

## Rare Disease Coverage Trends

# HAE Coverage in 2026: Innovation Drives a New Competitive Baseline

Hereditary Angioedema (HAE) is a rare and potentially life-threatening genetic disorder characterized by unpredictable swelling episodes. Until recently, the treatment landscape has remained relatively stagnant.

Historically, HAE therapies have been divided into three categories:

- **Acute treatments** (e.g., BERINERT, KALBITOR) to manage active attacks
- **Short-term prophylaxis** for anticipated triggers
- **Long-term prophylaxis** (e.g., CINRYZE, HAEGARDA, TAKHZYRO) to prevent attacks altogether

Danazol, a cost-effective long-term prophylactic, stands out with notably higher payer coverage with 72% of formularies favoring the drug.

The market is undergoing a notable evolution from reactive management to proactive prevention. As HAE shifts away from high-burden injectable or infusions toward self-administered agents and targeted oral or subcutaneous drugs; both physicians and payers will face substantial challenges in:

- Transitioning patients who are stable on established regimens
- Evaluating clinical and economic value across new therapeutic modalities

Between June and August 2025, the HAE therapeutic landscape experienced a notable shift with the approval of three new treatments—**ANDEMBRY**, **EKTERLY**, and **DAWNZERA**. These agents introduce a novel mechanism of action, a new formulation, and a new dosing regimen, respectively. December 2025 marked the release of **ORLADEYO** oral pellets for children, expanding access to a well-established prophylactic treatment.

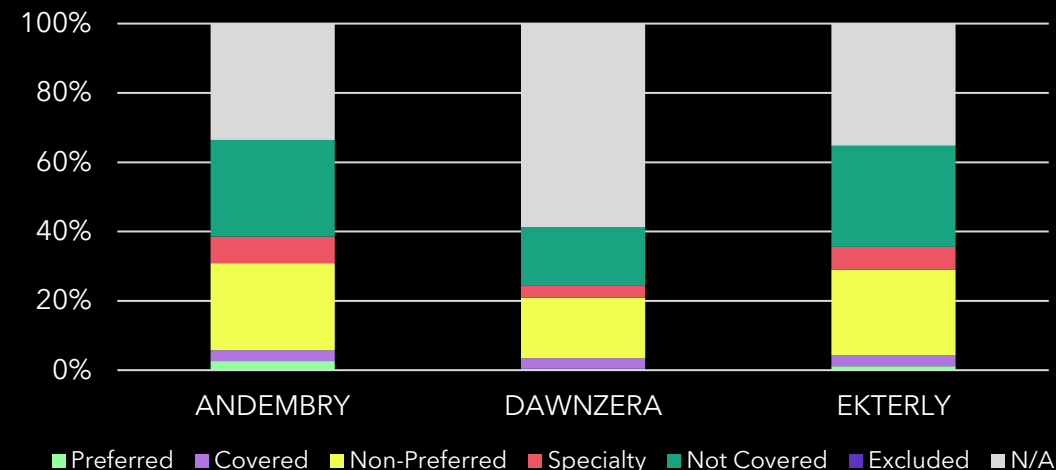
Stay ahead of shifting coverage trends and emerging therapies across rare and complex diseases like HAE with Clarivate's DRG Fingertip foundations [here](#).

Fingertip Coverage | Fingertip Restrictions | Fingertip Publisher | Fingertip PolicyTrack



DRG Fingertip data shows new HAE therapies are being considered for inclusion, with room for coverage to improve through 2026:

Figure 1. Percentage of lives by pharmacy status



## Strategic Implications

- **Early uptake signals a shifting baseline.** Among commercial formularies, ANDEMBRY 3% coverage gain in January 2026 indicates early traction for a newly launched therapy—suggesting payers remain open to rapid adoption when products address unmet need or offer operational advantages.
- **New entrants are redefining competitive dynamics.** With oral and extended-dosing formulations expanding patient choice, newer therapies are placing pressure on established injectables. Early formulary moves—such as CVS preferring ORLADEYO (oral) and TAKHZYRO (subcutaneous) while elevating CINRYZE and HAEGARDA—show how route of administration and dosing convenience are becoming decisive levers.
- **Fragmented HAE coverage is driving increased payer scrutiny.** As innovation accelerates, payers are weighing cost, route of administration, dosing flexibility and overall therapeutic value - factors that are expected to influence evolving prescribing patterns and formulary dynamics in the near term.