

## **Alcohol Use Disorder (AUD) - Market Insight, Epidemiology And Market Forecast - 2032**

Market Report | 2022-09-01 | 152 pages | DelveInsight

### **AVAILABLE LICENSES:**

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### **Report description:**

DelveInsight's 'Alcohol Use Disorder - Market Insights, Epidemiology, and Market Forecast-2032' report deliver an in-depth understanding of the Alcohol Use Disorder, historical and forecasted epidemiology as well as the Alcohol Use Disorder market trends in the United States, the EU-5 (Germany, France, Italy, Spain, and the United Kingdom) and Japan.

The Alcohol Use Disorder market report provides current treatment practices, emerging drugs, market share of the individual therapies, and the current and forecasted 7MM Alcohol Use Disorder market size from 2019 to 2032. The Report also covers current Alcohol Use Disorder treatment practice, market drivers, market barriers, SWOT analysis, reimbursement, market access, and unmet medical needs to curate the best of the opportunities and assesses the underlying potential of the market.

Geography Covered

- The United States
- The EU5 (Germany, France, Italy, Spain, and the United Kingdom)
- Japan

Study Period: 2019-2032

Alcohol Use Disorder Understanding and Treatment Algorithm

Alcohol Use Disorder Overview

Alcohol use disorder (AUD) is a highly prevalent, chronic, relapsing condition characterized by an impaired ability to stop or control alcohol use despite significant impairment, distress, or other adverse consequences. It is one of the most common substance use disorders globally with millions impacted by it. Its variability in clinical presentation, suggests a complex interaction between various environmental, physiological, psychological, social, and biological factors resulting in disease development and progression.

It is a highly heterogeneous condition with complex biology, that impacts a person physically, emotionally, and socially and is controlled by many genes and gene-by-environment interactions, wherein a robust genetic influence predisposes certain individuals to develop AUD. A serious public health threat, it causes significant societal harm with high morbidity and mortality. A person with AUD may experience both intoxication and withdrawal symptoms such as unstable moods, poor judgment, slurred

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speech, problems with attention or memory, poor coordination, sweating, rapid heartbeat, hand tremors, problems sleeping, nausea and vomiting, hallucinations, restlessness and agitation, anxiety, and occasionally seizures. It is classified as mild, moderate, or severe, based on the number of symptoms experienced by an individual.

#### Alcohol Use Disorder Diagnosis

The US Preventive Services Task Force has recommended three methods to screen for heavy alcohol use. These methods are the Alcohol Use Disorders Identification Test (AUDIT), the AUDIT-C, or a single question such as "How many times in the past year have you had 5 (for men) or 4 (for women) or more drinks in a day?"

The diagnosis of AUD requires testing an individual based on DSM-V diagnostic criteria, to assess if symptoms of AUD are present. DSM-V lists various potential criteria for AUD, covering four main aspects of alcohol use which are impaired control, social impairment, risky use, and pharmacological effects. The presence of at least two of these symptoms indicates an AUD. DSM-V criteria also help determine the severity of AUD. Based on the number of symptoms present the individual is classified into mild, moderate, and severe cases of AUD.

Besides the DSM criteria, another internationally accepted diagnostic criteria is the ICD published by the World Health Organization (WHO). Alcohol Dependence Syndrome according to ICD-10 has 6 central features, of which the presence of 3 or more in a clustered way, typically over 12 months or more is indicative of AUD.

Continued in the report?..

#### Alcohol Use Disorder Treatment

Management strategies for patients presenting with AUD need to be tailored depending on the presenting complaint, the level and duration of use, the severity of dependence, the presence of any additional comorbid substance use disorders, any physical and/or mental health conditions; and motivation to change. Management always needs to start with the engagement of the patient in the process and understanding their initial goals for treatment.

Mostly the main goal of AUD treatment is either complete abstinence or reduction of heavy drinking and the current treatment options include medication-assisted treatment, behavioral interventions, detox, and psychosocial assistance from rehab and support groups. The mainstay treatment though is psychosocial intervention but with high relapse rates, the best way is to combine pharmacotherapy with psychosocial counseling and intervention.

Currently, there are four US FDA-approved medication-assisted treatments for AUD, that includes Acamprosate, ANTABUSE (disulfiram), REVIA (oral naltrexone), and VIVITROL (extended-release injectable naltrexone). Besides these TOPAMAX (topiramate) is also endorsed by the National Institute on Alcohol Abuse and Alcoholism for the treatment of AUD.

