Texas Prior Authorization Program
Clinical Criteria

Drug/Drug Class

Xifaxan (Rifaximin)

Clinical Information Included in this Document

Xifaxan 200mg

- **Drugs requiring prior authorization**: the list of drugs requiring prior authorization for this clinical criteria
- **Prior authorization criteria logic**: a description of how the prior authorization request will be evaluated against the clinical criteria rules
- **Logic diagram**: a visual depiction of the clinical criteria logic
- **Supporting tables**: a collection of information associated with the steps within the criteria (diagnosis codes, procedure codes, and therapy codes); provided when applicable
- **References**: clinical publications and sources relevant to this clinical criteria

Xifaxan 550mg

- **Drugs requiring prior authorization**: the list of drugs requiring prior authorization for this clinical criteria
- **Prior authorization criteria logic**: a description of how the prior authorization request will be evaluated against the clinical criteria rules
- **Logic diagram**: a visual depiction of the clinical criteria logic
- **Supporting tables**: a collection of information associated with the steps within the criteria (diagnosis codes, procedure codes, and therapy codes); provided when applicable
- **References**: clinical publications and sources relevant to this clinical criteria

**Note**: Click the hyperlink to navigate directly to that section.
Revision Notes

- Updated to include formulary statement (The listed GCNS may not be an indication of TX Medicaid Formulary coverage. To learn the current formulary coverage, visit TxVendorDrug.com/formulary/formulary-search.) on each ‘Drug Requiring PA’ table
The listed GCNS may not be an indication of TX Medicaid Formulary coverage. To learn the current formulary coverage, visit TxVendorDrug.com/formulary/formulary-search.

<table>
<thead>
<tr>
<th>Label Name</th>
<th>GCN</th>
</tr>
</thead>
<tbody>
<tr>
<td>XIFAXAN 200 MG TABLET</td>
<td>93749</td>
</tr>
</tbody>
</table>
Xifaxan (Rifaximin) 200mg
Clinical Criteria Logic

1. Is the client greater than or equal to (≥) 12 years of age?
   [ ] Yes (Go to # 2)
   [ ] No (Deny)

2. Does the client have a diagnosis of infectious/traveler’s diarrhea in the last 90 days?
   [ ] Yes (Go to #3)
   [ ] No (Deny)

3. Does the client have a history of oral azithromycin or ciprofloxacin in the last 90 days?
   [ ] Yes (Go to #4)
   [ ] No (Deny)

4. Is the dose less than or equal to (≤) 600 mg per day?
   [ ] Yes (Approve – 3 days)
   [ ] No (Deny)
Xifaxan (Rifaximin) 200mg

Clinical Criteria Logic Diagram

Step 1
Is the client ≥ 12 years of age?

Yes

No

Deny Request

Step 2
Does the client have a diagnosis of infectious/traveler’s diarrhea in the last 90 days?

Yes

No

Deny Request

Step 3
Does the client have a history of oral azithromycin or ciprofloxacin in the last 90 days?

Yes

No

Deny Request

Step 4
Is the dose ≤ 600 mg per day?

Yes

Approve Request (3 days)

No

Deny Request
Xifaxan (Rifaximin)

Clinical Criteria Supporting Tables

### Step 2 (diagnosis of infectious/traveler’s diarrhea)
**Required diagnosis:** 1  
**Look back timeframe:** 90 days

<table>
<thead>
<tr>
<th>ICD-10 Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>A040</td>
<td>ENTEROPATHOGENIC ESCHERICHIA COLI INFECTION</td>
</tr>
<tr>
<td>A041</td>
<td>ENTEROTOXIGENIC ESCHERICHIA COLI INFECTION</td>
</tr>
<tr>
<td>A042</td>
<td>ENTEROINVASIVE ESCHERICHIA COLI INFECTION</td>
</tr>
<tr>
<td>A043</td>
<td>ENTEROHEMORRHAGIC ESCHERICHIA COLI INFECTION</td>
</tr>
<tr>
<td>A044</td>
<td>OTHER INTESTINAL ESCHERICHIA COLI INFECTIONS</td>
</tr>
<tr>
<td>A045</td>
<td>CAMPYLOBACTER ENTERITIS</td>
</tr>
<tr>
<td>A046</td>
<td>ENTERITIS DUE TO YERSINIA ENTEROCOLITICA</td>
</tr>
<tr>
<td>A047</td>
<td>ENTEROCOLITIS DUE TO CLOSTRIDIUM DIFFICILE</td>
</tr>
<tr>
<td>A048</td>
<td>OTHER SPECIFIED BACTERIAL INTESTINAL INFECTIONS</td>
</tr>
</tbody>
</table>

