

| Market Applicability | | | | | | | | | | | | | | |
|----------------------|----|----------|--------|--------|----|----|----|----|----|----|----|----|----|----|
| Market | DC | FL & FHK | FL MMA | FL LTC | GA | KS | KY | MD | NJ | NV | NY | TN | TX | WA |
| Applicable | X | X | NA | NA | X | NA | X | X | X | X | X | NA | NA | X |

*FHK- Florida Healthy Kids

Takhzyro (lanadelumab-flyo)

| Override(s) | Approval Duration |
|---------------------------------------|-------------------|
| Prior Authorization Quantity Limit | 1 year |

| Medications | Quantity Limit |
|-----------------------------|----------------------------------|
| Takhzyro (lanadelumab-flyo) | May be subject to quantity limit |

APPROVAL CRITERIA

Requests for Takhzyro (lanadelumab-flyo) may be approved if the following criteria are met:

- I. Individual is 12 years of age or older; **AND**
- II. Individual has a diagnosis of hereditary angioedema; **AND**
- III. Individual is using for prophylaxis against acute attacks of hereditary angioedema for either of the following:
 - A. Short-term prophylaxis prior to surgery, dental procedures or intubation; **OR**
 - B. Long-term prophylaxis and the individual has failed, or is intolerant to, or has a contraindication (such as pregnant, or breastfeeding) to 17 alpha-alkylated androgens (for example, danazol) or antifibrinolytic agents (for example, aminocaproic acid);

AND

- IV. Diagnosis is confirmed by a C4 level below the lower limit of normal as defined by laboratory test **AND** any of the following:
 - A. C1 inhibitor (C1-INH) antigenic level below the lower limit of normal as defined by the laboratory performing the test with documentation provided; **OR**
 - B. C1-INH functional level below the lower limit of normal as defined by the laboratory performing the test with documentation provided; **OR**
 - C. Presence of a known HAE-causing C1-INH mutation;

AND

- V. Individual has a history of moderate or severe attacks such as airway swelling, severe abdominal pain, facial swelling, nausea and vomiting, painful facial distortion.

This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.

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| Applicable | X | X | NA | NA | X | NA | X | X | X | X | X | NA | NA | X |

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| State Specific Mandates | | |
|-------------------------|-----------------------|--|
| State name N/A | Date effective N/A | Mandate details (including specific bill if applicable) N/A |

Key References:

Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2018. URL: <http://www.clinicalpharmacology.com>. Updated periodically.

DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/daily_med/about.cfm.

DrugPoints® System (electronic version). Truven Health Analytics, Greenwood Village, CO. Updated periodically.

Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2018; Updated periodically.

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