

# Initial Prior Authorization

## Acamprosate Calcium

### Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
acamprosate calcium (brand unavailable)	acamprosate calcium

### Indications

#### FDA-approved Indications

Acamprosate calcium delayed-release tablets are indicated for the maintenance of abstinence from alcohol in patients with alcohol dependence who are abstinent at treatment initiation. Treatment with acamprosate calcium delayed-release tablets should be part of a comprehensive management program that includes psychosocial support.

The efficacy of acamprosate calcium delayed-release tablets in promoting abstinence has not been demonstrated in subjects who have not undergone detoxification and not achieved alcohol abstinence prior to beginning acamprosate calcium delayed-release tablets treatment. The efficacy of acamprosate calcium delayed-release tablets in promoting abstinence from alcohol in polysubstance abusers has not been adequately assessed.

### Coverage Criteria

#### Alcohol Use Disorder

Authorization may be granted when the patient has a diagnosis of alcohol use disorder as defined by the Diagnostic and Statistical Manual of Mental Disorders (DSM-5) when ALL of the following criteria are met:

- The requested drug will be used as part of a comprehensive management program that includes psychosocial support.
- The patient is, or the patient will be, abstinent from alcohol at treatment initiation.

## Continuation of Therapy

### Alcohol Use Disorder

Authorization may be granted when the patient has a diagnosis of alcohol use disorder as defined by the Diagnostic and Statistical Manual of Mental Disorders (DSM-5) when ALL of the following criteria are met:

- The requested drug will be used as part of a comprehensive management program that includes psychosocial support.
- The patient meets ONE of the following:
  - The patient has achieved or maintained a positive clinical response (e.g., abstinence from alcohol, increase in abstinent days, decrease in heavy drinking episodes, improved physical health, improvements in psychosocial functioning) to the requested drug.
  - The patient has experienced improvement on prior therapy and the requested drug will be restarted due to relapse.

## Duration of Approval (DOA)

- 1975-A: DOA: 12 months

## References

1. Acamprosate calcium [package insert]. Morgantown, WV: Mylan Pharmaceuticals Inc.; November 2022.
2. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Waltham, MA: UpToDate, Inc.; 2024. <https://online.lexi.com>. Accessed October 29, 2024.
3. Micromedex® (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: <https://www.micromedexsolutions.com/> (cited: 10/29/2024).
4. Pharmacotherapy for Adults with Alcohol-Use Disorder (AUD) in Outpatient Settings. AHRQ Effective Health Care Program. [https://effectivehealthcare.ahrq.gov/sites/default/files/pdf/alcohol-misuse-drug-therapy\\_clinician.pdf](https://effectivehealthcare.ahrq.gov/sites/default/files/pdf/alcohol-misuse-drug-therapy_clinician.pdf). February 2016. Accessed October 29, 2024.

Reference number(s)
1975-A

5. Pharmacotherapy for Adults with Alcohol Use Disorders in Outpatient Settings: Systematic Review Update. AHRQ Evidence-based Practice Center Systematic Review Protocol. <https://effectivehealthcare.ahrq.gov/sites/default/files/product/pdf/alcohol-pharma-final-protocol.pdf>. February 2022. Accessed October 29, 2024.
6. Substance Abuse and Mental Health Services Administration. (2021). Prescribing Pharmacotherapies for Patients with Alcohol Use Disorder. Advisory.
7. Substance Abuse and Mental Health Services Administration and National Institute on Alcohol Abuse and Alcoholism, Medication for the Treatment of Alcohol Use Disorder: A Brief Guide. HHS Publication No. (SMA) 15-4907. Rockville, MD: Substance Abuse and Mental Health Services Administration 2015.
8. Reus VI, Fochtmann LJ, Bukstein O, et al. The American Psychiatric Association Practice Guideline for the Pharmacological Treatment of Patients with Alcohol Use Disorder. The American Journal of Psychiatry. January 5, 2018