Effective Date: 02/01/2026
Review date: 11/2025 Scope: Medicaid

DAWNZERA (donidalorsen)

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

A. FDA-approved Indications

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

All other indications are considered experimental/investigational and not medically necessary.

II. CRITERIA FOR INITIAL APPROVAL

Authorization for 6 months may be granted for prevention of hereditary angioedema attacks when all of the following criteria is met:

A. Member is ≥ 12 years of age.
B. Medication is prescribed by, or in consultation with an allergist/immunologist or a physician who specializes in the management of HAE
C. Member has documented diagnosis of HAE type I or type II and meets one of the following (a or b):
    a. Documentation that the member has C1 inhibitor deficiency or dysfunction as confirmed by laboratory testing; and meets one of the following criteria:
        i. C1 inhibitor (C1-INH) antigenic level below the lower limit of normal as defined by the laboratory performing the test, or
        ii. Normal C1-INH antigenic level and a low C1-INH functional level (functional C1-INH less than 50% or C1-INH functional level below the lower limit of normal as defined by the laboratory performing the test); OR
    b. Documentation that the member has normal C1 inhibitor as confirmed by laboratory testing and meets one of the following criteria:
        i. Member has an F12, angiopoietin-1, plasminogen, or kininogen-1 (KNG1), heparan sulfate-glucosamine 3-O-sulfotransferase 6 (HS3ST6), or myoferlin (MYOF) pathogenic variant as confirmed by genetic testing, or
        ii. Member has a documented family history of angioedema and the member's angioedema was refractory to a trial of high-dose antihistamine therapy (e.g., cetirizine at 40 mg per day or the equivalent) for at least one month.
D. Other causes of angioedema have been ruled out (e.g., angiotensin-converting

enzyme inhibitor [ACE-I] induced an angioedema, angioedema related to an estrogen containing drug, allergic angioedema).

E. Member requires long-term prophylactic treatment based on the provider's assessment of the patient's disease activity, quality of life, availability of health care resources, and/or failure to achieve adequate control by appropriate on-demand therapy [i.e., Ekterly (sebetralstat), Kalbitor (ecallantide), Icatibant, Ruconest (C1 esterase inhibitor) or Berinert (C1 esterase inhibitor), etc.]
F. Documentation that the member does not have moderate to severe hepatic impairment
G. Member will not use Dawnzera (donidalorsen) concomitantly with Andembry (garadacimab-gxii), Cinryze (C1-esterase inhibitor), Haegarda (C1-esterase inhibitor), Orladeyo (berotralstat), or Takhzyro(lanadelumab-flyo)
H. Documentation that the member has had an inadequate response, intolerance or contraindication to one of the following: Orladeyo (berotralstat), Takhyzro (lanadelumab-flyo), or Haegarda (C1-esterase inhibitor)

III. CONTINUATION OF THERAPY

Authorization of 6 months may be granted for continuation of therapy when all of the following criteria are met:

A. Documentation that the member meets all criteria for initial approval; AND
B. Documentation that member has experienced a significant reduction in frequency of attacks (e.g., ≥ 50%) since starting prophylactic treatment.
C. Documentation that member has reduced the use of medications to treat acute attacks since starting prophylactic treatment
D. Documentation that the provider has assessed the member for an alternative dosing regimen of Dawnzera 80mg with a reduced dosing frequency of every 8 weeks if clinically appropriate

IV. QUANTITY LIMIT

Dawnzera 80mg/0.8ml: 80mg every 28 days

V. DOSING AND ADMINISTRATION

Indication	Dose
Prophylaxis of Hereditary Angioedema (HAE) attacks	80 mg administered subcutaneously every 4 weeks **A dosage of 80 mg subcutaneously every 8 weeks may be considered.*

VI. REFERENCES

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