



PHARMACY COVERAGE GUIDELINES
SECTION: DRUGS

ORIGINAL EFFECTIVE DATE: 1/19/2017
LAST REVIEW DATE: 5/21/2020
LAST CRITERIA REVISION DATE: 5/21/2020
ARCHIVE DATE:

VIBERZI™ (eluxadoline) oral tablet XIFAXAN® (rifaximin) oral tablet

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Pharmacy Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

This Pharmacy Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide BCBSAZ complete medical rationale when requesting any exceptions to these guidelines.

The section identified as "Description" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as "Criteria" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Pharmacy Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Pharmacy Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

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This Pharmacy Coverage Guideline does not apply to FEP or other states' Blues Plans.

Information about medications that require precertification is available at www.azblue.com/pharmacy.

Some large (100+) benefit plan groups may customize certain benefits, including adding or deleting precertification requirements.

All applicable benefit plan provisions apply, e.g., waiting periods, limitations, exclusions, waivers and benefit maximums.

Precertification for medication(s) or product(s) indicated in this guideline requires completion of the [request form](#) in its entirety with the chart notes as documentation. **All requested data must be provided.** Once completed the form must be signed by the prescribing provider and faxed back to BCBSAZ Pharmacy Management at (602) 864-3126 or emailed to Pharmacyprecert@azblue.com. **Incomplete forms or forms without the chart notes will be returned.**

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Section A. Irritable Bowel Syndrome with Diarrhea:
Viberzi (eluxadoline)
Xifaxan (rifaximin)

Criteria:

- **Criteria for initial therapy:** Viberzi (eluxadoline) or Xifaxan (rifaximin) is considered *medically necessary* and will be approved when **ALL** of the following criteria are met:
1. Prescriber is a physician specializing in the patient's diagnosis or is in consultation with a Gastroenterologist
 2. Individual is 18 years of age or older
 3. A confirmed diagnosis of moderate to severe **Irritable Bowel Syndrome with Diarrhea (IBS-D)** with symptoms of moderate abdominal pain, discomfort and bloating
 4. The recurrent symptoms are present, on average, at least 1 day per week during the preceding 3 months associated **with 2 or more** of the following: related to defecation, associated with a change in stool frequency, associated with a change in stool form/appearance
 5. The abnormal diarrheal bowel movements are Bristol Stool Form Scale (BSFS) type 6 or 7
 6. Failed dietary modification that includes lactose restricted diet, if lactose-intolerant; exclusion of gas-producing foods; low carbohydrate diet and elimination of fermentable oligo-, di-, and monosaccharides and polyols (FODMAPs)
 7. Individual has failure, contraindication or intolerance to **BOTH** dicyclomine **AND** hyoscyamine
 8. Individual has failure, contraindication or intolerance to **EITHER** amitriptyline **OR** nortriptyline
 9. Will not be used for diarrhea complicated by fever or blood in stool
 10. Will not be used for diarrhea associated with use of antibiotics
 11. There are **NO** contraindications:
 - Contraindications for **Viberzi** (eluxadoline) include:
 - Individual without a gallbladder
 - Known or suspected biliary duct obstruction or sphincter of Oddi disease or dysfunction
 - Alcoholism, alcohol abuse or alcohol addiction, or in patients who drink > 3 alcoholic beverages per day
 - A history of pancreatitis; structural diseases of the pancreas, including known or suspected pancreatic duct obstruction
 - Severe hepatic impairment (Child-Pugh Class C)

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- A history of chronic or severe constipation or sequelae from constipation, or known or suspected mechanical gastrointestinal obstruction
- Known hypersensitivity reaction to Viberzi
- Contraindications for **Xifaxan** include:
 - History of hypersensitivity to rifaximin, rifamycin antimicrobial agents, or any of the components of Xifaxan

Initial approval duration:

Viberzi: 6 months
Xifaxan: 550 mg three times a day for 14-day course with two refills
No other dose, frequency, or duration will be approved

➤ **Criteria for continuation of coverage (renewal request):** Viberzi (eluxadoline) **only** is considered **medically necessary** and will be approved when **ALL** of the following criteria are met:

1. Individual continues to be seen by a physician specializing in the patient's diagnosis or is in consultation with a Gastroenterologist
2. Individual's condition has responded while on therapy
 - Response is defined as both:
 - Achieved and maintains BSFS type of 3 or 4 on at least 3 or 4 days
 - At least a 50% reduced symptoms of abdominal pain, discomfort, and bloating
3. Individual has been adherent with the medication
4. Individual has not developed any contraindications or other significant level 4 adverse drug effects that may exclude continued use
 - Contraindications as listed in the criteria for initial therapy section
 - Significant adverse effect such as:
 - Liver toxicity
 - Pancreatitis
 - Constipation
 - Hypersensitivity
5. There are no significant interacting drugs

