US HAEA

Insurance Reimbursement Guidebook for HAE Therapies

For Healthcare Professionals & Reimbursement Specialists

HAEA

US HEREDITARY ANGIOEDEMA ASSOCIATION

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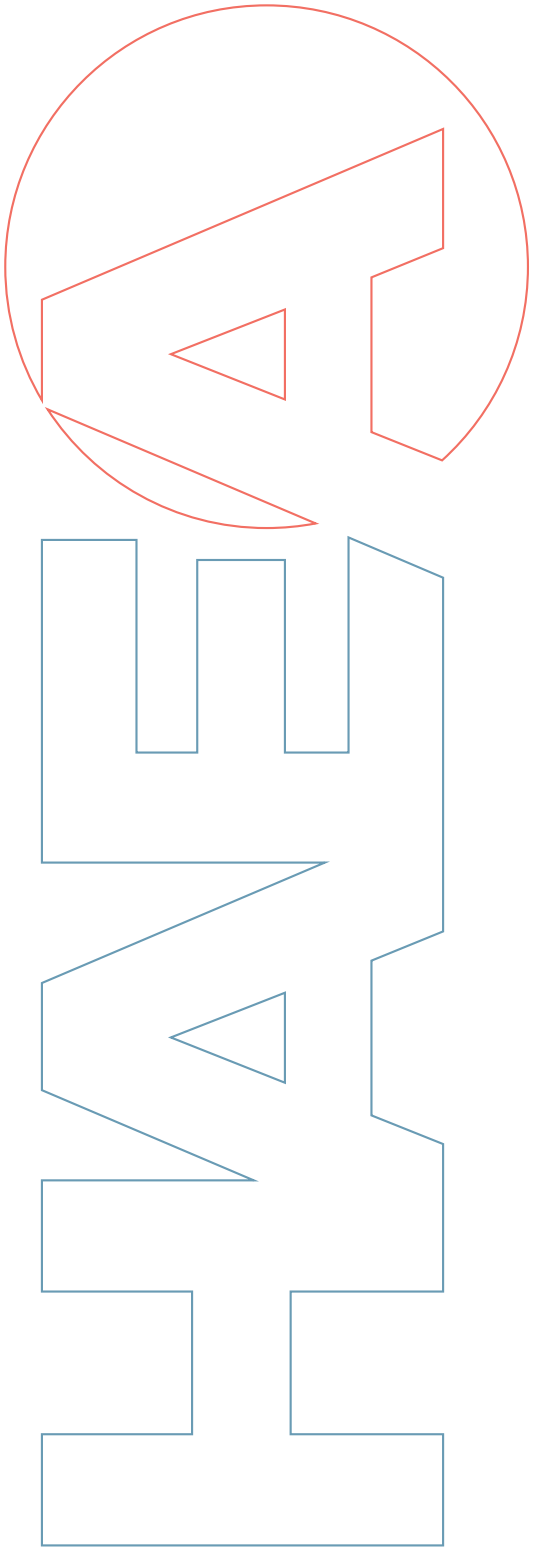
OVERVIEW OF THE US HAEA



HISTORY

Founded in 2000 and staffed by people with HAE and caregivers, the US HAEA is a non-profit advocacy organization dedicated to serving individuals with Hereditary Angioedema. The US HAEA has grown to a dynamic, highly successful non-profit organization with membership of over 8,000.

MISSION

To lead a nationwide advocacy movement that focuses on increasing HAE awareness and education, empowering access to suitable treatment, and fostering ground-breaking research that includes searching for a cure.

VISION

Unrestricted access to therapy so people affected by HAE are unburdened by symptoms and able to experience life to the fullest.

VALUES

To fulfill our community's highest priority needs with innovative programs, services, and activities that are delivered with an extraordinary level of empathy, kindness, and compassion.

This Guidebook is intended to help healthcare professionals and reimbursement specialists navigate the insurance process for medications to treat Hereditary Angioedema (HAE). The US Hereditary Angioedema Association (US HAEA) developed this Guidebook based on research into the prior authorization and reimbursement processes along with insights from physicians, people with HAE, physician office reimbursement specialists, and payers. The Guidebook highlights common challenges, offers suggestions on how to overcome them, and provides recommendations for attaining a successful outcome if an appeal is necessary.

The information provided in this Guidebook is not meant to be a substitute for medical advice, diagnosis, or treatment recommendations. It does not supersede information required by insurance companies for access to HAE medications. The HAEA is product and company neutral and does not endorse or recommend HAE medications.

A MESSAGE FROM THE US HAEA

Dear HAEA Friend,

Obtaining insurance approval for medicines that treat a rare disease like HAE can be a difficult and stressful process. The US HAEA has developed this Guidebook for healthcare professionals and reimbursement specialists navigating insurance challenges for HAE medicines.

We have also developed a similar guidebook for people with HAE to help them understand insurance challenges and how they can best assist your team throughout the process. This Guidebook demonstrates the US HAEA's commitment to helping people with HAE get access to the medicine prescribed by their healthcare professional.

Sincerely,

Anthony J. Castaldo
US HAEA President / CEO


ON
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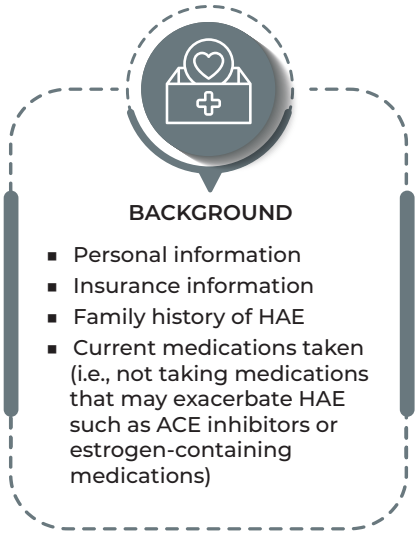
COMMON INFORMATION REQUIRED FOR PRIOR AUTHORIZATIONS

Below are common prior authorization (PA) requirements for HAE therapies. These common requirements can assist when preparing to submit a PA, but specific criteria needed for each medication and insurer should also be confirmed.

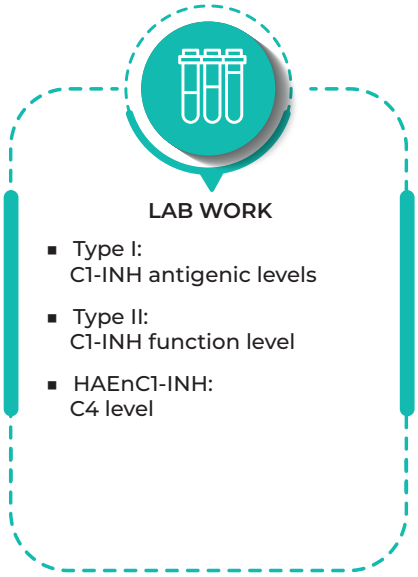


BACKGROUND

- Personal information
- Insurance information
- Family history of HAE
- Current medications taken (i.e., not taking medications that may exacerbate HAE such as ACE inhibitors or estrogen-containing medications)

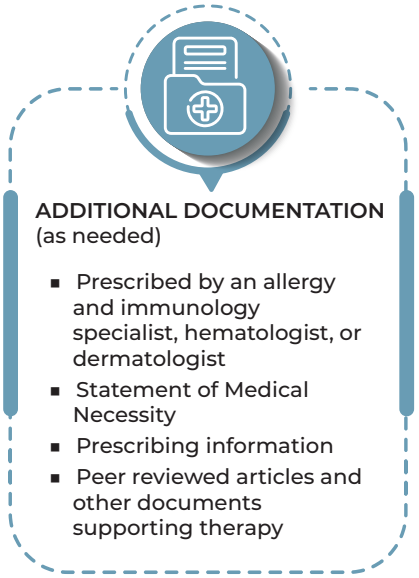
MEDICAL HISTORY

- History of HAE attacks (i.e., location, duration, severity, frequency)
- Diagnosis of HAE
- Therapy history (i.e., past HAE medications, duration taken, reason for stopping)



LAB WORK

- Type I:
  C1-INH antigenic levels
- Type II:
  C1-INH function level
- HAEnC1-INH:
  C4 level



ADDITIONAL DOCUMENTATION
(as needed)

- Prescribed by an allergy and immunology specialist, hematologist, or dermatologist
- Statement of Medical Necessity
- Prescribing information
- Peer reviewed articles and other documents supporting therapy

In addition to the information that is commonly requested, individual insurers may ask for additional items. It is important to check the PA requirements for each insurer.

