SENTARA HEALTH PLANS

MEDICAL PRIOR AUTHORIZATION/STEP-EDIT REQUEST*

Directions: The prescribing physician must sign and clearly print name (preprinted stamps not valid) on this request. All other information may be filled in by office staff; **fax to 1-844-668-1550**. No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. **If information provided is not complete, correct, or legible, authorization can be delayed**.

For Medicare Members: 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: https://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx. Additional indications may be covered at the discretion of the health plan.

Prophylaxis Hereditary Angioedema (HAE) (Medical)

Drug Requested: (select one drug below)

❑ **Andembry®** (garadacimab-gxii) **(J3590)**	❑ **Haegarda®** (C1 Esterase Inhibitor Human) **(J0599)**
❑ **Cinryze®** (C1 Esterase Inhibitor Human) **(J0598)**	❑ **Takhzyro™** (lanadelumab) **(J0593)**

MEMBER & PRESCRIBER INFORMATION: Authorization may be delayed if incomplete.

Member Name: ______________________________

Member Sentara #: ____________________ **Date of Birth:** ____________

Prescriber Name: ______________________________

Prescriber Signature: ____________________ **Date:** ____________

Office Contact Name: ______________________________

Phone Number: ____________________ **Fax Number:** ____________

NPI #: ______________________________

DRUG INFORMATION: Authorization may be delayed if incomplete.

Drug Form/Strength: ______________________________

Dosing Schedule: ____________________ **Length of Therapy**: ____________

Diagnosis: ____________________ **ICD Code, if applicable:** ____________

Weight (if applicable): ____________________ **Date weight obtained:** ____________

❑ Standard Review. In checking this box, the timeframe does not jeopardize the life or health of the member or the member's ability to regain maximum function and would not subject the member to severe pain.

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<u>Dosing Limit:</u> (see below)

- ❑ **Andembry:** Administer initial loading dose of 400 mg (two injections of 200 mg) subcutaneously on the first day of treatment followed by a maintenance dosage of 200 mg every month
  - ❑ Quantity Limit:
    - 200 mg auto-injector or syringe: 4 injections per 30 days
- ❑ **Cinryze:** Administer 1,000 units intravenous every 3 or 4 days
  - ❑ Quantity Limit:
    - Cinryze 500-unit vial: 16 vials per 30 days
  - ❑ Max Units Cinryze (per dose and over time)
    - 1,000 billable units per 30 days
- ❑ **Haegarda:** Administer 60 International Units (IU) per kg body weight twice weekly (every 3 or 4 days)
  - ❑ Quantity Limit:
    - Haegarda 2000 IU SDV kit: 16 kits per 28 days
    - Haegarda 3000 IU SDV kit: 8 kits per 28 days
  - ❑ Max Units Haegarda (per dose and over time)
    - 5,600 billable units per 28 days
- ❑ **Takhzyro:** For children ≥ 12 years of age, adolescents, and adults – Administer 300 mg every 2 weeks. Dosing every 4 weeks for well controlled members (e.g., attack free) for > 6 months. The recommended dosage of Takhzyro in pediatric patients 2 to less than 6 years of age is 150 mg administered SC once every 4 weeks
  - ❑ Quantity Limit:
    - 300 mg vial/syringe per 14 days
    - 150 mg syringe per 28 days
  - ❑ Max Units Takhzyro (per dose and over time)
    - 300 billable units per 14 days
    - 150 billable units per 28 days

CLINICAL CRITERIA: Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.
<u>Initial Authorization</u>: 12 months

<u>Treatment of acute attacks of Hereditary Angioedema Criteria</u>:

- ❑ Prescribed by or in consultation with a specialist in allergy, immunology, hematology, pulmonology or medical genetics

<u>AND</u>

- ❑ Provider attests the requested medication will **<u>NOT</u>** be used in combination with other prophylactic therapies targeting C1 inhibitors or kallikrein (e.g., Haegarda or Takhzyro)

<u>AND</u>

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- ❑ Provider attests the patient is avoiding **BOTH** of the following possible triggers for HAE attacks:
  - ❑ Estrogen-containing oral contraceptive agents **AND** hormone replacement therapy
  - ❑ Antihypertensive agents containing ACE inhibitors

AND

- ❑ Member must meet medication specific age requirement:
  - ❑ Andembry: Member must be at least 12 years of age
  - ❑ Cinryze: Member must be at least 6 years of age
  - ❑ Haegarda: Member must be at least 6 years of age
  - ❑ Takhzyro: Member must be at least 2 years of age

AND

- ❑ Member has a history of **ONE** of the following:
  - ❑ **Three (3) or more** severe HAE attacks per month (i.e., airway swelling, debilitating cutaneous or gastrointestinal episodes)
  - ❑ Disablement for more than 5 days per month by HAE
  - ❑ Recurrent laryngeal attacks caused by HAE

