

Louisiana Medicaid Chronic GI Motility Agents

The *Louisiana Uniform Prescription Drug Prior Authorization Form* should be utilized to request prior authorization for non-preferred chronic GI motility agents.

Additional Point-of-Sale edits may apply.

NOTE: *Some of these agents medications in this therapeutic category* may have **Black Box Warnings** and/or may be subject to **Risk Evaluation and Mitigation Strategy (REMS)** under FDA safety regulations. Please refer to individual prescribing information for details.

Approval Criteria for Initial and Reauthorization Requests for Non-Preferred Chronic GI Motility Agents

ALL of the following are required:

- For lubiprostone capsules (generic for Amitiza®) – there has been a treatment failure or *intolerable side effect with or contraindication to brand Amitiza®; OR*
- There is no preferred alternative that is the exact same chemical entity, formulation, strength, and delivery device; **AND**
- Previous use of a preferred product - **ONE** of the following is required:
 - The recipient has had a *treatment failure* with at least one preferred product; **OR**
 - The recipient has had an *intolerable side effect* to at least one preferred product; **OR**
 - The recipient has *documented contraindication(s)* to all of the preferred products that are appropriate to use for the condition being treated; **OR**
 - There is *no preferred product that is appropriate* to use for the condition being treated; **OR**
 - The prescriber states that the recipient is currently using the requested medication **AND** one of the following applies:
 - There is evidence in pharmacy claims of at least 60 days of the requested medication within the previous 90-day period; **OR**
 - There is evidence in pharmacy claims of less than 60 days of the requested medication **AND** the prescriber states the recipient has been treated with the requested medication in an inpatient facility; **OR**
 - There is evidence in pharmacy claims of less than 60 days of the requested medication **AND** the prescriber has verified that the pharmacy has dispensed at least 60 days of medication (billed to other insurance, and therefore not viewable in pharmacy claims); **AND**
- By submitting the authorization request, the prescriber attests to the following:
 - The prescribing information for the requested medication has been thoroughly reviewed, including any Black Box Warning, Risk Evaluation and Mitigation Strategy (REMS), contraindications, minimum age requirements, recommended dosing, and prior treatment requirements; **AND**
 - All laboratory testing and clinical monitoring recommended in the prescribing information have been completed as of the date of the request and will be repeated as recommended; **AND**
 - The recipient has no concomitant drug therapies or disease states medication and will not be receiving the requested medication in combination with any other medication that is contraindicated or not recommended per FDA labeling.

Duration of approval, both-initial and reauthorization approval: 12 months

References

Amitiza (lubiprostone) [package insert]. Bedminster, NJ: Takeda Pharmaceuticals American, Inc; November 2020. <https://general.takedapharm.com/amitizapi/>

Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; Retrieved from <https://www.clinicalkey.com/pharmacology/>

DiPiro JT, Talbert RL, Yee GC, Matzke GR, Wells BG, Posey L. eds. Pharmacotherapy: A Pathophysiologic Approach, 10e New York, NY: McGraw-Hill; Retrieved from <https://accesspharmacy.mhmedical.com/book.aspx?bookid=1861>

<u>Revision / Date</u>	<u>Implementation Date</u>
Single PDL Implementation	May 2019
Separated “Select Therapeutic Classes with Established Recent Claims” into individual therapeutic class documents <u>/ November 2019</u>	<u>November 2019</u> <u>January 2020</u>
<u>Added specific wording for use of Amitiza®, formatting changes, updated references / April 2021</u>	<u>April 2021</u> <u>July 2021</u>