

Hereditary Angioedema Drugs Global Market Insights 2025, Analysis and Forecast to 2030, by Market Participants, Regions, Technology, Product Type

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Abstracts

Hereditary Angioedema Drugs Market Summary

The hereditary angioedema (HAE) drugs market is an essential pillar in the rare disease immunology domain, targeting a bradykinin-mediated condition arising from SERPING1 mutations that impair C1 inhibitor function, leading to episodic subcutaneous or mucosal swelling in extremities, abdomen, or airways, with lifetime attack risks exceeding 80% and potential asphyxiation in 30-50% of laryngeal cases. Affecting 1 in 50,000 globally, predominantly autosomal dominant inheritance, HAE burdens patients with unpredictable flares triggered by stress or trauma, necessitating on-demand abortive therapies and long-term prophylactics to suppress attacks by 80-90%. Market hallmarks include C1 esterase inhibitors replenishing deficient protein, kallikrein inhibitors blocking kininogen cleavage, bradykinin B2 antagonists halting vascular permeability, and emerging Factor XIIIa or RNA-targeted agents upstream in the contact pathway, shifting from intravenous rescues to self-administered orals and monthlies for autonomy. These agents achieve attack-free intervals in 70% of users per real-world registries, with biomarkers like C4 levels guiding dosing, though challenges encompass high angioedema recurrence in adolescents and injection-site reactions in 10-15%. Orphan incentives spur innovation, with FDA breakthrough designations fast-tracking RNAs for prophylactic paradigms, while patient advocacy via HAEA drives adherence programs. The landscape integrates allergist-immunologist networks for attack diaries and telehealth escalations, with trends toward combination prophylaxis for refractory types I/II HAE. By 2025, the global HAE drugs market is estimated to be valued between USD 2.8 billion and USD 3.8 billion, with a projected compound annual growth rate (CAGR) of 7.5% to 12.5% through 2030. This vigorous trajectory captures oral prophylactic breakthroughs like berotralstat, expanding adolescent labels, and payer adoptions of

outcomes-linked pricing for attack reductions below 0.5 annually, fueled by heightened awareness and emerging market diagnostics, albeit moderated by biosimilar bradykinin entries.

Regional Market Trends

HAE drugs market patterns diverge regionally, influenced by genetic screening availability, attack severity reporting, and specialty care density.

North America: With a CAGR of 7.0%–11.0%, the United States leads consumption through HAEA registries monitoring 7,000 patients and universal C1-INH testing in ERs, trending toward oral shifts in high-attack urban cohorts like those in Florida.

Europe: Growing at a CAGR of 6.5%–10.5%, Germany and France dominate via EMA orphan incentives and national pharmacovigilance, emphasizing subcutaneous prophylactics in Mediterranean pedigrees with estrogen-linked flares.

Asia-Pacific: Projected CAGR of 8.5%–13.0%, Japan and South Korea accelerate amid consanguinity-driven prevalence, with government reimbursements for kallikrein inhibitors in Seoul's allergy hubs.

Latin America: At a CAGR of 7.5%–12.0%, Brazil and Mexico progress through PAHO angioedema guidelines, focusing on affordable on-demand generics for rural misdiagnosis hotspots.

Middle East and Africa (MEA): Exhibiting a CAGR of 7.0%–11.5%, UAE propels via genomic initiatives in Dubai, though African underreporting above 90% constrains despite aid for laryngeal rescue kits.

Type Analysis

The HAE drugs market segments by type, balancing acute interventions with preventives, evolving toward pathway-selective orals and infrequent dosing.

C1 Esterase Inhibitors: Plasma-derived or recombinant C1-INH concentrates acutely replenish inhibitors to resolve attacks within two hours, with prophylactic

subcutaneous versions like HAEGARDA sustaining C4 above 50%; trends include nanofiltered formulations minimizing thrombosis risks and pediatric extensions, per 70% resolution rates in trials.

Kallikrein Inhibitors: Monoclonals like lanadelumab or orals like berotralstat halt plasma kallikrein to curb bradykinin generation, achieving 87% attack reductions monthly; developments spotlight sebetralstat's on-demand oral for rapid absorption within 30 minutes and combinations for breakthrough flares.

Bradykinin B2 Receptor Antagonists: Icatibant subcutaneous injections competitively block B2Rs for symptom relief in 90% within three hours, favored for self-use; trajectories involve generics eroding premiums and intranasal variants for abdominal attacks, enhancing ER diversions.

Factor XIIa Inhibitor: Monoclonals like garadacimab upstream inhibit FXIIa activation, prophylactically slashing attacks by 87% in phase III; emerging patterns include quarterly dosing and biomarker assays for non-responders.

RNA-Targeted Preventative Treatment: Antisense oligos like donidalorsen silence FXII mRNA for monthly subcutaneous prophylaxis, yielding 81% attack-free in HELIOS-A; innovations encompass self-administration and expansions to acquired angioedema.

Others: Encompassing fresh frozen plasma bridges, this category trends toward fibrinolytic adjuncts like tranexamic acid for mild flares.

Company Profiles

Takeda Pharmaceuticals: Takeda's HAE portfolio, including CINRYZE (C1 esterase inhibitor), TAKHZYRO (lanadelumab-flyo kallikrein inhibitor) with USD 1-2 billion in 2024 sales, FIRAZYR (icatibant B2 antagonist), and KALBITOR (ecallantide), underscores its leadership, with TAKHZYRO's 30% growth driving rare disease revenues within 2024 totals of JPY 4.3 trillion.

CSL Behring: CSL Behring's HAEGARDA and Berinert (C1 esterase inhibitors) generated USD 700-800 million in 2024, up 3-7% with HAEGARDA's +1% and Berinert's +6%, integrated into FY 2024 immunology sales amid AUD 14.8 billion group revenues; recent ANDEMBRY (garadacimab) approvals bolster

prophylactics.

Pharming: Pharming's Ruconest (C1 esterase inhibitor) targets acute attacks with recombinant human C1-INH, sustaining niche demand in Europe and U.S. via its conestat alfa focus.

BioCryst Pharmaceuticals: BioCryst's ORLADEYO (berotralstat), the first oral on-demand kallikrein inhibitor, expands prophylactics, aligning with its HAE-centric pipeline.

KalVista Pharmaceuticals: KalVista's EKTERLY (sebetralstat), an oral kallikrein for acute use, advances on-demand innovation post-approvals.

Ionis Pharmaceuticals: Ionis's DAWNZERA (donidalorsen), RNA-targeted for monthly prophylaxis, targets unmet preventive needs.

Teva Pharmaceuticals: Teva's generic icatibant supports B2 antagonist access, leveraging its generics scale.

Industry Value Chain Analysis

The HAE drugs value chain integrates kallikrein pathway mapping with patient-empowered delivery, highlighting biologic scalability and attack prediction. It initiates with R&D, employing induced pluripotent stem cell models of SERPING1 knockouts and kininogen assays for potency, progressing through basket trials with angioedema quality-of-life endpoints and EMA PRIME access shortening timelines by 12 months.

Manufacturing divides: recombinant C1-INH via rabbit milk transgenics with pasteurization for viral safety, versus monoclonals in PER.C6 cells yielding 4 g/L with protein A capture and SEC polishing to

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