PREFERRED SPECIALTY MANAGEMENT POLICY

POLICY: Hereditary Angioedema – Prophylaxis Medications Preferred Specialty Management Policy

- Andembry® (garadacimab-gxii subcutaneous injection – CSL Behring)
- Cinryze® (C1 esterase inhibitor [human] intravenous infusion – Takeda)
- Dawnzera™ (donidalorsen subcutaneous injection – Ionis)
- Haegarda® (C1 esterase inhibitor [human] subcutaneous injection – CSL Behring)
- Takhzyro® (lanadelumab-flyo subcutaneous injection – Takeda)

REVIEW DATE: 12/17/2025; effective 03/02/2026

INSTRUCTIONS FOR USE

THE FOLLOWING COVERAGE POLICY APPLIES TO HEALTH BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. CERTAIN CIGNA COMPANIES AND/OR LINES OF BUSINESS ONLY PROVIDE UTILIZATION REVIEW SERVICES TO CLIENTS AND DO NOT MAKE COVERAGE DETERMINATIONS. REFERENCES TO STANDARD BENEFIT PLAN LANGUAGE AND COVERAGE DETERMINATIONS DO NOT APPLY TO THOSE CLIENTS. COVERAGE POLICIES ARE INTENDED TO PROVIDE GUIDANCE IN INTERPRETING CERTAIN STANDARD BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. PLEASE NOTE, THE TERMS OF A CUSTOMER'S PARTICULAR BENEFIT PLAN DOCUMENT [GROUP SERVICE AGREEMENT, EVIDENCE OF COVERAGE, CERTIFICATE OF COVERAGE, SUMMARY PLAN DESCRIPTION (SPD) OR SIMILAR PLAN DOCUMENT] MAY DIFFER SIGNIFICANTLY FROM THE STANDARD BENEFIT PLANS UPON WHICH THESE COVERAGE POLICIES ARE BASED. FOR EXAMPLE, A CUSTOMER'S BENEFIT PLAN DOCUMENT MAY CONTAIN A SPECIFIC EXCLUSION RELATED TO A TOPIC ADDRESSED IN A COVERAGE POLICY. IN THE EVENT OF A CONFLICT, A CUSTOMER'S BENEFIT PLAN DOCUMENT ALWAYS SUPERSEDES THE INFORMATION IN THE COVERAGE POLICIES. IN THE ABSENCE OF A CONTROLLING FEDERAL OR STATE COVERAGE MANDATE, BENEFITS ARE ULTIMATELY DETERMINED BY THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT. COVERAGE DETERMINATIONS IN EACH SPECIFIC INSTANCE REQUIRE CONSIDERATION OF 1) THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT IN EFFECT ON THE DATE OF SERVICE; 2) ANY APPLICABLE LAWS/REGULATIONS; 3) ANY RELEVANT COLLATERAL SOURCE MATERIALS INCLUDING COVERAGE POLICIES AND; 4) THE SPECIFIC FACTS OF THE PARTICULAR SITUATION. EACH COVERAGE REQUEST SHOULD BE REVIEWED ON ITS OWN MERITS. MEDICAL DIRECTORS ARE EXPECTED TO EXERCISE CLINICAL JUDGMENT WHERE APPROPRIATE AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. WHERE COVERAGE FOR CARE OR SERVICES DOES NOT DEPEND ON SPECIFIC CIRCUMSTANCES, REIMBURSEMENT WILL ONLY BE PROVIDED IF A REQUESTED SERVICE(S) IS SUBMITTED IN ACCORDANCE WITH THE RELEVANT CRITERIA OUTLINED IN THE APPLICABLE COVERAGE POLICY, INCLUDING COVERED DIAGNOSIS AND/OR PROCEDURE CODE(S). REIMBURSEMENT IS NOT ALLOWED FOR SERVICES WHEN BILLED FOR CONDITIONS OR DIAGNOSES THAT ARE NOT COVERED UNDER THIS COVERAGE POLICY (SEE "CODING INFORMATION" BELOW). WHEN BILLING, PROVIDERS MUST USE THE MOST APPROPRIATE CODES AS OF THE EFFECTIVE DATE OF THE SUBMISSION. CLAIMS SUBMITTED FOR SERVICES THAT ARE NOT ACCOMPANIED BY COVERED CODE(S) UNDER THE APPLICABLE COVERAGE POLICY WILL BE DENIED AS NOT COVERED. COVERAGE POLICIES RELATE EXCLUSIVELY TO THE ADMINISTRATION OF HEALTH BENEFIT PLANS. COVERAGE POLICIES ARE NOT RECOMMENDATIONS FOR TREATMENT AND SHOULD NEVER BE USED AS TREATMENT GUIDELINES. IN CERTAIN MARKETS, DELEGATED VENDOR GUIDELINES MAY BE USED TO SUPPORT MEDICAL NECESSITY AND OTHER COVERAGE DETERMINATIONS.

