Medical Benefit Drug Policy

Haegarda (C1 Esterase Inhibitor Subcutaneous [Human]) for Subcutaneous Injection

Policy Number: MC/PC 017
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Instructions for Use

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Related Policies

- N/A

Coverage Rationale

This policy is applicable to Haegarda (C1 Esterase Inhibitor Subcutaneous [Human]) for subcutaneous injection, freeze-dried powder for reconstitution only.

Prophylaxis of Hereditary Angioedema (HAE)

For initial coverage of Haegarda (C1 Esterase Inhibitor Subcutaneous [Human]) for subcutaneous injection for prophylaxis of hereditary angioedema (HAE), the following will be required:

- Diagnosis of hereditary angioedema (HAE) **and**
- One of the following:
  - Diagnosis has been confirmed by both of the following:
    - C4 level below the lower limit of normal
    - C1 inhibitor (C1-INH) deficiency or dysfunction (Type I or II HAE) as documented by ONE of the following:
      - C1-INH antigenic level below the lower limit of normal
      - C1-INH functional level below the lower limit of normal **or**
  - Diagnosis has been confirmed by both of the following:
    - Both of the following:
      - Normal C4 level
      - Normal C1-INH levels (HAE-nl-C1INH previously referred to as HAE Type III) **and**
    - One of the following:
      - Presence of a factor XII, plasminogen, angiopoietin-1, kininogen-1, myoferlin, or heparan sulfate-glucosamine 3-O-sulfotransferase 6 gene mutation as detected by an FDA-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA).

        - Patient has recurrent angioedema attacks that are refractory to high-dose antihistamines (e.g., cetirizine) with a confirmed family history of recurrent angioedema **and**
    - For prophylaxis against HAE attacks **and**
    - Not used in combination with other approved treatments for prophylaxis against HAE attacks **and**
    - Patient is 6 years of age or older **and**
    - Prescribed by or in consultation with one of the following:
        - Immunologist
        - Allergist

For reauthorization coverage of Haegarda (C1 Esterase Inhibitor Subcutaneous [Human]) for subcutaneous injection for prophylaxis of hereditary angioedema (HAE), the following will be required:

- Patient demonstrates positive clinical response to therapy (e.g., reduction in the number or rate of HAE attacks while on therapy) **and**
- Not used in combination with other approved treatments for prophylaxis against HAE attacks.

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

HCPCS Code	Description
J0599	Injection, C1 esterase inhibitor (human), HAEGARDA, 10 units

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

Background

Hereditary angioedema (HAE) is a rare, life-threatening autosomal disease affecting an estimated 1 in 10,000 to 100,000 globally and 6000 to 30,000 patients in the United States (U.S.). HAE is characterized by unpredictable recurrent episodes of angioedema (sometimes called "giant" swelling) with localized subcutaneous (SC) or submucosal edema lasting for up to 5 days. The angioedema can be disabling and, in the case of laryngeal attacks, life-threatening (Craig et al 2018, Fisch et al 2025, Reshef et al 2025, Zuraw and Farkas 2025). For the majority of patients, HAE first presents in childhood between 8 to 13 years of age, worsens around puberty, and persists throughout life with fluctuating severity of disease over time (Farkas et al 2017, Norris et al 2022, Zuraw and Christiansen 2016). HAE attack frequency ranges from as often as 2 to 3 times a week to 1 to 2 times a year. Approximately 50% of all patients with HAE will experience an attack involving the upper airway, while almost 80% will experience an abdominal attack (Dokmeci and Honsinger 2023). The mortality rate for patients with HAE, despite effective therapies, has been estimated to be as high as 13%. In undiagnosed laryngeal edema cases, mortality can be as high as 30% to 40% (Busse et al 2021, Zuraw and Farkas 2024).