Moreover, SELINCRO (nalmefene) is approved in the EU and Japan and is one of the first drugs that reduces alcohol cravings in individuals on an as-need basis and does not require abstinence. Other drugs are approved in certain specific countries like BACLOCUR (baclofen) in France and Sodium oxybate (SMO) in Italy. The market for AUD is also inclusive of many off-label and generic products such as gabapentin, varenicline, benzodiazepines, memantine, ondansetron, aripiprazole, and suvorexant, among others.

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#### Alcohol Use Disorder Epidemiology

The disease epidemiology covered in the report provides historical as well as forecasted epidemiology segmented by 12-month Diagnosed Prevalent Cases of Alcohol Use Disorder, Gender-specific Diagnosed Prevalent Cases of Alcohol Use Disorder, and Type-specific Diagnosed Prevalent Cases of Alcohol Use Disorder scenario of Alcohol Use Disorder in the 7MM covering the United States, the EU-5 countries (Germany, France, Italy, Spain, and the United Kingdom) and Japan from 2019 to 2032.

#### Key Findings

- In 2021, the 12-month diagnosed prevalent cases of AUD were estimated to be 25,027,206 cases in the 7MM. These cases are expected to increase by 2032 at a CAGR of 0.6% during the study period (2019-2032).
- Among the 7MM, the United States accounted for nearly 58% of the total 12-month diagnosed prevalent cases of AUD in the 7MM in the year 2021 which are expected to increase further by 2032.
- Among the EU5 countries, Germany had the highest 12-month diagnosed prevalent cases of AUD with 2,541,460 cases in 2021, while Spain had the lowest 12-month diagnosed prevalent population of AUD with 1,326,329 cases in 2021.
- In 2021, the 12-month diagnosed prevalent population of AUD in Japan was found to be 1,161,931, which is expected to change

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for the study period of 2019-2032.

- According to estimates based on DelveInsight's epidemiology model for AUD, the gender distribution of the disease suggests a male predominance across the 7MM, with 9,200,239 male and 5,407,953 female cases in the US in 2021.

- According to estimates based on DelveInsight's epidemiology model for AUD, the type-specific distribution of the disease suggests that young adults make up the majority of the AUD cases (32%), followed by young antisocial cases (21%). While there were least cases of the chronic severe type.

#### Alcohol Use Disorder Epidemiology

The epidemiology segment also provides the Alcohol Use Disorder epidemiology data and findings across the United States, the EU-5 (Germany, France, Italy, Spain, and the United Kingdom), and Japan.

#### Alcohol Use Disorder Drug Chapters

The drug chapter segment of the Alcohol Use Disorder report encloses the detailed analysis of Alcohol Use Disorder marketed drugs, mid-phase, and late-stage pipeline drugs. It also helps to understand the Alcohol Use Disorder clinical trial details, expressive pharmacological action, agreements and collaborations, approval, and patent details of each included drug, and the latest news and press releases.

#### Alcohol Use Disorder Emerging Drugs

##### AD04 (ondansetron): Adial Pharmaceuticals

AD04 (ondansetron) being developed by Adial Pharmaceuticals is a genetically targeted, serotonin-3 (5HT3) receptor antagonist that interrupts the reinforcing effects of alcohol, and thus reduces the urge to drink. It is being developed for the treatment of AUD in patients of select genotypes. The blockade of 5HT3 receptors influences the dopamine reward system activated by alcohol, decreasing dopamine release and attenuating the craving for alcohol. AD04 contains an ultra-low dose of ondansetron, which is currently marketed as an anti-emetic for post-operative and post-chemotherapy nausea. Adial Pharmaceuticals has completed ONWARD Phase III clinical trials which evaluated the efficacy, safety, and tolerability of AD04 in patients with AUD and selected polymorphisms in the serotonin genes. It plans to submit these results to both the US and European regulatory agencies for further development and is also exploring potential partnership opportunities in both the US and Europe. Also, EMA has accepted Adial's Pediatric Investigation Plan for the development of AD04, for the treatment of AUD in the pediatric population.

Products detail in the report?

