Updated: 06/2019
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Gateway Health
Prior Authorization Criteria

Hereditary Angioedema (HAE) Agents

All requests for Hereditary Angioedema (HAE) Agents require a prior authorization and will be screened for medical necessity and appropriateness using the criteria listed below.

Hereditary Angioedema (HAE) Agents Prior Authorization Criteria:
For all requests for Hereditary Angioedema (HAE) Agents all of the following criteria must be met:

- The medication requested is used for the management of HAE
- The member is within the FDA-approved age range for the medication requested
- Medication is being prescribed by an expert physician who is knowledgeable about the condition, has experience in managing patients with Hereditary Angioedema (HAE), and is familiar with all HAE management options (e.g., allergy and immunology specialist, hematologist, or dermatologist)
- The diagnosis of HAE is confirmed by laboratory values obtained on two separate instances (laboratory reports must contain reference ranges):
    - HAE I
        - Low C4 level; AND
        - Low C1-INH antigenic level
    - HAE II
        - Low C4 level; AND
        - Normal or elevated C1-INH antigenic level AND low C1-INH functional level
- There is a documented history of at least one symptom of a moderate to severe HAE attack (e.g., moderate to severe abdominal pain, facial swelling, airway swelling) in the absence of hives or a medication known to cause angioedema.
- The member is not taking any medications that may exacerbate HAE, including angiotensin-converting enzyme (ACE) inhibitors and estrogen-containing medications.
- The requested dose and frequency is in accordance with FDA-approved labeling, nationally recognized compendia, and/or evidence-based practice guidelines

Coverage may be provided for the treatment of HAE and the following criteria is met:

- Request must be for Firazyr, Kalbitor, Berinert, or Ruconest
- The member is receiving no more than one medication for the acute treatment of an HAE attack at one time
- Member is adherent to prophylactic therapy to control HAE symptoms and minimize HAE attacks if experiencing multiple HAE attacks per month necessitating an amount of medication over the quantity limit (refer to CP-206.33-MD-PA Quantity Limit policy) or has a documented clinically relevant contraindication, inadequate response to, or intolerance to prophylactic therapy. If receiving prophylactic therapy, the member is adherent based upon pharmacy claims or physician documentation.
- **Initial Duration of Approval:** 3 months

- **Reauthorization criteria**
  - Member continues to meet coverage criteria for HAE management and treatment
  - Must meet one of the following:
    - If taking an attenuated androgen, documentation the physician has completed a patient assessment at least twice within the past year
    - Documentation the physician has completed a patient assessment at least once within the past year
  - Documentation the member has clinically benefitted from medication in an acute HAE attack
- **Reauthorization Duration of approval:** 3 months

Coverage may be provided for short-term prophylaxis of HAE and the following criteria is met:

- Request must be for Cinryze or Haegarda
- The member is scheduled to undergo a surgical procedure or major dental work
- The type of procedure and date of procedure must be provided
- If member is 12 years of age or older and request is for a new start, must provide documentation of therapeutic failure, intolerance or contraindication with Haegarda
- **Duration of Approval:** 1 months

Coverage may be provided for long-term prophylaxis of HAE and the following criteria is met:

- Request must be for Cinryze, Takhzyro, or Haegarda
- Member has a history of one or more attacks per month resulting in documented E.R. treatment or hospitalization, a history of laryngeal attacks, two or more attacks per month involving the face, throat, or abdomen, or a history of multiple minor attacks sufficient to require quantities of medication exceeding quantity limits (refer to CP-206.33-MD-PA Quantity Limit Excess policy)
- If member is 12 years of age or older and request is for a new start, must provide documentation of therapeutic failure, intolerance or contraindication with Haegarda
- **Initial Duration of Approval:** 6 months
- **Reauthorization criteria**
  - Member continues to meet coverage criteria for HAE management and prophylaxis
  - Must meet one of the following:
    - If taking an attenuated androgen, documentation the physician has completed a patient assessment at least twice within the past year
    - Documentation the physician has completed a patient assessment at least once within the past year
  - Documentation demonstrating disease state improvement (e.g., a decrease in the number, severity, and/or duration of acute HAE attacks) is provided
- **Reauthorization Duration of approval:** 6 months

Coverage may be provided for any non-FDA labeled indication if it is determined that the use is a medically accepted indication supported by nationally recognized pharmacy compendia or peer-reviewed medical literature for treatment of the diagnosis(es) for which it is prescribed. These requests will be reviewed on a case by case basis to determine medical necessity.

When criteria are not met, the request will be forwarded to a Medical Director for review. The physician reviewer must override criteria when, in their professional judgment, the requested medication is medically necessary.