Renewal duration: 12 months

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Section B. Travelers' Diarrhea:
Xifaxan (rifaximin)

Criteria:

- **Criteria for therapy:** Xifaxan (rifaximin) is considered **medically necessary** and will be approved when **ALL** of the following criteria are met:
1. Individual is 12 years of age or older
 2. A confirmed diagnosis of **Travelers' diarrhea** caused by noninvasive strains of *Escherichia coli*
 3. Failure, intolerance, or contraindication to **EITHER** azithromycin **OR** ciprofloxacin **OR** levofloxacin
 4. There are **NO** contraindications:
 - Contraindications include:
 - History of hypersensitivity to rifaximin, rifamycin antimicrobial agents, or any of the components of Xifaxan
 5. Will not be used for diarrhea complicated by fever or blood in stool
 6. Will not be used for diarrhea caused by bacteria other than *Escherichia coli*
 7. Will not be used for diarrhea associated with use of antibiotics

Approval duration:

200 mg three times a day for 3 days, one-time approval, no refills
No other dose, frequency, or duration will be approved

Section C. Overt Hepatic Encephalopathy:
Xifaxan (rifaximin)

Criteria:

- **Criteria for initial therapy:** Xifaxan (rifaximin) is considered **medically necessary** and will be approved when **ALL** of the following criteria are met:
1. Prescriber is a physician specializing in the patient's diagnosis or is in consultation with a Gastroenterologist or Hepatologist
 2. Individual is 18 years of age or older
 3. A confirmed diagnosis of **overt hepatic encephalopathy**

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4. Failure, intolerance, or contraindication to **EITHER** lactulose **OR** neomycin **OR** metronidazole
5. There are **NO** contraindications
 - Contraindications include:
 - History of hypersensitivity to rifaximin, rifamycin antimicrobial agents, or any of the components of Xifaxan
6. Will not be used for diarrhea complicated by fever or blood in stool
7. Will not be used for diarrhea caused by bacteria other than *Escherichia coli*
8. Will not be used for diarrhea associated with use of antibiotics

Initial approval duration:

550 mg two times a day
No other dose or frequency will be approved

- **Continuation of coverage (renewal request):** Xifaxan (rifaximin) is considered **medically necessary** and will be approved when **ALL** of the following criteria are met:
1. Individual continues to be seen by a physician specializing in the patient's diagnosis or is in consultation with a Gastroenterologist or Hepatologist
 2. Individual's condition responded while on therapy
 - **Response for overt hepatic encephalopathy** is defined as **TWO** of the following:
 - Achieved and maintains no asterixis tremors or only few asterixis flaps
 - Achieved and maintains at least a 50% reduction in neurologic dysfunction, seen as a reduction in lethargy or apathy, disorientation for time or place, inappropriate behavior, euphoria or anxiety, somnolence, or coma
 - Achieved and maintains at least a 50% reduction in overt hepatic encephalopathy hospitalizations
 3. Individual has been adherent with the medication
 4. Individual has not developed any contraindications or other significant level 4 adverse drug effects that may exclude continued use
 - Contraindications as listed in the criteria for initial therapy section

Renewal duration:

For Overt Hepatic Encephalopathy:

550 mg two times a day for 1 year
No other dose or frequency will be approved



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Description:

Viberzi (eluxadoline) is indicated in adults for the treatment of irritable bowel syndrome with diarrhea (IBS-D). Eluxadoline is a mu-opioid receptor agonist. It is also a delta opioid receptor antagonist and a kappa opioid receptor agonist. In animals, eluxadoline interacts with opioid receptors in the gut. Stimulation of the opioid receptors within the gut causes inhibition of gastric emptying, inhibition of peristalsis, increased muscle tone, induction of non-propulsive motility, and a delay in gastrointestinal transit.

Xifaxan (rifaximin) is indicated for the treatment of: i) Travelers' diarrhea (TD) caused by noninvasive strains of *Escherichia coli* (*E. coli*) in adults and pediatric patients 12 years of age and older; ii) reduction in risk of overt hepatic encephalopathy (HE) recurrence in adults; and iii) irritable bowel syndrome with diarrhea (IBS-D) in adults. It should not be used in patients with diarrhea complicated by fever or blood in the stool or diarrhea due to pathogens other than *E. coli*. Xifaxan (rifaximin) is a semi-synthetic, non-aminoglycoside, non-systemic antibiotic and is structural analog of rifampin. Rifaximin acts by binding to the beta-subunit of the bacterial DNA-dependent RNA polymerase blocking one of the steps in transcription to inhibit bacterial RNA synthesis. The result is inhibition of bacterial protein synthesis and consequently it inhibits the growth of bacteria. It has been shown to be active against *E. coli*.

