

Drug Product	
Viberzi® (eluxadoline) tablet (oral)	Indication not funded
Indications	
<ul style="list-style-type: none"> Irritable Bowel Syndrome with diarrhea (IBS-D) 	
Dosage	
<ul style="list-style-type: none"> Adults: 100 mg orally twice daily with food 	<ul style="list-style-type: none"> Dose Adjustment: 75 mg twice daily in patients without a gallbladder, are unable to tolerate 100 mg dose, are receiving concomitant OATP1B1 inhibitors, or have mild or moderate hepatic impairment
Background	
<ul style="list-style-type: none"> IBS associated with recurrent painful abdominal distress with constipation, diarrhea, or both. Management typically consists of lifestyle and dietary modifications with or without adjunctive pharmacotherapy. Mu-opioid receptor agonism/delta-receptor antagonism thought to treat IBS-D with limited effects on constipation 	
Efficacy	
<ul style="list-style-type: none"> Two phase 3 double-blind, RCTs in IBS-D patients Both Studies demonstrated statistically significant difference in percent reduction of the composite endpoint compared to placebo at 12 weeks: <ul style="list-style-type: none"> Study 1: 8% (95% CI, 2.6 to 13.5; p<0.01; n=1280) Study 2: 13% (95% CI, 7.5 to 19.2; p<0.001; n=1145) 	<p>Composite Primary Endpoint:</p> <ul style="list-style-type: none"> ≥30% improvement of worst abdominal pain score in past 24 hrs compared to the baseline weekly average Reduction in the Bristol Stool Score (BSS) to <5 or the absence of a bowel movement if accompanied with ≥30% improvement as detailed above
Safety	
<p>Common adverse reactions:</p> <ul style="list-style-type: none"> Constipation and nausea (8% each); abdominal pain (7%). Nine cases of pancreatitis observed, which resolved with discontinuation. 	<p>Contraindication: History of biliary duct obstruction or sphincter of Oddi disease.</p> <p>Avoid use: History of pancreatitis, severe liver impairment, severe constipation, or in patients who drink >3 alcoholic beverages per day.</p>
Evidence Gaps/Limitations	
No additional studies found to support evidence for use in the treatment of other Oregon Health Plan (OHP) funded conditions or co-morbidities.	
Recommendation	
Restrict use for OHP-funded conditions through Prior Authorization.	
References	
<ol style="list-style-type: none"> Viberzi (eluxadoline) [Prescribing Information]. Cincinnati, OH; Patheon Pharmaceuticals, Inc. May 2015. FDA Center for Drug Evaluation and Research Summary Review. Available at:http://www.accessdata.fda.gov/drugsatfda_docs/nda/2015/206940Orig1s000SumR.pdf. Accessed November 24, 2015. 	