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Hereditary Angioedema Acute Treatment
PRIOR AUTHORIZATION FORM

Please complete and fax all requested information below including any progress notes, laboratory test results, or chart documentation as applicable to Gateway Health℠ Pharmacy Services. **FAX:** (888) 245-2049
If needed, you may call to speak to a Pharmacy Services Representative.
PHONE: (800) 392-1147 Monday through Friday 8:30am to 5:00pm

PROVIDER INFORMATION

Requesting Physician:	NPI:
Physician Specialty:	Office Contact:
Office Address:	Office Phone:
	Office Fax:
Pharmacy Name:	Pharmacy Phone:

MEMBER INFORMATION

Member Name:	DOB:	
Gateway ID:	Member weight in kg:	Date:

DRUG INFORMATION

Medication:	Dose & Frequency:
Quantity per 30 days:	Duration:
Is the member currently receiving requested medication? ☐ Yes ☐ No	Date Medication Initiated:

Is this medication being used for a chronic or long-term condition for which the medication may be necessary for the life of the patient? ☐ Yes ☐ No

MEDICAL HISTORY (Please attach applicable lab reports and progress notes)

Diagnosis:

1.) Hereditary angioedema ☐ Type 1 ☐ Type 2 ☐ Other:_____
2.) Has the member's diagnosis been confirmed by lab values obtained on 2 separate instances? ☐ Yes ☐ No
3.) Does the member have a history of at least 1 symptom of a moderate to severe HAE attack? ☐ Yes ☐ No

Is the member receiving more than one medication for the acute treatment of HAE? ☐ Yes ☐ No

Is the member taking any drugs that may exacerbate HAE (ACE inhibitors, estrogen-containing drugs)? ☐ Yes ☐ No

HAE attack history:

How many HAE attacks per month is the member experiencing? _____
What is the location and severity of the HAE attacks? _____

Is the member currently on prophylactic therapy for HAE? ☐ Yes ☐ No
If **yes**, what medication? _____
Has the member been adherent to the prescribed prophylactic regimen? ☐ Yes ☐ No

REAUTHORIZATION

How many doses of acute treatment does the member **currently** have on-hand? _____
How many HAE attacks per month has the member experienced since the last authorization? _____
How many doses of acute treatment have been required per HAE attack? _____
What is the planned frequency of phone assessments and/or office visits? _____
Is the member currently taking an attenuated androgen (e.g. danazol)? ☐ Yes ☐ No
Has the most recent chart documentation or notes been provided? ☐ Yes ☐ No
Has treatment resulted in clinical benefit during an acute HAE attack? ☐ Yes ☐ No
Please describe:_____

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Hereditary Angioedema Acute Treatment **PRIOR AUTHORIZATION FORM (CONTINUED) – PAGE 2 OF 2**	
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MEMBER INFORMATION	
Member Name:	DOB:
Gateway ID:	Member weight: _____pounds or _____kg
SUPPORTING INFORMATION or CLINICAL RATIONALE	
Prescribing Provider Signature	Date

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Hereditary Angioedema Prophylaxis
PRIOR AUTHORIZATION FORM

Please complete and fax all requested information below including any progress notes, laboratory test results, or chart documentation as applicable to Gateway Health[SM] Pharmacy Services. **FAX:** (888) 245-2049
If needed, you may call to speak to a Pharmacy Services Representative.
PHONE: (800) 392-1147 Monday through Friday 8:30am to 5:00pm

PROVIDER INFORMATION

Requesting Physician:	NPI:
Physician Specialty:	Office Contact:
Office Address:	Office Phone:
	Office Fax:
Pharmacy Name:	Pharmacy Phone:

MEMBER INFORMATION

Member Name:	DOB:	
Gateway ID:	Member weight in kg:	Date:

DRUG INFORMATION

Medication:	Dose & Frequency:
Quantity per 30 days:	Duration:
Is the member currently receiving requested medication? ☐ Yes ☐ No	Date Medication Initiated:

Is this medication being used for a chronic or long-term condition for which the medication may be necessary for the life of the patient? ☐ Yes ☐ No

MEDICAL HISTORY (Please attach applicable lab reports and progress notes)

Diagnosis:

1.) Hereditary angioedema ☐ Type 1 ☐ Type 2 ☐ Type 3 ☐ Other: _____
2.) Has the member's diagnosis been confirmed by lab values obtained on 2 separate instances? ☐ Yes ☐ No
3.) Does the member have a history of at least 1 symptom of a moderate to severe HAE attack? ☐ Yes ☐ No

Is the member taking any drugs that may exacerbate HAE (ACE inhibitors, estrogen-containing drugs)? ☐ Yes ☐ No

Please indicate the number of HAE attacks per month, location of attacks and attack severity: _____
Has the member had a trial/failure, intolerance, or contraindication to Haegarda? ☐ Yes ☐ No

Is the medication requested for short or long-term HAE prophylaxis? ☐ Short-term ☐ Long-term

Long-term Prophylaxis ☐ Yes ☐ No

1.) Please select **all** of the following applicable to the member and provide supporting documentation:
☐ One or more HAE attacks per month resulting in E.R. visits or hospitalizations ☐ History of laryngeal attacks
☐ Two or more HAE attacks per month involving the face, throat, or abdomen
☐ History of multiple minor HAE attacks sufficient enough to warrant acute treatment

Short-term Prophylaxis

1.) Type of procedure: _____ Date of procedure: _____

REAUTHORIZATION

What is the planned frequency of phone assessments and/or office visits? _____
Is the member currently taking an attenuated androgen (e.g. danazol)? ☐ Yes ☐ No
Has the most recent chart documentation or notes been provided? ☐ Yes ☐ No
Has the member shown improvement while on prophylactic therapy? ☐ Yes ☐ No
Please describe: _____

Prescribing Physician Signature	Date