

Navigating the coverage process for DAWNZERA™ (donidalorsen)



Exception, Prior Authorization & Appeals Guide

DAWNZERA is expected to be covered under the pharmacy benefit and, similar to other treatments for rare disease, patients may need to meet coverage criteria to receive approval from their insurance plan. This resource will help you understand potential coverage criteria for exception or prior authorization requests, what to do if coverage is denied, and how Ionis Every Step™ can help your office navigate this process.

INDICATION

DAWNZERA is indicated for prophylaxis to prevent attacks of hereditary angioedema (HAE) in adult and pediatric patients 12 years of age and older.

SELECT IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

DAWNZERA is contraindicated in patients with a history of serious hypersensitivity reactions, including anaphylaxis, to donidalorsen or any of the excipients in DAWNZERA.

Please see additional Important Safety Information throughout. Please see full Prescribing Information for DAWNZERA, also available at [DAWNZERAhcp.com](https://www.dawnzerahcp.com).

You've Prescribed DAWNZERA—What's Next?



Help your patients access DAWNZERA

Ionis Every Step verifies benefits, identifies plan-specific requirements, and provides prior authorization, appeal and reauthorization support



We start by checking the insurance plan's policy:

- If there is a policy, we will determine if a **prior authorization** is required and confirm the coverage criteria
 - It may take insurance plans 3 to 12 months to establish coverage policies for DAWNZERA after FDA approval
- If there is no established policy, we will determine if the insurance plan has an **exceptions process** and confirm potential documentation to support medical necessity based on criteria for other self-injected long-term prophylactic (LTP) HAE treatments
 - For your patients with Medicare Part D coverage, you could request a coverage determination that can lead to a formulary, quantity, or tiering exception

Visit DAWNZERAhcp.com or call 1-844-444-4305, Monday to Friday, 8 AM to 8 PM ET, for support and resources from Ionis Every Step throughout the approval process

Potential Information That May Be Required by the Insurance Plan



Below is a list of information that may be required by an insurance plan when you prescribe DAWNZERA. Ionis Every Step can help your office gather this information and guide you through the process.

Patient information

- ☐ Demographic information
- ☐ Insurance plan information
- ☐ Family history of HAE
- ☐ List of current and previous medications
 - If patient is taking medications that can trigger HAE (eg, contraceptives), note when the patient discontinued or plans to discontinue use¹

HAE diagnosis and history

- ☐ Diagnosis of HAE with diagnostic and current lab results (eg, C1-INH antigenic/functional levels, serum C4 level, and genetic testing, if applicable)
- ☐ History of HAE attacks (baseline and current frequency, severity, duration, location)
- ☐ List of current and previous medications taken for HAE
- ☐ Reasons for discontinuation of previous medications (eg, number of attacks, adverse events, breakthrough attacks, side effects)
- ☐ If applicable, documentation that attacks are refractory to antihistamines¹
- ☐ Confirmation that all other causes and treatable triggers of HAE have been identified and managed (eg, infection)¹

Additional documentation

- ☐ Any plan-specific documents/forms
- ☐ Copy of US Prescribing Information
- ☐ Relevant scientific literature supporting treatment
- ☐ If possible, include photos of a patient's HAE swells
- ☐ Letter of Medical Necessity

The Letter of Medical Necessity is an important step in the exceptions or prior authorization process.

Please see the next page for considerations on drafting this letter

¹CI-INH, C1-inhibitor; C4, complement component 4; FDA, US Food and Drug Administration; HAE, hereditary angioedema.

SELECT IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

Hypersensitivity Reactions

Hypersensitivity reactions, including anaphylaxis, have been reported in patients treated with DAWNZERA. If signs and symptoms of serious hypersensitivity reactions occur, discontinue DAWNZERA and institute appropriate therapy.

Please see additional Important Safety Information throughout. Please see full [Prescribing Information for DAWNZERA](#), also available at DAWNZERAhcp.com.

Considerations for Completing a Letter of Medical Necessity

When submitting an exception or prior authorization request, it's recommended to include a **Letter of Medical Necessity**. The insurance plan will review this document while making the coverage decision, as it presents the prescriber's rationale for treatment.



Sample Letter of Medical Necessity can be downloaded at DAWNZERAhcp.com or completed online at DAWNZERAhcp.com/Upload. Contact Ionis Every Step with any questions about completing the letter

Keep these considerations in mind when drafting your letter.