CIGNA NATIONAL FORMULARY COVERAGE:

OVERVIEW

Andembry, Cinryze, Dawnzera, Haegarda, and Takhzyro are all indicated for prophylaxis of **hereditary angioedema**.[1-5] Andembry and Dawnzera are indicated in patients ≥ 12 years of age; Cinryze and Haegarda are indicated in patients ≥ 6 years of age; and Takhzyro is indicated in patients ≥ 2 years of age.

POLICY STATEMENT

This Preferred Specialty Management program has been developed to encourage the use of the Preferred Product(s). For both medications (Preferred and Non-Preferred), the patient is required to meet the respective standard *Prior Authorization Policy* criteria. The patient is also required to try one Preferred Product prior to the approval of the Non-Preferred Product. Requests for the Non-Preferred Product will also be reviewed using the exception criteria (below). Patients meeting the standard *Hereditary Angioedema – Dawnzera Prior Authorization Policy* criteria who have not tried one of the Preferred Products will be offered a review for the Preferred Products using the respective standard *Prior Authorization Policy* criteria. All approvals are provided for 1 year in duration.

Note: Berinert (C1 esterase inhibitor [human] intravenous infusion) and Orladeyo® (berotralstat capsules) are not targeted in this policy.

Documentation: Documentation is required where noted in the criteria as **[documentation required]**. Documentation may include, but is not limited to, chart notes, prescription claims records, prescription receipts, and/or other information. All documentation must include patient-specific identifying information.

Preferred Product: Andembry, Cinryze, Haegarda, Takhzyro
Non-Preferred Product: Dawnzera

***Hereditary Angioedema – Prophylaxis Medications Preferred Specialty Management Policy* non-preferred product(s) is(are) covered as medically necessary when the following non-preferred product exception criteria is(are) met. Any other exception is considered not medically necessary.**

NON-PREFERRED PRODUCT EXCEPTION CRITERIA

Non-Preferred Product	Exception Criteria
Dawnzera	**1.** Approve for 1 year if the patient meets BOTH of the following (A and B): **A)** Patient meets the standard *Hereditary Angioedema – Dawnzera Prior Authorization Policy* criteria; AND **B)** Patient meets ONE of the following (i or ii): **i.** Patient has tried ONE of the Preferred Products: Andembry, Cinryze, Haegarda, or Takhzyro **[documentation required]**; OR **ii.** Patient is continuing therapy with Dawnzera. **2.** If the patient has met the standard *Hereditary Angioedema – Dawnzera PA Policy* criteria (1A) but has not met one of the

	exception criteria (1B), offer to review for the Preferred Products using the respective standard *Hereditary Angioedema Prior Authorization Policy*.

REFERENCES

1. Andembry® subcutaneous injection [prescribing information]. King of Prussia, PA: CSL Behring; June 2025.
2. Cinryze® intravenous infusion [prescribing information]. Cambridge, MA: Takeda; November 2024.
3. Dawnzera™ subcutaneous injection [prescribing information]. Carlsbad, CA: Ionis; August 2025.
4. Haegarda® subcutaneous injection [prescribing information]. Kankakee, IL: CSL Behring; January 2022.
5. Takhzyro® subcutaneous injection [prescribing information]. Lexington, MA: Takeda; January 2025.

HISTORY

Type of Revision	Summary of Changes	Review Date
New Policy	Effective 03/02/2026	12/17/2025