

Considerations for Drafting a Letter of Medical Necessity

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The Sample Letter of Medical Necessity on the following page may be customized by your office and used when requesting coverage for your patients prescribed DAWNZERO.

When to submit a Letter of Medical Necessity

It may be helpful to submit a Letter of Medical Necessity in the following situations:

- As part of an exception, prior authorization, or reauthorization request
- When requesting a tiering or formulary exception
- As part of a request to appeal a coverage denial

To reduce potential delays in getting your patients started on treatment, please keep the following tips in mind when drafting a Letter of Medical Necessity

- **Review the insurance plan's guidelines for documentation requirements**
- **Clearly state the prescriber's credentials and relevant affiliations**, including any HAE-specific experience
- **Provide a comprehensive and concise clinical description of the patient's medical history**, including
 - Diagnosis of HAE
 - Family history of HAE
 - Previous and current medications for prophylactic and acute treatment
 - Rationale for treatment
- **Include the prescriber's signature**
- **Include any required forms and relevant documentation**, such as
 - Documented HAE diagnosis and ICD-10-CM code(s)
 - Documented C1-INH antigenic/functional levels and serum C4 levels (at diagnosis and treatment decision)
 - Location, severity, duration, and frequency of HAE attacks at diagnosis and at treatment decision
 - Include documentation of emergency department visits, hospitalizations, or instances of intubation
 - Previous response to prophylactic and acute treatments
 - **NOTE:** Some prophylactic treatments may supplement C1-INH and cause levels to appear as normal in lab work. It is important to list **all** previous prophylactic treatments and provide reasoning(s) why your patient may appear to have normal C1-INH levels
 - Photos of the patient's HAE swells
 - Relevant scientific literature
 - US Prescribing Information for DAWNZERO
- **Ensure information included** in the letter and additional documentation **is accurate and complete**
- **Document all communication** (written and verbal) with the patient's insurance plan

Instructions for using the sample letter

- Replace [magenta/bracketed] text with specific office/clinic or patient information
- Tailor the content based on your clinical judgment and the patient's unique circumstance

**Use your office's letterhead to draft the Letter of Medical Necessity
and remove this page before submission.**

C1-INH, C1 Inhibitor; HAE, hereditary angioedema; ICD-10-CM, International Classification of Diseases, Tenth Revision, Clinical Modification.

Sample Letter of Medical Necessity
[Office/Clinic Letterhead]

[Date]
[Insurance Plan Contact Name]
[Title]
[Insurance Plan Organization Name]
[Address]
[City, State ZIP]

Re: Letter of Medical Necessity for DAWNZERA™ (donidalorsen)
Patient Name: [Patient Name]
DOB: [MM/DD/YYYY]
Policy ID Number: [Policy #]
Group Number: [Group #, if applicable]
Claim Number: [Claim #, if applicable]

Dear [Insurance Plan Contact Name or Medical Reviewer],

My name is [Prescriber Name], and I am [medical specialty] writing on behalf of my patient, [Patient Name], to document the medical necessity of DAWNZERA™ (donidalorsen). DAWNZERA is indicated for prophylaxis to prevent attacks of hereditary angioedema (HAE) in adults and pediatric patients 12 years of age and older and was approved by the US Food and Drug Administration (FDA) on August 21, 2025. HAE is a rare and lifelong genetic disease characterized by unpredictable swelling attacks that can be fatal. I have [number of years] of experience treating patients with HAE. Included below is my rationale for treatment with DAWNZERA and additional information about the patient's medical history and diagnosis of HAE (ICD-10-CM code: D84.1).

[Patient Name], [Patient Age], was diagnosed with HAE on [MM/DD/YYYY]. During this time, [Patient Name] had [list baseline C1-INH antigenic/functional levels and serum C4 levels; if patient has Type III HAE, provide an explanation on normal C1 level and genetic testing, if available] and current levels are [list C1-INH antigenic/functional levels and serum C4 levels]. [Describe the patient's HAE history, including family history of HAE as well as location, severity, duration, and frequency of attacks over the past month and year]. [Describe any emergency department visits, hospitalizations, or instances of intubation due to severe HAE attacks].

[Patient Name]'s HAE medication history includes [list past and current prophylactic treatments, current acute treatments; include any reasons for discontinuation/switching to a new medication (eg, number of attacks, adverse events, inadequate response); provide reasoning(s) why some prophylactic treatments may supplement C1-INH and cause your patient's levels to appear as normal in lab work].

[If relevant to your patient, describe any of the following scenarios:

- Patient fits the criteria and would like to try DAWNZERA
- Patient has normal C1-INH levels, as a result of current treatment
- Patient is on DAWNZERA but changing insurance plans]

Based on my professional opinion and [Patient Name]'s medical history, I believe that DAWNZERA is medically necessary and an appropriate treatment. I have enclosed the following documentation in support of this request:

- Documented HAE diagnosis and ICD-10-CM code(s)
- Documented C1-INH antigenic/functional levels and serum C4 levels (at diagnosis and treatment decision)
- Frequency at diagnosis, current frequency, severity, and location of HAE attacks
- Previous response to prophylactic and acute treatments
- Photos of the patient's HAE swells
- Relevant scientific literature
- US Prescribing Information for DAWNZERA

Should you have any questions or need additional information, please contact my office at [phone number] or [email]. Thank you for your consideration and prompt review of this request.

Sincerely,

[Physician name, credentials, NPI number]

[Practice name and address]

[Insurance Plan Provider Number]

Phone number: [Practice phone number] Fax number: [Practice fax number]

Enclosures: [US Prescribing Information for DAWNZERO™ (donidalorsen), FDA approval letter, relevant medical records and lab results, relevant scientific literature]