

Considerations for Drafting a Letter of Appeal

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The Sample Letter of Appeal on the following page may be customized by your office and used when requesting a reconsideration of a coverage denial for your patient prescribed DAWNZERA.

When to submit a Letter of Appeal

If your patient's insurance plan denies an exception or prior authorization request for DAWNZERA, it may be helpful to submit a Letter of Appeal to support your rationale for treatment and request that the insurance plan overturn the denial.

Please note that if the exception or prior authorization was rejected, you may not need a Letter of Appeal; you may be able to resubmit by providing the correct and/or missing information required.

Tips to keep in mind when drafting a Letter of Appeal

- **Understand coverage criteria and deadlines** for insurance plans
- **Review the denial letter thoroughly** to identify reason(s) for denial
- **Refer to the specific reason(s) for denial**—it is important to reference the exact language from the denial letter
- **Explain clinical rationale for treatment** with DAWNZERA
- **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
 - If applicable, documentation that attacks are refractory to antihistamines
 - Confirmation that all other causes and treatable triggers have been identified and managed (eg, infection)
 - Copy of the denial letter
 - Relevant scientific literature
 - US Prescribing Information for DAWNZERA
- 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 Appeal
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 Appeal
[Office/Clinic Letterhead]

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

Re: Appeal for Coverage Denial of 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 a [medical specialist] writing on behalf of my patient, [Patient Name], to appeal the recent denial of coverage for 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. In your letter dated [denial letter date], coverage was denied due to [insert specific reason from denial letter]. I have reviewed your letter and, based on my professional opinion, believe that DAWNZERA is the appropriate treatment and medically necessary for [Patient Name] and the coverage decision should be reversed.

[Patient Name], [Patient Age], was diagnosed with HAE (ICD-10-CM code: D84.1) on [MM/DD/YYYY] based on [list family history of HAE, C1-INH antigenic/functional levels and serum C4 levels at the time of diagnosis; if patient has Type III HAE, provide an explanation on normal C1-INH antigenic/functional level and genetic testing, if available] and current levels are [list C1-INH antigenic/functional levels and serum C4 levels]. They experience approximately [insert number] attacks per [month or year]. Swelling attacks are [mild, moderate, severe] and affect their [throat, face, abdomen, extremities, other]. The patient's attacks are accompanied by [pain, vomiting, diarrhea, other] and cause significant disability for [number] days. Many of these attacks have resulted in [insert number of 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 reason(s) 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]. I have assessed my patient thoroughly and have ruled out other potential causes of their attacks, such as [insert all that apply (eg, allergic angioedema, side effects of certain medications)].

I have enclosed additional documentation to further support medical necessity of DAWNZERA

- 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
- Copy of the denial letter
- Relevant scientific literature
- US Prescribing Information for DAWNZERA

The enclosed information supports the claim that treatment with DAWNZERA for this patient is medically necessary, and I disagree with the prior denial of this request. I am committed to helping my patient reach our treatment goals, and trust that the enclosed information will establish the need to reverse the coverage decision and approve this treatment.

Please contact me at [phone number] or [email] if additional information is required to overturn this decision. 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 DAWNZERA™ (donidalorsen), FDA approval letter, copy of denial letter, Letter of Medical Necessity, relevant medical records and lab results, relevant scientific literature]