

Document ID#: 1035214
Subject: Irritable Bowel Disease and Chronic Constipation
Medications
Effective Date: March 13, 2007

| | | | |
|---------------------------------------------------------|----|--------------------------------------------|-----|
| Clinical Documentation and Prior Authorization Required | √ | Type of Review - Case Management | |
| Not Covered | | Type of Review – Clinical Review | √ |
| Pharmacy (RX) or Medical (MED) Benefit | RX | Administrative Process (Internal Use Only) | LPN |

Note: Background, applicable product and disclaimer information can be found on the last page.

Overview

Zelnorm™ (tegaserod) is a serotonin-4 (5-HT₄) receptor agonist that is indicated for the short-term treatment of constipation-predominant irritable bowel syndrome (IBS) in women. Zelnorm helps to normalize GI motility, stimulate intestinal secretion and inhibit visceral sensitivity, all of which act to reduce the constipation, bloating and cramping associated with IBS. Zelnorm is indicated for an initial course of 4 to 6 weeks. For patients who respond to the first course, a second 4-6 week course can be considered.

Amitiza™ (lubiprostone) is a locally acting chloride channel activator that enhances a chloride-rich intestinal fluid secretion without altering sodium and potassium concentrations in the serum. By increasing intestinal fluid secretion, Amitiza increases motility in the intestine, thereby increasing the passage of stool and alleviating symptoms associated with chronic idiopathic constipation. The recommended adult dosage of Amitiza is 24mcg given twice daily with food. Health care providers and patients should periodically assess the need for continued therapy.

Pharmacy Coverage Guidelines

Tufts Health Plan may authorize coverage of Zelnorm (tegaserod) OR Amitiza (lubiprostone) for the treatment of **chronic idiopathic constipation** when **all** of the following criteria are met:

1. The Member has failed conservative treatment with **at least one** of the following cathartics/fiber supplements:
 - Citrucel® (Unifiber®, Maltsupex®)
 - Bisacodyl (Dulcolax®, Correctol®, Alophen®)
 - Polycarbophil (Fibercon®, Konsyl Fiber®)
 - Psyllium (Metamucil®, Konsyl®, Genfiber)
 - Miralax (GlycoLax™)
 - Sennosides (Senokot®, Senna-c®, Ex-Lax®,)

Note: Tufts Health Plan may authorize coverage of an initial 12-week course of coverage for the treatment of chronic idiopathic constipation when the above criteria are met. Requests for coverage beyond 12 weeks must include documentation that medication is effective in improving symptoms. Subsequent coverage may be authorized for up to one year.

For the diagnosis of **irritable bowel syndrome (IBS)**, Tufts Health Plan may authorize coverage of **Zelnorm** (tegaserod) if the following criteria are met:

1. The Member has constipation-predominant irritable bowel syndrome (IBS)
2. The Member has failed a conservative treatment with at least one of the cathartics/fiber supplements listed above

Note: Tufts Health Plan may authorize coverage of a 12-week course of therapy with Zelnorm (tegaserod) when the above criteria are met. An additional 12-week course of Zelnorm (tegaserod) may be authorized for exacerbations of IBS if a Member fails a subsequent minimum 6-week course of laxative therapy/cathartics as listed above.

Limitations

Tufts Health Plan will not authorize coverage of Zelnorm (tegaserod) for Members over the age of 65 who are being treated for chronic idiopathic constipation.

Codes

None.

References

1. Burnham TH, Novak K, eds. Drug Facts and Comparisons. January 2003 (updated monthly).
2. McEvoy GK, ed. American Hospital Formulary Service/AHFS Drug Information 2002. Bethesda: The American Society of Health-System Pharmacists, Inc. 2002.
3. Manufacturer' s Web Site: www.zelnorm.com. Novartis Pharmaceuticals Corporation, East Hanover, NJ. 2003.
4. Manufacturer' s Web Site: www.zelnorm.com. Novartis Pharmaceuticals Corporation, East Hanover, NJ. 2004.
5. Manufacturer' s Web Site: www.zelnorm.com. Novartis Pharmaceuticals Corporation, East Hanover, NJ. 2005.
6. eFacts and Comparisons online; <http://online.factsandcomparisons.com>
7. American Hospital Formulary Service/AHFS website: www.ahfs.org, Copyright ©1997-2005, American Society of Health-System Pharmacists, Inc.

Approval History

Reviewed by the Pharmacy and Therapeutics Committee in March 2003.

