ALASKA MEDICAID Prior Authorization Criteria

ViberziTM 75mg, 100mg tablets (eluxadoline)

FDA INDICATIONS AND USAGE¹

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

APPROVAL CRITERIA^{1,2}

- 1. Patient is 18 years of age or older **AND**;
- 2. Patient has a diagnosis of irritable bowel syndrome with diarrhea (IBS-D) AND;
- 3. Patient is not on concomitant opioids or benzodiazepine AND;
- 4. Patient has trialed at least one TCA or SSRI for a period of 8 weeks AND;
- 5. Patient has trialed at least one antispasmodic agent (i.e. hyoscyamine) **AND**;
- 6. Patient has trialed at least one antidiarrheal agent (i.e. loperamide)

DENIAL CRITERIA^{1,2}

- 1. Patient < 18 years of age **OR**;
- 2. Patient has a known hypersensitivity, contraindication, or intolerance to ViberziTM OR;
- 3. Patient has a biliary duct obstruction or sphincter of Oddi dysfunction **OR**;
- 4. Patient does not have a gallbladder **OR**;
- 5. Patient has severe hepatic impairment **OR**:
- 6. Patient a history of severe constipation **OR**;
- 7. Patient has a history of alcoholism, alcohol abuse, alcohol addiction, or drinks more than 3 alcoholic beverages/day **OR**:
- 8. Patient has a history of pancreatitis or structural disease of the pancreas

CAUTIONS¹

- Pancreatitis and Sphincter of Oddi Spasm: Monitor patients for new or worsening abdominal pain, with or without nausea and vomiting, or acute biliary pain with liver or pancreatic enzyme elevations; immediately discontinue VIBERZI and seek medical attention if symptoms develop.
- Constipation: Instruct patients to stop VIBERZI and immediately contact their healthcare provider if they develop severe constipation. Avoid use with other drugs that may cause constipation (i.e. opioids).

DURATION OF APPROVAL

- Initial Approval: up to 3 months
- Reauthorization Approval: up to 12 months with a reported improvement

ViberziTM Criteria Version: 1 Original: 8/06/2018 Approval: 9/21/2018

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OUANTITY LIMITS

- 60 75mg tablets per month
- 60 100mg tablets per month

REFERENCES / FOOTNOTES:

- 1. Viberzi (eluxadoline) [prescribing information]. Irvine, CA: Allergan; April 2018. Accessed August 2018.
- 2. Chang L, Lembo A, Sultan. American Gastroenterology Association Institute Technical Review on the Pharmacological Management on Irritable Bowel Syndrome. *Gastroenterology*. 2014; 147(5):1149-1172. Available from: https://www.gastrojournal.org/article/S0016-5085(14)01090-7/pdf. Accessed on August 6, 2018.

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