

**Non-Formulary Criteria for Use: Rifaximin for Treatment of Hepatic Encephalopathy
in Cirrhotic and Post-transplant Patients**
VHA Pharmacy Benefits Management Strategic Healthcare Group and the Medical Advisory Panel
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The following recommendations are based on current medical evidence. The content of the document is dynamic and will be revised as new clinical data become available. The purpose of this document is to assist practitioners in clinical decision making, to standardize and improve the quality of patient care, and to promote cost-effective drug prescribing. The clinician, however, must make the ultimate judgment regarding the propriety of any course of treatment in light on individual patient situations

Refer to the Rifaximin Monograph and Rifaximin for Treatment of Hepatic Encephalopathy in Cirrhotic Patients at www.pbm.va.gov or <http://vaww.pbm.va.gov>.

CURRENT FDA STATUS
-Rifaximin has orphan drug designation for use in hepatic encephalopathy and is currently undergoing Phase III clinical trials. -Rifaximin has FDA approved indication for treatment of travelers' diarrhea caused by noninvasive strains of <i>Escherichia coli</i> . It should not be used in patients with diarrhea complicated by fever or blood in stool or diarrhea due to pathogens other than <i>E. coli</i> .
EXCLUSION CRITERIA (If one is selected, patient is NOT eligible)
<i>Contraindications:</i> <input type="checkbox"/> Known hypersensitivity to rifaximin.
INCLUSION CRITERIA
<u>Refractory to lactulose (Select both to be eligible):</u> <input type="checkbox"/> Patient continues to experience hepatic encephalopathy despite receiving lactulose at a dose that obtains 2 – 3 loose stools per day. <input type="checkbox"/> Both endpoints (persistent symptoms of hepatic encephalopathy and number of loose stools per day) are documented in patient's medical record.
<u>Intolerance to lactulose (Select both to be eligible):</u> <input type="checkbox"/> Patient with ≥ 4 loose stools per day despite dosage reductions. <input type="checkbox"/> Both endpoints (number of loose stools per day and dosage adjustments) are documented in the patient's medical record.
DOSAGE AND ADMINISTRATION*
Rifaximin 400mg orally three times daily. This can be taken with or without food. Prescription should be limited to no more than a 3 month supply.
RECOMMENDED MONITORING
After evaluating for initial response and tolerability, reassess medical treatment for hepatic encephalopathy every 3 months to confirm on-going need of rifaximin therapy. In addition to assessing the clinical signs and symptoms of hepatic encephalopathy, it is important to monitor the hydration status and electrolytes of the patient.

*In Phase III clinical trials, rifaximin 550mg orally twice daily is being evaluated for treatment of HE. The 550mg tablet of rifaximin is currently not available in the United States.