Medication Policy Manual

Policy No: dru473

Topic: Non-preferred Oral Medications for Inflammatory Bowel Disease

balsalazide, Giazo®

budesonide sustained release (SR), Uceris®

mesalamine controlled-release (CR), Pentasa®

mesalamine DR, Asacol HD®

mesalamine DR, Delzicol®

olsalazine, Dipentum®

Date of Origin: December 16, 2016

Committee Approval Date: September 8, 2017

Next Review Date: September 2018

Effective Date: October 1, 2017

IMPORTANT REMINDER

This Medication Policy has been developed through consideration of medical necessity, generally accepted standards of medical practice, and review of medical literature and government approval status.

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control.

The purpose of Medication Policy is to provide a guide to coverage. Medication Policy is not intended to dictate to providers how to practice medicine. Providers are expected to exercise their medical judgment in providing the most appropriate care.

Description

Budesonide is a corticosteroid used to treat inflammatory bowel disease, such as Crohn's and ulcerative colitis. 5-aminosalicylate acid (5-ASA) are medications used to treat ulcerative colitis. This policy applies only to oral formulations of these medications.

Policy/Criteria

I. Most contracts require prior authorization approval of non-preferred oral medications for inflammatory bowel disease (IBD) prior to coverage. Non-preferred oral medications for IBD may be considered medically necessary when preferred options (as specified in Table 1) are ineffective, not tolerated, or all are contraindicated.

Table 1. Non-preferred IBD medications with comparable alternatives

Non-preferred IBD medications	Preferred alternatives
balsalazide disodium tablets (Giazo®)	generic balsalazide capsules
budesonide SR tablets (Uceris®)	generic budesonide DR capsules
mesalamine CR capsules (Pentasa®)	mesalamine extended-release (ER) capsules (Apriso®) AND mesalamine DR tablets (Lialda®)
mesalamine DR tablets (Asacol HD®)	
mesalamine DR capsules (Delzicol®)	
olsalazine sodium capsules (Dipentum®)	

II. Administration, Quantity Limitations, and Authorization Period

A. OmedaRx considers non-preferred oral medications for inflammatory bowel disease to be a self-administered medication.

B. When prior authorization is approved, non-preferred oral medications for inflammatory bowel disease may be authorized in quantities as follows:

Non-preferred Product	Quantity Limit
balsalazide disodium (Giazo)	#180 per 30 days
budesonide SR tablets (Uceris)	#30 per 30 days
mesalamine CR capsules (Pentasa)	#240 per 30 days
mesalamine DR tablets (Asacol HD), capsules (Delzicol)	#180 per 30 days
olsalazine sodium capsules (Dipentum)	#120 per 30 days

C. Authorization may be reviewed at least every 6 months to confirm that current medical necessity criteria are met and that the medication is effective.

Position Statement

Summary

- The intent of the policy is to allow coverage of non-preferred oral medications for inflammatory bowel disease (IBD) when lower cost preferred brand and generic oral medications for IBD are not effective, not tolerated, or are contraindicated.
- All oral medications for IBD, including budesonide and 5ASAs, have similar effects; however individual responses may be variable. [1-3]
- There is no reliable evidence that any non-preferred oral medications for IBD, including oral budesonide or 5ASA products, is safer or more efficacious than another. [1-3] Therefore, generic and preferred branded products for IBD offer the best value as lower cost options.

- Current evidence-based guidelines do not recommend any one oral budesonide or oral 5ASA product over another for the majority of patients. [1-2]
- Non-preferred oral medications for IBD and AB-rated generic alternative(s) fulfill the following requirements of therapeutically equivalent products [5]
    * They are approved as safe and effective;
    * They contain identical amounts of the same active drug ingredient in the same dosage form and route of administration;
- Non-preferred oral budesonide may be covered in quantities up to 9 mg per day, the maximum recommended dose. Non-preferred oral 5ASA products may be covered in quantities up to the maximum recommended dose. [4] Higher doses have not been shown to be more effective or safer.

Cross References
None

References

1. Lichtenstein, GR, Hanauer, SB, Sandborn, WJ. Management of Crohn's disease in adults. *Am J Gastroenterol*. 2009;104:465-83; quiz 4, 84. PMID: 19174807
2. Kornbluth, A, Sachar, DB. Ulcerative colitis practice guidelines in adults: American College Of Gastroenterology, Practice Parameters Committee. *Am J Gastroenterol*. 2010;105:501-23; quiz 24. PMID: 20068560
3. Feagan, BG, Macdonald, JK. Oral 5-aminosalicylic acid for maintenance of remission in ulcerative colitis. *Cochrane Database of Systematic Reviews*. 2012 Oct 17;10:CD000544. PMID: 23076890
4. Facts & Comparisons 4.0 (electronic version, updated periodically). Wolters Kluwer Health, Inc.
5. Food and Drug Administration. FDA Orange Book. [cited 01/21/2016]; Available from: http://www.fda.gov/Drugs/DevelopmentApprovalProcess/ucm079068.htm##Therapeutic Equivalence-Related Terms

Revision History

Revision Date	Revision Summary
09/08/2017	No changes to coverage criteria with this annual update.
12/16/2016	New policy (effective 1/1/2017)