

# Hepatic Encephalopathy Market Report 2034: Epidemiology Data, Pipeline Therapies, Latest FDA Approvals by DelveInsight

*Hepatic Encephalopathy companies are Salix Pharmaceuticals, Bausch Health, Axcella Health, Inc., Umecrine Cognition, Vedanta Biosciences*

LAS VEGAS, NV, UNITED STATES, December 18, 2024 /EINPresswire.com/ -- DelveInsight's "Hepatic Encephalopathy Market Insights, Epidemiology, and Market Forecast-2034" report offers an in-depth understanding of the Hepatic Encephalopathy, historical and forecasted epidemiology as well as the Hepatic Encephalopathy market trends in the United States, EU4 (Germany, Spain, Italy, France) the United Kingdom and Japan.

To Know in detail about the Hepatic Encephalopathy market outlook, drug uptake, treatment scenario and epidemiology trends, Click here; [Hepatic Encephalopathy Market Forecast](#)

Recent developments in the Hepatic Encephalopathy Market:

On November 18, 2024, Bausch Health Companies Inc. (NYSE: BHC, TSX: BHC) and its gastroenterology (GI) division, Salix Pharmaceuticals, announced the first results from their late-stage RED-C clinical trial program. These findings will be presented at The Liver Meeting® hosted by the American Association for the Study of Liver Disease (AASLD) in San Diego, CA. The RED-C clinical program aims to evaluate the efficacy of a next-generation therapeutic—a soluble solid dispersion (SSD) immediate-release rifaximin product—in delaying the onset of first overt hepatic encephalopathy (OHE) hospitalization. Currently, there are no globally approved medications for primary prophylaxis or delaying the progression to the first episode of OHE in cirrhosis patients. Another key objective of this study is to assess the impact of this next-generation treatment on significant clinical outcomes, including all-cause hospitalization rates, the first occurrence of an OHE event requiring hospitalization, and overall mortality.

As of September 27, 2024, Neuropathix is advancing therapies for hepatic encephalopathy, with drugs currently at various stages of development.

Additionally, ASKA Pharmaceutical and the University of Tsukuba are both actively involved in developing treatments for hepatic encephalopathy, with progress updates provided as of September 27, 2024.

In November 2023, Vedanta Biosciences presented the findings of a late-breaking poster detailing the results of an investigator-sponsored, randomized, placebo-controlled Phase 2a study of VE303 as a potential therapy for hepatic encephalopathy. The topline results from the study indicated that VE303 demonstrated an acceptable safety and tolerability profile overall.

Some of the key facts of the Hepatic Encephalopathy Market Report:

The Hepatic Encephalopathy market size is anticipated to grow with a significant CAGR during the study period (2020-2034).

The total Hepatic Encephalopathy (HE) market size across the 7MM was approximately USD 1,680 million in 2023 and is expected to grow throughout the forecast period (2024-2034). This growth will be driven by increasing awareness of the disease, improvements in diagnostic capabilities, and the introduction of emerging targeted therapies for HE.

Among the EU4 and the UK, Germany accounted for the largest share of the HE market in 2023, with 31%, while Spain had the smallest share, contributing just 10% to the overall market in the same year.

In 2023, Japan held the second-largest share of the HE treatment market, making up about 4% of the total market across the 7MM.

Key Hepatic Encephalopathy Companies: Salix Pharmaceuticals, Bausch Health, Axcella Health, Inc., Umeocrine Cognition, Vedanta Biosciences, Patricia Bloom, Rebiotix, and others

The Hepatic Encephalopathy Market report offers insights into current treatment approaches, emerging therapies, the market share of individual treatments, and the current and projected market size for Hepatic Encephalopathy across the 7MM from 2020 to 2034. It also examines current treatment algorithms, identifies unmet medical needs, and explores opportunities to capitalize on the market's growth potential.

The diagnosed prevalence of Hepatic Encephalopathy is expected to rise, driven by factors such as increased awareness, growing healthcare concerns, longer life expectancy, and changes in cirrhosis-related admissions.

