PRIOR AUTHORIZATION CRITERIA

BRAND NAME (generic)

(acamprosate calcium)

Status: CVS Caremark Criteria Type: Initial Prior Authorization

POLICY

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

The requested drug will be covered with prior authorization when the following criteria are met:

• The patient has a diagnosis of alcohol use disorder as defined by the Diagnostic and Statistical Manual of Mental Disorders (DSM-5)

AND

 The requested drug will be used as part of a comprehensive management program that includes psychosocial support

AND

The request is for continuation of therapy

AND

 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)

OR

 The patient has experienced improvement on prior therapy and the requested drug will be restarted due to relapse

OR

The patient is, or the patient will be, abstinent from alcohol at treatment initiation

REFERENCES

- 1. Acamprosate calcium [package insert]. Pennington, NJ: Zydus Pharmaceuticals (USA) Inc.; December 2021.
- 2. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Hudson, Ohio: UpToDate, Inc.; 2022; Accessed October 4, 2022.
- 3. Micromedex (electronic version). IBM Watson Health, Greenwood Village, Colorado, USA. Available at: https://www.micromedexsolutions.com. Accessed October 4, 2022.
- Prescribing Medications for Alcohol Dependence Excerpt from Helping Patients Who Drink Too Much: A Clinician's Guide. U.S. Department of Health and Human Services, National Institutes of Health National Institute on Alcohol Abuse and Alcoholism. NIH Publication 07–3769.
 - https://pubs.niaaa.nih.gov/publications/Practitioner/CliniciansGuide2005/PrescribingMeds.pdf. October 2008 Update. Accessed October 13, 2022.

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1

- 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.pdff. February 2016. Accessed October 13, 2022.
- 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.