A

ENHANCED SPECIALTY GUIDELINE MANAGEMENT

TAKHZYRO (lanadelumab-flyo)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indication
Prophylaxis to prevent attacks of hereditary angioedema (HAE) in patients 12 years of age and older

All other indications are considered experimental/investigational and are not a covered benefit.

II. DOCUMENTATION

Submission of the following information is necessary to initiate the prior authorization review:
A. C4 levels and C1 inhibitor functional and antigenic protein levels
B. F12, angiopoietin-1 or plasminogen gene mutation testing, if applicable
C. Chart notes confirming family history of angioedema, if applicable

III. CRITERIA FOR INITIAL APPROVAL

Authorization of 12 months may be granted for prevention of hereditary angioedema attacks when the requested medication will not be used in combination with Cinryze or Haegarda and either of the following criteria is met:
A. Member has C1 inhibitor deficiency or dysfunction as confirmed by laboratory testing:
    1. C1 inhibitor (C1-INH) antigenic level is below the lower limit of normal as defined by the laboratory performing the test or
    2. 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:
    1. Member has an F12, angiopoietin-1, or plasminogen gene mutation as confirmed by genetic testing, or
    2. 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.

IV. CONTINUATION OF THERAPY

Authorization of 12 months may be granted for continuation of therapy when all of the following criteria are met:
A. Member meets the criteria for initial approval.
B. Member has experienced reduction in frequency, severity, and/or duration of attacks since starting treatment.

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V. REFERENCES

1. Takhzyro [package insert]. Lexington, MA: Dyax Corp.; August 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;00:1-22.
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.