# Criteria for Nonformulary Use of Tegaserod

VA Pharmacy Benefits Management Strategic Healthcare Group and Medical Advisory Panel

*The following recommendations are based on current medical evidence and expert opinion from clinicians. The content of the document is dynamic and will be revised as new clinical data becomes available. The purpose of this document is to assist practitioners in clinical decision-making, to standardize and improve the quality of patient care, and to promote cost-effective drug prescribing. The clinician should utilize this guidance and interpret it in the clinical context of individual patient situations*

Refer to the National PBM Drug Monographs for Tegaserod (Zelnorm®) at
http://vaww.pbm.va.gov/drugmonograph/tegaserod%20addendum.pdf or
http://vaww.pbm.va.gov/ubb/uploads/admin5/visn21tegaserod(addendum).pdf or
http://vaww.pbm.va.gov/drugmonograph/tegaserod%20monograph%20022003.pdf for recommendations on dosing, precautions, and monitoring

| **Exclusion Criteria** | **#1** |
|---|---|
| ☐ Treatment of idiopathic chronic constipation for patients age 65 or older<br>☐ Treatment of constipation predominant irritable bowel syndrome (IBS) in men<br>☐ Chronic idiopathic constipation due to pelvic floor dysfunction<br>☐ IBS with alternating symptoms of constipation and diarrhea<br>☐ Diarrhea predominant IBS<br>☐ Treatment of diabetic gastroparesis*<br>☐ Treatment of GERD<br>☐ Chronic constipation induced by medications or caused by other co-morbid conditions<br>☐ CrCl $\leq$ 15 ml/min/1.73m$^2$ | ☐ Yes<br>☐ No<br><br>*If Yes to any of these conditions, patient is ineligible to receive tegaserod*<br><br>*"Exceptions to these exclusion criteria should be adjudicated on a case-by-case basis through the nonformulary process."<br><br>*If No to #1, proceed to #2.* |
| **Inclusion Criteria** | **#2** |
| Tegaserod should only be used for patients who do not meet the exclusion criteria above and who have one of the following diagnosis:<br>☐ Treatment of idiopathic chronic constipation for patients under the age of 65 years who have documented failure of all current formulary agents (agents listed in cost section of Drug Monograph). Non-formulary request should come from a GI specialist or other designated person with expertise in this area.<br>☐ Short-term treatment of constipation predominant irritable bowel syndrome in women | ☐ Yes<br>☐ No<br><br>*If yes (and no for #1), patient is eligible to receive tegaserod* |
| **Dosing** | **#3** |
| ☐ Constipation predominant IBS: The recommended dose is 6mg taken twice daily before meals for 4-6 weeks. For patients who respond to therapy during this time period, an additional 4-6 weeks of treatment can be considered.<br>☐ Treatment of idiopathic chronic constipation: The recommended dose is 6mg taken twice daily before meals. The patient must be limited to a 30-day supply with no refills.<br>☐ Efficacy beyond 12 weeks has not been substantiated by clinical trials.<br>☐ Tegaserod should be taken 30 minutes prior to meals.<br>☐ Reassessment for efficacy by documenting symptom and/or quality of life improvement in the patient's medical record is needed for continued use. | |
| **Monitoring** | **#4** |
| ☐ Constipation predominant IBS: Patients should be reevaluated after 4-6 weeks to document any significant improvement. For patients who respond to therapy during this time period, an additional 4-6 weeks of treatment can be considered.<br>☐ Treatment of idiopathic chronic constipation: Patients should be reevaluated after a 30 day trial. The patient must keep a daily report of stool frequency or other data deemed relevant by prescriber. A new consult must be provided for further refills. | |
| Discontinuation Criteria | |
| ☐ No documented symptom relief after 4 weeks: abdominal pain or discomfort<br>☐ No documented constipation relief after 4 weeks: change in frequency, consistency or form of stool | |

Approved by Physician: Date/Time

Updated versions may be found at http://vaww.pbm.va.gov or www.pbm.va.gov
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