

SmartPA Criteria Proposal

Drug/Drug Class:	Inflammatory Bowel Disease Agents, Rectal PDL Edit <i>(formerly Ulcerative Colitis Agents, Rectal PDL Edit)</i>
First Implementation Date:	June 18, 2009
Revised Date:	July 6, 2023
Prepared For:	MO HealthNet
Prepared By:	MO HealthNet/Conduent
Criteria Status:	<input type="checkbox"/> Existing Criteria <input checked="" 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: Inflammatory Bowel Disease (IBD) describes disorders such as ulcerative colitis (UC) and Crohn's disease (CD) which involve chronic inflammation in the digestive tract. An estimated 1.3% of US adults reported being diagnosed with IBD in 2015. UC is characterized by recurring inflammation and ulcers in the lining of the colon and rectum. CD is also characterized by inflammation but may involve any portion of the digestive tract, from the oral cavity to the perianal area. Inflammation in CD can affect the entire thickness of the bowel wall and may skip or leave normal areas in between patches of inflammation. Both UC and CD are typically characterized by diarrhea, rectal bleeding, abdominal pain, fatigue, and weight loss. The goals of IBD therapy are to reduce inflammation, leading to symptom relief and reduced risk of further complications from disease.

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"> Mesalamine Kit/Supp Mesalamine (gen sfRowasa®) 	<ul style="list-style-type: none"> Budesonide Foam (gen Uceris®) Canasa® Rowasa® Enema/Kit sfRowasa® Enema Uceris® Foam

Type of Criteria: Increased risk of ADE Preferred Drug List
 Appropriate Indications Clinical Edit

Data Sources: Only Administrative Databases Databases + Prescriber-Supplied

Setting & Population

- Drug class for review: Inflammatory Bowel Disease 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

- Evidence-Based Medicine and Fiscal Analysis: "Ulcerative Colitis Agents, Rectal – Therapeutic Class Review", Conduent Business Services, L.L.C., Richmond, VA; January 2022.
- Evidence-Based Medicine Analysis: "Ulcerative Colitis Agents (Rectal)", UMKC-DIC; Last updated November 2022.
- Dahlhamer JM, Zammitti EP, Ward BW, Wheaton AG, Croft JB. Prevalence of Inflammatory Bowel Disease Among Adults Aged ≥18 Years - United States, 2015. *MMWR Morb Mortal Wkly Rep* 2016;65:1166–1169. DOI: <http://dx.doi.org/10.15585/mmwr.mm6542a3external icon>.
- USPDI, Micromedex; 2023.
- Facts and Comparisons eAnswers (online); 2023 Clinical Drug Information, LLC.