JOHNS HOPKINS MEDICINE JOHNS HOPKINS HEALTHCARE	Johns Hopkins HealthCare LLC **Pharmacy Public** **Pharmacy Management Drug Policies**	*Policy Number*	MEDS149
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	Subject **Takhzyro**	*Revision Date*	04/20/2022
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This document applies to the following Participating Organizations:

Priority Partners

Keywords: Takhzyro

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I. POLICY

A. Takhzyro (lanadelumab-flyo) will require prior authorization for appropriate use. The process for initiating a prior authorization request can be found in policy PHARM 20.
   1. PPMCO members are subject to the Priority Partners formulary, available at www.ppmco.org.
   2. USFHP members are subject to prior authorization criteria, step-edits and days-supply limits outlined in the Tricare Policy Manual. Tricare Policy supersedes JHHC Medical/Pharmacy Policies. Tricare limits may be accessed at: http://pec.ha.osd.mil/formulary_search.php?submenuheader=1

II. POLICY CRITERIA

A. **Takhzyro** may be approved for patients meeting the following:
   1. **Hereditary angioedema (HAE)**
      a. Patient is 12 years of age or older
      b. Documentation has been submitted showing the following:
         I. Takhzyro will be used as prophylaxis to prevent attacks of HAE
         II. Patient meets one of the following:
            i. Patient has C1 inhibitor deficiency, supported by laboratory test results, as well as one of the following:
               1. C1 inhibitor (C1-INH) antigenic level below the lower limit of normal as defined by laboratory test
               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 test)
            ii. Patient has normal C1 inhibitor, supported by laboratory test results, as well as one of the following:
               1. an F12, angiopoietin-1, plasminogen, or kininogen-1 (KNG1) gene mutation as confirmed by genetic testing
               2. 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

III. AUTHORIZATION PERIOD/LIMITATIONS

A. Initial approval will be limited to 6 months of therapy
B. Approval for continuation of therapy may be extended in 6-month intervals with documentation of the following:
   1. Patient has had a beneficial response to treatment, evidenced by the following:
      a. Significant reduction in frequency of attacks (e.g. ≥50%) since starting treatment
      b. Reduction in the use of medications to treat acute attacks
   2. Takhzyro is being dosed every 4 weeks, or dosing every 4 weeks has been considered if the patient is well-controlled on therapy.

IV. EXCLUSIONS

A. Takhzyro will not be approved for the following:
   1. Pediatric patients younger than 12 years of age
   2. Concurrent use with Cinryze or Haegarda
   3. Any indications or usage that is not FDA-approved, or guideline-supported
B. The use of physician samples, or manufacturer product discounts, does not guarantee coverage under the provisions of the medical and/or pharmacy benefit. All pertinent criteria must be met in order to be eligible for benefit coverage.

V. REFERENCES

1. Takhzyro [prescribing information]. Lexington, MA: Dyax Corp.; February 2022.
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.

VI. APPROVALS

Signature on file at JHHC

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