SmartPA Criteria Proposal

Drug/Drug Class:	Ulcerative Colitis Agents – Rectal PDL Edit
First Implementation Date:	June 18, 2009
Proposed Date:	March 19, 2020
Prepared For:	MO HealthNet
Prepared By:	MO HealthNet/Conduent
Criteria Status:	☐Existing Criteria ☒Revision of Existing Criteria ☐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
• Mesalamine Kit/Supp	• Canasa® • Mesalamine (gen sfRowasa®) • 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: 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
  - 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:	☐	Progress Notes:	☐
MedWatch Form:	☐	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 2020.
2. Evidence-Based Medicine and Fiscal Analysis: "Ulcerative Colitis Agents, Rectal – 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. Lippincott, Williams, Wilkins. PDR Electronic Library, Montvale NJ; 2020.
5. USPDI, Micromedex; 2020.
6. Facts and Comparisons eAnswers (online); 2020 Clinical Drug Information, LLC.