EXCERPTS FROM COMMON PRIOR AUTHORIZATION REQUIREMENTS

PROPHYLACTIC THERAPIES

EXCERPTS FROM COMMON PA REQUIREMENTS FOR PROPHYLACTIC THERAPIES

- History of HAE symptoms
- For the routine use of angioedema prevention; not to be used with other prophylactic HAE treatment
- Prior treatment with 17 alpha-alkylated androgens, or antifibrinolytic agents, was ineffective, or not tolerated (step therapy)

EXCERPTS FROM COMMON PA RENEWAL REQUIREMENTS FOR PROPHYLACTIC THERAPIES

- Member meets the criteria for initial approval
- Member has experienced reduction in frequency, severity, and/or duration of attacks since starting treatment

ON-DEMAND THERAPIES

EXCERPT FROM COMMON PA REQUIREMENTS FOR ON-DEMAND THERAPIES

- For the treatment of an acute HAE attack; not to be used in combination with other acute HAE treatment

EXCERPTS FROM COMMON PA RENEWAL REQUIREMENTS FOR ON-DEMAND THERAPIES

- Member meets the criteria for initial approval
- Member has experienced reduction in severity and/or duration of attacks when they use the requested medication to treat an acute attack

*Sources-
https://www.aetnabetterhealth.com/pennsylvania/assets/pdf/pharmacy/Guidelines/Hereditary-Angioedema-Guideline-4.1.20-ua.pdf
http://www.aetna.com/cpb/medical/data/700_799/0782.html

TIPS FOR SUBMITTING A PRIOR AUTHORIZATION

PA requirements may differ depending on the type of HAE medications, and PA renewals may have different requirements for on-demand and prophylactic therapies.

Request an expedited review for all forms (~48 hours turnaround)

- Any delay in receiving medication could jeopardize the life or health of a patient.
- Submitting an expedited review of the PA results in a faster turnaround time. In some states, the law mandates establishing and tracking a specific turnaround time.

Check the insurance plan PA criteria before submitting

- Each insurer is likely to have medication-specific prior authorization criteria on their website.
- Checking first will help ensure that all criteria are met and all information is submitted.
- This can lead to fewer denials due to unmet criteria and avoid unnecessary delays.

Prepare for future reauthorizations

- PAs are needed every 6-12 months, it would be beneficial to put a note in the system your practice uses for follow-ups.

TIPS FOR SUBMITTING A PRIOR AUTHORIZATION

Regularly follow-up with insurance plans to ensure timely approval

- Regular follow-up will ensure that any issues are recognized and resolved quickly.
- If you do not see a change in the approval status within 48 hours, it is best to reach out to the insurance provider directly to see if more information is needed.

If step therapy is required, a letter of medical exception can be submitted

- Insurance companies will need justification for avoiding step therapy (for example: an individual experienced a previous adverse event or has contraindications).

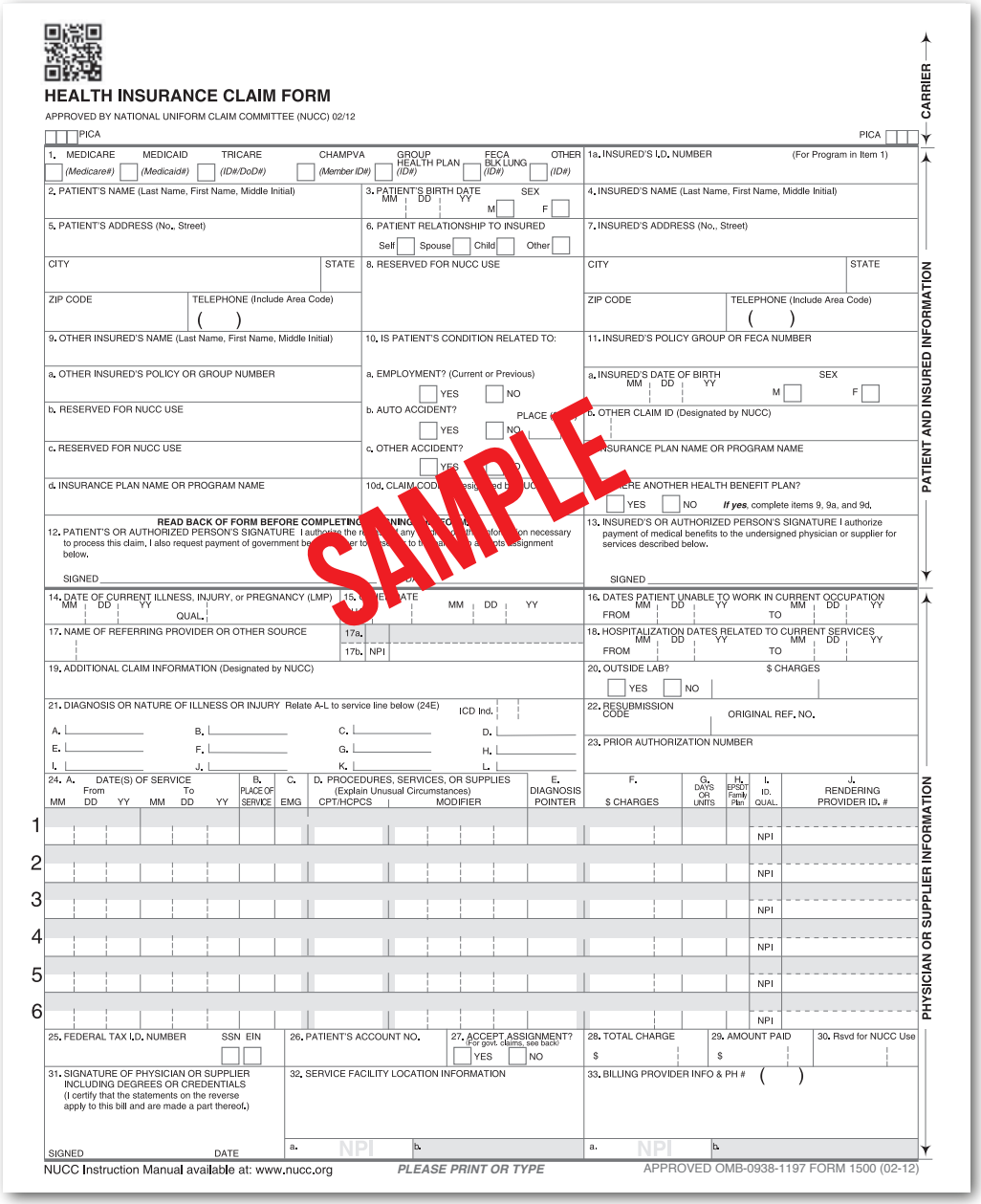
If a denial is received, submit an appeal as soon as possible

- Expediting submission of an appeal will result in a quicker decision.
- Patients can also submit an appeal. If that approach is selected, the appeal is best supported with physician input and representation.

STEPS TO FILE A REIMBURSEMENT CLAIM

Once the PA is approved by the insurance provider and manufacturer, the insurance provider selects the Specialty Pharmacy, which will fill out paperwork to support the reimbursement claim. The Specialty Pharmacy will send the completed documents to the physician's office.

Sample reimbursement claim forms that you may see during this process follow for your information.



HEALTH INSURANCE CLAIM FORM

APPROVED BY NATIONAL UNIFORM CLAIM COMMITTEE (NUCC) 02/12

PICA

1. MEDICARE (Medicare#) MEDICAID (Medicaid#) TRICARE (ID#/DoD#) CHAMPVA (Member ID#) GROUP HEALTH PLAN (ID#) FECA BLK LUNG (ID#) OTHER (ID#)

1a. INSURED'S I.D. NUMBER (For Program in Item 1)

2. PATIENT'S NAME (Last Name, First Name, Middle Initial)

3. PATIENT'S BIRTH DATE MM DD YY SEX M F

4. INSURED'S NAME (Last Name, First Name, Middle Initial)

5. PATIENT'S ADDRESS (No., Street)

6. PATIENT RELATIONSHIP TO INSURED Self Spouse Child Other

7. INSURED'S ADDRESS (No., Street)

CITY STATE

8. RESERVED FOR NUCC USE

CITY STATE

ZIP CODE TELEPHONE (Include Area Code) ( )

ZIP CODE TELEPHONE (Include Area Code) ( )

9. OTHER INSURED'S NAME (Last Name, First Name, Middle Initial)

10. IS PATIENT'S CONDITION RELATED TO:

11. INSURED'S POLICY GROUP OR FECA NUMBER

a. OTHER INSURED'S POLICY OR GROUP NUMBER

a. EMPLOYMENT? (Current or Previous) YES NO

a. INSURED'S DATE OF BIRTH MM DD YY SEX M F

b. RESERVED FOR NUCC USE

b. AUTO ACCIDENT? YES NO PLACE (

b. OTHER CLAIM ID (Designated by NUCC)

c. RESERVED FOR NUCC USE

c. OTHER ACCIDENT? YES

c. INSURANCE PLAN NAME OR PROGRAM NAME

d. INSURANCE PLAN NAME OR PROGRAM NAME

10d. CLAIM CODE

ERE ANOTHER HEALTH BENEFIT PLAN? YES NO *If yes*, complete items 9, 9a, and 9d.

