

# Hereditary Angioedema Therapeutic Market – Global Industry Size, Share, Trends, Opportunity, and Forecast, 2018-2028 Segmented By Drug Class (C1-esterase inhibitor, Bradykinin B2 receptor antagonist, Kallikrein inhibitor, Others), By Treatment Type (Prophylaxis, On-demand), by region, and Competition

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## Abstracts

Global Hereditary Angioedema Therapeutic Market has valued at USD 4.38 billion in 2022 and is anticipated to witness an impressive growth in the forecast period with a CAGR of 8.01% through 2028. Hereditary Angioedema (HAE) is a rare genetic disorder that affects a person's immune system and causes episodes of severe swelling. This swelling typically occurs in the deeper layers of the skin and mucous membranes, often involving the face, hands, feet, abdomen, and airways. HAE is a hereditary condition, meaning it is passed down from one generation to the next through a faulty or deficient gene. There are several types of HAE, but the most common are caused by mutations in two genes: SERPING1 and F12. HAE is characterized by sudden and unpredictable attacks of swelling, which can range in severity and typically last for a few days. These attacks can affect various parts of the body. One of the most critical and potentially life-threatening aspects of HAE is when swelling occurs in the airway. Swelling of the throat and larynx can lead to difficulty breathing, which is a medical emergency. HAE is hereditary, meaning it is passed from parents to their children. If one parent has HAE, there is a 50% chance of passing the condition on to their offspring.

Ongoing research into HAE and the development of novel therapies, such as gene-editing techniques like CRISPR/Cas9 and other innovative treatments, are driving market growth. Many HAE therapies have received orphan drug designations, which

provide incentives for pharmaceutical companies to develop treatments for rare diseases like HAE. The HAE market has been expanding to reach more countries and regions, increasing the patient population and treatment demand. The development of more convenient treatment options, such as oral medications, has improved patient compliance and the overall market. Advances in diagnostic techniques have improved the accuracy and speed of HAE diagnosis, leading to more patients seeking treatment. The use of combination therapies, which include both prophylactic and on-demand treatments, has gained traction, further driving market demand.

## Key Market Drivers

### Advancements in Research and Development

Researchers have developed innovative therapies for HAE, including gene-editing techniques like CRISPR/Cas9 and RNA-based therapies. These approaches aim to address the underlying genetic mutations that lead to HAE. The development of oral medications provides more convenient treatment options for patients, reducing the need for frequent injections or infusions. This advancement improves patient compliance and quality of life. Long-acting prophylactic therapies have been developed to reduce the frequency of HAE attacks. These treatments require less frequent administration, providing a more convenient and effective option for some patients. Monoclonal antibodies that target specific components of the HAE pathway, such as kallikrein or bradykinin, have been developed. These antibodies aim to prevent or mitigate HAE attacks by blocking key pathways involved in swelling and inflammation. Research into genetic therapy options, including gene silencing and gene editing techniques, is ongoing. These therapies seek to address the genetic mutations that cause HAE, potentially offering curative approaches. Researchers have identified biomarkers that can help predict HAE attacks or assess treatment response. These biomarkers are valuable for personalized treatment strategies.

Advances in understanding the role of the complement system in HAE have led to the development of complement inhibitors as potential therapies. These drugs target components of the complement system, which is implicated in HAE attacks. Personalized medicine approaches are being explored, considering individual patient genetics and responses to treatments to tailor therapy plans. Researchers have developed animal models of HAE to better understand the disease, test potential therapies, and advance preclinical research. Ongoing clinical trials are evaluating the safety and efficacy of new HAE therapies. These trials provide valuable data and contribute to the development of improved treatments. The inclusion of patient-reported

outcomes in clinical trials and research has helped ensure that therapies address the real-world needs and experiences of HAE patients. Advances in diagnostic tools, including genetic testing and assays for biomarkers, have made it easier to diagnose HAE accurately and quickly. This factor will help in the development of the Global Hereditary Angioedema Therapeutic Market.