HAE is predominantly facilitated by an excessive production of bradykinin, a potent vasodilatory peptide which mediates swelling in HAE through vasodilation and vascular leakage. Component 1 esterase inhibitor (C1-INH) controls bradykinin production through inhibition of key steps in the contact system (Banerji et al 2017, Lumry 2018). The most common causes of HAE involve either a deficiency (type I HAE; 85% of cases) or dysfunction (type II HAE; 15% of cases) of C1-INH (collectively referred to as HAE-C1INH). In very rare cases, HAE may also present with normal C1-INH (HAE-nC1INH or

type III) resulting from variants in other genes (Busse et al 2021, Farkas et al 2017, Maurer et al 2022, Zuraw and Farkas 2025).

The various HAE therapies act on different targets to reduce bradykinin production and its effects to decrease angioedema and improve outcomes in patients with HAE. Effective HAE management includes prophylactic treatment to prevent attacks and acute ("on-demand") treatment to arrest an ongoing attack (Busse et al 2021, Farkas et al 2017, Maurer et al 2022).

Clinical Evidence

The efficacy of Haegarda for prophylaxis of HAE attacks was evaluated in COMPACT, a 32-week Phase 3, double-blind, placebo-controlled, crossover randomized trial in 90 patients with HAE (Longhurst et al 2017).

- Treatment with Haegarda 60 IU/kg subcutaneous (SC) injection twice weekly reduced the rate of attacks by 84%, with a mean difference of -3.51 attacks per month vs placebo (95% CI, -4.21 to -2.81; $p < 0.001$). Treatment with Haegarda also significantly reduced the severity and duration of HAE attacks compared with placebo.
- In the COMPACT OLE trial, patients treated with Haegarda 60 IU/kg (n = 63) were attack-free for 98% of days, with a median HAE monthly attack rate of 0.09 (range, 0.0 to 4.0) over the 2.7 year observation period (Craig et al 2019, Craig et al 2022b). A total of 44% of these patients were attack-free during the study.

Clinical Guidelines

2021 International World Allergy Organization (WAO)/European Academy of Allergy and Clinical Immunology (EAACI) guideline for the management of HAE (Maurer et al 2022)
This guideline refers to the management of type I and type II HAE. Type I HAE is due to deficient C1-INH (characterized by low antigenic and functional C1-INH levels); type II HAE is due to dysfunctional C1-INH (characterized by normal [or elevated] antigenic but low functional C1-INH levels).

- **Long-term prophylaxis**
    - The goals of treatment in HAE are to achieve complete control of the disease and to normalize patients' lives (Evidence level D; Strength of recommendation: Strong; 100% agreement).
        - Complete control of disease equates to no longer having attacks, which can currently only be achieved by long-term prophylaxis (eg, regular use of medication that reduces the burden of the disease by preventing attacks).
    - It is recommended that patients are evaluated for long-term prophylaxis at every visit; disease activity, burden, and control as well as patient preference should be taken into consideration (Evidence level D; Strength of recommendation: Strong; 96% agreement).
        - Patients should be evaluated for long-term prophylaxis at every health care visit, and at least once a year.
        - The goal of long-term prophylaxis is to achieve full control of disease burden while attempting to minimize treatment burden and AEs.
    - The guideline recommends any of 3 medications (ie plasma-derived C1-INH, lanadelumab-flyo, or berotralstat) for the first-line long-term prophylactic treatment of patients with HAE-C1INH based on the results of RCTs. Where all 3 agents are available, the choice of which one to use should be made by shared decision making. Currently, there is not enough evidence to recommend any of these 3 treatment options over each other.
        - Plasma-derived C1-INH is recommended as a first-line therapy for long-term prophylaxis (Evidence level A; Strength of recommendation: Strong; 87% agreement). Plasma-derived C1-INH is a preferred long-term prophylaxis agent for the prevention of HAE attacks. Dosing should be twice a week based upon the half-life of plasma-derived C1-INH, while dose and/or frequency may need to be adjusted for optimal efficacy.
        - Lanadelumab-flyo is recommended as a first-line therapy for long-term prophylaxis (Evidence level A; Strength of recommendation: Strong; 89% agreement). Lanadelumab-flyo is a preferred

