

## POLICY AND PROCEDURE

POLICY NUMBER: *RX.PA.173.E*

REVISION DATE: *05/13*

PAGE NUMBER: 1 of 3

**POLICY TITLE:** *5-Aminosalicylic Acid Derivative Step*  
**DEPARTMENT:** *Clinical Pharmacy Services- Utilization Management*  
**ORIGINAL DATE:** *September 2011 (as adopted from UPMC Health Plan)*

**Last P & T Committee Approval Date:** *February 2018*

**Product Applicability:** *mark all applicable products below:*

<b>COMMERCIAL</b>	<input type="checkbox"/> HMO <input type="checkbox"/> PPO   Products: <input type="checkbox"/> Small   Exchange: <input type="checkbox"/> Shop <input checked="" type="checkbox"/> All <input type="checkbox"/> Indiv. <input type="checkbox"/> Indiv. <input type="checkbox"/> Large
<b>OTHER</b>	<input checked="" type="checkbox"/> Self-funded/ASO

### PURPOSE

The purpose of this policy is to define the prior authorization process for Lialda (mesalamine) and Dipentum (olsalazine).

Lialda (Mesalamine) is a locally-acting 5-aminosalicylic acid medication indicated for induction of remission in patients with active, mild to moderate ulcerative colitis and for the maintenance of remission of ulcerative colitis.

Dipentum (Olsalazine) is a 5-aminosalicylic acid derivative indicated for the maintenance of remission of ulcerative colitis in patients who are intolerant of sulfasalazine.

### DEFINITIONS

N/A

### POLICY

**5-Aminosalicylic Acid Derivative Step**

**POLICY NUMBER: RX.PA.173.E**

**REVISION DATE: 05/13**

**PAGE NUMBER: 2 of 3**

It is the policy of the Health Plan to maintain a prior authorization process that promotes appropriate utilization of specific drugs with potential for misuse or limited indications. This process involves a review using Food and Drug Administration (FDA) criteria to make a determination of Medical Necessity, and approval by the Pharmacy & Therapeutics Committee of the criteria for prior authorization, as described in RX.002 Pharmacy and Therapeutics Committee and RX.003-Prior Authorization Process.

The drugs, Lialda (mesalamine) and Dipentum (olsalazine), are subject to the prior authorization process.

**PROCEDURE**

**Initial Authorization Criteria:**

*Must meet all of the criteria listed under the respective header:*

**1. Automatic coverage:**

- Must have a documented pharmacy claim history of prior therapy with balsalazide (generic Colazal), Apriso, Asacol, Asacol HD, or Delzico

**2. Member without claims history:**

- Must have documentation indicating that the member has failed or had intolerance to balsalazide, Apriso, Asacol, Asacol HD, or Delzicol

**Limitations:**

<b>Length of Authorization (if above criteria met)</b>	
Initial Authorization	Up to duration of member's membership with plan
Reauthorization	N/A

If the established criteria are not met, the request is referred to a Medical Director for review.

**REFERENCES**

1. Apriso [package insert]. Morrisville, NC: Salix Pharmaceuticals, Inc; July 2009.
2. Asacol [package insert]. Rockaway, NJ: Warner Chilcott (US), LLC; January 2011.
3. Colazal [package insert]. Morrisville, NC: Salix Pharmaceuticals, Inc; 2000.
4. Lialda [package insert]. Wayne, PA: Shire US, Inc; July2011.
5. Delzicol [package insert]. Rockaway , NG: Warner Chilcott (US), LLC; February 2013.
6. Dipentum [package insert]. Stockholm, Sweden: Pharmacia AB; November 2011.



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**POLICY NUMBER: RX.PA.173.E**

**REVISION DATE: 05/13**

**PAGE NUMBER: 3 of 3**

**RECORD RETENTION**

Records Retention for Evolent Health documents, regardless of medium, are provided within the Evolent Health records retention policy and as indicated in CORP.028.E Records Retention Policy and Procedure.

**REVIEW HISTORY**

DESCRIPTION OF REVIEW / REVISION	DATE APPROVED
<i>Annual review</i>	<i>02/17, 02/18</i>