READ BACK OF FORM BEFORE COMPLETING

12. PATIENT'S OR AUTHORIZED PERSON'S SIGNATURE I authorize the r any information necessary to process this claim, I also request payment of government be er to to the and assignment below.

SIGNED

13. INSURED'S OR AUTHORIZED PERSON'S SIGNATURE I authorize payment of medical benefits to the undersigned physician or supplier for services described below.

SIGNED

14. DATE OF CURRENT ILLNESS, INJURY, or PREGNANCY (LMP) MM DD YY QUAL.

15. MM DD YY

16. DATES PATIENT UNABLE TO WORK IN CURRENT OCCUPATION MM DD YY FROM MM DD YY TO

17. NAME OF REFERRING PROVIDER OR OTHER SOURCE

17a.

17b. NPI

18. HOSPITALIZATION DATES RELATED TO CURRENT SERVICES MM DD YY FROM MM DD YY TO

19. ADDITIONAL CLAIM INFORMATION (Designated by NUCC)

20. OUTSIDE LAB? YES NO $ CHARGES

21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY Relate A-L to service line below (24E) ICD Ind.

A. B. C. D.

E. F. G. H.

I. J. K. L.

22. RESUBMISSION CODE ORIGINAL REF. NO.

23. PRIOR AUTHORIZATION NUMBER

24. A. DATE(S) OF SERVICE From MM DD YY	To MM DD YY	B. PLACE OF SERVICE	C. EMG	D. PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances) CPT/HCPCS	MODIFIER	E. DIAGNOSIS POINTER	F. $ CHARGES	G. DAYS OR UNITS	H. EPSDT Family Plan	I. ID. QUAL.	J. RENDERING PROVIDER ID. #
1										NPI	
2										NPI	
3										NPI	
4										NPI	
5										NPI	
6										NPI	

25. FEDERAL TAX I.D. NUMBER SSN EIN

26. PATIENT'S ACCOUNT NO.

27. ACCEPT ASSIGNMENT? (For govt. claims, see back) YES NO

28. TOTAL CHARGE $

29. AMOUNT PAID $

30. Rsvd for NUCC Use

31. SIGNATURE OF PHYSICIAN OR SUPPLIER INCLUDING DEGREES OR CREDENTIALS (I certify that the statements on the reverse apply to this bill and are made a part thereof.)

SIGNED DATE

32. SERVICE FACILITY LOCATION INFORMATION

a. NPI b.

33. BILLING PROVIDER INFO & PH # ( )

a. NPI b.

NUCC Instruction Manual available at: www.nucc.org

PLEASE PRINT OR TYPE

APPROVED OMB-0938-1197 FORM 1500 (02-12)

CARRIER

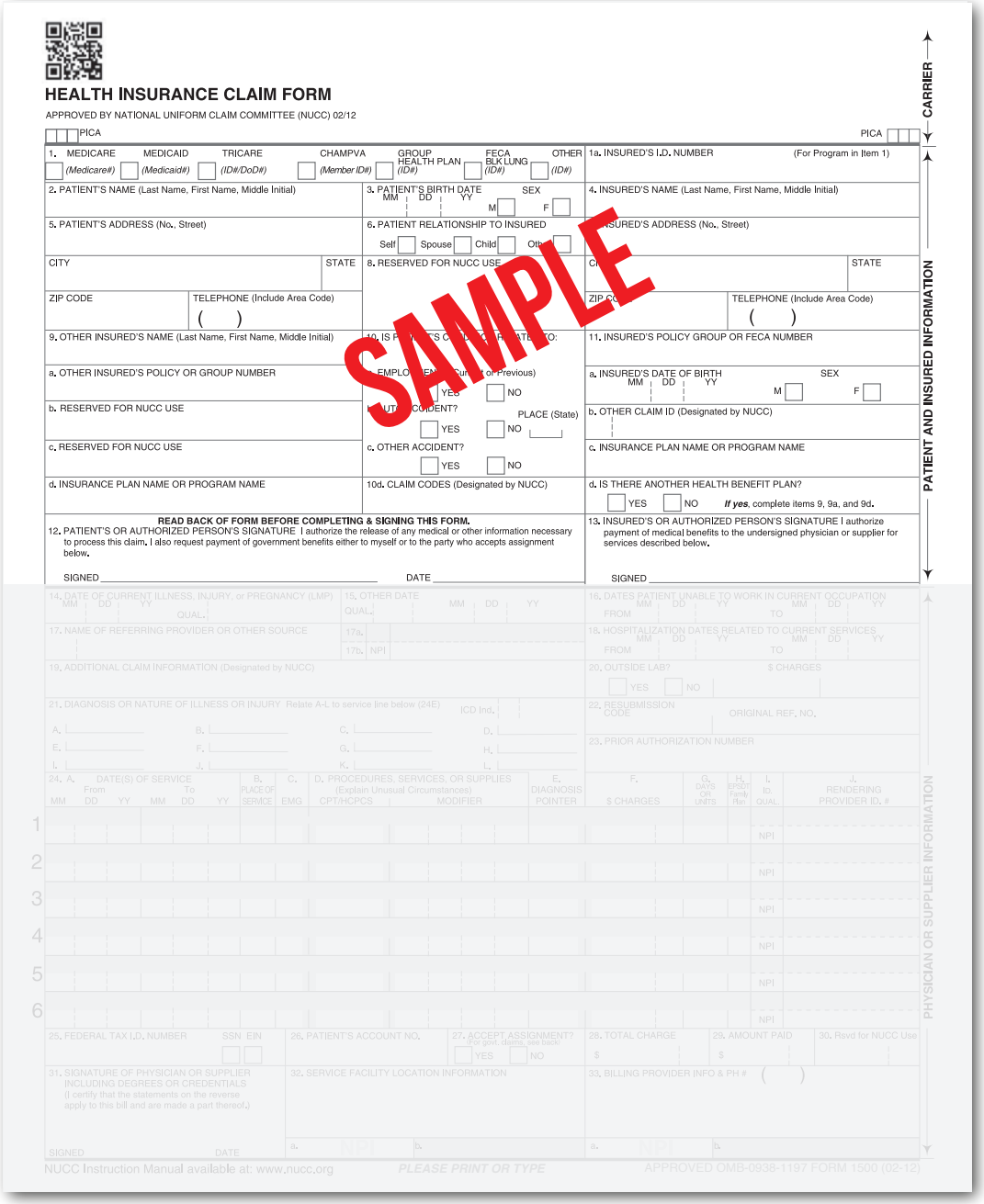
PATIENT AND INSURED INFORMATION

PHYSICIAN OR SUPPLIER INFORMATION

SAMPLE

FILING A REIMBURSEMENT CLAIM

Reimbursement claim forms typically begin by requesting information on the patient's personal and insurance details. It is important that this information is up-to-date and consistent with the information on file for the patient. We have included an example claim form to show the first section.



HEALTH INSURANCE CLAIM FORM

APPROVED BY NATIONAL UNIFORM CLAIM COMMITTEE (NUCC) 02/12

PICA

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1a. INSURED'S I.D. NUMBER (For Program in Item 1)

2. PATIENT'S NAME (Last Name, First Name, Middle Initial)

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4. INSURED'S NAME (Last Name, First Name, Middle Initial)

5. PATIENT'S ADDRESS (No., Street)

6. PATIENT RELATIONSHIP TO INSURED Self Spouse Child Other

7. INSURED'S ADDRESS (No., Street)

CITY STATE

8. RESERVED FOR NUCC USE

CITY STATE

ZIP CODE TELEPHONE (Include Area Code) ( )

ZIP CODE TELEPHONE (Include Area Code) ( )

9. OTHER INSURED'S NAME (Last Name, First Name, Middle Initial)

10. IS PATIENT'S CONDITION RELATED TO:

11. INSURED'S POLICY GROUP OR FECA NUMBER

a. OTHER INSURED'S POLICY OR GROUP NUMBER

a. EMPLOYMENT? (Current or Previous) YES NO

a. INSURED'S DATE OF BIRTH MM DD YY SEX M F

b. RESERVED FOR NUCC USE

b. AUTO ACCIDENT? PLACE (State) YES NO

b. OTHER CLAIM ID (Designated by NUCC)

c. RESERVED FOR NUCC USE

c. OTHER ACCIDENT? YES NO

c. INSURANCE PLAN NAME OR PROGRAM NAME

d. INSURANCE PLAN NAME OR PROGRAM NAME

10d. CLAIM CODES (Designated by NUCC)

d. IS THERE ANOTHER HEALTH BENEFIT PLAN? YES NO *If yes*, complete items 9, 9a, and 9d.