long-term prophylaxis agent for the prevention of HAE attacks due to its efficacy and the fact it is administered via SC injection.
        - Berotralstat is recommended as a first-line therapy for long-term prophylaxis (Evidence level A; Strength of recommendation: Strong; 81% agreement). Berotralstat is a preferred long-term prophylaxis agent for the prevention of HAE attacks due to its efficacy and the fact it is an oral medication.
    - The use of androgens is recommended only as second-line long-term prophylaxis (Evidence level C; Strength of recommendation: Strong; 89% agreement). Androgens are associated with many AEs, contraindications and drug interactions. These effects are numerous and involve the majority of patients; careful monitoring is required with long-term androgen prophylaxis.
- **Management of HAE C1-INH (HAE-1/2) in children**
    - C1-INH or icatibant is recommended for the treatment of HAE attacks in children < 12 years of age (Evidence level A; Strength of recommendation: Strong; 94% agreement).
        - C1-INH and icatibant are the only approved on-demand treatments for children with HAE-1/2.
        - Preprocedural prophylaxis is recommended for medical, surgical and dental procedures associated with any mechanical impact to the upper aerodigestive tract. Plasma-derived C1-INH is considered the first-line option, while short courses of attenuated androgens should only be used second line when C1-INH is not available. On-demand therapy should be available as short-term prophylaxis is not 100% effective.
        - The indications for long-term prophylaxis in adolescents are the same as for adults.
        - The preferred therapy in children < 12 years of age is plasma-derived C1-INH. The dosing interval and dose may need to be adjusted according to individual response.
- **Management of HAE C1-INH (HAE-1/2) during pregnancy and lactation**
    - Plasma-derived C1-INH is recommended as the preferred therapy during pregnancy and lactation (Evidence level D; Strength of recommendation: Strong; 100% agreement).
        - A C1-INH is recommended as first-line therapy for pregnant or breast-feeding patients with HAE-1/2. SDP may be used when C1-INH is not available, and FFP when SDP is not available.
        - The use of ecallantide, lanadelumab-flyo and berotralstat in pregnancy is off label and not recommended, as no published experience is currently available.
        - Preprocedural prophylaxis is recommended, preferably with C1-INH for interventions that come with a risk of attacks such as chorionic villus sampling, amniocentesis, and induced surgical abortion.

2020 U.S. Hereditary Angioedema Association (HAEA) Medical Advisory Board guidelines for the management of HAE (Busse et al 2021)

These guidelines reflect the consensus of a broad panel of expert U.S. HAE physicians, and build upon the 2013 HAEA recommendations for management of HAE (*Zuraw et al 2013*). All recommendations were approved by a unanimous vote. The recommendations presented in this section focus on the treatment of HAE-C1INH (type I and II HAE), unless otherwise noted.

- **Goals of treatment**
    - The goals of the HAE management plan are to “normalize” life as much as possible, ensuring that patients are able to engage in all work, school, family, and leisure activities as desired without limitation from angioedema symptoms.
    - The core approach to the pharmacologic care for HAE rests on 4 guiding principles: availability of effective on-demand acute therapy for all patients; early treatment to prevent attack progression; treatment of attacks irrespective of the site of swelling; and incorporation of long-term prophylaxis based on highly individualized decision-making reflecting a physician-patient partnership.
- **Management of HAE**
    - HAE management plans must be individualized to each patient’s needs due to wide variability in HAE symptoms, response to and tolerance of various HAE medications, and numerous factors impacting clinical course and QoL. Treatment plans should be monitored regularly and adjusted based on the needs of the patient (Strength of recommendation: Strong; Quality of evidence: Moderate).