According to the Centers for Disease Control (CDC), bacteria are the most common cause of TD. TD is rarely life threatening, but it can be severely debilitating in children and the elderly, as severe dehydration can occur. The most common pathogen is enterotoxigenic *E. coli*, followed by *Campylobacter jejuni*, *Shigella* species and *Salmonella* species. Antibiotics are used in the treatment of TD and are effective in cases caused by bacterial pathogens as long as they are susceptible to the particular antibiotic prescribed. Microbial resistance to antibiotics is on the rise and is dependent on many factors one of which is area traveled.

HE is a syndrome characterized by personality changes, intellectual impairment, and a depressed level of consciousness. In HE there is the occurrence of confusion, altered level of consciousness, and coma as a result of liver failure. The 2014 American Association for the Study of Liver Disease (AASLD) and the European Association for the Study of the Liver (EASL) practice guideline define HE as a brain dysfunction caused by liver insufficiency and manifests as a wide spectrum of neurological or psychiatric abnormalities ranging from subclinical alterations to coma. The guideline states that lactulose has been shown to reduce recurrence of HE after an episode of overt HE and it can prevent the development of the first episode. It is considered the agent of first choice for episodic overt HE. Rifaximin is considered add-on therapy to lactulose for prevention of overt HE. AASLD & EASL state that neomycin and metronidazole are alternatives choices for the treatment of over HE.

Irritable bowel syndrome (IBS) is a chronic, relapsing and often life-long functional bowel disorder in which abdominal pain or discomfort is associated with defecation and/or a change in bowel habits. IBS is characterized by symptoms of abdominal pain or discomfort associated with abnormal stool frequency, abnormal stool form, abnormal stool passage, and/or bloating or abdominal distension, which may or may not be relieved by defecation. Symptoms vary and are often associated with food intake and, characteristically, with defecation. Symptoms interfere with daily life and social functioning in many patients.

IBS may be subtyped on the basis of the patient's stool characteristics: IBS with diarrhea (IBS-D), IBS with constipation (IBS-C), IBS with mixed bowel habits or cyclic pattern (IBS-M), and un-subtyped IBS (IBS-U). Treatment is determined by the predominant symptom. Milder, less frequent episodes may be managed with



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dietary modifications such as eliminating or minimizing foods that worsen symptoms (such as those that contain caffeine, lactose, or artificial sweeteners for IBS-D) or eating a high-fiber diet (for IBS-C or IBS-D) and increasing fluid intake (for IBS-C).

Other lifestyle measures IBS include stress management and dietary interventions such as a diet low in fermentable oligo-, di-, and monosaccharides and polyols (FODMAP). FODMAPs are incompletely absorbed in the small intestine and ferment in the colon. They include foods with fructose (such as apples, pears, honey, high-fructose corn syrup), lactose (milk), fructans or galactans (wheat, onions), and polyols (some fruits and vegetables, artificial sweeteners such as sorbitol). Individuals with IBS may see symptom improvement with gluten restriction. This may be due to the fact that gluten is found in wheat, a high FODMAP food. Recent data confirms a role for probiotics in IBS, but also makes it clear that the effects of probiotics in IBS are highly strain-specific.

Small intestinal bacterial overgrowth (SIBO) occurs with greater frequency in patients who have been diagnosed with IBS compared to healthy controls. The classical features of SIBO are those of digestive problems and malabsorption. SIBO is most common in IBS-D but also occurs in IBS-C. Symptoms of SIBO include bloating, abdominal pain, diarrhea or constipation among others and the symptoms of SIBO overlap with those of IBS, which suggests that SIBO is related to IBS. Some researchers believe that SIBO may lead to IBS. Statistically significant reduction in IBS symptoms occurs following antibiotic therapy for SIBO. However, more research is needed to show a link between SIBO and IBS. SIBO is rare unless the patient has a primary or secondary motility disorder, has had surgery, such as ileocecal resection or bariatric surgery, or has impaired immunity (such as immunoglobulin A deficiency). Also recent research has shown that the lactulose hydrogen breath test does not actually measure SIBO, and that SIBO is unlikely to be the cause of IBS.