AND

- ❑ Treatment of member with "on-demand" therapy (i.e., Kalbitor®, Firazyr®, Ruconest®, or Berinert®) did **NOT** provide satisfactory control or access to "on-demand therapy" is limited **(failure is defined as more than 5 attacks/month for 4 months consecutively within the same year)**

AND

- ❑ Member failed, is intolerant, or has a contraindication to attenuated (17 alpha-alkylated) androgens (e.g., Danazol®) for HAE prophylaxis

Member has ONE of the following clinical presentations that is consistent with a HAE subtype, confirmed by repeat blood testing (please submit chart notes for symptoms and lab values to confirm the HAE subtype):

II.A. ❑ HAE I: (all bullet points must apply)

- ❑ 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)
- ❑ Low C4 level (C4 below the lower limit of normal as defined by the laboratory performing the test)
- ❑ Low C1-INH functional level (C1-INH functional level below the lower limit of normal as defined by the laboratory performing the test) **in addition to ONE** of the following:
  - ❑ Member has a family history of HAE
  - ❑ Acquired angioedema has been ruled out (i.e., patient onset of symptoms occur prior to 30 years old, normal C1q levels, patient does not have underlying disease such as lymphoma or benign monoclonal gammopathy [MGUS])

OR

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II.B. ❑ HAE II (C1-Inhibitor dysfunction): (all bullet points must apply)

- ❑ Normal to elevated C1-INH antigenic level
- ❑ Low C4 level (C4 below the lower limit of normal as defined by the laboratory performing the test)
- ❑ Low C1-INH functional level (C1-INH functional level below the lower limit of normal as defined by the laboratory performing the test) **in addition to <u>ONE</u>** of the following:
  - ❑ Member has a family history of HAE
  - ❑ Acquired angioedema has been ruled out (i.e., onset of symptoms occurred prior to 30 years old, normal C1q levels, patient does not have underlying disease such as lymphoma or benign monoclonal gammopathy [MGUS])

<u>OR</u>

II.C. ❑ HAE III with normal C1-INH: (all bullet points must apply)

- ❑ Normal C1-INH antigenic level
- ❑ Normal C4 level
- ❑ Normal C1-INH functional level
- ❑ Repeat blood testing during an attack has confirmed the member does **<u>NOT</u>** have abnormal lab values indicative of HAE I or HAE II
- ❑ Member had an inadequate response or intolerance to an adequate trial of prophylactic therapy with **<u>ONE</u>** of following:
  - ❑ antifibrinolytic agent: (❑ tranexamic acid (TXA) **OR** ❑ aminocaproic acid)
  - ❑ 17α- alkylated androgen: danazol
  - ❑ progestins (female members only)

<u>AND</u>

- ❑ **ONE of the following:**
- ❑ Member has a known HAE-causing mutation (e.g., mutation of coagulation factor XII gene [F12 mutation], mutation in the angiopoietin-1 gene, mutation in the plasminogen gene or kininogen-1)
- ❑ Member has a family history of HAE and documented evidence of lack of efficacy of chronic high-dose antihistamine therapy (e.g., cetirizine standard dosing at up to four times daily or an alternative equivalent, given for at least one month or an interval long enough to expect three or more angioedema attacks) **AND** corticosteroids

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Reauthorization: Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

- ❑ Member must continue to meet initial criteria

AND

- ❑ Significant improvement in severity and duration of attacks has been achieved and sustained

AND

- ❑ Member has experienced an absence of unacceptable toxicity from the drug (e.g., hypersensitivity reactions)

AND

- ❑ For Takhzyro Renewal Only: Has the member been attack free for greater than > 6 months?
  - ❑ Yes- approve dosing every 4 weeks
  - ❑ No- approve dosing every 2 weeks

Medication being provided by: **Please check applicable box below.**

- ❑ **Location/site of drug administration:** ____

  NPI or DEA # of administering location: ____

OR

- ❑ **Specialty Pharmacy**

For urgent reviews: Practitioner should call Sentara Health Plans Pre-Authorization Department if they believe a standard review would subject the member to adverse health consequences. Sentara Health Plan's definition of urgent is a lack of treatment that could seriously jeopardize the life or health of the member or the member's ability to regain maximum function.

*****Use of samples to initiate therapy does not meet step edit/ preauthorization criteria.*****

****Previous therapies will be verified through pharmacy paid claims or submitted chart notes.****

***Approved by Pharmacy and Therapeutics Committee**: ~~9/19/2013;~~ **7/24/2025**
REVISED/UPDATED/REFORMATTED: ~~11/20/2013; 10/31/2014; 4/3/2015; 5/22/2015; 12/30/2015; 1/29/2016; 8/17/2016; 9/22/2016; 12/11/2016; 7/30/2017; 9/13/2017; 11/16/2017; 3/31/2018; 5/18/2018; 12/11/2018; 3/16/2019; 7/6/2019; 9/20/2019; 4/1/2021; 6/30/2021;3/31/2023~~; **8/21/2025**