##### MN-166 (ibudilast): MediciNova

MN-166 (ibudilast) being developed by MediciNova is a novel, first-in-class, non-opioid glial cell modulator that inhibits phosphodiesterases (PDE) -4 and PDE-10 and macrophage migration inhibitory factor (MIF). It leads to a decrease in pro-inflammatory cytokines. Ibudilast is being developed to treat AUD through its anti-inflammatory and pro-neurotrophic mechanisms. It suppresses pro-inflammatory cytokines

IL-1

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TNF- $\alpha$ , and IL-6 and upregulates the anti-inflammatory cytokine IL-10. MediciNova is currently conducting Phase II trials to evaluate MN-166 for the treatment of AUD. It has an exclusive license agreement with Kyorin Pharmaceutical for the global development and commercialization of MN-166.

Products detail in the report?

##### CORT118335 (mifepristone): Corcept Therapeutics

CORT118335 by Corcept Therapeutics is a glucocorticoid receptor (GR) antagonist being developed for the treatment of AUD. Aberrant glucocorticoid signaling via GRs plays a critical role in AUD. The GR antagonist mifepristone decreased alcohol consumption in dependence during acute withdrawal and protracted abstinence. However, the regulation of CeA synaptic GABA transmission by GR is currently unknown. Corcept Therapeutics by doing academic collaborations is trying to augment development efforts for the treatment of AUD. Recently a Phase II trial by Scripps Research Institute in collaboration with NIAAA was completed for the treatment of moderate or severe AUD with CORT118335. However further update from the company is awaited.

Products detail in the report?

List of products to be continued in the report?

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## Alcohol Use Disorder Market Outlook

AUD also has economic consequences, costing a substantial amount annually. Current pharmaceutical and behavioral treatments may assist patients in reducing alcohol use or facilitating alcohol abstinence.

At present, there are four approved therapies for the treatment of AUD that includes disulfiram, Naltrexone (oral), acamprosate, and VIVITROL. Most of these therapies were approved decades ago and have their generics in the market. The current AUD market in the US is dominated by these therapies.

Naltrexone, the best-studied of the approved medications, is an antagonist of the mu-opioid receptor with an additional affinity for kappa and delta opioid receptors. In 1994, the US FDA approved oral naltrexone sold by DuPont under the brand name REVIA for the treatment of alcoholism. Though it significantly reduced alcohol craving and drinking rates it required strict compliance. To address this issue the extended-release depot formulation of naltrexone was developed to improve adherence. In April 2006, the US FDA approved VIVITROL (naltrexone for extended-release injectable suspension) marketed by Alkermes. This once-a-month injectable formulation of naltrexone helped in maintaining therapeutic medication levels in the body through a single intramuscular injection every four weeks. The demand for complete abstinence before the treatment is started is the major disadvantage of Naltrexone. Though an FDA-recommended first-line treatment that reduces binge drinking, naltrexone is a costly drug with an FDA label warning that significantly impacts its market availability.

Another decade-old approved drug, Acamprosate, the first approved treatment for alcohol dependence in Europe, is often considered an 'artificial alcohol' or a 'functional glutamate antagonist. Multiple meta-analyses have found acamprosate to reduce alcohol consumption compared to placebo and increased cumulative duration of abstinence. It is FDA-approved for abstinence maintenance in AUD patients who are abstinent when beginning treatment. Usually administered as the first line of treatment it is best for maintaining sobriety once the patient has achieved abstinence.

ANTABUSE (disulfiram), the first US FDA-approved (in 1951) medication for AUD treatment, is the oldest drug in the AUD market. Marketed by Odyssey pharmaceuticals it is an oral aldehyde dehydrogenase inhibitor that acts by blocking the metabolism of alcohol. NICE guidelines suggest that disulfiram should be used as a second-line treatment when other approved medications fail. However, there is no consensus on the trial methodology for assessing the efficacy of disulfiram since it cannot be appraised fairly in double-blind, RCTs due to its mechanism of action.

Besides these SELINCRO (nalmefene) developed by Lundbeck is approved in the EU and Japan and addresses the need for abstinence in AUD patients. Being the drug that addresses the major unmet of abstinence, it has shown immense success in the European and Japanese markets. However, it has not been approved for sale in the US.

The considerable heterogeneity of AUD patients makes it especially challenging to design a single drug capable of treating AUD patients as a whole. Current pharmacotherapies are often characterized by limited efficacy and there is a large treatment gap in alcohol dependence with the current treatments only moderately effective in preventing relapse. The need for abstinence and the associated social stigma further complicates the treatment regime. The expected launch of potential therapies that include AD04 (ondansetron) (Adial Pharmaceuticals), CORT118335 (mifepristone) (Corcept Therapeutics), and MN-166 (ibudilast) (MediciNova) may address this unmet need, increase the market size in the coming years, assisted by an increase in the diagnosed prevalent population of AUD during the forecast period [2022-2032].

