BlueCross BlueShield Federal Employee Program

VIBERZI
(eluxadoline)

RATIONALE FOR INCLUSION IN PA PROGRAM

Background

Viberzi is an oral medication that activates receptors in the nervous system that can lessen bowel contractions in adult patients with irritable bowel syndrome with diarrhea (IBS-D) (1).

Regulatory Status

FDA-approved indication: Viberzi is a mu-opioid receptor agonist, indicated in adults for the treatment of irritable bowel syndrome with diarrhea (IBS-D) (1).

Viberzi is contraindicated in people with known or suspected biliary duct obstruction or sphincter of Oddi disease or dysfunction, alcoholism, alcohol abuse or drink more than 3 alcoholic beverages per day, a history of pancreatitis including known or suspected pancreatic duct obstruction, severe hepatic impairment (Child-Pugh Class C), severe constipation or sequelae from constipation or mechanical gastrointestinal obstruction (1).

In patients with mild (Child-Pugh Class A) or moderate (Child-Pugh Class B) hepatic impairment, plasma concentrations of Viberzi increase. Viberzi should be given at a reduced dose of 75 mg twice daily to these patients. Monitor patients with any degree of hepatic impairment for impaired mental or physical abilities needed to perform potentially hazardous activities such as driving a car or operating machinery and for other drug-related adverse reactions (1).

Following a single oral 100 mg dose in subjects with varying degrees of liver impairment and healthy subjects, mean Viberzi plasma exposure was 6-fold, 4-fold, and 16-fold higher in mild, moderate, and severe hepatically impaired subjects (Child Pugh Class A, B, C), respectively, compared to subjects with normal liver function (1).

Also, Viberzi should be given at a reduced dose of 75 mg twice daily in patients who do not have a gallbladder, are unable to tolerate the 100 mg dose, or are receiving concomitant OATP1B1 inhibitors (1).

Safety and effectiveness in pediatric patients have not been established (1).

Summary

VIBERZI
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Viberzi is an oral medication that activates receptors in the nervous system that can lessen bowel contractions in adult patients with irritable bowel syndrome with diarrhea (IBS-D)in patients 18 years of age or older. Safety and effectiveness in pediatric patients have not been established (1).

Prior approval is required to ensure the safe, clinically appropriate, and cost-effective use of Viberzi while maintaining optimal therapeutic outcomes.

References

1. Viberzi [package insert]. Madison, NJ: Allergan USA, Inc.; June 2020.
2. Blake MR, Raker JM, Whelan K. Validity and reliability of the Bristol Stool Form Scale in healthy adults and patients with diarrhoea-predominant irritable bowel syndrome. Aliment Pharmacol Ther. 2016 Oct;44(7):693-703. doi: 10.1111/apt.13746. Epub 2016 Aug 5.