JOHNS HOPKINS HEALTH PLANS	Johns Hopkins Health Plans **Pharmacy Public** **Medical Management Drug Policies**	*Policy Number*	MMDP115
		Effective Date	01/15/2025
		Approval Date	07/17/2024
	Subject **Takhzyro**	*Supersedes Date*	N/A
		Page	1 of 3

This document applies to the following Participating Organizations:

US Family Health Plan

Keywords: Takhzyro

Table of Contents		Page Number
I.	POLICY	1
II.	POLICY CRITERIA	1
III.	AUTHORIZATION PERIOD/LIMITATIONS	2
IV.	EXCLUSIONS	2
V.	RECOMMENDED DOSE	2
VI.	CODES	2
VII.	REFERENCES	2
VIII.	APPROVALS	2

I. POLICY

A. Takhzyro (lanadelumab-flyo) will require prior authorization for medical benefit coverage to ensure appropriate use. The process for initiating a prior authorization request can be found in policy PHARM 20.

II. POLICY CRITERIA

A. Takhzyro may be approved for patients who meet the following:
   1. Hereditary angioedema (HAE)
      1. Documentation has been submitted showing all the following:
         1. Takhzyro will be used for prevention of hereditary angioedema attacks
         2. Takhzyro will not be used in combination with any other medication used for prophylaxis of HAE attacks
         3. Patient has one of the following:
            1. Patient has C1 inhibitor deficiency or dysfunction as confirmed by laboratory testing and meets one of the following:
               1. C1 inhibitor (C1-INH) antigenic level below the lower limit of normal as defined by the laboratory performing the 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 performing the test).
            2. Patient has normal C1 inhibitor as confirmed by laboratory testing and meets one of the following criteria:
               1. Patient has an F12, angiopoietin-1, plasminogen, kininogen-1 (KNG1), heparan sulfate-glucosamine3-O-sulfotransferase 6 (HS3ST6), or myoferlin (MYOF) gene mutation as confirmed by genetic testing
               2. Patient has a documented family history of angioedema and the angioedema was refractory to a trial of high-dose antihistamine therapy (i.e., cetirizine at 40 mg per day or the equivalent) for at least one month

III. AUTHORIZATION PERIOD/LIMITATIONS

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

IV. EXCLUSIONS

A. Takhzyro will not be covered for the following:
   1. Any indications or uses that are not FDA-approved, or guideline-supported

V. RECOMMENDED DOSE

Please refer to the FDA-approved prescribing information, or clinical guidelines, for indication-specific dosing details.

VI. CODES

Note: The following CPT/HCPCS codes are included below for informational purposes. Inclusion or exclusion of a CPT/HCPCS code(s) below does not signify or imply member coverage or provider reimbursement. The member's specific benefit plan determines coverage.

Medication	HCPCS/CPT Code
Injection, lanadelumab-flyo, 1 mg	J0593

VII. REFERENCES

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VIII. APPROVALS

Signature on file at JHHP

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		Page	3 of 3

DATE OF REVISION	SUMMARY OF CHANGE
07/17/2024	Policy creation
01/15/2025	Removed prescriber specialty requirement

Review Date: 07/17/2024

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