READ BACK OF FORM BEFORE COMPLETING & SIGNING THIS FORM.

12. PATIENT'S OR AUTHORIZED PERSON'S SIGNATURE I authorize the release of any medical or other information necessary to process this claim. I also request payment of government benefits either to myself or to the party who accepts assignment below.

SIGNED DATE

13. INSURED'S OR AUTHORIZED PERSON'S SIGNATURE I authorize payment of medical benefits to the undersigned physician or supplier for services described below.

SIGNED

14. DATE OF CURRENT ILLNESS, INJURY, or PREGNANCY (LMP) MM DD YY QUAL.

15. OTHER DATE QUAL. MM DD YY

16. DATES PATIENT UNABLE TO WORK IN CURRENT OCCUPATION MM DD YY FROM TO

17. NAME OF REFERRING PROVIDER OR OTHER SOURCE

17a.

17b. NPI

18. HOSPITALIZATION DATES RELATED TO CURRENT SERVICES MM DD YY FROM TO

19. ADDITIONAL CLAIM INFORMATION (Designated by NUCC)

20. OUTSIDE LAB? YES NO $ CHARGES

21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY Relate A-L to service line below (24E) ICD Ind.

A. B. C. D. E. F. G. H. I. J. K. L.

22. RESUBMISSION CODE ORIGINAL REF. NO.

23. PRIOR AUTHORIZATION NUMBER

24. A. DATE(S) OF SERVICE From To MM DD YY MM DD YY | B. PLACE OF SERVICE | C. EMG | D. PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances) CPT/HCPCS MODIFIER | E. DIAGNOSIS POINTER | F. $ CHARGES | G. DAYS OR UNITS | H. EPSDT Family Plan | I. ID. QUAL. | J. RENDERING PROVIDER ID. #

1 NPI

2 NPI

3 NPI

4 NPI

5 NPI

6 NPI

25. FEDERAL TAX I.D. NUMBER SSN EIN

26. PATIENT'S ACCOUNT NO.

27. ACCEPT ASSIGNMENT? (For govt. claims, see back) YES NO

28. TOTAL CHARGE $

29. AMOUNT PAID $

30. Rsvd for NUCC Use

31. SIGNATURE OF PHYSICIAN OR SUPPLIER INCLUDING DEGREES OR CREDENTIALS (I certify that the statements on the reverse apply to this bill and are made a part thereof.)

SIGNED DATE

32. SERVICE FACILITY LOCATION INFORMATION

a. NPI b.

33. BILLING PROVIDER INFO & PH # ( )

a. NPI b.

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PLEASE PRINT OR TYPE

APPROVED OMB-0938-1197 FORM 1500 (02-12)

CARRIER

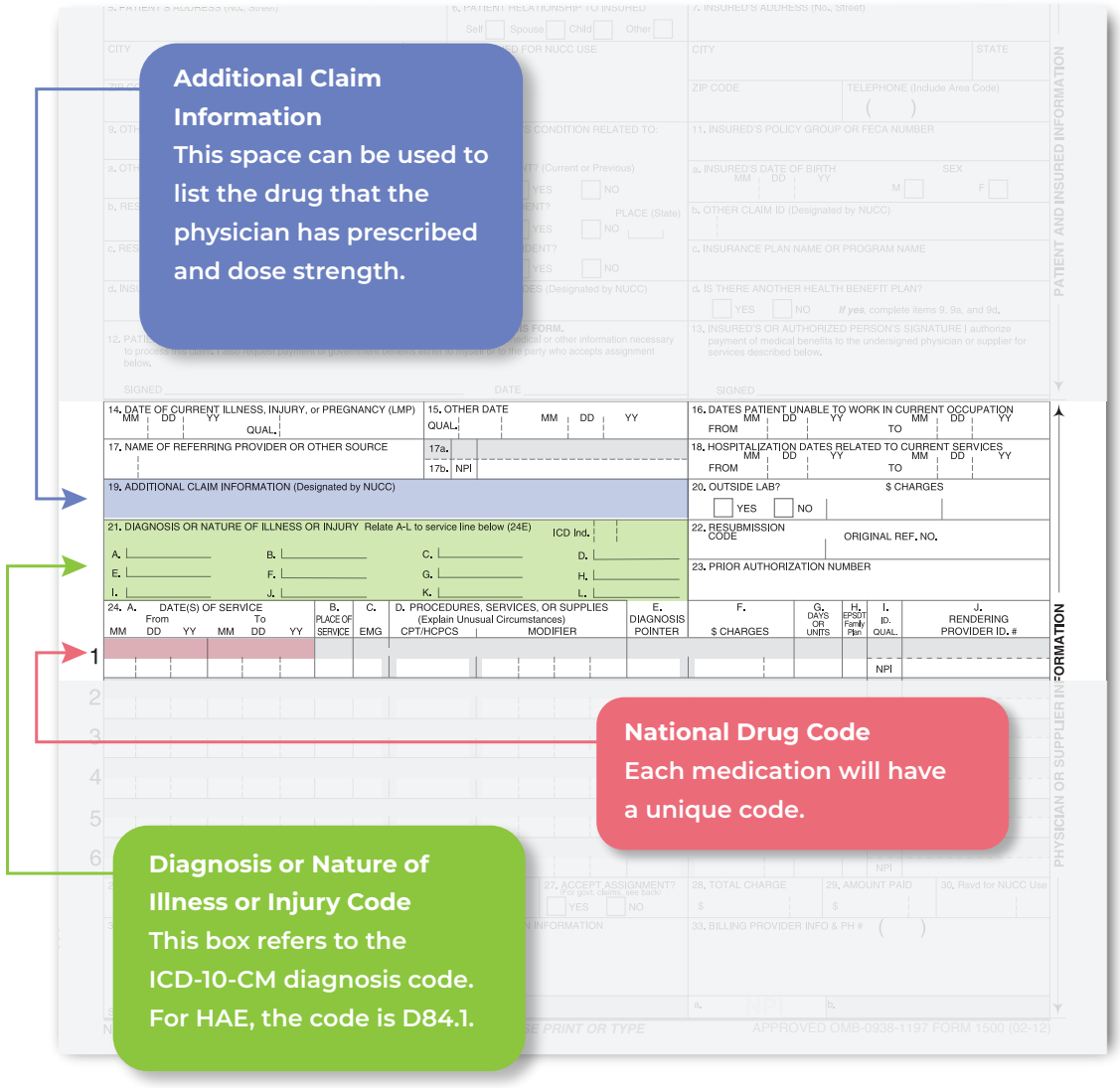
PATIENT AND INSURED INFORMATION

PHYSICIAN OR SUPPLIER INFORMATION

SAMPLE

FILING A REIMBURSEMENT CLAIM

The next section of a reimbursement claim form will ask for information on the HAE medication that has been prescribed, and for the HAE diagnosis. Insurance companies typically require the medication details, diagnosis code (ICD-10-CM code), and national drug code (NDC). The below image shows how these may appear on a claim form.

