

SmartPA Criteria Proposal

Drug/Drug Class:	Inflammatory Bowel Disease Agents, Oral PDL Edit <i>(formerly Ulcerative Colitis Agents, Oral PDL Edit)</i>
First Implementation Date:	June 19, 2012
Proposed Date:	April 18, 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"> Balsalazide Lialda® Pentasa® Sulfasalazine DR & IR 	<ul style="list-style-type: none"> Apriso® Azulfidine® Azulfidine EN®-tabs® Budesonide (gen Uceris®) Colazal® Delzicol® Dipentum® Mesalamine (gen Apriso®) Mesalamine (gen Asacol HD®) Mesalamine (gen Delzicol®) Mesalamine (gen Lialda®) Mesalamine (gen Pentasa®) Ortikos™ Uceris®

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, Oral
- Age Range: All appropriate MO HealthNet participants aged 2 years or older

Approval Criteria

- Failure to achieve desired therapeutic outcomes with trial on 3 preferred agents
 - Documented trial period of preferred agents **OR**
 - Documented ADE/ADR to preferred agents **AND**
- For Azulfidine and Azulfidine EN-tabs: participant aged 2 years or older
- For Colazal, Delzicol or Lialda: participant aged 5 years or older
- For Ortikos: participant aged 8 years or older
- For all other agents: participant aged 18 years or older

Denial Criteria

- Lack of adequate trial on required preferred agents
- Therapy will be denied if all approval criteria are not met
- Claim exceeds maximum dosing limitations for the following:

Drug Description	Generic Equivalent	Max Unit/Day
APRISO ER 0.375 GM CAPSULE	MESALAMINE	4 capsules
ASACOL HD DR 800 MG TABLET	MESALAMINE	6 tablets
AZULFIDINE 500 MG TABLET	SULFASALAZINE	8 tablets
AZULFIDINE ENTAB 500 MG	SULFASALAZINE	8 tablets
COLAZAL 750 MG CAPSULE	BALSALAZIDE	9 capsules
DELZICOL DR 400 MG CAPSULE	MESALAMINE	6 capsules
DIPENTUM 250 MG CAPSULE	OLSALAZINE	2 capsules
LIALDA DR 1.2 GM TABLET	MESALAMINE	4 tablets
ORTIKOS ER 6 MG CAPSULE	BUDESONIDE	1 capsule
ORTIKOS ER 9 MG CAPSULE	BUDESONIDE	1 capsule
PASER GRANULES 4 GM PACKET	AMINOSALICYLIC ACID	3 packets
PENTASA 250 MG CAPSULE	MESALAMINE	8 capsules
PENTASA 500 MG CAPSULE	MESALAMINE	8 capsules
UCERIS 9 MG ER TABLET	BUDESONIDE	1 tablet

Required Documentation

Laboratory Results: ☐
MedWatch Form: ☐

Progress Notes: ☐
Other: ☐

Disposition of Edit

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

SmartPA PDL Proposal Form

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Default Approval Period

1 year

References

- Evidence-Based Medicine and Fiscal Analysis: “Therapeutic Class Review: GASTROINTESTINAL: Ulcerative Colitis Agents, Oral”, Gainwell Technologies; Last updated February 24, 2023.
- Evidence-Based Medicine Analysis: “Oral Ulcerative Colitis Agents”, 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.mm6542a3>external icon.
- USPDI, Micromedex; 2023.
- Facts and Comparisons eAnswers (online); 2023 Clinical Drug Information, LLC.