



## Prior Authorization Approval Criteria

### *Campral (acamprosate calcium)*

<b>Generic name:</b>	Acamprosate
<b>Brand name:</b>	Campral
<b>Medication class:</b>	antialcoholic agent
<b>FDA-approved uses:</b>	Maintenance of abstinence from alcohol in patients with alcohol dependence that is abstinent at treatment initiation.
<b>Usual dose range:</b>	Two 333 mg tablets (666 mg) three times daily.
<b>Duration of therapy:</b>	Optimal duration of therapy plus social support has not been established.

**Criteria for use** (*bullet points below are all inclusive unless otherwise noted*):

- Patient must have already quit drinking alcohol.
- Must be part of a comprehensive treatment program for alcohol dependence that should include a psychosocial support system.

**Contraindications:**

- Patients with known hypersensitivity reactions to acamprosate.
- Patients with severe renal impairment (CrCl 30 ml/min or less).

**Not approved if:**

- Patient has any contraindications to the use of Campral.
- Patient does not meet the above-stated criteria.

**Special considerations:**

- Similar drugs: disulfiram, naltrexone
  - Does not appear to be more effective than naltrexone.
- The value of acamprosate calcium in promoting abstinence in subjects who have not undergone detoxification and not achieved alcohol abstinence prior to the initiation of therapy has not been established.
- Therapy should be continued even if the patient relapses, as long as they continue to be part of a treatment program for alcohol dependence.
- Risk of adverse events of a suicidal nature (suicidal ideation, suicide attempts, completed suicides) was higher in the patients treated with acamprosate than placebo.

FCHP Pharmacy and Therapeutics Committee approval: \_\_\_\_\_

Date: \_\_\_\_\_

Adopted: 04/13/05