

SmartPA Criteria Proposal

Drug/Drug Class:	Ulcerative Colitis Agents, Oral PDL Edit
First Implementation Date:	June 19, 2012
Proposed Date:	March 18, 2021
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: 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 the 5-aminoosalicylic class of medication which consists of balsalazide, mesalamine, olsalazine and sulfasalazine which are generally indicated for the treatment of active mild-to-moderate UC and/or induction or maintenance of remission. Oral budesonide is indicated only for the induction of remission in patients with active mild-to-moderate UC as there is limited efficacy or safety data for the use of budesonide for maintenance of remission.

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® Asacol HD® Azulfidine® Azulfidine EN-tabs® Budesonide (gen Uceris®) Colazal® Delzicol® Dipentum® Mesalamine (gen Apriso®) Mesalamine HD (gen Asacol HD®) Mesalamine (gen Delzicol®) Mesalamine (gen Lialda®) Ortikos™ Uceris®

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, Oral
- Age range: 2 years of age or older: sulfasalazine IR, sulfasalazine DR, Azulfidine®, Azulfidine EN®
- Age range: 5 years of age or older: balsalazide, Colazal®, Delzicol®, mesalamine (gen Delzicol®, gen Lialda®), Lialda®
- Age range: 18 years of age or older: Apriso®, Asacol HD®, budesonide (gen Uceris®) Dipentum®, mesalamine (gen Apriso®, gen Asacol HD®), Pentasa®, Uceris®

Approval Criteria

- Participant is of appropriate age per agent (see above) **AND**
- 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

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
AZULFIDINE 500 MG TABLET	SULFASALAZINE	8 tablets
AZULFIDINE ENTAB 500 MG	SULFASALAZINE	8 tablets
APRISO ER 0.375 GM CAPSULE	MESALAMINE	4 capsules
ASACOL HD DR 800 MG TABLET	MESALAMINE	6 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
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

Default Approval Period

1 year

References

1. Evidence-Based Medicine Analysis: "Oral Ulcerative Colitis Agents", UMKC-DIC; January 2021.
2. Evidence-Based Medicine and Fiscal Analysis: "Ulcerative Colitis Agents, Oral – 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. Centers for Disease Control and Prevention. (2020). Data and Statistics; Inflammatory Bowel Disease Prevalence (IBD) in the United States. Retrieved from <https://www.cdc.gov/ibd/data-statistics.htm>
5. Lippincott, Williams, Wilkins. PDR Electronic Library, Montvale NJ; 2021.
6. USPDI, Micromedex; 2021.
7. Facts and Comparisons eAnswers (online); 2021 Clinical Drug Information, LLC.