In 2023, the US held the largest share of diagnosed Hepatic Encephalopathy cases in the 7MM, accounting for 61%, followed by Japan with around 9% of the total cases. In Europe, the UK reported the highest number of cases, contributing to approximately 8% of the total 7MM cases.

The Hepatic Encephalopathy market size in the US was the largest in 2023, reaching about USD 1460 million, and is expected to grow further by 2034.

Despite a high diagnosed prevalence, with around 342,000 diagnosed cases in the 7MM in 2023, the Hepatic Encephalopathy treatment market is still limited by the scarcity of therapies specifically targeting the condition.

Emerging therapies are expected to significantly influence the Hepatic Encephalopathy treatment market, potentially driving substantial growth.

The Hepatic Encephalopathy market is expected to surge due to the disease's increasing prevalence and awareness during the forecast period. Furthermore, launching various multiple-stage Hepatic Encephalopathy pipeline products will significantly revolutionize the Hepatic Encephalopathy market dynamics.

## Hepatic Encephalopathy Overview

Hepatic encephalopathy (HE) is a brain disorder that develops in individuals with liver disease. It represents a complex spectrum of disease, ranging from a subtle condition with no obvious signs or symptoms to severe forms that can lead to life-threatening complications. HE is broadly

classified into two categories based on severity: covert hepatic encephalopathy (CHE) and overt hepatic encephalopathy (OHE). Diagnosing and defining HE remains challenging, as CHE lacks the clear clinical signs present in OHE.

HE is considered a predictor of mortality, with liver function and prognosis deteriorating following its diagnosis. Patients are often referred to liver transplant centers at later stages, making this an expensive option. Additionally, HE imposes significant burdens on patients, affecting psychological and social functioning in addition to morbidity and mortality. The financial strain extends to caregivers, hospitalization, and society at large. Furthermore, HE can reduce the patient's ability to work, leading to lower productivity and lost wages, thus diminishing their overall quality of life. Given the considerable social and financial costs, cost-effective management of HE is crucial, with early prevention being key to minimizing these societal and economic impacts.

Hepatic encephalopathy is a common complication of liver dysfunction, including acute liver failure and cirrhosis, presenting as a range of neuropsychiatric symptoms, from subtle cognitive impairment to coma. There is no definitive diagnostic test for HE; diagnosis relies on clinical suspicion, ruling out other causes, and using clinical tests that may support the diagnosis. Although various tests are used in clinical trials, they have not yet gained widespread acceptance. The current diagnostic approach involves excluding other causes, confirming liver disease, and conducting psychometric testing. Ammonia levels, regardless of their concentration, do not contribute to the diagnosis, staging, or prognosis of HE. Furthermore, many conditions can mimic or be associated with HE, requiring consideration for differential diagnosis. Therefore, there is an unmet need for more effective diagnostic tests—whether laboratory or imaging-based—that enable earlier diagnosis and better treatment monitoring.

CHE lacks specific manifestations, and no clinical markers effectively distinguish it from other neurological disorders of metabolic origin in cirrhosis patients that are not directly related to liver disease. Ammonia levels within the normal range are highly predictive of the absence of HE and rarely result in false negatives. Consequently, there is a pressing need for clear diagnostic guidelines and specific procedures for diagnosing HE and its subtypes.

Current treatment for HE primarily relies on lactulose and rifaximin. However, both therapies have limited efficacy due to low patient compliance, largely because of their side effects. Lactulose can be difficult to administer in acute settings and often results in poor compliance due to gastrointestinal (GI) issues. Rifaximin can cause side effects such as peripheral edema, GI discomfort, nausea, and dizziness. Around 55-65% of high-risk patients receive these standard treatments, but few continue the therapy due to poor adherence. Additionally, rifaximin is not recommended for patients with severe hepatic impairment (Child-Pugh C) due to higher systemic exposure in these individuals. Clinical trials have been limited to patients with MELD scores < 25, and the therapies' effects on ammonia levels have proven ineffective in several cases. There is a need for drugs with novel mechanisms of action (MoA) that demonstrate clinical efficacy in managing OHE episodes and improving neurocognition. The current treatments, including lactulose, generally take more than 24 hours to show improvements in the West-Haven Score, indicating the need for faster, more effective management to reduce hospital stays and associated costs. The existing pipeline for HE treatments is not sufficiently robust, with unmet

needs for novel therapies for both hospital and outpatient settings, as well as strategies to prevent recurrence.