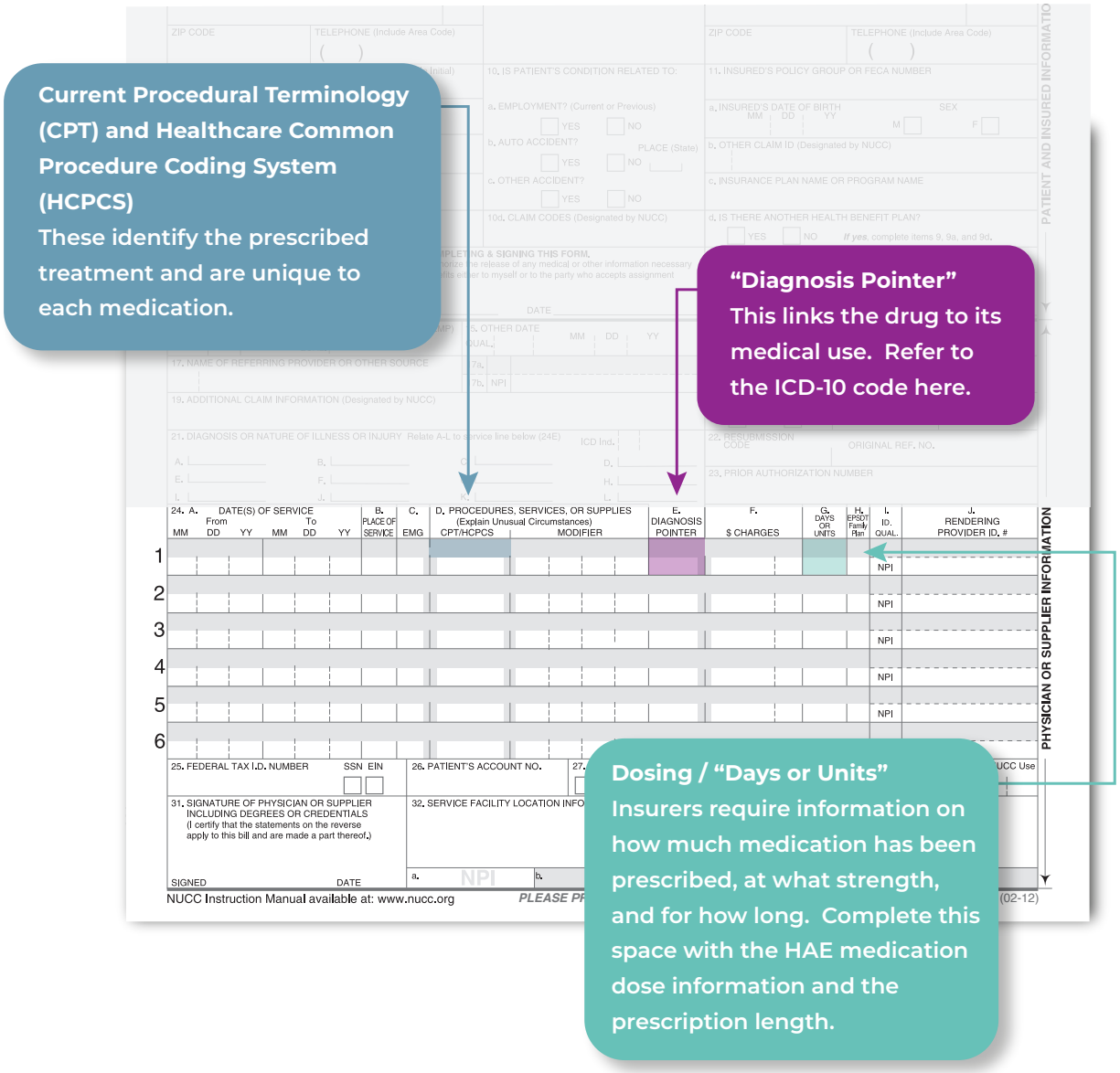


State Medicaid and Medicare plans may require a different format

THE APPEALS PROCESS

The last section of a reimbursement claim typically requires additional details on what the physician has prescribed to treat the patient's HAE; typically procedure codes (CPT and HCPCS), the diagnosis pointer, and detailed dosing information. The image below shows how these may appear on a claim form.

All reimbursement claim forms will require an HCPCS code to indicate the medication and dosing being prescribed.



State Medicaid and Medicare plans may require a different format

TIPS FOR FILING A REIMBURSEMENT CLAIM

Properly filing a reimbursement claim is critical to continuous coverage for HAE medication. The process is often complicated, but here are tips shared by insurers to help navigate the process.

Save a copy of a successfully submitted claim form for an HAE medication	▪ This can serve as an example to complete future forms. Be sure to make note of any additional files that were shared with the insurer.
Check the insurance provider website for specific document requirements for HAE	▪ It may be possible that an insurance provider has additional requirements beyond those mentioned in this Guidebook, and their website will outline these for review.
Remember to confirm the appropriate website link or e-mail and when possible, submit electronically	▪ Electronic medical records can be shared more quickly and securely than fax or mail. Many insurance companies have their own portals to submit these forms, which would be the most direct option.
Ensure the patient maintains copies of their lab work in case they switch plans or want to send documents to the insurance provider	▪ People with HAE are very involved with their treatment plan. It is important that they also maintain copies of any lab work, diagnosis forms, treatment, and attack records which can be helpful if they switch plans or treating physicians.
Make a phone call instead of communicating with insurance companies via mail or e-mail	▪ If you have any questions about a section of the PA, claim form, or denial, the quickest and most direct way to reach out to the insurer is by making a phone call to ask direct questions.

NAVIGATING DIFFICULT SITUATIONS

This section provides sample letters that a prescribing physician can use to avoid or resolve challenges associated with access to an HAE medicine.

For support in resolving these and other insurance issues, please reach out to a HAE Health Advocate at the US HAEA via our website at www.haea.org, or via phone at 866.798.5598.

LETTER OF APPEAL

If a PA form or reimbursement claim is denied, the physician can write a letter of appeal to potentially overturn the decision.

LETTER OF MEDICAL NECESSITY

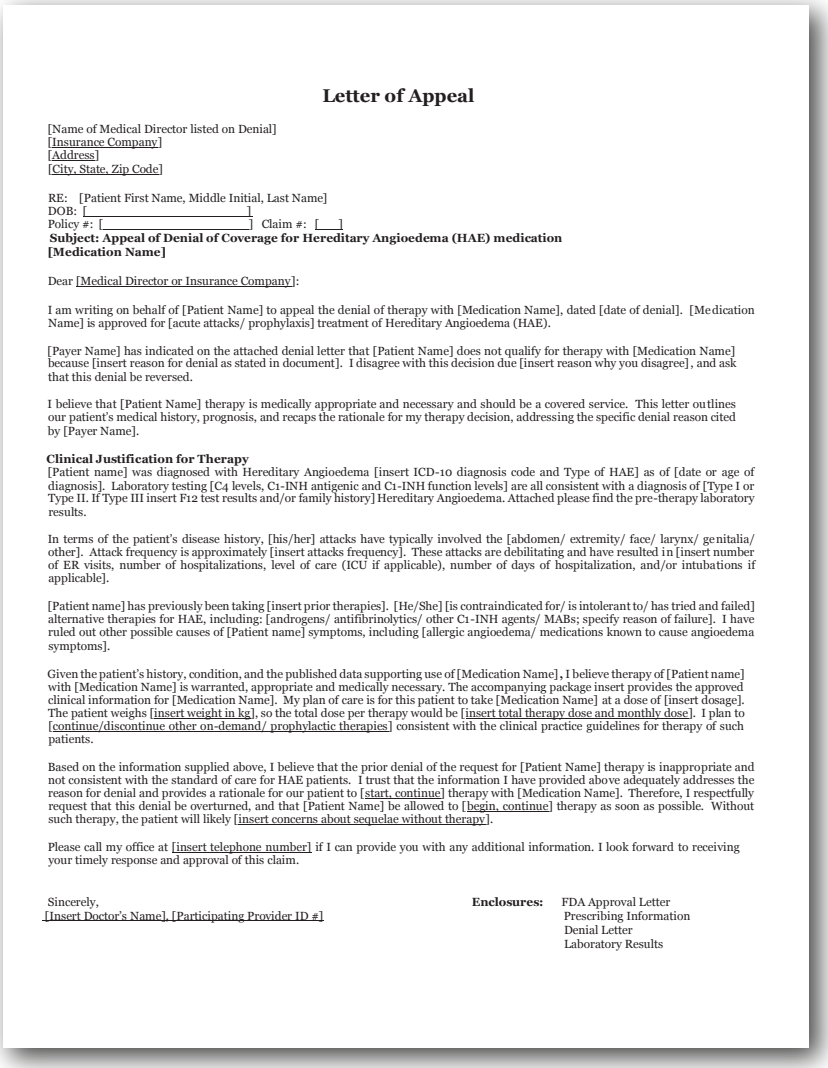
If a physician seeks to prescribe an HAE medication that does not follow the insurer's HAE medical policy, the physician can submit a letter of medical necessity to explain why the patient requires the prescribed therapy.

LETTER OF FORMULARY EXCEPTION

The physician can submit a letter of formulary exception to request approval for medication that is not covered by the patient's insurance plan.

LETTER OF APPEAL

The sample letter (and instructions) below can be used to appeal an authorization or reimbursement denial. An appeal letter can provide additional information and/or the rationale for the physician's treatment decision.



Letter of Appeal

[Name of Medical Director listed on Denial]
[Insurance Company]
[Address]
[City, State, Zip Code]

RE: [Patient First Name, Middle Initial, Last Name]
DOB: [_____]
Policy #: [_____] Claim #: [___]
Subject: Appeal of Denial of Coverage for Hereditary Angioedema (HAE) medication [Medication Name]

Dear [Medical Director or Insurance Company]:

I am writing on behalf of [Patient Name] to appeal the denial of therapy with [Medication Name], dated [date of denial]. [Medication Name] is approved for [acute attacks/ prophylaxis] treatment of Hereditary Angioedema (HAE).