Guidelines recommend non-pharmacologic and over-the-counter therapy as first line therapy for IBS-D. Antispasmodics such as dicyclomine and hyoscyamine reduce abdominal spasms and cramps through reduced smooth muscle contractions. They may improve pain and global symptoms. Their efficacy is based on continuous use and the effect is rated as modest. Tricyclic antidepressants (amitriptyline, nortriptyline) improve abdominal pain and GI symptoms. Modest improvements may not be seen for several weeks. Loperamide may improve abdominal pain, stool consistency & frequency, but may require continuous use. Ondansetron blocks vagal stimulation of the gut, reducing motility & secretions, may reduce loose stools, frequency, and urgency. Lotronex (alosetron) also blocks vagal stimulation of the gut, reducing motility & secretions, it improves pain & stool consistency. Use is associated with a high risk for constipation and rarely, idiopathic ischemic colitis. It is FDA-approved for use in women with IBS-D who have failed conventional treatment. Xifaxan (rifaximin), a semi-synthetic, non-aminoglycoside, non-systemic antibiotic and is structural analog of rifampin, modestly improves abdominal pain and stool consistency. It is limited to a maximum of three 14-day courses of therapy using 550 mg three times a day. Viberzi (eluxadoline) may also modestly improves abdominal pain & loose stool

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Definitions:

Traveler's Diarrhea:

J Travel Med 2017: Guidelines for the prevention and treatment of travelers' diarrhea: a graded expert panel report		
Azithromycin	1000 mg once OR 500 mg once daily for 3 days	Preferred for dysentery (diarrhea with the presence of blood and mucus) or febrile diarrhea & pregnant women
Levofloxacin	500 mg once OR 500 mg once daily for 3 days	Fluoroquinolones are associated with multiple adverse effects
Ciprofloxacin	750 mg once OR 500 mg twice daily for 3 days	
Ofloxacin	400 mg once OR 400 mg once daily for 3 days	
Rifaximin	200 mg three times daily for 3 days	Not for use with dysentery or febrile diarrhea
Rifamycin	388 mg twice daily for 3 days	

Hepatic encephalopathy:

Hepatic encephalopathy is a brain dysfunction caused by liver insufficiency and/or portosystemic shunting; it manifests as a wide spectrum of neurological or psychiatric abnormalities ranging from subclinical alterations to coma. Overt hepatic encephalopathy is diagnosed clinically based on two types of symptoms: impaired mental status, as defined by the West Haven Criteria (WHC), and impaired neuromotor function.

West Haven Criteria (also known as Conn Score)		
Minimal (Grade 0)	<ul style="list-style-type: none"> • No asterixis • No detectable change in behavior • No detectable change in mental status • Minimal encephalopathy 	Minimal encephalopathy may not be obvious on clinical examination but can be detected by abnormal results of established psychometric or neuropsychological tests
Grade 1	<ul style="list-style-type: none"> • Trivial lack of awareness or attention • Euphoria or anxiety • Shortened attention span • Impairment of addition or subtraction • Altered sleep rhythm 	Despite oriented in time and space (see below), the patient appears to have some cognitive/behavioral decay with respect to his or her standard on clinical examination or to the caregivers
Grade 2	<ul style="list-style-type: none"> • Lethargy or apathy • Disorientation for time • Subtle obvious personality change • Amnesia of recent events • Inappropriate behavior • Dyspraxia • Slurred speech • Asterixis 	Disoriented for time (at least three of the followings are wrong: day of the month, day of the week, month, season, or year) ± the other mentioned symptoms

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Grade 3	<ul style="list-style-type: none"> • Somnolence to semi-stupor • Responsive to verbal stimuli • Confused • Gross disorientation • Bizarre behavior • Clonus • Nystagmus • Positive Babinski sign 	Disoriented also for space (at least three of the following wrongly reported: country, state [or region], city, or place) ± the other mentioned symptoms
Grade 4	Coma	Does not respond even to painful stimuli

Asterixis grade:

- 0 = no tremor
- 1 = few flaps
- 2 = occasional flaps
- 3 = frequent flaps
- 4 = continuous flaps

Irritable Bowel Syndrome (Rome IV criteria)

Recurrent bothersome symptoms of abdominal pain, AND altered bowel habits on average, at least one day per week in the last three months with symptoms onset at 6 months before the diagnosis

Recurrent abdominal pain with two or more of the following:

- Related to defecation
- Associated with a change in frequency of stool
- Associated with a change in form (appearance) of stool

Bristol Stool Form Scale (BSFS)

