

(UnitedHealthcare Pharmacy
Clinical Pharmacy Programs)

Program Number	2026 P 2389-1
Program	Prior Authorization/Medical Necessity
Medication	Dawnzera™ (donidalorsen)*
P&T Approval Date	1/2026
Effective Date	4/1/2026

1. Background:

Dawnzera* is a prekallikrein directed antisense oligonucleotide indicated for prophylaxis to prevent attacks of hereditary angioedema (HAE) in adult and pediatric patients 12 years of age and older.

2. Coverage Criteria ^a:

A. Initial Authorization

1. **Dawnzera*** will be approved based on **all** of the following criteria:

a. Diagnosis of hereditary angioedema (HAE) as confirmed by **one** of the following:

(1) C1 inhibitor (C1-INH) deficiency or dysfunction (Type I or II HAE) as documented by **one** of the following (per laboratory standard):

- (a) C1-INH antigenic level below the lower limit of normal
- (b) C1-INH functional level below the lower limit of normal

-OR-

(2) HAE with normal C1 inhibitor levels and **one** of the following:

- (a) Confirmed presence of variant(s) in the gene(s) for factor XII, angiotensin-converting enzyme 1, plasminogen-1, kininogen-1, myoferlin, and heparan sulfate-glucosaminase 3-O-sulfotransferase 6
- (b) Recurring angioedema attacks that are refractory to high-dose antihistamines with confirmed family history of angioedema
- (c) Recurring angioedema attacks that are refractory to high-dose antihistamines with unknown background de-novo mutation(s) (i.e., no family history) (HAE-unknown)

-AND-

b. Prescribed for the prophylaxis of HAE attacks

-AND-

- c. Not used in combination with other products indicated for prophylaxis against HAE attacks (e.g., Andembry, Cinryze, Haegarda, Orladeyo, Takhzyro)

-AND-

- d. Prescriber attests that patient has experienced attacks of a severity and/or frequency such that they would clinically benefit from prophylactic therapy with Dawnzera*

-AND-

- e. History of failure to all of the following (document date of trial and list reason for therapeutic failure):

- (1) Andembry (garadacimab)
- (2) Haegarda (C1 esterase inhibitor, human)
- (3) Takhzyro (lanadelumab)

-AND-

- f. Prescribed by one of the following:

- (1) Immunologist
- (2) Allergist

Authorization will be issued for 12 months.

B. Reauthorization

1. **Dawnzera*** will be approved based on all of the following criteria:

- a. Documentation of positive clinical response to Dawnzera* therapy

-AND-

- b. Reduction in the utilization of on-demand therapies used for acute attacks (e.g., Berinert, Ekterly, icatibant, Firazyr, Ruconest, Sajazir) as determined by claims information, while on Dawnzera* therapy

-AND-

- c. Prescribed for the prophylaxis of HAE attacks

-AND-

- d. Not used in combination with other products indicated for prophylaxis against HAE attacks (e.g., Andembry, Cinryze, Haegarda, Orladeyo, Takhzyro)

-AND-

e. Prescribed by **one** of the following:

- (1) Immunologist
- (2) Allergist

Authorization will be issued for 12 months.

^a State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

* Dawnzera is typically excluded from coverage. Coverage reviews may be in place if required by law or the benefit plan.

3. Additional Clinical Programs:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4. References:

1. Dawnzera [package insert]. Carlsbad, CA: Ionis Pharmaceuticals, Inc.; September 2025.
2. Wu, E. Hereditary angioedema with normal C1 inhibitor. In: UpToDate, Saini, S (Ed), UpToDate, Waltham, MA, 2025.
3. 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

Program	Prior Authorization/Medical Necessity - Dawnzera™ (donidalorsen)
Change Control	
1/2026	New program.