

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