### Step 3 (history of oral azithromycin or ciprofloxacin)
**Required quantity:** 1  
**Look back timeframe:** 90 days

<table>
<thead>
<tr>
<th>Label Name</th>
<th>GCN</th>
</tr>
</thead>
<tbody>
<tr>
<td>AZITHROMYCIN 1 GM PWD PACKET</td>
<td>48790</td>
</tr>
<tr>
<td>AZITHROMYCIN 100 MG/5 ML SUSP</td>
<td>48792</td>
</tr>
<tr>
<td>AZITHROMYCIN 200 MG/5 ML SUSP</td>
<td>61199</td>
</tr>
<tr>
<td>AZITHROMYCIN 250 MG TABLET</td>
<td>48793</td>
</tr>
<tr>
<td>AZITHROMYCIN 500 MG TABLET</td>
<td>61198</td>
</tr>
<tr>
<td>AZITHROMYCIN 600 MG TABLET</td>
<td>48794</td>
</tr>
<tr>
<td>CIPRO 10% SUSPENSION</td>
<td>47057</td>
</tr>
<tr>
<td>CIPRO 250 MG TABLET</td>
<td>47050</td>
</tr>
<tr>
<td>CIPRO 5% SUSPENSION</td>
<td>47056</td>
</tr>
<tr>
<td>CIPRO 500 MG TABLET</td>
<td>47051</td>
</tr>
<tr>
<td>CIPROFLOXACIN ER 1,000 MG TAB</td>
<td>20315</td>
</tr>
<tr>
<td>CIPROFLOXACIN ER 500 MG TABLET</td>
<td>18898</td>
</tr>
<tr>
<td>CIPROFLOXACIN HCL 100 MG TAB</td>
<td>47053</td>
</tr>
<tr>
<td>CIPROFLOXACIN HCL 250 MG TAB</td>
<td>47050</td>
</tr>
<tr>
<td>CIPROFLOXACIN HCL 500 MG TAB</td>
<td>47051</td>
</tr>
<tr>
<td>CIPROFLOXACIN HCL 750 MG TAB</td>
<td>47052</td>
</tr>
</tbody>
</table>
### Step 3 (history of oral azithromycin or ciprofloxacin)

**Required quantity:** 1  
**Look back timeframe:** 90 days

<table>
<thead>
<tr>
<th>Label Name</th>
<th>GCN</th>
</tr>
</thead>
<tbody>
<tr>
<td>ZITHROMAX 1 GM POWDER PACKET</td>
<td>48790</td>
</tr>
<tr>
<td>ZITHROMAX 100 MG/5 ML SUSP</td>
<td>48792</td>
</tr>
<tr>
<td>ZITHROMAX 200 MG/5 ML SUSP</td>
<td>61199</td>
</tr>
<tr>
<td>ZITHROMAX 250 MG TABLET</td>
<td>48793</td>
</tr>
<tr>
<td>ZITHROMAX 500 MG TABLET</td>
<td>61198</td>
</tr>
<tr>
<td>ZITHROMAX 600 MG TABLET</td>
<td>48794</td>
</tr>
</tbody>
</table>
The listed GCNS may not be an indication of TX Medicaid Formulary coverage. To learn the current formulary coverage, visit TxVendorDrug.com/formulary/formulary-search.

<table>
<thead>
<tr>
<th>Label Name</th>
<th>GCN</th>
</tr>
</thead>
<tbody>
<tr>
<td>XIFAXAN 550 MG TABLET</td>
<td>28530</td>
</tr>
</tbody>
</table>
Xifaxan (Rifaximin) 550mg

Clinical Criteria Logic

1. Is the client greater than or equal to (≥) 18 years of age?
   - [ ] Yes (Go to # 2)
   - [ ] No (Deny)

2. Does the client have a diagnosis of hepatic encephalopathy in the last 730 days?
   - [ ] Yes (Go to #4)
   - [ ] No (Go to #3)

3. Does the client have a diagnosis of irritable bowel syndrome with diarrhea (IBS-D) in the last 730 days?
   - [ ] Yes (Go to #6)
   - [ ] No (Deny)