- HAE management plans should include: (A) effective on-demand medication for every patient, (B) consideration of long-term prophylactic medications to prevent HAE attacks, and (C) use of short-term prophylactic medications before medical procedures or other events known to trigger HAE symptoms (Strength of recommendation: Strong; Quality of evidence: Moderate).

- **Long-term prophylaxis**
  - The goal of long-term prophylactic treatment is to decrease the overall number, severity, and burden of angioedema attacks.
  - The decision on when to use long-term prophylactic treatment cannot be made on rigid criteria but should reflect the needs of the individual patient (Strength of recommendation: Strong; Quality of evidence: High).
    - Decisions regarding which patients should be considered for long-term prophylaxis should consider the patient's QoL and treatment preferences in the context of attack frequency, attack severity, comorbid conditions, and access to emergent treatment.
    - Because disease severity may change over time, the need to start or continue long-term prophylaxis should be periodically reviewed and discussed with the patient.
  - Long-term prophylactic treatment of HAE C1-INH should include first-line medications (Cinryze, Haegarda, or lanadelumab-flyo) (Strength of recommendation: Strong; Quality of evidence: High).
    - As there are significant differences in route of administration, safety profiles, and efficacy between these drugs, patient preference and experience need to be considered in the selection of the most appropriate therapy.
    - Second-line therapies include the anabolic androgens (ie, danazol) and antifibrinolytics (eg, tranexamic acid or aminocaproic acid); these agents should be reserved for when first-line medications are not available or when the patient will only accept oral therapy, with acknowledgment of potential AEs.
    - The availability of new first-line oral prophylactic medications (ie, berotralstat; not approved at the time these guidelines were published) may also influence the choice of long-term prophylaxis.
    - Cinryze has been shown to be both safe and effective for the prophylactic treatment of HAE; however, repeated IV administration can result in loss of readily accessible veins unless great care is taken to preserve the veins. Indwelling ports are discouraged due to the risk of thrombosis and infection, unless deemed medically necessary.
    - Patients on long-term prophylaxis should also have access to on-demand treatment.
  - **Additional considerations for children**
    - HAE C1-INH often presents in childhood and an early diagnosis is essential for minimizing the risks of morbidity and mortality (Strength of recommendation: Strong; Quality of evidence: High).
    - Indications for the use of first-line HAE medications are the same in children as in adults, although regulatory differences affect the use of some medications depending on the child's age (Strength of recommendation: Strong; Quality of evidence: Moderate).
  - **Specific issues in the management of HAE in women**
    - During pregnancy and breast-feeding, C1-INH is the recommended HAE medication for use as either on-demand or prophylactic therapy (Strength of recommendation: Strong; Quality of evidence: Moderate).

HAE with normal C1-INH: An updated international consensus paper on diagnosis, pathophysiology, and treatment (Zuraw et al 2025)

- A rare form of HAE, where C1-INH levels are normal (HAE-nC1INH), was first described in 2000. Since that time, new types of apparent non-mast-cell-mediated angioedema with normal quantity and activity of C1-INH have been described, in some cases with proven genetic pathogenic variants that cosegregate with angioedema expression within families. Multiple pathogenic variants have been described in the literature.
- Due to the paucity of high-level evidence, all recommendations in this consensus are based on expert opinion.

- Overall, treatment strategies used for HAE-nC1INH are similar to those of HAE-C1INH and include the use of on-demand treatment, short-term prophylaxis, and long-term prophylaxis.
- Since HAE-nC1INH is a group of conditions that are similar in clinical manifestation but differ in their pathogenesis; therefore, differences in treatment responses across the different subtypes of HAE-nC1INH are expected.

