



IBS-D Prior Authorization with Quantity Limit Program Summary

POLICY REVIEW CYCLE

Effective Date
01-01-2026

Date of Origin

POLICY AGENT SUMMARY PRIOR AUTHORIZATION

| Target Brand Agent(s) | Target Generic Agent(s) | Strength | Targeted MSC | Available MSC | Final Age Limit | Preferred Status |
|-----------------------|-------------------------|----------|---------------|---------------|-----------------|------------------|
| Xifaxan | Rifaximin Tab 550 MG | 550 MG | M ; N ; O ; Y | N | | |

POLICY AGENT SUMMARY QUANTITY LIMIT

| Target Brand Agent Name(s) | Target Generic Agent Name(s) | Strength | QL Amount | Dose Form | Day Supply | Duration | Addtl QL Info | Allowed Exceptions | Targeted NDCs When Exclusions Exist |
|----------------------------|------------------------------|----------------|-----------|-----------|------------|----------|--------------------------------|--------------------|-------------------------------------|
| Lotronex | alosetron hcl tab | 0.5 MG ; 1 MG | 60 | Tablets | 30 | DAYS | QL cumulative across strengths | | |
| Viberzi | eluxadoline tab | 100 MG ; 75 MG | 60 | Tablets | 30 | DAYS | | | |
| Xifaxan | Rifaximin Tab 200 MG | 200 MG | 9 | Tablets | 30 | DAYS | | | |
| Xifaxan | Rifaximin Tab 550 MG | 550 MG | 126 | Tablets | 365 | DAYS | | | |

ADDITIONAL QUANTITY LIMIT INFORMATION

| Wildcard | Target Brand Agent Name(s) | Target Generic Agent Name(s) | Strength | Additional QL Information | Targeted NDCs When Exclusions Exist | Effective Date | Term Date |
|--------------|----------------------------|------------------------------|---------------|--------------------------------|-------------------------------------|----------------|-----------|
| 525540151003 | Lotronex | alosetron hcl tab | 0.5 MG ; 1 MG | QL cumulative across strengths | | | |

CLIENT SUMMARY – PRIOR AUTHORIZATION

| Target Brand Agent Name(s) | Target Generic Agent Name(s) | Strength | Client Formulary |
|----------------------------|------------------------------|----------|---|
| Xifaxan | Rifaximin Tab 550 MG | 550 MG | HIM Quarterly 2025 ; HIM Quarterly 2026 ; IL HIM Annual 2025 ; IL HIM Annual 2026 ; NM HIM Annual 2025 ; NM HIM Annual 2026 ; TX HIM Annual 2025 ; TX HIM Annual 2026 |

CLIENT SUMMARY – QUANTITY LIMITS

| Target Brand Agent Name(s) | Target Generic Agent Name(s) | Strength | Client Formulary |
|----------------------------|------------------------------|----------------|--|
| Lotronex | alosetron hcl tab | 0.5 MG ; 1 MG | Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Quarterly 2025 ; HIM Quarterly 2026 ; IL HIM Annual 2026 ; IL HMO Performance Quarterly ; IL non-HMO Performance Full ; Jade ; MT Performance Full ; NM HIM Annual 2026 ; NM Performance Full ; OK Performance Full ; Performance ; Performance Annual ; Performance Biosimilar ; Performance Select ; Performance Select Biosimilar ; TX HIM Annual 2026 ; Topaz ; Whole Foods |
| Viberzi | eluxadoline tab | 100 MG ; 75 MG | Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Quarterly 2025 ; HIM Quarterly 2026 ; IL HIM Annual 2026 ; IL HMO Performance Quarterly ; IL non-HMO Performance Full ; Jade ; MT Performance Full ; NM HIM Annual 2026 ; NM Performance Full ; OK Performance Full ; Performance ; Performance Annual ; Performance Biosimilar ; Performance Select ; Performance Select Biosimilar ; TX HIM Annual 2026 ; Topaz ; Whole Foods |
| Xifaxan | Rifaximin Tab 200 MG | 200 MG | Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Quarterly 2025 ; HIM Quarterly 2026 ; IL HIM Annual 2026 ; IL HMO Performance Quarterly ; IL non-HMO Performance Full ; Jade ; MT Performance Full ; NM HIM Annual 2026 ; NM Performance Full ; OK Performance Full ; Performance ; Performance Annual ; Performance Biosimilar ; Performance Select ; Performance Select Biosimilar ; TX HIM Annual 2026 ; Topaz ; Whole Foods |
| Xifaxan | Rifaximin Tab 550 MG | 550 MG | Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Quarterly 2025 ; HIM Quarterly 2026 ; IL HIM Annual 2026 ; IL HMO Performance Quarterly ; IL non-HMO Performance Full ; Jade ; MT Performance Full ; NM HIM Annual 2026 ; NM Performance Full ; OK Performance Full ; Performance ; Performance Annual ; Performance Biosimilar ; Performance Select ; Performance Select Biosimilar ; TX HIM Annual 2026 ; Topaz ; Whole Foods |