- ✓ State that you are writing on behalf of your patient to **document medical necessity** for DAWNZERA
- ✓ Describe your **patient's experience** with HAE, including diagnosis, attack history (eg, location, severity, duration, frequency), relevant lab results, and ED visits, hospitalizations, or instances of intubation
- ✓ List the patient's **HAE medication history**, including current and previous treatments, any contraindications, and reasons for discontinuation (eg, number of attacks, AEs, breakthrough attacks, side effects)
- ✓ Note any **important considerations**, such as if your patient is new to LTP treatment, has normal C1-INH levels on treatment, or is changing insurance plans
- ✓ Include additional documents, which may include
 - US Prescribing Information for DAWNZERA
 - FDA approval letter
 - Relevant medical records and lab results
 - Relevant scientific literature

SELECT IMPORTANT SAFETY INFORMATION

ADVERSE REACTIONS

Most common adverse reactions (incidence ≥ 5%) are injection site reactions, upper respiratory tract infection, urinary tract infection, and abdominal discomfort.

Please see additional Important Safety Information throughout. Please see full [Prescribing Information](#) for DAWNZERA, also available at DAWNZERAhcp.com.

Process to Submit Exception or Prior Authorization

Follow these simple steps to complete your exception or prior authorization request.

1 Send documentation to Ionis Every Step

Ionis Every Step will collect the following from your office:

- Patient's clinical information
- Letter of Medical Necessity
- Any completed insurance plan-specific forms (eg, specific exceptions process forms for Medicare Part D)

2 Submit the exception or prior authorization package to the insurance plan

You can typically submit to the insurance plan using 1 of 2 methods. It's important to confirm the insurance plan's process, as it will vary from plan to plan.



Electronically: If this option is available, Ionis Every Step can provide a link to submit



Verbally: Your office may need to call the insurance plan and verbally request coverage

- Have all documents from the submission package on hand to refer to during the call
- Take detailed notes during the call (eg, representative's name, confirmation number, next steps)
- If requested by the insurance plan, send any additional information in a timely manner















Providing all documentation required by the insurance plan to Ionis Every Step early in the process may help avoid unnecessary delays

AE, adverse event; C1-INH, C1-inhibitor; ED, emergency department; FDA, US Food and Drug Administration; HAE, hereditary angioedema; LTP, long-term prophylactic.

If your submission is approved, skip to page 10

Potential Reasons for Denied Exception or Prior Authorization Requests

The insurance plan may deny coverage of DAWNZERA for several reasons. The recommendations below may help avoid denials.

Reason for denial	Recommendations
 Lack of documentation supporting diagnosis	 Confirm that correct ICD-10-CM code and supporting documentation for diagnosis are included
 Lab results not reflecting the patient diagnosis	 Explain (eg, via Letter of Appeal) any lab results not reflecting the diagnosis (eg, C1-INH antigenic/functional or serum C4 levels in normal range without additional documentation) ¹
 Current use of another LTP treatment for HAE	 Explain why (eg, via Letter of Appeal) the patient will be discontinuing their current LTP treatment
 Trial and failure with a plan-preferred alternate treatment not documented	 Explain why (eg, via Letter of Appeal) preferred alternate treatments are not appropriate for the patient
 Lack of additional documentation	 Check coverage criteria to confirm additional documentation needs (eg, information about the patient's HAE attack frequency or documentation of prescription/consultation with specialist)
 Incorrect request form or process used based on specific insurance plan	 Visit the insurance plan's website to confirm specific forms and processes