[Payer Name] has indicated on the attached denial letter that [Patient Name] does not qualify for therapy with [Medication Name] because [insert reason for denial as stated in document]. I disagree with this decision due [insert reason why you disagree], and ask that this denial be reversed.

I believe that [Patient Name] therapy is medically appropriate and necessary and should be a covered service. This letter outlines our patient's medical history, prognosis, and recaps the rationale for my therapy decision, addressing the specific denial reason cited by [Payer Name].

Clinical Justification for Therapy
[Patient name] was diagnosed with Hereditary Angioedema [insert ICD-10 diagnosis code and Type of HAE] as of [date or age of diagnosis]. Laboratory testing [C4 levels, C1-INH antigenic and C1-INH function levels] are all consistent with a diagnosis of [Type I or Type II. If Type III insert F12 test results and/or family history] Hereditary Angioedema. Attached please find the pre-therapy laboratory results.

In terms of the patient's disease history, [his/her] attacks have typically involved the [abdomen/ extremity/ face/ larynx/ genitalia/ other]. Attack frequency is approximately [insert attacks frequency]. These attacks are debilitating and have resulted in [insert number of ER visits, number of hospitalizations, level of care (ICU if applicable), number of days of hospitalization, and/or intubations if applicable].

[Patient name] has previously been taking [insert prior therapies]. [He/She] [is contraindicated for/ is intolerant to/ has tried and failed] alternative therapies for HAE, including: [androgens/ antifibrinolytics/ other C1-INH agents/ MABs; specify reason of failure]. I have ruled out other possible causes of [Patient name] symptoms, including [allergic angioedema/ medications known to cause angioedema symptoms].

Given the patient's history, condition, and the published data supporting use of [Medication Name], I believe therapy of [Patient name] with [Medication Name] is warranted, appropriate and medically necessary. The accompanying package insert provides the approved clinical information for [Medication Name]. My plan of care is for this patient to take [Medication Name] at a dose of [insert dosage]. The patient weighs [insert weight in kg], so the total dose per therapy would be [insert total therapy dose and monthly dose]. I plan to [continue/discontinue other on-demand/ prophylactic therapies] consistent with the clinical practice guidelines for therapy of such patients.

Based on the information supplied above, I believe that the prior denial of the request for [Patient Name] therapy is inappropriate and not consistent with the standard of care for HAE patients. I trust that the information I have provided above adequately addresses the reason for denial and provides a rationale for our patient to [start, continue] therapy with [Medication Name]. Therefore, I respectfully request that this denial be overturned, and that [Patient Name] be allowed to [begin, continue] therapy as soon as possible. Without such therapy, the patient will likely [insert concerns about sequelae without therapy].

Please call my office at [insert telephone number] if I can provide you with any additional information. I look forward to receiving your timely response and approval of this claim.

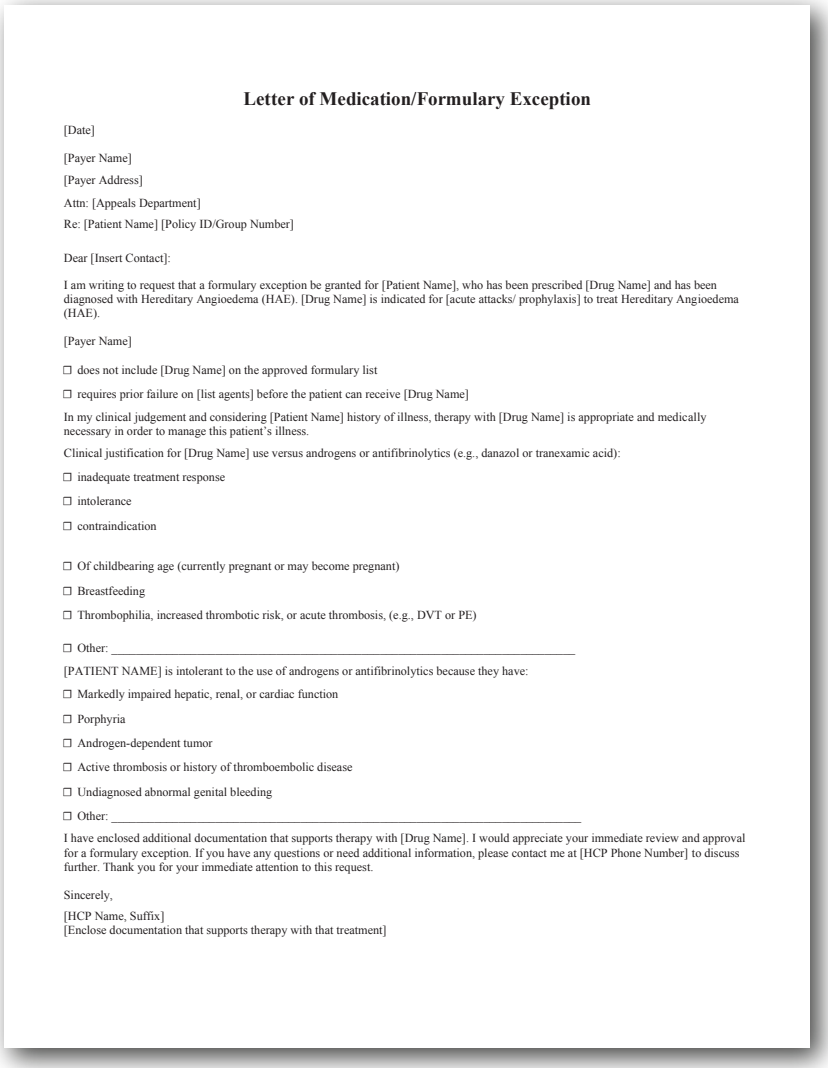
Sincerely,
[Insert Doctor's Name], [Participating Provider ID #]

Enclosures: FDA Approval Letter
Prescribing Information
Denial Letter
Laboratory Results

- Most insurers provide a brief rationale for the denial but these often use technical terms that patients are not familiar with and as a result, can be anxiety inducing
- To appeal the decision, write an appeal letter (such as the example to the left) and be sure to follow any guidelines outlined by the patient's insurer
- The prescribing physician may also be able to conduct a "peer-to-peer" discussion with an insurer's physician to discuss the treatment selection
- It may be necessary to provide additional information, for example:
  - The patient's attack history and overview of prior therapies (this is critical for patients with HAEnC1-INH since they may not have lab results to confirm their HAE but still require treatment)
  - The patient's lab results confirming their HAE diagnosis
- To ensure that the HAE patient does not experience a treatment gap, it is critical to submit the appeal as soon as possible after receiving the denial

LETTER OF FORMULARY EXCEPTION

The physician can submit a letter of formulary exception to request approval for medication that is not covered by the patient's insurance plan.



Letter of Medication/Formulary Exception

[Date]

[Payer Name]

[Payer Address]

Attn: [Appeals Department]

Re: [Patient Name] [Policy ID/Group Number]

Dear [Insert Contact]:

I am writing to request that a formulary exception be granted for [Patient Name], who has been prescribed [Drug Name] and has been diagnosed with Hereditary Angioedema (HAE). [Drug Name] is indicated for [acute attacks/ prophylaxis] to treat Hereditary Angioedema (HAE).

[Payer Name]

☐ does not include [Drug Name] on the approved formulary list

☐ requires prior failure on [list agents] before the patient can receive [Drug Name]

In my clinical judgement and considering [Patient Name] history of illness, therapy with [Drug Name] is appropriate and medically necessary in order to manage this patient's illness.

Clinical justification for [Drug Name] use versus androgens or antifibrinolytics (e.g., danazol or tranexamic acid):

☐ inadequate treatment response

☐ intolerance

☐ contraindication

☐ Of childbearing age (currently pregnant or may become pregnant)

☐ Breastfeeding

☐ Thrombophilia, increased thrombotic risk, or acute thrombosis, (e.g., DVT or PE)

☐ Other: _____

[PATIENT NAME] is intolerant to the use of androgens or antifibrinolytics because they have:

☐ Markedly impaired hepatic, renal, or cardiac function

☐ Porphyria

☐ Androgen-dependent tumor

☐ Active thrombosis or history of thromboembolic disease

☐ Undiagnosed abnormal genital bleeding

☐ Other: _____

I have enclosed additional documentation that supports therapy with [Drug Name]. I would appreciate your immediate review and approval for a formulary exception. If you have any questions or need additional information, please contact me at [HCP Phone Number] to discuss further. Thank you for your immediate attention to this request.

