

SmartPA Criteria Proposal

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|-----------------------------------|--|
| Drug/Drug Class: | Ulcerative Colitis Agents – Oral PDL Edit |
| First Implementation Date: | June 19, 2012 |
| Proposed Date: | March 19, 2020 |
| 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 (gen Asacol HD®) Mesalamine (gen Delzicol®) Mesalamine (gen Lialda®) 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®**)
- Age range: 18 years of age or older: Apriso®, Asacol HD®, budesonide (gen Uceris®) Dipentum®, Lialda®, mesalamine (gen **Apriso®**, gen Asacol HD®, gen Lialda®), 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
 - Documented ADE/ADR to preferred agents

Denial Criteria

- Lack of adequate trial on required preferred agents
- Therapy will be denied if no approval criteria are 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: "Oral Ulcerative Colitis Agents", UMKC-DIC; January 2020.
2. Evidence-Based Medicine and Fiscal Analysis: "Ulcerative Colitis Agents, Oral – Therapeutic Class Review", Conduent Business Services, L.L.C., Richmond, VA; February 2020.
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; 2020.
6. USPDI, Micromedex; 2020.
7. Facts and Comparisons eAnswers (online); 2020 Clinical Drug Information, LLC.

SmartPA PDL Proposal Form

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