SELECT IMPORTANT SAFETY INFORMATION

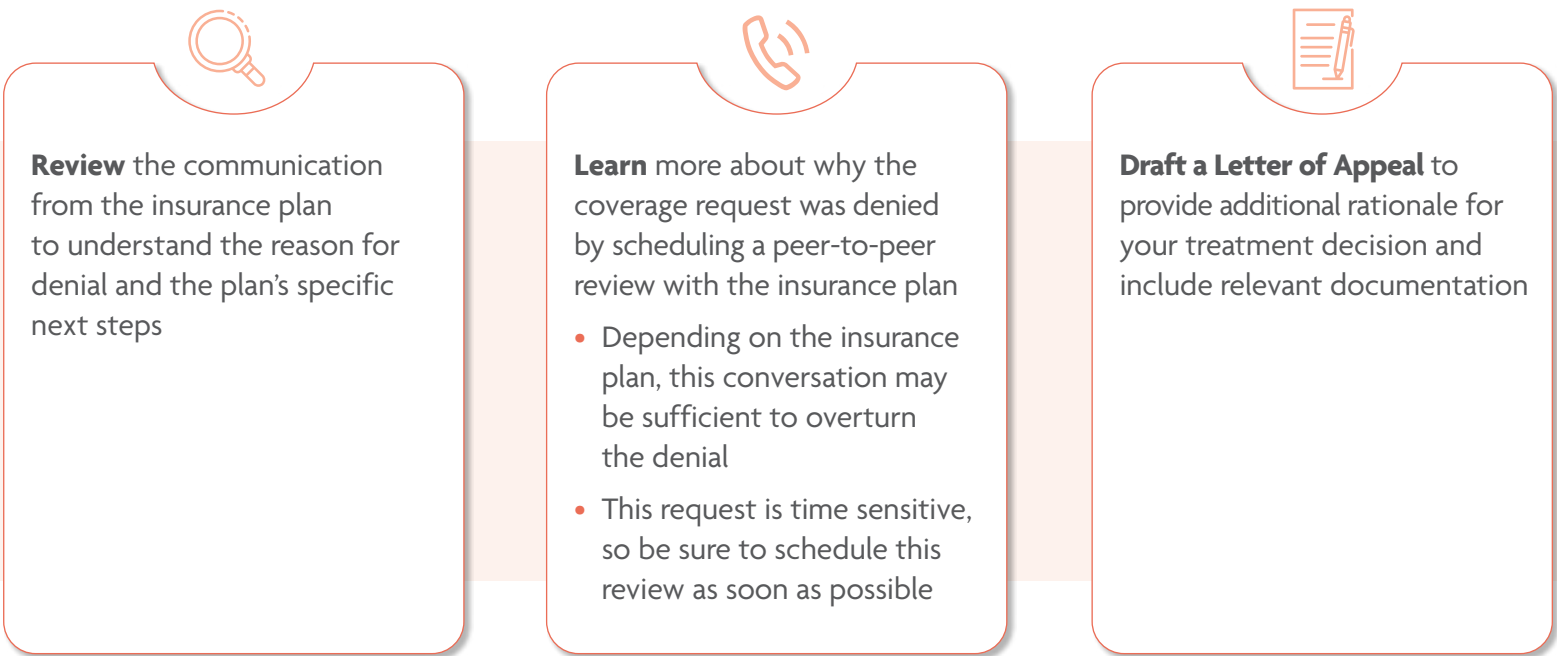
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Next Steps if Coverage Is Denied

If you receive a denial, you can appeal and ask the plan to reconsider their decision. Get started with the steps below.

