PRIOR AUTHORIZATION CRITERIA

BRAND NAME*
(generic)
(acamprosate calcium)

Status: CVS Caremark Criteria ***REG***
Type: Initial Prior Authorization
Ref # 1975-A

** Drugs that are listed in the target drug box include both brand and generic and all dosage forms and strengths unless otherwise stated. OTC products are not included unless otherwise stated.*

FDA-APPROVED INDICATIONS

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

The efficacy of acamprosate calcium in promoting abstinence has not been demonstrated in subjects who have not undergone detoxification and not achieved alcohol abstinence prior to beginning acamprosate calcium treatment. The efficacy of acamprosate calcium 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 AND the requested drug will be prescribed as part of a comprehensive psychosocial treatment program

AND

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

RATIONALE

The intent of the criteria is to provide coverage consistent with product labeling, FDA guidance, standards of medical practice, evidence-based drug information, and/or published guidelines. Acamprosate calcium is indicated for the maintenance of abstinence from alcohol in patients with alcohol dependence that are abstinent at treatment initiation. Treatment with acamprosate calcium should be part of a comprehensive management program that includes psychosocial support.[1-3]

Acamprosate calcium has not been shown to provide therapeutic benefit in individuals who have not undergone detoxification and have not achieved

abstinence from alcohol ingestion prior to initiation of the drug.[1-4] Therefore, the patient should be abstinent from alcohol at the time acamprosate calcium therapy is initiated.

According to the Agency for Healthcare Research and Quality (AHRQ) research protocol, FDA approved medications for the treatment of alcohol use disorder are usually prescribed for 3 to12 months. Additionally, as stated by the National Institutes of Health/National Institute on Alcohol Abuse and Alcoholism, the risk for relapse to alcohol dependence is very high in the first 6 to 12 months after initiating abstinence and gradually diminishes over several years. Although optimal treatment duration has not been established, it is reasonable to continue treatment for a year or longer if the patient responds to medication during this time when the risk of relapse is highest.[4-5]

REFERENCES

1. Acamprosate calcium [package insert]. Pennington, NJ: Zydus Pharmaceuticals USA Inc.; September 2019.
2. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Hudson, OH: Wolters Kluwer Clinical Drug Information, Inc. http://online.lexi.com/. Accessed November 2019.
3. Micromedex (electronic version). Truven Health Analytics, Greenwood Village, Colorado, USA. http://www.micromedexsolutions.com/. Accessed November 2019.
4. 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 November 2019.
5. Pharmacotherapy for Adults with Alcohol-Use Disorders in Outpatient Settings - Research Protocol. AHRQ Effective Health Care Program. http://www.effectivehealthcare.ahrq.gov/search-for-guides-reviews-and-reports/?pageaction=displayproduct&productid=1483. April, 26, 2013. Accessed November 2019.

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)
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)
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

CRITERIA FOR APPROVAL

1	Does the patient have a diagnosis of alcohol use disorder AND will the requested drug be prescribed as part of a comprehensive psychosocial treatment program?	Yes	No
2	Is the patient, or will the patient be, abstinent from alcohol at treatment initiation?	Yes	No

Guidelines for Approval	
Duration of Approval	**12 Months**
Set 1	
Yes to question(s)	**No to question(s)**
1	None
2	

Mapping Instructions			
	Yes	**No**	**DENIAL REASONS – DO NOT USE FOR MEDICARE PART D**
1	Go to 2	Deny	You do not meet the requirements of your plan. Your plan covers this drug when you meet all of these conditions: - You have alcohol use disorder - Your health care provider prescribes this drug as part of a total treatment program Your request has been denied based on the information we have. [Short Description: No approvable diagnosis]
2	Approve, 12 months	Deny	You do not meet the requirements of your plan. Your plan covers this drug if you will not be drinking alcohol at the start of treatment. Your request has been denied based on the information we have. [Short Description: Not abstinent from alcohol]