According to DelveInsight, the overall dynamics of the AUD market is anticipated to change in the coming years owing to the expected launch of emerging therapies.

### Key Findings

- The market size of the Alcohol Use Disorder in the seven major markets was USD 564.0 million in 2021, which is further expected to increase by 2032 at a Compound Annual Growth Rate (CAGR) of 8.8% for the study period (2019-2032).
- The launch of potential therapies, AD04 (ondansetron), CORT118335 (mifepristone), and MN-166 (ibudilast) are expected to increase the market size in the coming years, assisted by an increase in the diagnosed prevalent population of AUD.
- The United States accounts for the largest market size for Alcohol Use Disorder, in comparison to the EU-5 (Germany, Italy, France, Spain, and the United Kingdom) and Japan.
- Among the EU5 countries, Germany had the highest market size with approximately USD 35.7 million in 2021. This is expected to further increase, with Germany estimated to capture the maximum market followed by the UK in 2032.
- The market size for Alcohol Use Disorder in Japan was valued at approximately USD 10.2 million in 2021. It is expected that the

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market will increase mainly due to the launch of upcoming therapy during the forecast period (2022-2032).

#### The United States Market Outlook

This section provides the total Alcohol Use Disorder market size and market size by therapies in the United States.

#### The EU-5 Market Outlook

The total Alcohol Use Disorder market size and market size by therapies in Germany, France, Italy, Spain, and the United Kingdom are provided in this section.

#### Japan Market Outlook

The total Alcohol Use Disorder market size and market size by therapies in Japan are provided.

#### Alcohol Use Disorder Drugs Uptake

This section focuses on the rate of uptake of the potential drugs recently launched in the Alcohol Use Disorder market or expected to get launched in the market during the study period 2019-2032. The analysis covers the Alcohol Use Disorder market uptake by drugs; patient uptake by therapies; and sales of each drug.

This helps in understanding the drugs with the most rapid uptake, and the reasons behind the maximal use of new drugs and allows, the comparison of the drugs based on market share and size which again will be useful in investigating factors important in market uptake and in making financial and regulatory decisions.

#### Alcohol Use Disorder Development Activities

The report provides insights into different therapeutic candidates in phase II, and phase III stages and also analyzes key players involved in developing targeted therapeutics.

#### Pipeline Development Activities

The report covers detailed information on collaborations, acquisitions, mergers, licensing, and patent details for Alcohol Use Disorder emerging therapies.

#### Reimbursement Scenario in Alcohol Use Disorder

Approaching reimbursement proactively can have a positive impact both during the late stages of product development and well after product launch. In the report, we consider reimbursement to identify economically attractive indications and market opportunities. When working with finite resources, the ability to select the markets with the fewest reimbursement barriers can be a critical business and price strategy.

#### Competitive Intelligence Analysis

We perform competitively and market Intelligence analysis of the Alcohol Use Disorder market by using various competitive intelligence tools that include-SWOT analysis, PESTLE analysis, Porter's five forces, BCG Matrix, Market entry strategies, etc. The inclusion of the analysis entirely depends upon the data availability.

#### Scope of the Report

- The report covers a descriptive overview of Alcohol Use Disorder, explaining its etiology, signs and symptoms, pathophysiology, genetic basis, and currently available therapies.
- Comprehensive insight has been provided into the Alcohol Use Disorder epidemiology and treatment.
- Additionally, an all-inclusive account of both the current and emerging therapies for Alcohol Use Disorder is provided, along with the assessment of new therapies, which will have an impact on the current treatment landscape.
- A detailed review of the Alcohol Use Disorder market; historical and forecasted is included in the report, covering the 7MM drug outreach.
- The report provides an edge while developing business strategies, by understanding trends shaping and driving the 7MM Alcohol Use Disorder market.

#### Report Highlights

- The robust pipeline with novel MOA and oral ROA and increasing incidence will positively drive the Alcohol Use Disorder market.
- The companies and academics are working to assess challenges and seek opportunities that could influence Alcohol Use Disorder R&D. The therapies under development are focused on novel approaches to treat/improve the disease condition.
- Major players are involved in developing therapies for Alcohol Use Disorder. The launch of emerging therapies will significantly impact the Alcohol Use Disorder market.
- Our in-depth analysis of the pipeline assets across different stages of development (phase III and phase II), different emerging

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trends, and comparative analysis of pipeline products with detailed clinical profiles, key cross-competition, launch date along with product development activities will support the clients in the decision-making process regarding their therapeutic portfolio by identifying the overall scenario of the research and development activities.