### Increasing Orphan Drug Designations

Orphan Drug Designations (ODDs) play a significant role in driving the demand for Hereditary Angioedema (HAE) therapeutic options. ODDs are regulatory designations granted by government agencies, such as the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA), to drugs or therapies intended to treat rare diseases, including HAE. ODDs provide incentives for pharmaceutical companies to invest in the research and development of therapies for rare diseases like HAE. These incentives can include tax credits, grants, and exclusive marketing rights. The promise of ODDs encourages innovation in the field of HAE therapeutics. Companies are more likely to explore new and innovative treatment approaches, leading to a wider range of options for patients. ODDs make HAE therapies more attractive to investors because they reduce the financial risk associated with developing drugs for rare conditions. This increased investment can accelerate research and development efforts. Therapies with orphan drug status may benefit from expedited regulatory reviews, including faster approvals. This means that promising HAE treatments can reach the market more quickly, meeting the urgent needs of patients.

ODDs typically grant market exclusivity for a certain period after drug approval. During this exclusivity period, no other company can market the same drug for the same rare disease. This exclusivity can make HAE therapies more financially viable for pharmaceutical companies. The availability of treatments due to ODDs can expand access to HAE therapies for patients who might not have had viable treatment options before. ODDs have attracted multiple pharmaceutical companies to develop HAE therapies, which can lead to increased competition in the market. Competition often results in improved treatment options and potentially lower costs for patients. While ODDs are typically granted on a national level, they can also have a global impact. The development of HAE therapies under ODDs can benefit patients worldwide as these treatments become available in different regions. Patient advocacy groups often play a role in advocating for ODDs for rare diseases like HAE. Their efforts can help raise awareness, accelerate the development of treatments, and drive demand for these therapies. This factor will pace up the demand of the Global Hereditary Angioedema Therapeutic Market.

## Rising Demand of Combination Therapies

Combination therapies involve the use of two or more treatments, often a combination of prophylactic and on-demand therapies, to manage Hereditary Angioedema (HAE) effectively. HAE is a complex condition with both acute attacks and a need for long-term prevention. Combination therapies address both aspects, offering a comprehensive approach to managing the disease. By combining prophylactic and on-demand therapies, patients can experience a significant reduction in the frequency and severity of attacks. This improved control over the condition can lead to greater demand for these therapies. Effective combination therapies can significantly improve the quality of life for HAE patients. They can experience fewer attacks, less severe symptoms, and a reduced need for emergency medical interventions. Patients who achieve better control of their HAE through combination therapies are often more satisfied with their treatment, leading to increased demand and adherence to these regimens. Effective combination therapy can reduce the need for emergency room visits and hospitalizations, resulting in cost savings for both patients and healthcare systems. This cost-effectiveness can drive demand.

Combination therapies can be tailored to the individual patient's needs. Patients and healthcare providers can work together to create a treatment plan that best suits the patient's lifestyle and medical history. The trend toward patient-centered care encourages shared decision-making between patients and healthcare providers. This approach often favors combination therapies when they align with the patient's preferences and needs. Medical guidelines and recommendations for managing HAE often advocate for combination therapies as an effective strategy. Healthcare providers are more likely to follow these recommendations, increasing the adoption of combination treatments. The pharmaceutical industry continues to develop new combination therapies for HAE, with improvements in existing treatments and the introduction of new, more convenient options. Competition among pharmaceutical companies in the HAE therapeutic market has led to the development of various combination therapies, providing patients with a broader range of treatment options. Patient advocacy groups and awareness campaigns have played a role in educating patients and healthcare providers about the benefits of combination therapies, contributing to increased demand. This factor will accelerate the demand of the Global Hereditary Angioedema Therapeutic Market.

## Key Market Challenges

## Access and Affordability

Hereditary Angioedema therapies can be very expensive. The cost of these therapies, which may include both prophylactic and on-demand treatments, can place a significant financial burden on patients and their families. Access to HAE therapies is often dependent on insurance coverage. Not all insurance plans cover these treatments, and even when coverage exists, copayments and deductibles can be prohibitively high for some patients. Access to HAE therapies can vary based on geographic location. Patients in less developed or remote areas may face greater challenges in accessing specialized care and treatments. In some regions, certain HAE therapies may not be readily available due to regulatory approvals, distribution challenges, or affordability issues. This can limit treatment options for patients. Some patients may experience delayed diagnosis due to limited access to healthcare resources or a lack of awareness about HAE among healthcare providers. Delayed diagnosis can lead to more severe symptoms and complications. For patients without access to or affordability of HAE therapies, the cost of emergency medical care, including hospitalization, can be a significant financial burden. The high cost of HAE treatments and the potential for lifelong treatment can result in financial stress for patients and their families, affecting their overall well-being. Vulnerable populations, including those with lower socioeconomic status or limited access to healthcare resources, may face greater challenges in accessing and affording HAE treatments.