Seven types of stool are:

- Type 1: Separate hard lumps, like nuts (hard to pass); also known as *goat feces*
- Type 2: Sausage-shaped, but lumpy
- Type 3: Like a sausage but with cracks on its surface
- Type 4: Like a sausage or snake, smooth and soft
- Type 5: Soft blobs with clear cut edges (passed easily)
- Type 6: Fluffy pieces with ragged edges, a mushy stool
- Type 7: Watery, no solid pieces, entirely liquid

Types 1 & 2 indicate constipation
Types 3 & 4 indicate the ideal stools (especially the latter)
Types 5, 6 & 7 specify diarrheal stools

Irritable bowel syndrome with predominant diarrhea (IBS-D)

Abnormal bowel movements are usually diarrhea (BSFS type 6 and 7)
More than 25% of BM with BSFS types 6 or 7 and less than 25% of BM with BSFS types 1 or 2

Based on the patient's reported predominant bowel habit on days with abnormal bowel movements

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Off laxatives and off antidiarrheal agents

IBS with predominant constipation (IBS-C)

More than one fourth (25%) of bowel movements with Bristol stool form types 1 or 2
Less than one-fourth (25%) of bowel movements with Bristol stool form types 6 or 7
Based on the patient's reported predominant bowel habit on days with abnormal bowel movements
Off laxatives and off antidiarrheal agents

IBS with mixed bowel habits (IBS-M)

More than one fourth (25%) of bowel movements with Bristol stool form types 1 or 2 and
More than one-fourth (25%) of bowel movements with Bristol stool form types 6 or 7
Based on the patient's reported predominant bowel habit on days with abnormal bowel movements
Off laxatives and off antidiarrheal agents

IBS unclassified (IBS-U)

Patients who meet diagnostic criteria for IBS but whose bowel habits cannot be accurately categorized into 1 of the 3 groups above should be categorized as having IBS unclassified
Based on the patient's reported predominant bowel habit on days with abnormal bowel movements

Off laxatives and off antidiarrheal agents

Resources:

Viberzi (eluxadoline) product information accessed 04-03-20 at DailyMed

Xifaxan (rifaximin) product information accessed 04-03-20 at DailyMed

Viberzi (eluxadoline). Package Insert. Revised by manufacturer 11/2017. Accessed 03-14-2018.

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Moayyedi P, Mearin F, Azpiroz F, et al. Irritable bowel syndrome diagnosis and management: A simplified algorithm for clinical practice. United Euro Gastroenterol J 2017; 5 (6): 773-788

Vilstrup H, Amodio P, Bajaj J, et al.: Practice Guideline: Hepatic encephalopathy in chronic liver disease: 2014 Practice Guideline by AASLD and EASL



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World Gastroenterology Organization Global Guidelines: Irritable Bowel Syndrome: A global Perspective Update September 2015

Weinberg DS, Smalley W, Heidelbaugh JJ, and Sultan S.: American Gastroenterological Association Institute Guideline on the Pharmacological Management of Irritable Bowel Syndrome. *Gastroenterology* 2014; 147:1146-1148

Ford AC, Moayyedi P, Lacy BE, et al.: American College of Gastroenterology Monograph on the Management of Irritable Bowel Syndrome and Chronic Idiopathic Constipation. *Am J Gastroenterol* 2014; 109 Aug Suppl 1:S2-S26

Lacy BE, Mearin F, Chang L, et al.: Bowel Disorders. *Gastroenterology* 2016; 150 (6):1393-1407

UpToDate: Travelers' diarrhea: Clinical manifestations, diagnosis, and treatment. Current through June 2019

UpToDate: Travelers' diarrhea: Microbiology, epidemiology, and prevention. Current through May, 2018

UpToDate: Hepatic encephalopathy in adults: Clinical manifestations and diagnosis. Current through May, 2018

UpToDate: Hepatic encephalopathy in adults: Treatment. Current through May, 2018

UpToDate: Treatment of irritable bowel syndrome in adults. Current through Jun 2019

UpToDate: Small intestinal bacterial overgrowth: Clinical manifestations and diagnosis. Current through Mar, 2018

UpToDate: Treatment of irritable bowel syndrome in adults. Current through Mar, 2018

UpToDate: Clinical manifestations and diagnosis of irritable bowel syndrome in adults. Current through Mar, 2018

UpToDate: Pathophysiology of irritable bowel syndrome. Current through Mar, 2018

UpToDate: Small intestinal bacterial overgrowth: Clinical manifestations and diagnosis. Current through Mar, 2018
