Takhzyro™ (lanadelumab-flyo)
(Subcutaneous)

Document Number: IC-0392

Last Review Date: 10/02/2018
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Dates Reviewed: 10/2018

I. Length of Authorization

Coverage will be provided for 6 months and may be renewed.

II. Dosing Limits

A. Quantity Limit (max daily dose) [Pharmacy Benefit]:

- Takhzyro 300 mg/2 mL SDV: 1 vial every 14 days

B. Max Units (per dose and over time) [Medical Benefit]:

- 300 mg per 14 days

III. Initial Approval Criteria

Coverage is provided in the following conditions:

Prophylaxis to prevent Hereditary Angioedema (HAE) attacks †

- Must be prescribed by, or in consultation with, a specialist in: allergy, immunology, hematology, pulmonology, or medical genetics; **AND**
- Patient must be at least 12 years of age; **AND**
- Patient has a history of one of the following criteria for long-term HAE prophylaxis:
  - History of two (2) or more severe HAE attacks per month (i.e., airway swelling, debilitating cutaneous or gastrointestinal episodes); **OR**
  - Patient is disabled more than 5 days per month by HAE; **OR**
  - History of at least one laryngeal attacks caused by HAE; **AND**
- Treatment of patient with "on-demand" therapy (i.e., Kalbitor, Firazyr, Ruconest, or Berinert) did not provide satisfactory control or access to "on-demand therapy" is limited; **AND**
- Not used in combination with C1 inhibitor prophylaxis (e.g., Cinryze or Haegarda); **AND**
- Confirmation the patient is avoiding the following possible triggers for HAE attacks:
  - Estrogen-containing oral contraceptive agents AND hormone replacement therapy
  - Antihypertensive agents containing ACE inhibitors; **AND**

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- Patient has one of the following clinical presentations consistent with HAE subtype, which must be confirmed by repeat blood testing:

HAE I (C1-Inhibitor deficiency)

• Low C1 inhibitor (C1-INH) antigenic level (C1-INH antigenic level below the lower limit of normal as defined by the laboratory performing the test); **AND**
• Low C4 level (C4 below the lower limit of normal as defined by the laboratory performing the test); **AND**
• Low C1-INH functional level (C1-INH functional level below the lower limit of normal as defined by the laboratory performing the test); **AND**
    o Patient has a family history of HAE; **OR**
    o Onset of HAE symptoms occurred before age 30; **OR**
    o Normal C1q level

HAE II (C1-Inhibitor dysfunction)
• Normal to elevated C1-INH antigenic level; **AND** • Low C4 level (C4 below the lower limit of normal as defined by the laboratory performing the test); **AND** • Low C1-INH functional level (C1-INH functional level below the lower limit of normal as defined by the laboratory performing the test)
HAE with normal C1INH (formerly known as HAE III)
• Prophylaxis for HAE with normal C1-INH is not routinely recommended and will be evaluated on a case by case basis

† FDA Approved Indication(s)

IV. Renewal Criteria

Coverage can be renewed based upon the following criteria:

- Patient continues to meet the criteria identified in section III; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: severe hypersensitivity reactions, etc.; **AND**
- Significant improvement in severity and duration of attacks have been achieved and sustained; **AND**
- Patients who have demonstrated improvement/stabilization of disease and are well-controlled (e.g., attack free) for at least 6 months should attempt a trial of every 4 week dosing.

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V. Dosage/Administration

Indication	Dose
Prophylaxis of Hereditary Angioedema (HAE) attacks	Administer 300 mg subcutaneously every 2 weeks. – *A dosing interval of 300 mg every 4 weeks is also effective and may be considered if the patient is well-controlled (e.g., attack free) for more than 6 months.*

VI. Billing Code/Availability Information

Jcode:

- J3590 – Unclassified Biologics
- C9399 – Unclassified drugs or biologicals (HOPPS only)

NDC:

- Takhzyro 300 mg/2 mL single-use vial: 47783-0644-xx

VII. References

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Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
D84.1	Defects in the complement system

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD): N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp

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Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto Government Benefit Administrators, LLC
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA, LLC
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC

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