Alvimopan (Entereg®)
Criteria for Nonformulary Use
10 April 2009
VHA Pharmacy Benefits Management Services and the Medical Advisory Panel

These criteria were based on the best clinical evidence currently available. The recommendations in this document are dynamic, and will be revised as new clinical information becomes available. This guidance is intended to assist practitioners in providing consistent, high-quality, cost-effective drug therapy. These criteria are not intended to interfere with clinical judgment; the clinician must ultimately decide the course of therapy based on individual patient situations. A summary of the literature review used to support the criteria for use of alvimopan is available at http://www.pbm.va.gov or vaww.pbm.va.gov.

FDA-approved indication: acceleration of time to upper and lower gastrointestinal recovery following partial large or small bowel resection surgery with primary anastomosis in patients greater than 18 years of age

Exclusion Criteria *If ANY criterion below is met, then the patient should NOT receive alvimopan.*

- ☐ Hypersensitivity to alvimopan or product components.
- ☐ Chronic opioid use for 1 week or greater prior to procedure
- ☐ Severe hepatic impairment (Child-Pugh C) or End Stage Renal Disease
- ☐ Epidural anesthesia is scheduled to be used during surgery
- ☐ Complete Bowel Obstruction
- ☐ Recent treatment with alvimopan in current episode of care (No studies evaluated safety and efficacy of more than one treatment course.)
- ☐ Situations where pre-operative dose cannot be administered
- ☐ Inflammatory Bowel Disease
- ☐ Patients scheduled for total abdominal hysterectomy, total colectomy, ileostomy, or colostomy
- ☐ Any non-FDA approved indication (E.A.S.E. program—see Entereg Ordering Instructions and VAMC Registration Form)

Inclusion Criteria *All of the following (A–C) must be fulfilled in order to meet criteria.*

A. Undergoing partial large or small bowel resection surgery

B. Intravenous postoperative opioid pain management is planned

C. A post-operative plan including encouraged mobility, removal of the NGT within one day of surgery, and early re-introduction of liquids and solid foods is planned

** Particular consideration should be given to patients considered at risk for prolonged post operative ileus (PPOI)

a. Prior occurrence of PPOI after any surgical procedure.
b. Anticipation of extensive (over 2 hours) adhesiolysis associated with a small or large bowel resection.
c. Significant en bloc resection of intra-abdominal organs including large or small bowel.

Discontinuation Criteria

- ☐Maximum of 15 doses allowed
- ☐Maximum of 7 days or until hospital discharge
- ☐Return of bowel function (i.e., bowel movement)

Refills

No refills allowed

Dosing (No adjustments necessary for mild-moderate renal or hepatic disorder)

12 mg orally twice daily, with first dose administered 30 minutes to 5 hours prior to surgery (max. 2 doses per day)

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