| Target Brand Agent Name(s) | Target Generic Agent Name(s) | Strength | Client Formulary |
|----------------------------|------------------------------|----------|--|
| | | | ; NM Performance Full ; OK Performance Full ; Performance ; Performance Annual ; Performance Biosimilar ; Performance Select ; Performance Select Biosimilar ; TX HIM Annual 2026 ; Topaz ; Whole Foods |

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

| Module | Clinical Criteria for Approval |
|------------------|--|
| Xifaxan 550mg | <p>Target Agent(s) will be approved when ALL of the following are met:</p> <ol style="list-style-type: none"> 1. ONE of the following: <ol style="list-style-type: none"> A. The patient has a diagnosis of irritable bowel syndrome with diarrhea (IBS-D) OR B. The patient is at risk of recurrent overt hepatic encephalopathy OR C. The patient has a diagnosis of travelers' diarrhea AND BOTH of the following: <ol style="list-style-type: none"> 1. The traveler's diarrhea is caused by noninvasive strains of Escherichia coli AND 2. The patient does not have diarrhea complicated by fever or blood in the stool or diarrhea due to pathogens other than Escherichia coli OR D. The patient has another FDA labeled indication for the requested agent OR E. The patient has another indication that is supported in compendia for the requested agent and route of administration AND 2. If the patient has an FDA labeled indication, then ONE of the following: <ol style="list-style-type: none"> A. The patient's age is within FDA labeling for the requested indication for the requested agent OR B. There is support for using the requested agent for the patient's age for the requested indication AND 3. The patient does NOT have any FDA labeled contraindications to the requested agent AND 4. ONE of the following: <ol style="list-style-type: none"> A. The requested dosage strength is FDA labeled for the requested FDA labeled indication or supported in compendia for the requested indication OR B. There is support for the requested dosage strength for the requested FDA labeled or compendia supported indication <p>Compendia Allowed: AHFS or DrugDex 1, 2A, or 2B level of evidence, or NCCN 1, 2A or 2B</p> <p>Length of Approval:</p> <p>BCBSOK: 36 months BCBSIL and BCBSMT: 12 months</p> <p>All other plans: Travelers' Diarrhea: 1 month (3 months for BCBSNM) Hepatic Encephalopathy: 12 months IBS-D: 12 months Any other indication: 3 months</p> <p>NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.</p> <p>The requested agent will also be approved when ONE of the following is met:</p> |

| Module | Clinical Criteria for Approval |
|--------|---|
| | <p>1. The request is for a BCBS NM Fully Insured or NM HIM member and ALL of the following:</p> <ul style="list-style-type: none"> A. The patient does NOT have any FDA labeled contraindications to the requested agent AND B. The requested indication is a rare disease AND C. ONE of the following: <ul style="list-style-type: none"> 1. The patient has another FDA labeled indication for the requested agent and route of administration OR 2. The patient has another indication that is supported in compendia for the requested agent and route of administration OR <p>2. ALL of the following:</p> <ul style="list-style-type: none"> A. The member resides in Ohio AND B. The plan is Fully Insured or HIM Shop (SG) AND C. The patient does NOT have any FDA labeled contraindications to the requested agent AND D. ONE of the following: <ul style="list-style-type: none"> 1. The patient has another FDA labeled indication for the requested agent and route of administration OR 2. The patient has another indication that is supported in compendia for the requested agent and route of administration OR 3. The prescriber has submitted TWO articles from major peer-reviewed professional medical journals [e.g., Journal of American Medical Association (JAMA), New England Journal of Medicine (NEJM), Lancet] supporting the proposed use(s) as generally safe and effective. Accepted study designs may include, but are not limited to, randomized, double blind, placebo controlled clinical trials. NOTE: Case studies are not acceptable [journal articles required] <p>Non-oncology compendia allowed: DrugDex level 1, 2A or 2B, AHFS-DI (narrative text must be supportive)</p> <p>Oncology compendia allowed: NCCN 1 or 2A, AHFS-DI (narrative text must be supportive), DrugDex level 1, 2A, or 2B, or Clinical Pharmacology (narrative text must be supportive), Lexi-Drugs evidence level A, peer-reviewed medical literature</p> <p>Length of Approval:</p> <p>BCBSOK: 36 months All other plans: 12 months</p> <p>NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria</p> |

