

ALASKA MEDICAID
Prior Authorization Criteria

**Dawnzera™
(donidalorsen)**

FDA INDICATIONS AND USAGE¹

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

APPROVAL CRITERIA^{1,2,3}

1. Patient meets FDA labeled age **AND**;
2. Prescribed by or in consultation with an allergist or immunologist **AND**;
3. Patient has the diagnosis of hereditary angioedema due to C1-esterase inhibitor deficiency (HAE-C1-INH) [type 1 or type 2] **AND**;
4. Dawnzera™ will be used for HAE prophylaxis **AND**;
5. Patient has a documented history of 3 or more moderate to severe HAE attacks per month **AND**;
6. Medications with an established link to angioedema (e.g. angiotensin converting enzyme inhibitors, estrogen replacement therapy, etc.) have been evaluated and discontinued where appropriate **AND**;
7. Patient has tried and failed or has a documented clinical contraindication to at least two preferred agents approved for HAE prophylaxis from two different therapeutic classes.

DENIAL CRITERIA¹

1. Failure to meet approval criteria **OR**;
2. Dawnzera™ prescribed to be used in combination with another agent indicated for HAE prophylaxis

CAUTIONS¹

- The safety of Dawnzera™ in pregnancy or breastfeeding has not been determined.
- The most common adverse reactions include injection site reactions, upper respiratory tract infection, urinary tract infection, and abdominal discomfort.

DURATION OF APPROVAL

- Initial Approval: up to 3 months
- Reauthorization Approval: up to one year

QUANTITY LIMIT

- 1 80mg autoinjector per 28 days

REFERENCES / FOOTNOTES:

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1. Dawnzera™ (donidalorsen) [prescribing information]. Carlsbad, CA: Ionis Pharmaceuticals Inc.; August 2025
2. 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.
3. Riedl MA, Tachdjian R, Lumry WR, et al. Efficacy and safety of donidalorsen for hereditary angioedema. *N Engl J Med*. 2024;391(1):21-31.