### Hepatic Encephalopathy Epidemiology Insights

The total number of diagnosed Hepatic Encephalopathy cases in the US is expected to grow significantly, with a strong compound annual growth rate (CAGR) through 2034, increasing from approximately 209 thousand cases in 2023.

Among European countries, the UK had the highest diagnosed prevalence of Hepatic Encephalopathy, accounting for 28% of cases, followed by Germany in 2023. Conversely, Spain had the lowest diagnosed prevalence, representing around 9% of cases in the same year.

In Japan, Covert Hepatic Encephalopathy (CHE) accounted for the majority of diagnosed cases, with approximately 17.7 thousand cases in 2023, while Overt Hepatic Encephalopathy (OHE) cases were around 11.8 thousand in the same year.

In the US, Hepatic Encephalopathy cases were distributed across seven age groups: <25 years, 25-34 years, 35-44 years, 45-54 years, 55-64 years, 65-74 years, and 75+ years. Our estimates show that the highest number of cases were in the 45-54 age group (41%), while the lowest number was in the <25 years group (3%) in 2023.

According to assessments by DelveInsight's analysts, males account for the majority of Hepatic Encephalopathy cases compared to females. In the US, there were approximately 152 thousand male cases and 57 thousand female cases of Hepatic Encephalopathy in 2023.

### Hepatic Encephalopathy Epidemiology Segmentation:

The Hepatic Encephalopathy market report proffers epidemiological analysis for the study period 2020–2034 in the 7MM segmented into:

Total Prevalence of Hepatic Encephalopathy

Prevalent Cases of Hepatic Encephalopathy by severity

Gender-specific Prevalence of Hepatic Encephalopathy

Diagnosed Cases of Episodic and Chronic Hepatic Encephalopathy

Download the report to understand which factors are driving Hepatic Encephalopathy epidemiology trends @ Hepatic Encephalopathy Epidemiology Forecast

### Hepatic Encephalopathy Drugs Uptake and Pipeline Development Activities

The drugs uptake section focuses on the rate of uptake of the potential drugs recently launched in the Hepatic Encephalopathy market or expected to get launched during the study period. The analysis covers Hepatic Encephalopathy market uptake by drugs, patient uptake by therapies, and sales of each drug.

Moreover, the therapeutics assessment section helps understand the drugs with the most rapid uptake and the reasons behind the maximal use of the drugs. Additionally, it compares the drugs based on market share.

The report also covers the Hepatic Encephalopathy Pipeline Development Activities. It provides valuable insights about different therapeutic candidates in various stages and the key companies involved in developing targeted therapeutics. It also analyzes recent developments such as collaborations, acquisitions, mergers, licensing patent details, and other information for emerging therapies.

## Hepatic Encephalopathy Key Companies

Salix Pharmaceuticals, Bausch Health, Axcella Health, Inc., Umecrine Cognition, Vedanta Biosciences, Patricia Bloom, Rebiotix

## Hepatic Encephalopathy Therapies

Xifaxan (Rifaximin/OHE7), AXA1665, GR3027 (Golexanolone)

Discover more about therapies set to grab major Hepatic Encephalopathy market share @ [Hepatic Encephalopathy Treatment Landscape](#)

## Hepatic Encephalopathy Market Insights

The current landscape of Hepatic Encephalopathy (HE) therapeutics relies primarily on medications. In the United States, the most commonly used treatments for HE include lactulose and rifaximin. Nutrition also plays a critical role in managing the condition and preventing recurrence.

