

Checklist for the Exceptions and Prior Authorization Process

Below is a list of possible criteria that may be required by an insurance plan when prescribing DAWNZERA. Confirm the required information with the insurance plan, as criteria may vary plan to plan.



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^{1,2}
 - Type I: Documented C1-INH antigenic and serum C4 levels
 - Type II: Documented C1-INH functional levels and serum C4 levels
 - Type III (normal C1-INH levels): Genetic testing results may be required
- ☐ Baseline and current details on the HAE attack characteristics below
 - Frequency, severity, duration, and location
 - Number of emergency department visits, hospitalizations, and intubations
- ☐ List of medications taken for HAE
 - Acute (current)
 - Long-term prophylaxis (LTP) (previous and current)
- ☐ 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 (as needed)

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



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 or submitting the letter

C1-INH, C1-inhibitor; HAE, hereditary angioedema; US, United States.

INDICATION

DAWNZERA[™] (donidalorsen) 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 on the next page. Please see full Prescribing Information for DAWNZERA, also available at DAWNZERAhcp.com.

Considerations for Exception or Prior Authorization Requests

DAWNZERA
(donidalorsen) 80 mg / 0.8 mL
injection



Keep in mind that Ionis Every Step will **determine if the insurance plan has a coverage policy in place** for DAWNZERA

- If so, we can confirm the insurance plan's coverage criteria
- If not, we can confirm the insurance plan's process for exceptions and what type of criteria may be required



Use any **insurance plan-specific forms** required by the patient's insurance plan



Document any **confirmation numbers** for future reference



If possible, **request an expedited review** of the exception or prior authorization request



Check that your patient's coverage was approved **before initiating treatment** with DAWNZERA

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

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 on the next page. Please see full Prescribing Information for DAWNZERA, also available at [DAWNZERAhcp.com](https://www.dawnzerahcp.com).

Let's Get Your Patient Started



Ionis Every Step is with you every step of the way to help you and your office navigate the coverage process. Our team can help with:

	Verifying your patient's benefits
	Checking the insurance plan's policy for DAWNZERA
	Identifying plan-specific requirements
	Collecting documentation to help your office with exception and prior authorization submissions

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

SELECT IMPORTANT SAFETY INFORMATION

ADVERSE REACTIONS

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

References: 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. 2. Miranda AR, Ue AP, Sabbag DV, et al. Hereditary angioedema type III (estrogen-dependent) report of 3 cases and literature review. *An Bras Dermatol*. 2013;88(4):578-584. doi:10.1590/abd1806-4841.20131818.

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