JOHNS HOPKINS MEDICINE JOHNS HOPKINS HEALTHCARE	Johns Hopkins HealthCare LLC **Pharmacy Public** **Pharmacy Management Drug Policies**	*Policy Number*	MEDS098
		Effective Date	04/20/2016
		Review Date	04/20/2016
	Subject **Viberzi**	*Revision Date*	12/07/2021
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This document applies to the following Participating Organizations:

Priority Partners

Keywords: viberzi

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I. POLICY

A. Viberzi (eluxadoline) will require prior authorization to ensure appropriate use. It will require prior authorization for outpatient prescription drug benefit coverage to ensure this medication is used only when clinically appropriate. The process for initiating a prior authorization request can be found in policy PHARM 20.
   1. PPMCO members are subject to the Priority Partners formulary, available at www.ppmco.org.
   2. USFHP members are subject to prior authorization criteria, step-edits and days-supply limits outlined in the Tricare Policy Manual. Tricare Policy supersedes JHHC Medical/Pharmacy Policies. Tricare limits may be accessed at: http://pec.ha.osd.mil/formulary_search.php?submenuheader=1

II. POLICY CRITERIA

A. Viberzi may be approved for patients meeting the following:
   1. Patient is 18 years of age or older
   2. Documented diagnosis of diarrhea predominant irritable bowel disease (IBS-D)
   3. Documented trial and inadequate response, or contraindication, to medications from TWO of the following medication classes:
      a. Antispasmodic agents (e.g. dicyclomine, hyoscyamine)
      b. Antidiarrheal agents (e.g. loperamide)
      c. Tricyclic antidepressants

B. Requested quantity is not greater than the FDA recommended dose of 2 tablets per day

III. AUTHORIZATION PERIOD/LIMITATIONS

A. Initial approval will be restricted to 3 months of therapy.

B. Approval for continuation of therapy can be extended in 12-month intervals with clinical documentation showing:
   1. The patient has not developed a contraindication to therapy as outlined in the exclusion section below **AND**
   2. The patient has had a beneficial response to therapy as evidenced by **at least ONE** of the following:
      a. Improved stool frequency and consistency
      b. Improved abdominal pain

IV. EXCLUSIONS

A. Viberzi will **NOT** be approved for the following:
   1. Other indications not included in the criteria stated above
   2. Patients who have any of the following contraindications:
      a. Known or suspected biliary duct obstruction, or sphincter of Oddi disease or dysfunction
      b. Alcoholism, alcohol abuse or addiction, or drinking more than 3 alcoholic beverages per day
      c. History of pancreatitis, orstructural diseases of the pancreas, including known or suspected pancreatic duct obstruction
      d. Severe hepatic impairment (Child-Pugh Class C)
      e. History of chronic or severe constipation
      f. Known or suspected mechanical gastrointestinal obstruction

B. The use of physician samples, or manufacturer product discounts, does not guarantee coverage under the provisions of the medical and/or pharmacy benefit. All pertinent criteria must be met in order to be eligible for benefit coverage.

V. RECOMMENDED DOSE

A. Initial dose: 100mg taken orally twice daily with food
B. Initial dose: 75mg taken orally twice daily with food for patients who:
   1. do not have a gallbladder
   2. cannot tolerate the 100mg strength tablet
   3. are receiving concomitant OATP1B1 (Organic Anion Transporting Polypeptide) inhibitors
   4. have mild (Child-Pugh Class A) or moderate (Child-Pugh Class B) hepatic impairment

VI. REFERENCES

1. Viberzi [prescribing information]. Madison, NJ: Allergan USA, Inc. June 2020
2. Weinberg, D et al. American Gastroenterological Association Institute Guideline on the Pharmacological Management of Irritable Bowel Syndrome. Gastroenterology 2014; 147:1146–1148.

VII. APPROVALS

Signature on file at JHHC

DATE OF REVISION	SUMMARY OF CHANGE
04/20/2016	New Policy
07/27/2017	Updated Exclusions section regarding physician samples
07/01/2018	Removed EHP Line of Business
12/07/2021	Updated layout

Review Dates: 04/20/2016

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