Reference number(s)
REG 1975-A

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. February 2016. Accessed October 29, 2024.

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

Document History

Written by: UM Development (SE)

Date Written: 12/2009

Revised: (KD/SE) 09/2010 (CAS adapted; (CT) 08/2011, 06/2012, 10/2012 (extended duration); (RP) 05/2013, 05/2014; (LN) 04/2015 (added denial reasons); (CT) 05/2015, 05/2016, (JG) 05/2017 (created new for regulatory); (DS) 11/2017 (no clinical changes), 11/2018 (no clinical changes), 11/2019 (updated alcohol dependence to alcohol use disorder), (SF) 11/2020 (updated document title, separated diagnosis and treatment questions), 02/2021 (updated Q1); (DRS) 12/2021 (no clinical changes), 11/2022 (added continuation of therapy criteria), 11/2023 (no clinical changes); (KEJ) 11/2024 (no clinical changes)

Reviewed: Medical Affairs: (WLF) 12/2009; (KP) 10/2010, 08/2011, 06/2012, 10/2012; (LMS) 05/2013, 05/2014; (KJC) 05/2015; (ME) 05/2016; (JG) 05/2017; (AM) 11/2018; (CHART) 11/27/2019, 02/27/2020 (FYI for CPO rec), 12/03/2020, 12/02/2021, 12/01/2022, 11/30/2023, 11/21/2024

External Review: 03/2010, 12/2010, 10/2011, 10/2012; 08/2013, 08/2014, 08/2015, 08/2016, 06/2017, 02/2018, 02/2019, 02/2020, 02/2022, 03/2023, 02/2024, 02/2025

MDC: REG

CRITERIA FOR APPROVAL

1	Does the patient have a diagnosis of alcohol use disorder as defined by the Diagnostic and Statistical Manual of Mental Disorders (DSM-5)? [If Yes, then go to 2. If No, then no further questions.]	Yes	No
2	Will the requested drug be used as part of a comprehensive management program that includes psychosocial support?	Yes	No

	[If Yes, then go to 3. If No, then no further questions.]		
3	Is the request for continuation of therapy? [If Yes, then go to 4. If No, then go to 6.]	Yes	No
4	Has the patient 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? [If Yes, then no further questions. If No, then go to 5.]	Yes	No
5	Has the patient experienced improvement on prior therapy and the requested drug will be restarted due to relapse? [No further questions]	Yes	No
6	Is the patient, or will the patient be, abstinent from alcohol at treatment initiation? [No further questions]	Yes	No

Mapping Instructions			
	Yes	**No**	**DENIAL REASONS**
1.	Go to 2	Deny	Your plan only covers this drug when it is used for certain health conditions. Covered use is for alcohol use disorder. Your plan does not cover this drug for your health condition that your doctor told us you have. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review. [Short Description: Diagnosis]
2.	Go to 3	Deny	Your plan only covers this drug if you will be taking this drug as a part of a certain treatment plan. We have denied your request because you are not (or will not be) taking this drug as a part of a total treatment program. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more

			details. You can also request other plan documents for your review. [Short Description: Not a component of a regimen]
3.	Go to 4	Go to 6	
4.	Approve, 12 Months	Go to 5	
5.	Approve, 12 Months	Deny	Your plan only covers this drug if it works well for you. We have denied your request because the drug did not work well for you. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review. [Short Description: Continuation: Efficacy]
6.	Approve, 12 Months	Deny	We have denied your request because your plan does not cover this drug if you are using alcohol at the start of treatment. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review. [Short Description: Exclusion]