4. Does the client have a 15-day history of lactulose in the last 90 days?
   - [ ] Yes (Go to #5)
   - [ ] No (Deny)

5. Is the dose less than or equal to (≤) 1,100mg per day?
   - [ ] Yes (Approve - 365 days)
   - [ ] No (Deny)

6. Is the dose less than or equal to (≤) 1,650mg per day?
   - [ ] Yes (Approve – 365 days)
   - [ ] No (Deny)
Xifaxan (Rifaximin) 550mg
Clinical Criteria Logic Diagram

**Step 1**
Is the client ≥ 18 years of age?
- No
- Yes
  - Deny Request

**Step 2**
Does the client have a diagnosis of hepatic encephalopathy in the last 730 days?
- Yes
  - Deny Request
  - No
  - Yes
  - No
  - Yes
  - No

**Step 4**
Does the client have a 15-day history of lactulose in the last 90 days?
- No
  - No
  - Deny Request
  - Yes
  - Deny Request

**Step 5**
Is the dose ≤ 1,100mg per day?
- No
  - Deny Request
  - Yes
  - Approve Request (365 days)

**Step 6**
Is the dose ≤ 1,650mg per day?
- Yes
  - Approve Request (365 days)
  - No
  - Deny Request
### Step 2 (diagnosis of hepatic encephalopathy)

**Required diagnosis:** 1  
**Look back timeframe:** 730 days

<table>
<thead>
<tr>
<th>ICD-10 Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>K7290</td>
<td>HEPATIC FAILURE, UNSPECIFIED WITHOUT COMA</td>
</tr>
<tr>
<td>K7291</td>
<td>HEPATIC FAILURE, UNSPECIFIED WITH COMA</td>
</tr>
</tbody>
</table>

### Step 3 (diagnosis of irritable bowel syndrome with diarrhea)

**Required diagnosis:** 1  
**Look back timeframe:** 730 days

<table>
<thead>
<tr>
<th>ICD-10 Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>K580</td>
<td>IRRITABLE BOWEL SYNDROME WITH DIARRhea</td>
</tr>
</tbody>
</table>

### Step 4 (history of lactulose)

**Required quantity:** 1  
**Look back timeframe:** 90 days

<table>
<thead>
<tr>
<th>Label Name</th>
<th>GCN</th>
</tr>
</thead>
<tbody>
<tr>
<td>CONSTULOSE 10 GM/15 ML SOLN</td>
<td>10167</td>
</tr>
<tr>
<td>ENULOSE 10 GM/15 ML SOLUTION</td>
<td>10160</td>
</tr>
<tr>
<td>GENERLAC 10 GM/15 ML SOLUTION</td>
<td>10160</td>
</tr>
<tr>
<td>KRISTALOSE 10 GM PACKET</td>
<td>10162</td>
</tr>
<tr>
<td>KRISTALOSE 20 GM PACKET</td>
<td>11118</td>
</tr>
<tr>
<td>LACTULOSE 10 GM/15 ML SOLUTION</td>
<td>10167</td>
</tr>
</tbody>
</table>


Publication History

The Publication History records the publication iterations and revisions to this document. Notes for the most current revision are also provided in the Revision Notes on the first page of this document.

<table>
<thead>
<tr>
<th>Publication Date</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>01/31/2011</td>
<td>Initial publication and posting to website</td>
</tr>
</tbody>
</table>
| 10/21/2011       | • Added a new section to specify the drugs requiring prior authorization for each strength of Xifaxan  
                  • In the “Clinical Edit Criteria Logic” and “Clinical Edit Criteria Logic Diagram” sections, clarified wording in step 3  
                  • In the “Clinical Edit Supporting Tables” sections, revised tables to specify the diagnosis codes pertinent to step 2 of the logic diagram  
                  • In the “Clinical Edit Supporting Tables” sections, revised tables to specify the drugs pertinent to step 3 of the logic diagram |
| 04/03/2015       | • Updated to include ICD-10s |
| 10/06/2015       | • Updated to include new indications for Xifaxan 550mg |
| 04/12/2018       | • Annual review by staff  
                  • Removed ICD-9 codes  
                  • Updated question #3 to include azithromycin in logic and logic diagram, pages 4-5  
                  • Updated Table 2 and 3, pages 6-7  
                  • Updated references, page 12 |
| 03/29/2019       | • Updated to include formulary statement (The listed GCNS may not be an indication of TX Medicaid Formulary coverage. To learn the current formulary coverage, visit TxVendorDrug.com/formulary/formulary-search.) on each ‘Drug Requiring PA’ table |