## Resistance and Allergic Reactions

Over time, some Hereditary Angioedema patients may develop resistance to certain therapeutic options, such as C1-esterase inhibitors or other medications. This resistance can result in reduced treatment efficacy, leading to more frequent or severe attacks. When resistance occurs, healthcare providers often need to explore alternative treatment options, which can be limited. Finding an effective alternative can be challenging, and not all patients respond equally to the available therapies. Some patients may experience allergic reactions to certain HAE therapies. Allergic reactions can range from mild to severe and may necessitate discontinuation of the treatment, making it necessary to seek alternatives. Severe allergic reactions can lead to anaphylaxis, a potentially life-threatening condition. The risk of anaphylaxis from HAE therapy can deter both patients and healthcare providers from using specific treatments. Resistance and allergic reactions raise safety concerns for patients. Some may be hesitant to continue using treatments that have caused adverse reactions in the past, leading to suboptimal management of their condition. Due to resistance or allergic reactions, some patients may discontinue their prescribed HAE therapies. This can



result in uncontrolled symptoms and increased risk of severe attacks. The need for alternative therapies, increased medical monitoring, and management of allergic reactions can lead to higher healthcare costs for both patients and healthcare systems. When patients must switch between or combine multiple therapies to address resistance or allergic reactions, treatment regimens can become more complex and challenging to manage.

## Key Market Trends

### Patient Advocacy

Patient advocacy groups and organizations work to raise awareness about Hereditary Angioedema (HAE) among the public, healthcare providers, and policymakers. They provide educational resources to help people better understand the condition. Advocacy efforts emphasize the importance of early diagnosis and encourage individuals experiencing symptoms to seek medical evaluation promptly. Early diagnosis is essential for effective HAE management. Patient advocacy groups advocate for improved access to HAE treatments, including insurance coverage and reimbursement support. They work to reduce financial barriers that can limit access to therapies. Advocacy organizations often fund or facilitate research into HAE, helping to advance our understanding of the condition and contributing to the development of new treatment options. Patient advocacy groups may encourage patient participation in clinical trials, promoting the development of innovative therapies and the collection of real-world data. Advocacy efforts can influence healthcare policies and regulations related to HAE. These organizations work to ensure that the needs of HAE patients are considered in policymaking decisions. Patient advocates work to improve the overall quality of life for individuals living with HAE. They may address psychosocial challenges, mental health support, and the importance of patient-centered care. Advocacy for HAE is part of a broader movement to raise awareness about rare diseases and the unique challenges they pose for patients and healthcare systems.

### Segmental Insights

#### Drug Class Insights

In 2022, the Global Hereditary Angioedema Therapeutic Market largest share was held by C1-esterase inhibitor segment and is predicted to continue expanding over the coming years. C1-esterase inhibitors have a long history of efficacy in managing HAE attacks. These therapies effectively replace or supplement the deficient C1-esterase

inhibitor protein, which is at the root of HAE. Their effectiveness in reducing the severity and duration of HAE attacks has made them a preferred choice for many patients and healthcare providers. C1-esterase inhibitors were among the earliest HAE treatments available. Over the years, they have established a strong track record for safety and effectiveness. Their reliability and familiarity have contributed to their significant market share. C1-esterase inhibitors are often recommended in international treatment guidelines for HAE. These guidelines provide clear recommendations for healthcare professionals, reinforcing their use. C1-esterase inhibitors are available in different administration forms, including intravenous (IV) and subcutaneous (SC). This variety allows patients and healthcare providers to choose the most suitable method, considering factors such as convenience and patient preference. C1-esterase inhibitors are typically used for on-demand or acute attack management in HAE. Given that HAE attacks can be sudden and unpredictable, these therapies are crucial for patients. In many regions, C1-esterase inhibitors have established insurance coverage and reimbursement mechanisms, making them more accessible and affordable for patients.

