ALASKA MEDICAID
Prior Authorization Criteria

Amitiza® (lubiprostone) or Linzess™ (linaclotide)

FDA INDICATIONS and USAGE

AMITIZA:

1. Amitiza® is indicated for the treatment of chronic idiopathic constipation in adults.
2. Amitiza is indicated for the treatment of opioid-induced constipation (OIC) in adults with chronic non-cancer pain.

Limitations of Use:

- Effectiveness of Amitiza in the treatment of opioid-induced constipation in patients taking diphenylheptane opioids (e.g., methadone) has not been established.

3. Amitiza is indicated for the treatment of irritable bowel syndrome with constipation (IBS-C) in women ≥ 18 years old.

LINZESS:

A guanylate cyclase-C agonist indicated in adults for treatment of:

- Irritable bowel syndrome with constipation (IBS-C)
- Chronic idiopathic constipation (CIC)

DOSAGE FORM/STRENGTH

- Amitiza; 8mcg and 24mcg capsule
- Linzess; 145mcg and 290mcg capsule

APPROVAL CRITERIA

1. Diagnosis from the 'Indication and Usage' section and must be supported by documentation from the patient's medical record; **AND**
2. Age restrictions apply, must be 18 years of age or older; **AND**
3. Submit dates of trial or inadequate response from **two** of the following groups:
   - Fiber supplements
   - Stimulant laxatives
   - Osmotic laxatives

LENGTH OF AUTHORIZATION

- Coverage may be approved for 12 months.

QUANTITY LIMIT

- **AMITIZA;** maximum two (2) capsules per day either strength
- **LINZESS**
  - IBS-C; maximum one (1) capsule per day of 290mcg
  - CIC; maximum one (1) capsule per day of 145mcg

Reminder: You are encouraged to report negative side effects of prescription drugs to the FDA. Visit http://www.fda.gov/Safety/MedWatch/default.htm or call 1-800-FDA-1088

REFERENCES

- Amitiza® [package insert]. Deerfield, IL; Takeda Pharmaceuticals Americal, Inc., April 2013.
- Linzess™ [package insert]. St. Louis, MO; Forest Pharmaceuticals, Inc., July 2014.