DRUG QUANTITY MANAGEMENT POLICY – PER RX

POLICY: Infectious Disease – Xifaxan Drug Quantity Management Policy – Per Rx
- Xifaxan® (rifaximin tablets – Salix)

REVIEW DATE: 08/04/2025

INSTRUCTIONS FOR USE

THE FOLLOWING COVERAGE POLICY APPLIES TO HEALTH BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. CERTAIN CIGNA COMPANIES AND/OR LINES OF BUSINESS ONLY PROVIDE UTILIZATION REVIEW SERVICES TO CLIENTS AND DO NOT MAKE COVERAGE DETERMINATIONS. REFERENCES TO STANDARD BENEFIT PLAN LANGUAGE AND COVERAGE DETERMINATIONS DO NOT APPLY TO THOSE CLIENTS. COVERAGE POLICIES ARE INTENDED TO PROVIDE GUIDANCE IN INTERPRETING CERTAIN STANDARD BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. PLEASE NOTE, THE TERMS OF A CUSTOMER'S PARTICULAR BENEFIT PLAN DOCUMENT [GROUP SERVICE AGREEMENT, EVIDENCE OF COVERAGE, CERTIFICATE OF COVERAGE, SUMMARY PLAN DESCRIPTION (SPD) OR SIMILAR PLAN DOCUMENT] MAY DIFFER SIGNIFICANTLY FROM THE STANDARD BENEFIT PLANS UPON WHICH THESE COVERAGE POLICIES ARE BASED. FOR EXAMPLE, A CUSTOMER'S BENEFIT PLAN DOCUMENT MAY CONTAIN A SPECIFIC EXCLUSION RELATED TO A TOPIC ADDRESSED IN A COVERAGE POLICY. IN THE EVENT OF A CONFLICT, A CUSTOMER'S BENEFIT PLAN DOCUMENT ALWAYS SUPERSEDES THE INFORMATION IN THE COVERAGE POLICIES. IN THE ABSENCE OF A CONTROLLING FEDERAL OR STATE COVERAGE MANDATE, BENEFITS ARE ULTIMATELY DETERMINED BY THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT. COVERAGE DETERMINATIONS IN EACH SPECIFIC INSTANCE REQUIRE CONSIDERATION OF 1) THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT IN EFFECT ON THE DATE OF SERVICE; 2) ANY APPLICABLE LAWS/REGULATIONS; 3) ANY RELEVANT COLLATERAL SOURCE MATERIALS INCLUDING COVERAGE POLICIES AND; 4) THE SPECIFIC FACTS OF THE PARTICULAR SITUATION. EACH COVERAGE REQUEST SHOULD BE REVIEWED ON ITS OWN MERITS. MEDICAL DIRECTORS ARE EXPECTED TO EXERCISE CLINICAL JUDGMENT WHERE APPROPRIATE AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. WHERE COVERAGE FOR CARE OR SERVICES DOES NOT DEPEND ON SPECIFIC CIRCUMSTANCES, REIMBURSEMENT WILL ONLY BE PROVIDED IF A REQUESTED SERVICE(S) IS SUBMITTED IN ACCORDANCE WITH THE RELEVANT CRITERIA OUTLINED IN THE APPLICABLE COVERAGE POLICY, INCLUDING COVERED DIAGNOSIS AND/OR PROCEDURE CODE(S). REIMBURSEMENT IS NOT ALLOWED FOR SERVICES WHEN BILLED FOR CONDITIONS OR DIAGNOSES THAT ARE NOT COVERED UNDER THIS COVERAGE POLICY (SEE "CODING INFORMATION" BELOW). WHEN BILLING, PROVIDERS MUST USE THE MOST APPROPRIATE CODES AS OF THE EFFECTIVE DATE OF THE SUBMISSION. CLAIMS SUBMITTED FOR SERVICES THAT ARE NOT ACCOMPANIED BY COVERED CODE(S) UNDER THE APPLICABLE COVERAGE POLICY WILL BE DENIED AS NOT COVERED. COVERAGE POLICIES RELATE EXCLUSIVELY TO THE ADMINISTRATION OF HEALTH BENEFIT PLANS. COVERAGE POLICIES ARE NOT RECOMMENDATIONS FOR TREATMENT AND SHOULD NEVER BE USED AS TREATMENT GUIDELINES. IN CERTAIN MARKETS, DELEGATED VENDOR GUIDELINES MAY BE USED TO SUPPORT MEDICAL NECESSITY AND OTHER COVERAGE DETERMINATIONS.

CIGNA NATIONAL FORMULARY COVERAGE:

OVERVIEW

Xifaxan, a rifamycin antibiotic, is indicated for the following uses:[1]
- **Hepatic encephalopathy**, to reduce the risk of overt disease in adults.
- **Irritable bowel syndrome with diarrhea**, in adults.
- **Travelers' diarrhea**, caused by noninvasive *Escherichia coli* in patients ≥ 12 years of age.

Dosing

The recommended dose of Xifaxan is as follows:[1]
- Hepatic encephalopathy: 550 mg twice daily.
- Irritable bowel syndrome with diarrhea: 550 mg three times daily (TID) for 14 days. If there is a recurrence of symptoms, patients can be retreated up to two times at the same dose.

- Travelers' diarrhea: 200mg TID for 3 days.

Availability

Xifaxan is available as 200 mg and 550 mg tablets.[1] Xifaxan 200 mg tablets are supplied in 30 tablet bottles. Xifaxan 550 mg tablets are supplied in 60 tablet bottles and blister packs.

Off-Label Dosing

Guidelines also support the use of Xifaxan in the following conditions:[2]

- Chronic antibiotic-dependent pouchitis: 550 mg to 1 gram every 12 hours.
- Chronic antibiotic-dependent pouchitis as maintenance therapy: 200 mg once daily (QD). May increase dose based on clinical response and tolerability up to 1,800 mg QD.
- Induction therapy of chronic antibiotic: 600 mg to 1,200 mg divided every 8 hours in combination with ciprofloxacin for 2 weeks.

POLICY STATEMENT

This Drug Quantity Management program has been developed to promote the safe, effective, and economic use of Xifaxan. If the Drug Quantity Management rule is not met for the requested medication at the point of service, coverage will be determined by the Criteria below. All approvals are provided for 1 year in duration.

Drug Quantity Limits

Product	Strength and Form	Retail Maximum Quantity per Rx	Home Delivery Maximum Quantity per Rx
Xifaxan® (rifaximin tablets)	200 mg tablets	9 tablets	27 tablets
	550 mg tablets	60 tablets	180 tablets

EXCEPTIONS TO THE QUANTITY LIMITS LISTED ABOVE ARE COVERED AS MEDICALLY NECESSARY WHEN THE FOLLOWING CRITERIA ARE MET. ANY OTHER EXCEPTION IS CONSIDERED NOT MEDICALLY NECESSARY.

CRITERIA

Xifaxan 200 mg tablets

1. If the patient has chronic antibiotic-dependent pouchitis, approve 300 tablets per dispensing at retail and 900 tablets per dispensing at home delivery.

Xifaxan 550 mg tablets

No overrides recommended.

REFERENCES

1. Xifaxan® tablets [prescribing information]. Bridgewater, NJ: Salix; November 2023.
2. Barnes EL, Agrawal M, Syal G, et al. AGA clinical practice guideline on the management of pouchitis and inflammatory pouch disorders. *Gastroenterology*. 2024;166(1):59-85.

HISTORY

Type of Revision	Summary of Changes	Review Date
New Policy	New policy was created to provide overrides to existing quantity limits.	09/18/2024
Annual Revision	No criteria changes.	08/04/2025