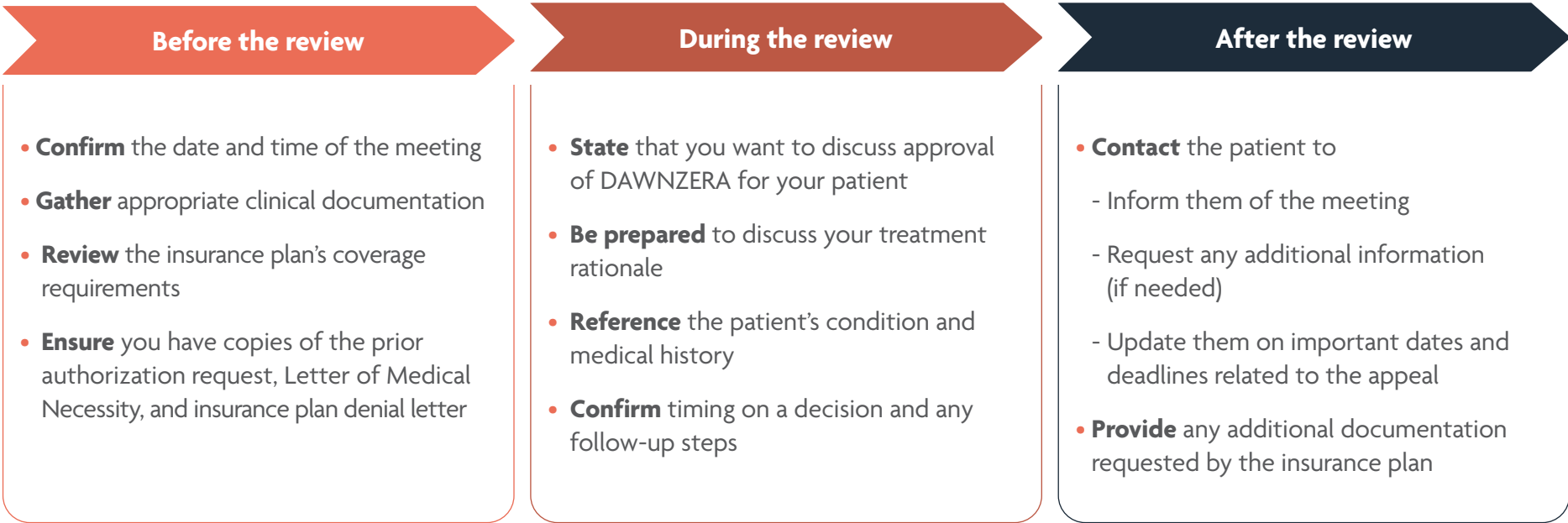


Call Ionis Every Step at 1-844-444-4305 for support with the appeal process

C1-INH, C1-inhibitor; C4, complement component 4; HAE, hereditary angioedema; ICD-10-CM, International Classification of Diseases, Tenth Revision, Clinical Modification; LTP, long-term prophylactic.

Considerations for Requesting a Peer-to-Peer Medical Review

You may have the option to request a peer-to-peer review to learn more about why the coverage request was denied and potentially overturn the coverage decision. This can be requested before drafting the Letter of Appeal.



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Considerations for Completing a Letter of Appeal



Your office can submit a Letter of Appeal to the insurance plan to request a reconsideration of the coverage denial.



Download a sample Letter of Appeal from [DAWNZERAhcp.com](#) and contact Ionis Every Step with any questions about completing the letter


Keep these considerations in mind when drafting your letter.

- ✓ Review the communication from the insurance plan to **understand the reason** for denial and send denial letter to Ionis Every Step
- ✓ Use the **same language** from the insurance plan's letter to explain the reasons for denial
- ✓ State that you are writing on behalf of your patient to **appeal the denial of coverage** for DAWNZERA
- ✓ Describe your **patient's experience**, including diagnosis, attack history (eg, location, severity, duration, frequency), relevant lab results, and ED visits, hospitalizations, or instances of intubation
- ✓ List the patient's **HAE medication history**, including current and previous treatments, any contraindications, and reasons for discontinuation (eg, number of attacks, AEs, breakthrough attacks, side effects)
- ✓ Reiterate that, based on your clinical judgment, DAWNZERA is **appropriate and medically necessary** for your patient
- ✓ Include **additional documents**, such as
 - US Prescribing Information for DAWNZERA
 - FDA approval letter
 - Copy of denial letter
 - Letter of Medical Necessity
 - Relevant medical records and lab results
 - Relevant scientific literature


AE, adverse event; ED, emergency department; HAE, hereditary angioedema; FDA, US Food and Drug Administration.

What’s Next After Coverage Is Approved?


A coverage approval means that the insurance plan has decided to cover DAWNZERA for your patient. After receiving a coverage approval, consider these next steps.



Confirm the length of approval with the insurance plan (eg, 6 or 12 months) and what information is required to request reauthorization




Follow up with the Ionis Every Step Specialty Pharmacy to ensure the prescription was received



Let patients know that they will **need to speak to the Ionis Every Step Specialty Pharmacy** to arrange delivery of DAWNZERA

- To help ensure these calls are answered, encourage your patient to save the specialty pharmacy’s number in their phone



Plan ahead—**ask patients to keep track** of the frequency, severity, and duration of the HAE attacks while on treatment to support clinical response requirement for reauthorization

- Patients can use DAWNZERA Direct to track this information

Ionis Every Step can help set expectations for your patients when receiving and starting DAWNZERA. Call 1-844-444-4305 for more support

HAE, hereditary angioedema.

Indication and Important Safety Information for DAWNZERA



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For additional support accessing DAWNZERA:



Call 1-844-444-4305

Monday to Friday, 8 AM to 8 PM ET



Visit DAWNZERAhcp.com/Ionis-Every-Step-Support

Reference: 1. Maurer M, Magerl M, Betschel S, et al. The international WAO/EAACI guideline for the management of hereditary angioedema-the 2021 revision and update. *Allergy*. 2022;77(7):1961-1990. doi:10.1111/all.15214.

Please see Important Safety Information on Page 11. Please see full Prescribing Information for DAWNZERA, also available at DAWNZERAhcp.com.



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DAWNZERA 
(donidalorsen) 80 mg / 0.8 mL
injection