### Treatment Type Insights

In 2022, the Global Hereditary Angioedema (HAE) Therapeutic Market largest share was held by on-demand segment and is predicted to continue expanding over the coming years. Patients with HAE often require on-demand treatments to manage acute attacks. The demand for these treatments is consistent, as patients can experience sudden and unpredictable attacks of swelling. Therefore, the on-demand segment caters to a critical and immediate patient need. On-demand treatments have a well-established track record of effectively managing acute HAE attacks. This proven efficacy can make them a preferred choice for both patients and healthcare providers. On-demand treatments are often used alongside prophylactic therapies. While prophylactic treatments aim to prevent attacks, on-demand therapies are crucial for addressing attacks when they do occur. This combination approach is common in HAE management. On-demand treatments are designed to be convenient and easy to administer during an attack, which can make them more appealing to patients. They are often available in a more user-friendly format, such as pre-filled syringes or auto-injectors. On-demand treatments for HAE have been available for a longer time and have become a standard of care. They have had more time to establish a presence in the market compared to newer prophylactic or long-acting therapies.

### Regional Insights

The North America region dominates the Global Hereditary Angioedema Therapeutic

Market in 2022. North America has a relatively higher prevalence of HAE compared to other regions, which necessitates a more extensive market for HAE therapies. The region's healthcare system has been proactive in diagnosing and treating HAE, leading to a larger patient population. The region boasts advanced healthcare infrastructure, which includes well-established healthcare facilities, medical expertise, and research institutions. This infrastructure is crucial for the development and distribution of HAE therapies. North America is home to numerous pharmaceutical and biotechnology companies that have been at the forefront of HAE research and development. These companies have contributed to the creation of innovative therapies for the condition. Regulatory agencies such as the U.S. Food and Drug Administration (FDA) have been supportive of HAE therapies, expediting approvals and providing incentives for the development of orphan drugs. Fast Track designations, orphan drug designations, and other regulatory mechanisms have facilitated the introduction of new treatments.

### Key Market Players

CSL Limited

Takeda Pharmaceutical Company Limited

Pharming Healthcare Inc

Sanofi S.A.

BioCryst Pharmaceuticals Inc

Ionis Pharmaceuticals, Inc

Shire Plc

Attune Pharmaceuticals, Inc

Adverum Biotechnologies, Inc

KalVista Pharmaceuticals, Inc

### Report Scope:

In this report, the Global Hereditary Angioedema Therapeutic Market has been



segmented into the following categories, in addition to the industry trends which have also been detailed below:

Hereditary Angioedema Therapeutic Market, By Drug Class:

C1-esterase inhibitor

Bradykinin B2 receptor antagonist

Kallikrein inhibitor

Others

Hereditary Angioedema Therapeutic Market, By Treatment Type:

Prophylaxis

On-demand

Hereditary Angioedema Therapeutic Market, By region:

North America

United States

Canada

Mexico

Asia-Pacific

China

India

South Korea

Australia

Japan

Europe

Germany

France

United Kingdom

Spain

Italy

South America

Brazil

Argentina

Colombia

Middle East & Africa

South Africa

Saudi Arabia

UAE

## Competitive Landscape

Company Profiles: Detailed analysis of the major companies presents in the Global Hereditary Angioedema Therapeutic Market.

## Available Customizations:

Global Hereditary Angioedema Therapeutic Market report with the given market data,

*Hereditary Angioedema Therapeutic Market – Global Industry Size, Share, Trends, Opportunity, and Forecast, 201...*

Tech Sci Research offers customizations according to a company's specific needs. The following customization options are available for the report:

#### Company Information

Detailed analysis and profiling of additional market players (up to five).

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  - 16.10.4. Financials (In case of listed companies)
  - 16.10.5. Recent Developments
  - 16.10.6. SWOT Analysis

## **17. STRATEGIC RECOMMENDATIONS**

## 18. ABOUT US & DISCLAIMER



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