#### Alcohol Use Disorder Report Insights

- Patient Population
- Therapeutic Approaches
- Alcohol Use Disorder Pipeline Analysis
- Alcohol Use Disorder Market Size and Trends
- Market Opportunities
- Impact of upcoming Therapies

#### Alcohol Use Disorder Report Key Strengths

- 11-Years Forecast
- The 7MM Coverage
- Alcohol Use Disorder Epidemiology Segmentation
- Key Cross Competition
- Highly Analyzed Market
- Drugs Uptake

#### Alcohol Use Disorder Report Assessment

- Current Treatment Practices
- Unmet Needs
- Pipeline Product Profiles
- Market Attractiveness
- Market Drivers and Barriers
- SWOT analysis

#### Key Questions

##### Market Insights:

- What was the Alcohol Use Disorder market share (%) distribution in 2019 and how it would look like in 2032?
- What would be the Alcohol Use Disorder total market size as well as market size by therapies across the 7MM during the forecast period (2022-2032)?
- What are the key findings pertaining to the market across the 7MM and which country will have the largest Alcohol Use Disorder market size during the forecast period (2022-2032)?
- At what CAGR, the Alcohol Use Disorder market is expected to grow at the 7MM level during the forecast period (2022-2032)?
- What would be the Alcohol Use Disorder market outlook across the 7MM during the forecast period (2022-2032)?
- What would be the Alcohol Use Disorder market growth till 2032 and what will be the resultant market size in the year 2032?
- How would the market drivers, barriers, and future opportunities affect the market dynamics and subsequent analysis of the associated trends?

##### Epidemiology Insights:

- What are the disease risk, burdens, and unmet needs of Alcohol Use Disorder?
- What is the historical Alcohol Use Disorder patient pool in the United States, the EU5 (Germany, France, Italy, Spain, and the UK), and Japan?
- What would be the forecasted patient pool of Alcohol Use Disorder at the 7MM level?
- What will be the growth opportunities across the 7MM with respect to the patient population pertaining to Alcohol Use Disorder?
- Out of the above-mentioned countries, which country would have the highest incidence population of Alcohol Use Disorder during the forecast period (2022-2032)?
- At what CAGR the population is expected to grow across the 7MM during the forecast period (2022-2032)?

##### Current Treatment Scenario, Marketed Drugs, and Emerging Therapies:

- What are the current options for the treatment of Alcohol Use Disorder along with the approved therapy?

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- What are the current treatment guidelines for the treatment of Alcohol Use Disorder in the US and Europe?
- What are the Alcohol Use Disorder marketed drugs and their MOA, regulatory milestones, product development activities, advantages, disadvantages, safety, and efficacy, etc.?
- How many companies are developing therapies for the treatment of Alcohol Use Disorder?
- How many emerging therapies are in the mid-stage and late stages of development for the treatment of Alcohol Use Disorder?
- What are the key collaborations (Industry-Industry, Industry-Academia), Mergers and acquisitions, and licensing activities related to the Alcohol Use Disorder therapies?
- What are the recent novel therapies, targets, mechanisms of action, and technologies developed to overcome the limitation of existing therapies?
- What are the clinical studies going on for Alcohol Use Disorder and their status?
- What are the key designations that have been granted for the emerging therapies for Alcohol Use Disorder?
- What is the 7MM historical and forecasted market for Alcohol Use Disorder?

#### Reasons to buy

- The report will help in developing business strategies by understanding trends shaping and driving Alcohol Use Disorder.
- To understand the future market competition in the Alcohol Use Disorder market and an insightful review of the key market drivers and barriers.
- Organize sales and marketing efforts by identifying the best opportunities for Alcohol Use Disorder in the US, the EU-5 (Germany, Spain, Italy, France, and the United Kingdom), and Japan.
- Identification of strong upcoming players in the market will help in devising strategies that will help in getting ahead of competitors.
- Organize sales and marketing efforts by identifying the best opportunities for the Alcohol Use Disorder market.
- To understand the future market competition in the Alcohol Use Disorder market.

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