ELUXADOLINE

Generic	Brand	HICL	GCN	Exception/Other
ELUXADOLINE	VIBERZI	42445		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Is the patient being treated for irritable bowel syndrome with diarrhea (IBS-D) and meets the following criteria?
   - The patient is at least 18 years old
   - The medication is prescribed by or in consultation with a gastroenterologist
   - The patient has had a trial of or contraindication to Xifaxan (rifaximin) **AND** either tricyclic anti-depressants (e.g., amitriptyline, desipramine) **OR** dicyclomine

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: Our guideline for **ELUXADOLINE (Viberzi)** requires a diagnosis of irritable bowel syndrome with diarrhea (IBS-D). Additional guideline requirements apply. The following criteria must also be met:
   - The patient is at least 18 years old
   - The medication is being prescribed by or in consultation with a gastroenterologist
   - The patient has had a trial of or contraindication to Xifaxan (rifaximin) **AND** either tricyclic anti-depressants (e.g., amitriptyline, desipramine) **OR** dicyclomine

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INITIAL CRITERIA (CONTINUED)

2. Does the patient meet **ANY** of the following criteria?
   - Patient does not have a gallbladder
   - Patient is receiving concomitant OATP1B1 inhibitors (e.g., atazanavir, cyclosporine, eltrombopag, gemfibrozil, lopinavir, rifampin, ritonavir, saquinavir, tipranavir)
   - Patient has mild or moderate hepatic impairment
   - Patient is intolerant to Viberzi 100mg

   If yes, **approve ELUXADOLINE 75MG for 12 weeks by GPID with a quantity limit of #2 tablets per day.**
   APPROVAL TEXT: Renewal requires that the patient has experienced at least 30% decrease in abdominal pain (on a 0-10 point pain scale) and the patient has experienced at least 50% reduction in the number of days per week with a stool consistency of mushy stool (Bristol Stool scale type 6) or entirely liquid stool (Bristol Stool scale type 7).

   If no, **approve ELUXADOLINE 100MG for 12 weeks by GPID with a quantity limit of #2 tablets per day.**
   APPROVAL TEXT: Renewal requires that the patient has experienced at least 30% decrease in abdominal pain (on a 0-10 point pain scale) and the patient has experienced at least 50% reduction in the number of days per week with a stool consistency of mushy stool (Bristol Stool scale type 6) or entirely liquid stool (Bristol Stool scale type 7).

RENEWAL CRITERIA

1. Is the patient being treated for irritable bowel syndrome with diarrhea (IBS-D) and meets **ALL** of the following criteria?
   - Patient has experienced at least 30% decrease in abdominal pain (on a 0-10 point pain scale)
   - Patient has experienced at least 50% reduction in the number of days per week with a stool consistency of mushy stool (Bristol Stool scale type 6) or entirely liquid stool (Bristol Stool scale type 7)

   If yes, **approve for 12 months by HICL with a quantity limit of #2 tablets per day.**
   If no, do not approve.
   DENIAL TEXT: Our guideline for **ELUXADOLINE (Viberzi)** renewal requires a diagnosis of irritable bowel syndrome with diarrhea (IBS-D). Additional guideline requirements apply. The following criteria must also be met:
   - Patient has experienced at least 30% decrease in abdominal pain (on a 0-10 point pain scale).
   - Patient has experienced at least 50% reduction in the number of days per week with a stool consistency of mushy stool (Bristol Stool scale type 6) or entirely liquid stool (Bristol Stool scale type 7).

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RATIONALE

To ensure appropriate utilization of Viberzi for irritable bowel syndrome with diarrhea (IBS-D).

Per the American College of Gastroenterology, there is high quality evidence that tricyclic anti-depressants are effective in providing symptom relief in IBS-D. However, tolerance to these agents could be an issue for some patients. Rifaximin is indicated for the treatment of IBS-D.

Renewal criteria for IBS-D is based on the definition of a responder used in Study 1 and 2 of the Viberzi pivotal trials. Efficacy of Viberzi was assessed in both trials using an overall composite responder primary endpoint. The primary endpoint was defined by the simultaneous improvement in the daily worst abdominal pain score by ≥30% as compared to the baseline weekly average AND a reduction in the BSS to <5 on at least 50% of the days within a 12-week time interval. Improvement in daily worst abdominal pain in the absence of a concurrent bowel movement was also considered a response day.

FDA APPROVED INDICATIONS

Viberzi is a mu-opioid receptor agonist, indicated in adults for the treatment of irritable bowel syndrome with diarrhea (IBS-D).

DOSING

The recommended dosage in adults is 100 mg twice daily taken with food.
The recommended dosage is 75 mg twice daily taken with food in patients who:

- do not have a gallbladder
- are unable to tolerate the 100 mg dose
- are receiving concomitant OATP1B1 inhibitors

REFERENCES

- Patheon Pharmaceuticals, Inc. Viberzi package insert. Cincinnati, OH 45209. May 2015.
- Salix Pharmaceuticals, Inc. Xifaxan package insert. Raleight, NC. May 2015.
- Task Force on the Management of Functional Bowel Disorders. American College of Gastroenterology Monograph on the Management of Irritable Bowel syndrome and Chronic Idiopathic Constipation. Am J Gastroenterol 2014; 109:S2-S26.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 06/16/16
Created: 02/16
Client Approval: 06/16
P&T Approval: 02/16