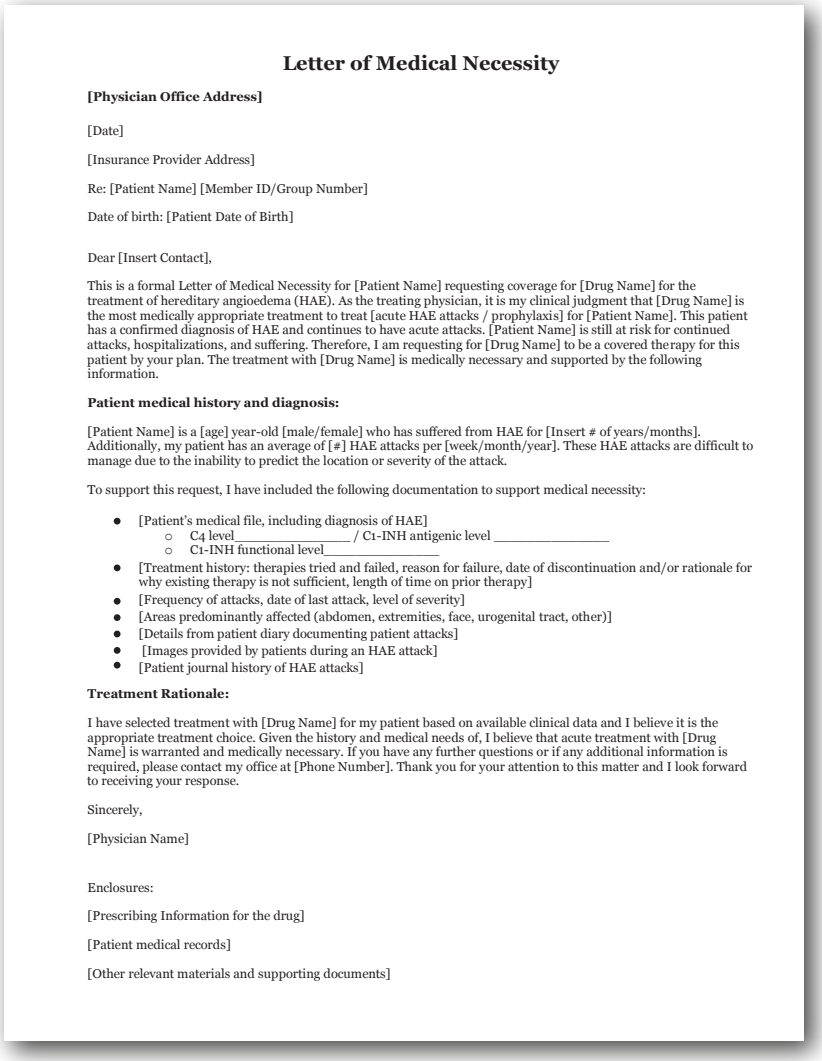
Sincerely,

[HCP Name, Suffix]
[Enclose documentation that supports therapy with that treatment]

- Physicians may decide to prescribe an HAE medication that is not currently covered by the patient's insurance
- If so, the physician may submit a formulary exception letter along with the PA form to justify the need for the prescribed HAE treatment
- Most insurers publish HAE medical policies online which may provide detail on why the therapy is not on formulary; this information can be helpful to address specific reasons for the prescribed HAE treatment
- It may be necessary to provide supplemental information such as:
  - Prescribing information and/or peer reviewed articles
  - Patient's attack history and overview of prior therapies
  - Patient's lab results confirming an HAE diagnosis
- Since there is a chance that this exception is not granted by the insurance provider, to prevent unnecessary stress it is best to prepare the patient to receive a denial or rejection, and discuss alternative treatment approaches

LETTER OF MEDICAL NECESSITY

The physician can submit a letter of medical necessity to provide additional information justifying the clinical appropriateness of the physician's treatment approach and choice of medication.



Letter of Medical Necessity

[Physician Office Address]

[Date]

[Insurance Provider Address]

Re: [Patient Name] [Member ID/Group Number]

Date of birth: [Patient Date of Birth]

Dear [Insert Contact],

This is a formal Letter of Medical Necessity for [Patient Name] requesting coverage for [Drug Name] for the treatment of hereditary angioedema (HAE). As the treating physician, it is my clinical judgment that [Drug Name] is the most medically appropriate treatment to treat [acute HAE attacks / prophylaxis] for [Patient Name]. This patient has a confirmed diagnosis of HAE and continues to have acute attacks. [Patient Name] is still at risk for continued attacks, hospitalizations, and suffering. Therefore, I am requesting for [Drug Name] to be a covered therapy for this patient by your plan. The treatment with [Drug Name] is medically necessary and supported by the following information.

Patient medical history and diagnosis:

[Patient Name] is a [age] year-old [male/female] who has suffered from HAE for [Insert # of years/months]. Additionally, my patient has an average of [#] HAE attacks per [week/month/year]. These HAE attacks are difficult to manage due to the inability to predict the location or severity of the attack.

To support this request, I have included the following documentation to support medical necessity:

- [Patient's medical file, including diagnosis of HAE]
  - C4 level_____ / C1-INH antigenic level _____
  - C1-INH functional level_____
- [Treatment history: therapies tried and failed, reason for failure, date of discontinuation and/or rationale for why existing therapy is not sufficient, length of time on prior therapy]
- [Frequency of attacks, date of last attack, level of severity]
- [Areas predominantly affected (abdomen, extremities, face, urogenital tract, other)]
- [Details from patient diary documenting patient attacks]
- [Images provided by patients during an HAE attack]
- [Patient journal history of HAE attacks]

Treatment Rationale:

I have selected treatment with [Drug Name] for my patient based on available clinical data and I believe it is the appropriate treatment choice. Given the history and medical needs of, I believe that acute treatment with [Drug Name] is warranted and medically necessary. If you have any further questions or if any additional information is required, please contact my office at [Phone Number]. Thank you for your attention to this matter and I look forward to receiving your response.

Sincerely,

[Physician Name]

Enclosures:

[Prescribing Information for the drug]

[Patient medical records]

[Other relevant materials and supporting documents]

- This sample letter can be used in any situation when a physician prescribes an HAE medication that falls outside of the insurer's HAE medical policy
- For example, the physician may want to prescribe a non-preferred medication or avoid step therapy
- Letters of medical necessity can also be used if a physician recommends a branded HAE therapy over a generic
- It may be necessary to provide supplemental information such as:
  - Prescribing information
  - Patient's attack history and overview of prior therapies
  - Patient's lab results confirming an HAE diagnosis
  - Patient's prior HAE medications and reason for change
- Since there is a chance that this exception is not granted by the insurance provider, to prevent unnecessary stress it is best to prepare the patient to receive a denial or rejection, and discuss alternative treatment approaches

TIPS FOR NAVIGATING THE INSURANCE PROCESS

To avoid delays or denials, it is important to ask your patient to keep you updated about any change in insurance

- Change in insurance coverage (whether a switch to another insurance provider or change in benefits/plan) can mean different requirements for access to treatment.

You may be able to submit the reimbursement claim electronically via the insurance providers website

- Check with the insurance provider prior to submitting because reimbursement forms and/or processes vary by insurer.
- Most insurance providers allow for electronic submission of reimbursement claims which expedites the process, and ensures all necessary information is shared.

Communicate and explain denial rationale to the patient to avoid misunderstandings and stress

- An insurance coverage denial is an anxiety inducing experience, contacting the patient and explaining the steps being taken can help reduce the stress level for the patient.

It is best to overshare information about a patient's HAE with insurance companies

- Payers prefer receiving extra information than receiving less (e.g., patient's medical history, diagnosis, current condition, previous treatments and response).

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US HAEA SUPPORT SERVICES

The US HAEA is dedicated to providing unbiased information and personalized services for people with HAE, their caregivers and families.

