Prior Authorization Review Panel

CHC-MCO Policy Submission

A separate copy of this form must accompany each policy submitted for review.
Policies submitted without this form will not be considered for review.

Plan: PA Health & Wellness	**Submission Date**:
Policy Number:	**Effective Date:** **Revision Date:**
Policy Name:	**HC Approval Date:**

Type of Submission – Check all that apply:

- ☐ **New Policy**
- ☐ **Revised Policy***
- ☐ **Annual Review – No Revisions**
- ☐ **Attestation of HC PARP Policy –** *This option should only be used during Readiness Review for Community HealthChoices. The policy must be identical to the PARP approved policy for the HealthChoices Program, with the exception of revisions/clarifications adding the term "Community HealthChoices" to the policy.*

***All revisions to the policy must be highlighted using track changes throughout the document.**

Please provide any changes or clarifying information for the policy below:

This policy is being retired and replaced by the following policy:

Retire, replaced by PA.CP.PST.01 Step Therapy

Name of Authorized Individual (Please type or print): **Francis G. Grillo, MD**	**Signature of Authorized Individual:**

Clinical Policy: Mesalamine Oral Therapy

Reference Number: PA.CP.PST.08
Effective Date: 01/18
Last Review Date: 07/18

Coding Implications
Revision Log

Description
Mesalamine is an aminosalicylate. The following mesalamine products require prior authorization: Apriso™, Asacol® HD, Pentasa® and Delzicol®..

FDA approved indication
Oral mesalamine is indicated for ulcerative colitis.

Limitation of use:
- Asacol HD: Safety and effectiveness of Asacol HD beyond 6 weeks have not been established.

Policy/Criteria
Provider must submit documentation (which may include office chart notes and lab results) supporting that member has met all approval criteria

It is the policy of Pennsylvania Health and Wellness ® that mesalamine (Apriso, Asacol HD, Pentasa, Delzicol) is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Step Therapy for Oral Mesalamine (must meet all)**:**

1. One of the following applies (a or b)
   a. Request for Delzicol: previous use of Lialda at up to maximally indicated doses unless contraindicated or clinically significant adverse effects are experienced; **Generic Lialda is a preferred agent*
   b. Request for all other agents: must meet the following (i and ii):
      i. Previous use of 4 weeks-of sulfasalazine, sulfasalazine EC, or balsalazide at up to maximally indicated doses unless contraindicated or clinically significant adverse effects are experienced;
      i. Previous use of 4 weeks-of two PDL oral mesalamine agents at up to maximally indicated doses unless contraindicated or clinically significant adverse effects are experienced;
2. Dose does not exceed FDA approved maximum recommended dose.

Approval duration:12 months

II. Continued Therapy

A. Step Therapy for Oral Mesalamine (must meet all)**:**

1. Currently receiving medication via Pennsylvania Health and Wellness benefit or member has previously met initial approval criteria or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;
2. If request is for a dose increase, new dose does not exceed FDA approved maximum recommended dose.

Approval duration: 12 months

III. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
FDA: Food & Drug Administration
PDL: preferred drug list

IV. Dosage and Administration

Drug	Dosing Regimen	Maximum Dose
Apriso (mesalamine)	Four 0.375 g capsules daily	1.5 g/day
Asacol HD (mesalamine)	1600 mg three times a day	4.8 g/day
Lialda (mesalamine)	Two to four 1.2 g tablets daily	4.8 g/day
Pentasa (mesalamine)	1 g four times a day (total of 4 g daily)	4 g/day
Delzicol (mesalamine)	Two 400 mg capsules three times daily	2.4 g/day

V. Product Availability

Drug	Availability
Apriso (mesalamine)	0.375 mg extended-release capsule
Asacol HD (mesalamine)	800 mg delayed-release tablet
Lialda (mesalamine)	1.2 g delayed-release tablet
Pentasa (mesalamine)	250 mg, 500 mg controlled-release capsule
Delzicol (mesalamine)	Delayed-release capsules (containing four 100 mg tablets): 400 mg

VI. References

1. Kornbluth A and Sachar DB, “Ulcerative Colitis Practice Guidelines in Adults: American College of Gastroenterology, Practice Parameters Committee,” Am J Gastroenterol, 2010, 105(3):501-23.
2. Mottet C, Vader JP, Felley C, et al, "Appropriate Management of Special Situations in Crohn's Disease (Upper Gastro-Intestinal; Extra-Intestinal Manifestations; Drug Safety during Pregnancy and Breastfeeding): Results of a Multidisciplinary International Expert Panel-EPACT II," J Crohns Colitis, 2009, 3(4):257-63.
3. Mesalamine. In: Clinical Pharmacology. Tampa, FL: Gold Standard; 2015. Available athttp://www.clinicalpharmacology-ip.com. Accessed November 2017.
4. Asacol HD Prescribing Information. Irvine, CA: Allergan USA, Inc.; May 2016. Available at http://www.allergan.com. Accessed November 2017.
5. Apriso Prescribing Information. Raleigh, NC: Salix Pharmaceuticals, Inc., July 2009. Available at https://www.aprisorx.com. Accessed November 2017.
6. Lialda Prescribing Information. Lexington, MA: Shire US Inc., November 2015. Available at http://pi.shirecontent.com. Accessed November 2017.
7. Pentasa Prescribing Information. Lexington, MA: Shire US Inc.,October 2015. Available at https://www.pentasaus.com/. Accessed November 2017.
8. Delzicol Prescribing Information. Irvine, CA: Allergan USA, Inc. July 2017. Available at https://www.delzicol.com/. Accessed November 5, 2017.

Reviews, Revisions, and Approvals	Date	Approval Date
Updated approval period from 6 to 12 months. Reviewed and updated references	02/18	
Retire, replaced by PA.CP.PST.01 Step Therapy	01/19	