Management of pediatric HAE type I and II: A search for international consensus (Norris et al 2022)
This international consensus review was conducted to identify and compare guidelines for the management of HAE as they pertain to managing HAE type and type II in pediatrics. The consensus review was based on 6 guidelines identified via a literature search of publications evaluating the use of medications for the treatment of HAE in pediatric patients over the previous 5 years, including the 2017 HAWK consensus (Farkas et al 2017), 2020 U.S. HAEA guidelines (Busse et al 2021), the 2021 WAO/EAACI consensus guidelines (Maurer et al 2022), 2019 Canadian HAE Network guideline update, a consensus update on therapeutic strategies for children and adolescents in German-speaking countries, and an Argentine HAE consensus. It was noted that although treatment differences varied based on geographic region and health system, many of the guidelines only had minimal differences on close review.

- Overall, the guidelines stress early detection of HAE status, coordination with physicians and centers with specialization in HAE management, and empowering patients with both the ability to self-administer medications.
- Acute HAE attacks: Most consensus supported the use of plasma-derived C1-INH as first-line therapy, with several alternatives available based on individual preference and country of origin.
- Short-term prophylaxis: IV C1-INH is a preferred therapy. Long-term prophylaxis: Although rarely required in children, guidelines are shifting away from use of attenuated androgens and tranexamic acid to therapies such as SC C1-INH, lanadelumab-flyo, and berotralstat.

U.S. Food and Drug Administration (FDA)

This section is to be used for informational purposes only. FDA approval alone is not a basis for coverage.

Haegarda is a plasma-derived concentrate of C1 Esterase Inhibitor (Human) (C1-INH) indicated for routine prophylaxis to prevent Hereditary Angioedema (HAE) attacks in patients 6 years of age and older.

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Policy History/Revision Information

Date	Summary of Changes
02/15/2024	Approved by OptumRx P&T Committee
05/15/2025	Annual review. Updated references.
05/15/2026	Annual review. Updates made to background, guideline section, and references.

Instructions for Use

This Medical Benefit Drug Policy provides assistance in interpreting standard benefit plans. When deciding coverage, the member specific benefit plan document must be referenced as the terms of the member specific benefit plan may differ from the standard plan. In the event of a conflict, the member specific benefit plan document governs. Before using this policy, please check the member specific benefit plan document and any applicable federal or state mandates. The insurance reserves the right to modify its Policies and Guidelines as necessary. This Medical Benefit Drug Policy is provided for informational purposes. It does not constitute medical advice.

OptumRx may also use tools developed by third parties to assist us in administering health benefits. OptumRx Medical Benefit Drug Policies are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.

Nondiscrimination & Language Access Policy

Discrimination is Against the Law. Aspirus Health Plan, Inc. complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability, or sex, (including sex characteristics, including intersex traits; pregnancy or related conditions; sexual orientation, gender identity and sex stereotypes), consistent with the scope of sex discrimination described at 45 CFR § 92.101(a)(2). Aspirus Health Plan, Inc. does not exclude people or treat them less favorably because of race, color, national origin, age, disability, or sex.

Aspirus Health Plan, Inc.:
Provides people with disabilities reasonable modifications and free appropriate auxiliary aids and services to communicate effectively with us, such as:

- Qualified sign language interpreters.
- Written information in other formats (large print, audio, accessible electronic formats, other formats).

Provides free language assistance services to people whose primary language is not English, which may include:

- Qualified interpreters.
- Information written in other languages.

If *you* need reasonable modifications, appropriate auxiliary aids and services, or language assistance services, contact the Nondiscrimination Grievance Coordinator at the address, phone number, fax number, or email address below.

If *you* believe that Aspirus Health Plan, Inc. has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability, or sex, *you* can file a *grievance* with:

Nondiscrimination Grievance Coordinator
Aspirus Health Plan, Inc.
PO Box 1890
Southampton, PA 18966-9998
Phone: 1-866-631-5404 (TTY: 711)
Fax: 763-847-4010
Email: customerservice@aspirushealthplan.com

You can file a *grievance* in person or by mail, fax, or email. If *you* need help filing a *grievance*, the Nondiscrimination Grievance Coordinator is available to help *you*.