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

| Module | Clinical Criteria for Approval |
|-------------------------|--|
| Lotronex /Viberzi QL | <p>Quantity Limit for the Target Agent(s) will be approved when ONE of the following is met:</p> <ul style="list-style-type: none"> 1. The requested quantity (dose) does NOT exceed the program quantity limit OR 2. The requested quantity (dose) exceeds the program quantity limit AND ONE of the following: <ul style="list-style-type: none"> A. BOTH of the following: <ul style="list-style-type: none"> 1. The requested agent does NOT have a maximum FDA labeled dose for the requested indication AND 2. There is support for therapy with a higher dose for the requested indication OR B. BOTH of the following: <ul style="list-style-type: none"> 1. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication AND 2. There is support for why the requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does NOT exceed the program quantity limit OR |

| Module | Clinical Criteria for Approval |
|---------------|---|
| | <p data-bbox="354 180 1382 323"> c. BOTH of the following: <ol style="list-style-type: none"> <li data-bbox="469 212 1382 268">1. The requested quantity (dose) exceeds the maximum FDA labeled dose for the requested indication AND <li data-bbox="469 268 1305 323">2. There is support for therapy with a higher dose for the requested indication </p> <p data-bbox="232 363 638 394">Length of Approval: 12 months</p> |
| Xifaxan QL | <p data-bbox="232 405 1373 462">Quantity Limit for the Target Agent(s) will be approved when ONE of the following is met:</p> <ol style="list-style-type: none"> <li data-bbox="280 501 1284 529">1. The requested quantity (dose) does NOT exceed the program quantity limit OR <li data-bbox="280 529 1325 585">2. The requested quantity (dose) exceeds the program quantity limit AND ONE of the following: <ol style="list-style-type: none"> <li data-bbox="354 590 1365 701"> A. BOTH of the following: <ol style="list-style-type: none"> <li data-bbox="469 617 1235 674">1. The requested agent is for reduction in risk of overt hepatic encephalopathy (HE) recurrence AND <li data-bbox="469 674 1362 701">2. The requested quantity (dose) does NOT exceed 2 tablets per day OR <li data-bbox="354 701 1414 842"> B. BOTH of the following: <ol style="list-style-type: none"> <li data-bbox="469 728 1414 785">1. The requested agent does NOT have a maximum FDA labeled dose for the requested indication AND <li data-bbox="469 785 1305 842">2. There is support for therapy with a higher dose for the requested indication OR <li data-bbox="354 842 1411 1020"> C. BOTH of the following: <ol style="list-style-type: none"> <li data-bbox="469 869 1333 926">1. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication AND <li data-bbox="469 926 1411 1020">2. There is support for why the requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does NOT exceed the program quantity limit OR <li data-bbox="354 1020 1382 1161"> D. BOTH of the following: <ol style="list-style-type: none"> <li data-bbox="469 1047 1382 1104">1. The requested quantity (dose) exceeds the maximum FDA labeled dose for the requested indication AND <li data-bbox="469 1104 1305 1161">2. There is support for therapy with a higher dose for the requested indication <p data-bbox="232 1201 498 1232">Length of Approval:</p> <p data-bbox="232 1268 472 1295">BCBSIL: 12 months</p> <p data-bbox="232 1335 415 1362"><u>All other plans:</u></p> <p data-bbox="232 1362 583 1390">Travelers' Diarrhea: 1 month</p> <p data-bbox="232 1390 670 1417">Hepatic Encephalopathy: 12 months</p> <p data-bbox="232 1417 456 1444">IBS-D: 12 months</p> <p data-bbox="232 1444 607 1472">Any other indication: 3 months</p> |