

# SmartPA Criteria Proposal

<b>Drug/Drug Class:</b>	Ulcerative Colitis Agents, Rectal PDL Edit
<b>First Implementation Date:</b>	June 18, 2009
<b>Proposed Date:</b>	March 18, 2021
<b>Prepared For:</b>	MO HealthNet
<b>Prepared By:</b>	MO HealthNet/Conduent
<b>Criteria Status:</b>	<input checked="" type="checkbox"/> Existing Criteria <input type="checkbox"/> Revision of Existing Criteria <input type="checkbox"/> New Criteria

## Executive Summary

**Purpose:** The MO HealthNet Pharmacy Program will implement a state-specific preferred drug list.

**Why Issue Selected:** Ulcerative colitis (UC) is a chronic, inflammatory bowel disease that affects roughly one million people in the United States. There is currently no cure for this disease state but the 2018 American Gastroenterological Association guidelines on the management of mild-to-moderate UC offer recommendations on providing symptom relief and improving quality of life through long-term remission. The treatment recommendations include rectal mesalamine which is indicated for the treatment of active mild-to-moderate UC and/or induction or maintenance of remission. Rectal budesonide is indicated for the remission induction in patients with active mild-to-moderate distal UC extending up to 40cm from the anal verge.

Total program savings for the PDL classes will be regularly reviewed.

Program-Specific Information:	Preferred Agents	Non-Preferred Agents
	<ul style="list-style-type: none"> <li>Mesalamine Kit/Supp</li> </ul>	<ul style="list-style-type: none"> <li>Canasa®</li> <li>Mesalamine (gen sfRowasa®)</li> <li>Rowasa® Enema/Kit</li> <li>sfRowasa® Enema</li> <li>Uceris® Foam</li> </ul>

**Type of Criteria:**  Increased risk of ADE  
 Appropriate Indications

Preferred Drug List  
 Clinical Edit

**Data Sources:**  Only Administrative Databases

Databases + Prescriber-Supplied

## Setting & Population

- Drug class for review: Ulcerative Colitis Agents, Rectal
- Age range: All appropriate MO HealthNet participants

## Approval Criteria

- Failure to achieve desired therapeutic outcomes with trial on 1 preferred agent
  - Documented trial period of preferred agents **OR**
  - Documented ADE/ADR to preferred agents

## Denial Criteria

- Lack of adequate trial on required preferred agents
- Therapy will be denied if all approval criteria are not met

## Required Documentation

Laboratory Results:   
MedWatch Form:

Progress Notes:   
Other:

## Disposition of Edit

Denial: Exception Code "0160" (Preferred Drug List)  
Rule Type: PDL

## Default Approval Period

1 year

## References

1. Evidence-Based Medicine Analysis: "Ulcerative Colitis Agents (Rectal)", UMKC-DIC; January 2021.
2. Evidence-Based Medicine and Fiscal Analysis: "Ulcerative Colitis Agents, Rectal – Therapeutic Class Review", Conduent Business Services, L.L.C., Richmond, VA; March 2021.
3. Ko CW, Singh S, Feuerstein JD, et al, on behalf of the American Gastroenterological Association Institute Clinical Guidelines Committee. *Gastroenterology*. 2018 Dec 18. pii: S0016-5085(18)35407-6. doi: 10.1053/j.gastro.2018.12.009. [Epub ahead of print].
4. Lippincott, Williams, Wilkins. PDR Electronic Library, Montvale NJ; 2021.
5. USPDI, Micromedex; 2021.
6. Facts and Comparisons eAnswers (online); 2021 Clinical Drug Information, LLC.