Amitiza (lubiprostone)
Policy Number: C5113-C

CRITERIA EFFECTIVE DATES:

ORIGINAL EFFECTIVE DATE	LAST REVIEWED DATE	NEXT REVIEW DATE
03/2013	01/2019	01/2020
J CODE	**TYPE OF CRITERIA**	**LAST P&T APPROVAL**
NA	RxPA	Q3

PRODUCTS AFFECTED: Amitiza (lubiprostone)

DRUG CLASS: Gastrointestinal Chloride Channel Activators

ROUTE OF ADMINISTRATION: Oral

PLACE OF SERVICE: Retail Pharmacy

AVAILABLE DOSAGE FORMS: Amitiza CAPS 24MCG, Amitiza CAPS 8MCG

FDA-APPROVED USES: Treatment of irritable bowel syndrome with constipation (IBS-C) in women ≥ 18 years old, treatment of chronic idiopathic constipation (CIC) in adults, treatment of opioid-induced constipation (OIC) in adults with chronic, non-cancer pain

Limitation of Use: Effectiveness of Amitiza in the treatment of OIC in patients taking diphenylheptane opioids (e.g. methadone) has not been established

COMPENDIAL APPROVED OFF-LABELED USES: None

COVERAGE CRITERIA: INITIAL AUTHORIZATION DIAGNOSIS: irritable bowel syndrome with constipation, chronic idiopathic constipation, opioid-induced constipation

REQUIRED MEDICAL INFORMATION:

A. OPIOID INDUCED CONSTIPATION:
   1. Documented diagnosis of opioid-induced constipation in adults with chronic, non-cancer pain defined as less than 3 SBMs (spontaneous bowel movements) per week, on average, with one or more of the following symptoms of constipation for at least 6 months: Very hard stools for at least a quarter of all bowel movements OR Sensation of incomplete evacuation following at least a quarter of all bowel movements OR Straining with defecation at least a quarter of the time
      AND
   2. The member has chronic use of an opioid agent in the past 30 days
      AND
   3. The member is not currently receiving a diphenylheptane opioid (e.g. methadone)
      AND

4. The member has failed on or is intolerant to at least 2 of the following with or without a stool softener in the past 3 months: At least one stimulant laxative (e.g. bisacodyl); OR At least one osmotic laxative (e.g. PEG 3350); OR At least one saline laxative (e.g. magnesium citrate)

B. IRRITABLE BOWEL SYNDROME WITH CONSTIPATION(IBS-C)
1. Documentation diagnosis IBS-C defined as abdominal pain or discomfort occurring over at least 6 months with two or more of the following: Relieved with defecation, Onset associated with a change in stool frequency, or Onset associated with a change in stool AND
2. The member is female
AND
3. The member has failed on or is intolerant to at least 2 of the following with or without a stool softener in the past 3 months: At least one stimulant laxative (e.g. bisacodyl); OR At least one osmotic laxative (e.g. PEG 3350); OR At least one saline laxative (e.g. magnesium citrate)

C. CHRONIC IDIOPATHIC CONSTIPATION:
1. Documentation of symptoms for >3 months
AND
2. The member has failed on or is intolerant to at least 2 of the following with or without a stool softener in the past 3 months: At least one stimulant laxative (e.g. bisacodyl); OR At least one osmotic laxative (e.g. PEG 3350); OR At least one saline laxative (e.g. magnesium citrate)
AND
3. Amitiza (lubiprostone)will not be used in combination with other functional gastro-intestinal disorder drugs (Linzess, Motegrity, Trulance, Zermelo or Zelnorm)

DURATION OF APPROVAL: Initial authorization: 3 months, Continuation of therapy: 12 months

QUANTITY: max of #60 capsules per 30 days

PRESCRIBER REQUIREMENTS: Prescribed by or in consultation with a gastroenterologist

AGE RESTRICTIONS: 18 years of age and older

GENDER: Male and female

CONTINUATION OF THERAPY:
A. FOR ALL INDICATIONS:
1. Documentation that the member has demonstrated a beneficial response to Amitiza, per the prescribing physician (e.g. increased number of bowel movements from baseline)
AND
2. The member has no contraindications to Amitiza.

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION: All other uses of Amitiza (lubiprostone) are considered experimental/investigational and therefore, will follow Molina's Off-Label policy

OTHER SPECIAL CONSIDERATIONS: None

BACKGROUND:

Amitiza is a type-2 chloride channel activator that stimulates chloride secretion in the GI tract. Through this action, Amitiza enhances GI fluid secretion and transit time which alleviates constipation. Amitiza is minimally absorbed and has low systemic bioavailability after oral administration. Amitiza is indicated for the treatment of opioid-induced constipation (OIC) in adults with chronic non-cancer pain, including patients with chronic pain related to prior cancer or its treatment who do not require frequent (e.g. weekly) opioid dosage escalation; chronic idiopathic constipation (CIC) in adults; and irritable bowel syndrome with constipation (IBS-C) in women ≥ 18 years of age. A limitation of use for Amitiza in OIC is that its efficacy has not been established in patients taking diphenylheptane opioids (e.g., methadone).

APPENDIX: None

REFERENCES:

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3. Pare P, Bridges R, Champion MC, et al. Recommendations on chronic constipation (including constipation associated with irritable bowel syndrome) treatment. Can J Gastroenterol. 2007 Apr;21 Suppl B:3B-22B
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7. Tarumi Y, Wilson MP, Szafran O, Spooner GR. Randomized, double-blind, placebo-controlled trial of oral docusate in the management of constipation in hospice patients. J Pain Symptom Manage 2013;45:2-13.
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