Subsequent Endorsement Date(s) and Changes Made:

1. November 9, 2004 changes:
 - Add “chronic idiopathic constipation” in coverage criteria for Members under 65 years of age.
 - Subdivide the list of cathartics/fiber supplements into two columns and add generic names to the list.
 - Change “the Member must have failed conservative treatment with TWO or more of the following cathartics/fiber supplements” to “the Member must have failed conservative treatment with **AT LEAST ONE** of the following cathartics/fiber supplements in each of the column A **AND B**”.
2. April 12, 2005 changes:
 - Add to the **Coverage Limitations** “Tufts Health Plan will authorize coverage of a 12-week course of therapy when the above criteria are met. Requests for coverage of **Zelnorm** beyond 12 weeks must be reviewed by a Tufts Health Plan Medical Director.”
3. October 11, 2005 changes:
 - Delete column B (Lactulose, Enulose, Cephulac, Generlac, Kristalose) from the criteria.
 - Change the criteria **from**
“For EITHER indication above, the Member has failed conservative treatment with **AT LEAST ONE** of the following cathartics/fiber supplements in each of the column A **AND B**”
To
“For EITHER indication above, the Member has failed conservative treatment with **AT LEAST ONE** of the following cathartics/fiber supplements”
4. August 8, 2006 changes:
 - Changed topic from “**Zelnorm** (tegaserod)” to “**Zelnorm** (tegaserod) and **Amitiza**[™] (lubiprostone)”.
 - Added **Amitiza** to the criteria for the indication of chronic idiopathic constipation.
 - Moved criteria for the indication of irritable bowel syndrome and reported it as distinctive criteria for **Zelnorm**.
 - Moved **Zelnorm** specific age-related criteria “Tufts Health Plan will not authorize coverage of **Zelnorm** for Members over the age of 65 who are being treated for chronic idiopathic constipation.” to limitations.
5. March 13, 2007 changes:
 - Added note: “Tufts Health Plan may authorize coverage of an initial 12-week course of coverage for the treatment of chronic idiopathic constipation when the above criteria are met. Requests for coverage beyond 12 weeks must include documentation that medication is effective in improving symptoms. Subsequent coverage may be authorized for up to one year.”
 - Added note: “Tufts Health Plan may authorize coverage of a 12-week course of therapy with Zelnorm (tegaserod) when the above criteria are met. An additional 12-week course of Zelnorm (tegaserod) may be authorized for exacerbations of IBS if a Member fails a subsequent minimum 6-week course of laxative therapy/cathartics as listed above.”
 - Removed limitation: “Tufts Health Plan will authorize coverage of a 12-week course of therapy when the above criteria are met. Requests for coverage of Zelnorm beyond 12 weeks must be reviewed by a Tufts Health Plan Medical Director.”
 - Removed requirement that “the diagnosis is made by a gastroenterologist” from criteria for chronic idiopathic constipation.
 - Removed requirement that “the Member is female” from criteria for irritable bowel syndrome.

Background, Product and Disclaimer Information

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for Tufts Health Plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. They are used in conjunction with a Member's benefit document and in coordination with the Member's physician(s). Tufts Health Plan makes coverage decisions on a case-by-case basis considering the individual Member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the Tufts Health Plan service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. Tufts Health Plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

Pharmacy Medical Necessity Guidelines apply to all fully insured Tufts Health Plan offerings unless otherwise noted in this policy or the Member's benefit document. However, for Tufts Health Plan Medicare Preferred Members, the Pharmacy Medical Necessity Guidelines only apply to Medicare Part D covered drugs. Tufts Medicare Preferred defers to Medicare coverage guidelines when reviewing Medicare Part B covered drugs. Medicare's national and local coverage determinations for Part B covered drugs can be accessed via the CMS coverage database at <http://www.cms.hhs.gov/mcd/search.asp>. Medicare general coverage guidelines are located in Chapter 15 of the Medicare Benefit Policy Manual, which can be accessed at <http://www.cms.hhs.gov/Manuals/IOM/list.asp>. Generally, Tufts Medicare Preferred requires prior authorization for the same drugs that require prior authorization for the fully insured Tufts Health Plan offerings. Check the applicable formulary in the Pharmacy section of our Website at www.tuftshealthplan.com to determine if the drug requires you to get prior authorization. This Pharmacy Medical Necessity Guideline does not apply to Uniformed Services Family Health Plan Members or to certain delegated service arrangements. Unless otherwise noted in the Member's benefit document or applicable Pharmacy Medical Necessity Guideline, Pharmacy Medical Necessity Guidelines do not apply to CareLinkSM Members. For self-insured plans, drug coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a coverage guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern. Applicable state or federal mandates will take precedence.

Treating providers are solely responsible for the medical advice and treatment of Members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to Member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.