

## PHARMACY POLICY STATEMENT

### Nevada Medicaid

<b>DRUG NAME</b>	<b>Dawnzera (donidalorsen)</b>
BENEFIT TYPE	Pharmacy
STATUS	Prior Authorization Required

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. HAE is a rare autosomal dominant disease characterized by episodic unpredictable swelling, which can occur in a variety of anatomic locations. The swelling results from excess production of the vasodilator bradykinin. Attacks may be painful and cause functional impairment but are not associated with pruritis. The most common types of HAE are caused by deficiency (type 1) or dysfunction (type 2) of C1 inhibitor (C1-INH). Type 1 is the most prevalent.

Dawnzera (donidalorsen) will be considered for coverage when the following criteria are met:

#### Hereditary Angioedema (HAE)

For **initial** authorization:

1. Member is at least 12 years of age; AND
2. Medication must be prescribed by or in consultation with an allergist or immunologist; AND
3. Member has a diagnosis of HAE type I or type II confirmed by **both** of the following:
  - a) Low C4 level
  - b) Low (<50% of normal) C1 inhibitor antigenic and/or functional level; AND
4. Chart notes must document the member's baseline frequency of HAE attacks; AND
5. Member is inadequately controlled with on-demand treatment alone; AND
6. Dawnzera is being prescribed for ongoing prophylaxis and will not be used to treat acute attacks.
7. **Dosage allowed/Quantity limit:** 80 mg subcutaneously every 4 weeks. A dosage of 80 mg every 8 weeks may also be considered.  
QL: 1 autoinjector per 28 days

***If all the above requirements are met, the medication will be approved for 6 months.***

For **reauthorization**:

1. Chart notes must be provided that show a reduced frequency or number of acute attacks since starting treatment.

***If all the above requirements are met, the medication will be approved for an additional 12 months.***

**CareSource considers Dawnzera (donidalorsen) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.**

DATE	ACTION/DESCRIPTION
09/09/2025	New policy for Dawnzera created.

## References:

1. Dawnzera [prescribing information]. Ionis Pharmaceuticals Inc.; 2025.
2. Petersen RS, Bordone L, Riedl MA, et al. A phase 2 open-label extension study of prekallikrein inhibition with donidalorsen for hereditary angioedema. *Allergy*. 2024;79(3):724-734. doi:10.1111/all.15948
3. Riedl MA, Bernstein JA, Jacobs JS, et al. Donidalorsen Treatment of Hereditary Angioedema in Patients Previously on Long-Term Prophylaxis. *J Allergy Clin Immunol Pract*. Published online July 17, 2025. doi:10.1016/j.jaip.2025.06.018
4. Riedl MA, Yaras A, Bordone L, et al. Patient-Reported Outcomes in the Phase III OASIS-HAE Study of Donidalorsen for Hereditary Angioedema. *Allergy*. 2025;80(8):2361-2368. doi:10.1111/all.16563
5. Busse PJ, Christiansen SC, Riedl MA, et al. US HAEA Medical Advisory Board 2020 Guidelines for the Management of Hereditary Angioedema [published online ahead of print, 2020 Sep 6]. *J Allergy Clin Immunol Pract*. 2020;S2213-2198(20)30878-3. doi:10.1016/j.jaip.2020.08.046
6. Maurer M, Magerl M, Betschel S, et al. The international WAO/EAACI guideline for the management of hereditary angioedema - The 2021 revision and update. *World Allergy Organ J*. 2022;15(3):100627. Published 2022 Apr 7. doi:10.1016/j.waojou.2022.100627

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Revised date: 09/09/2025