You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at https://ocrportal.hhs.gov/ocr/portal/lobby.jsf, or by mail or phone at:

U.S. Department of Health and Human Services
200 Independence Avenue, SW
Room 509F, HHH Building
Washington, D.C. 20201
1.800.368.1019, 800.537.7697 (TDD)

Complaint forms are available at http://www.hhs.gov/ocr/office/file/index.html. This notice is available at Aspirus Health Plan, Inc.'s website: https://aspirushealthplan.com/webdocs/70021-AHP-NonDiscrim_Lang-Assist-Notice.pdf.

Language Assistance Services

Albanian: KUJDES: Nëse flitni shqip, për ju ka në dispozicion shërbime të asistencës gjuhësore, pa pagesë.Telefononi në 1-800-332-6501 (TTY: 711).

Arabic تنبيه: إذا كنت تتحدث اللغة العربية، فإن خدمات المساعدة اللغوية متاحة لك مجاناً. اتصل بن اعلى رقم الهاتف1-800-332-6501(رقم هاتف الصم والبك : 711)

French: ATTENTION: Si vous parlez français, des services d'aide linguistique vous sont proposés gratuitement. Appelez le 1-800-332-6501 (ATS: 711).

German: ACHTUNG: Wenn Sie Deutsch sprechen, stehen Ihnen kostenlos sprachliche Hilfsdienstleistungen zurVerfügung. Rufnummer: 1-800-332-6501 (TTY: 711).

Hindi: _यान द_: य_द आप ि हंदी बोलते ह_ तो आपके ि लए मु_त म_ भाषा सहायता सेवाएं उपल_ध ह_।1-800-332-6501 (TTY: 711) पर कॉल कर_।

Hmong: LUS CEEV: Yog tias koj hais lus Hmoob, cov kev pab txog lus, muaj kev pab dawb rau koj. Hu rau 1-800-332-6501 (TTY: 711).

Korean: 주의: 한국어를 사용하시는 경우, 언어 지원 서비스를 무료로 이용하실 수 있습니다.1-800-332-6501 (TTY: 711)번으로 전화해 주십시오.

Polish: UWAGA: Jeżeli mówisz po polsku, możesz skorzystać z bezpłatnej pomocy językowej. Zadzwoń pod numer1-800-332-6501 (TTY: 711).

Russian: ВНИМАНИЕ: Если вы говорите на русском языке, то вам доступны бесплатные услуги перевода.Звоните 1-800-332-6501 (телетайп: 711).

Spanish: ATENCIÓN: si habla español, tiene a su disposición servicios gratuitos de asistencia lingüística. Llame al1-800-332-6501 (TTY: 711).

Tagalog: PAUNAWA: Kung nagsasalita ka ng Tagalog, maaari kang gumamit ng mga serbisyo ng tulong sa wika nangwalang bayad. Tumawag sa 1-800-332-6501 (TTY: 711).

Traditional Chinese: 注意：如果您使用繁體中文， 您可以免費獲得語言援助服務。請 致電 1-800-332-6501 (TTY: 711)

Vietnamese: CHÚ Ý: Nếu bạn nói Tiếng Việt, có các dịch vụ hỗ trợ ngôn ngữ miễn phí dành cho bạn. Gọi số 1-800-332-6501 (TTY: 711).

Pennsylvania Dutch: Wann du Deitsch (Pennsylvania German / Dutch) schwetzscht, kannscht du mitaus Koschte ebbergricke, ass dihr helft mit die englisch Schprooch. Ruf selli Nummer uff: Call 1-800-332-6501 (TTY: 711).

Lao: ໂປດຊາບ: ຖ້າວ່າ ທ່ານເວົ້າພາສາ ລາວ, ການບໍລິການຊ່ວຍເຫຼືອດ້ານພາສາ,ໂດຍບໍ່ເສັງຄ່າ, ແມ່ນມີພ້ອມໃຫ້ທ່ານ. ໂທຣ 1-800-332-6501 (TTY: 711).

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