Second-line therapies, which are less widely accepted, include probiotics, branched-chain amino acids (BCAAs), flumazenil, zinc, and ammonia scavengers. Other agents used in HE management include oral antibiotics like neomycin, metronidazole, and rifaximin. These antibiotics work by reducing urease-producing bacteria in the intestines, which lowers ammonia production and absorption in the gastrointestinal tract. Neomycin and metronidazole, both of which have been in use for many years, are cost-effective options for treating HE.

## Hepatic Encephalopathy Market Outlook

The current approach to treating Hepatic Encephalopathy (HE) focuses on reducing ammonia levels, which is the core therapeutic strategy. This can be achieved through various interventions, including dietary protein modifications, purgatives such as nonabsorbable disaccharides and enemas, nonabsorbable antibiotics, and treatments that modulate interorgan ammonia levels like L-ornithine L-aspartate (LOLA), sodium benzoate, and phenylacetate. Other options include agents like flumazenil, bromocriptine, acarbose, probiotics, and emerging therapies like acetyl L-carnitine.

In cases where lactulose is not tolerated, rifaximin, a non-absorbable oral antibiotic, serves as an alternative and can even be used alongside lactulose. Lactulose and lactitol are also commonly prescribed for managing HE. For patients with severe HE requiring mechanical ventilation, airway protection is critical. Early airway maintenance, sedation, and ventilation help prevent elevated carbon dioxide levels and hypoxia. Once intubated, the patient's head should be elevated by 10-20° with minimal intervention to optimize intracranial pressure.

However, there is a significant need for newer, more effective therapies, especially for patients with advanced HE or worsening acute liver injury, as reducing plasma ammonia remains the primary therapeutic goal. Recent advancements in therapeutic strategies and novel targets are opening doors for emerging treatments.

One promising development is golexanolone, a novel small molecule currently under investigation by Umecrine Cognition. This drug, part of a new class of neurosteroid-based therapies, is designed for oral administration to treat patients with HE. Golexanolone targets enhanced GABAA receptor signaling, which is implicated in the neurological symptoms of HE, including impaired cognitive and motor functions. Early trial results have demonstrated its

potential to improve cognitive function, marking it as a potential breakthrough for treating covert hepatic encephalopathy (CHE)—a subtype that currently lacks an established treatment.

## Scope of the Hepatic Encephalopathy Market Report

Study Period: 2020–2034

Coverage: 7MM [The United States, EU5 (Germany, France, Italy, Spain, and the United Kingdom), and Japan]

Key Hepatic Encephalopathy Companies: Dana-Farber Cancer Institute, Huabo Biopharm Co., Ltd., Beijing Scitech-Mq Pharmaceuticals, Oxford BioMedica, Hutchison Medipharma Limited, Takeda, Amgen, Novartis, AVEO Pharmaceuticals, Inc., Merck Sharp & Dohme LLC, Pfizer, Calithera Biosciences, Inc, AbbVie, Bristol-Myers Squibb, Abbott, SCRI Development Innovations, LLC, Astellas Pharma Inc, and others

Key Hepatic Encephalopathy Therapies: Xifaxan (Rifaximin/OHE7), AXA1665, GR3027 (Golexanolone), and others

Hepatic Encephalopathy Therapeutic Assessment: Hepatic Encephalopathy current marketed and Hepatic Encephalopathy emerging therapies

Hepatic Encephalopathy Market Dynamics: Hepatic Encephalopathy market drivers and Hepatic Encephalopathy market barriers

Competitive Intelligence Analysis: SWOT analysis, PESTLE analysis, Porter's five forces, BCG Matrix, Market entry strategies

Hepatic Encephalopathy Unmet Needs, KOL's views, Analyst's views, Hepatic Encephalopathy Market Access and Reimbursement

To know more about Hepatic Encephalopathy companies working in the treatment market, visit @ [Hepatic Encephalopathy Clinical Trials and Therapeutic Assessment](#)

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