- **Access and Reimbursement:** The US HAEA Health Team is dedicated to assisting the US HAEA community in obtaining access to their HAE medications, and can help deal with denials, quantity limit overrides, and appeals. The US HAEA Health Team is also available to provide emotional support for any patients struggling with the stress associated with insurance challenges.
- **US HAEA Medical Advisory Board 2020 Guidelines for the Management of HAE:** The US HAEA and its Medical Advisory Board have developed and published guidelines for the management of people with HAE. Many insurance companies reference these Guidelines in their HAE medical policies. The guidelines are available for download on the US HAEA website at www.haea.org, by clicking on Resources/For Health Professionals.
- **US HAEA Website & Educational Webinars:** The US HAEA website offers a comprehensive overview of just about everything that is important to someone with HAE, caregivers, and healthcare professionals. In addition, the US HAEA hosts frequent webinars on a variety of highly relevant topics that are important to the US HAEA community. Please visit the US HAEA at www.haea.org for more information.
- **ADVANCE HAE app:** The ADVANCE HAE app makes it easy for patients to enter and monitor attack reports from virtually any place, and is available for download on the Apple and Google Play stores. The FREE app features include:
  - Personalized reminders for medication refills, physician appointments, and PA due dates.
  - A quick and simple new way to enter and review HAE Attack Reports.
  - Fast and convenient reporting via your own electronic device.
  - Customized health statistics based on data submitted.
  - Personalized health record with graphics illustrating your own HAE attack history.
- **Contact the US HAEA:** Contact the kind and compassionate HAE Advocates at the US HAEA with any questions about HAE, its treatment, insurance issues, and educational resources. To contact the US HAEA, visit our website at www.haea.org, or reach out by phone at 866.798.5598.

MANUFACTURER-SPONSORED SUPPORT PROGRAMS

SELF-ADMINISTRATION TRAINING
Manufacturers have published guides, videos, and/or in-person services for teaching self-administration.

FINANCIAL ASSISTANCE PROGRAMS
Manufacturers have programs that provide financial assistance for insurance premiums and co-pays.

SUPPORT PROGRAMS
Some manufacturers offer medication to bridge the gap during the process of obtaining an insurance approval.

AVAILABLE HAE TREATMENTS

BERINERT® is a plasma-derived C1 Esterase Inhibitor (Human) indicated for the treatment of HAE attacks in adult and pediatric patients. Berinert is delivered intravenously and is approved for self-administration. For more information visit: www.berinert.com.

Acute attacks

Adults and children

Self-administered

Intravenous

CINRYZE® is a C1 Esterase Inhibitor indicated for routine prevention against HAE attacks in adults, adolescents and pediatric patients (6 years of age and older). Cinryze is delivered intravenously and is approved for self-administration. For more information visit: www.cinryze.com.

Prevention medicine

Adults and children

Self-administered

Intravenous

FIRAZYR® is a bradykinin B2 receptor antagonist indicated for treatment of acute attacks of HAE in adults 18 years of age and older. Firazyr is delivered by subcutaneous injection and is approved for self-administration. For more information visit: www.firazyr.com.

Acute attacks

Adults

Self-administered

Subcutaneous injection

HAEGARDA® is a plasma-derived concentrate of C1 Esterase Inhibitor (Human) indicated for routine prevention of HAE attacks in patients 6 years of age and older. Haegarda is delivered by subcutaneous injection and is approved for self-administration. For more information visit: www.haegarda.com.

Prevention medicine

Adults and children

Self-administered

Subcutaneous injection

ICATIBANT (GENERIC) is a bradykinin B2 receptor antagonist indicated for treatment of acute attacks of Hereditary Angioedema (HAE) in adults 18 years of age and older. Generic Icatibant is delivered by subcutaneous injection and is approved for self-administration. Multiple manufacturers offer Generic Icatibant.

Acute attacks

Adults

Self-administered

Subcutaneous injection

KALBITOR® is a plasma kallikrein inhibitor indicated for treatment of acute attacks of HAE in patients 12 years of age and older. Kalbitor is delivered by subcutaneous injection and must be administered by a healthcare professional. For more information go to: www.kalbitor.com.

Acute attacks

Adults and adolescents

Administered by healthcare professional

Subcutaneous injection

ORLADEYO™ is a plasma kallikrein inhibitor indicated for routine prevention of HAE attacks in adults and pediatric patients 12 years and older. ORLADEYO is taken orally once daily. For more information go to: www.orladeyo.com.

Prevention medicine

Adults and adolescents

Self-administered

Oral capsule

RUCONEST® is a plasma free recombinant C1-Inhibitor concentrate for treatment of acute HAE attacks in adults and adolescents. Ruconest is delivered intravenously and is approved for self-administration. For more information go to: www.ruconest.com.

Acute attacks

Adults and adolescents

Self-administered

Intravenous

TAKHZYRO™ is a plasma kallikrein inhibitor (monoclonal antibody) indicated for routine prevention of HAE attacks in patients 12 years and older. TAKHZYRO is administered by subcutaneous injection and is approved for self-administration. For more information go to: www.takhzyro.com.

Acute attacks

Adults and adolescents

Self-administered

Subcutaneous injection

BERINERT®

C1 ESTERASE INHIBITOR

These codes will be used in reimbursement & appeals forms

CODE
ICD-10-CM
D84.1 Defects in the complement system

CODE
HCPCS
J0597
Injection, C1 Esterase Inhibitor (Human), BERINERT, 10 units

CODE
NATIONAL DRUG
BERINERT NDC number from package insert
63833-825-02
BERINERT NDC number to use on claim forms
63833-0825-02

CODE
CPT
96374
Intravenous push, single, or initial substance/drug

*Codes are effective as of October 2020

CINRYZE®

C1 ESTERASE INHIBITOR

These codes will be used in reimbursement & appeals forms

CODE
ICD-10-CM
D84.1 Defects in the complement system

CODE
HCPCS
J0598
Injection, C1 esterase inhibitor (human), 10 units

CODE
NATIONAL DRUG
CINRYZE NDC **42227-081-05;** C1 esterase inhibitor (human)

CODE
CPT
96374 Therapeutic, prophylactic or diagnostic injection, IV push, single or initial substance/drug
96375 Therapeutic, prophylactic or diagnostic injection, each additional sequential IV push (add-on code only)

FIRAZYR®

ICATIBANT

These codes will be used in reimbursement & appeals forms

CODE
ICD-10-CM
D84.1 Defects in the complement system

CODE
HCPCS
J1744
Injection, icatibant, 1 mg

CODE
NATIONAL DRUG
FIRAZYR NDC **54092-702-02,** cartons containing one single-use
FIRAZYR NDC **54092-702-03,** pack containing 3 cartons; each carton contains one single-use

CODE
CPT
96372
Therapeutic, prophylactic, or diagnostic injection; subcutaneous or intramuscular

Generic forms of Icatibant are also currently available.

HAEGARDA®

C1 ESTERASE INHIBITOR

These codes will be used in reimbursement & appeals forms

CODE
ICD-10-CM
D84.1 Defects in the complement system

CODE
HCPCS
J0599
Injection, C1-INH, HAEGARDA, 10 units

CODE
NATIONAL DRUG
HAEGARDA NDC **63833-0828-02;** Subcutaneous Injection; 2000 units
HAEGARDA NDC **63833-0829-02;** Subcutaneous Injection; 3000 units

CODE
CPT
96372
Therapeutic, prophylactic, or diagnostic injection; subcutaneous or intramuscular

KALBITOR®

ECALLANTIDE

These codes will be used in reimbursement & appeals forms

CODE
ICD-10-CM
D84.1 Defects in the complement system

CODE
HCPCS
J1290
Injection, ecallantide, 1 mg

CODE
NATIONAL DRUG
KALBITOR NDC **47783-101-01,** 3 single-use vials in 1 carton

CODE
CPT
96372
Therapeutic, prophylactic, or diagnostic injection; subcutaneous or intramuscular

RUCONEST®

C1 ESTERASE INHIBITOR

These codes will be used in reimbursement & appeals forms

CODE
ICD-10-CM
D84.1 Defects in the complement system

CODE
HCPCS
J0596
Injection, C1 esterase inhibitor (recombinant), RUCONEST, 10 units

CODE
NATIONAL DRUG
RUCONEST NDC **71274-350-02**

CODE
CPT
96374
Therapeutic, prophylactic, or diagnostic injection, IV push, single, or initial substance/drug

TAKHZYRO™

LANADELUMAB-FLYO

These codes will be used in reimbursement & appeals forms

CODE

ICD-10-CM

D84.1 Defects in the complement system

CODE

HCPCS

J0593

Injection, lanadelumab-flyo, 1 mg

CODE

NATIONAL DRUG

TAKHZYRO NDC **47783-644-01,** 300 mg/2 mL (150 mg/mL) vial

CODE

CPT

96401

Chemotherapy administration, subcutaneous or intramuscular; non-hormonal anti-neoplastic

ORLADEYO™

BEROTRALSTAT

These codes will be used in reimbursement & appeals forms

CODE

ICD-10-CM

D84.1 Defects in the complement system

CODE

NATIONAL DRUG

NDC 72769-101, 150 mg/1 capsule

NOTES

US Hereditary Angioedema Association
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ushaea

Hereditary Angioedema Association - HAEA

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