RxAdvance

Clinical Policy Title:	budesonide
Policy Number:	RxA.286
Drug(s) Applied:	Uceris®,
Original Policy Date:	02/07/2020
Last Review Date:	04/03/2024
Line of Business Policy Applies to:	All lines of business (except Medicare)

Criteria

I. **Initial Approval Criteria**

A. **Ulcerative Colitis** (must meet all):

1. Diagnosis of Ulcerative Colitis;
2. Prescribed by or in consultation with a gastroenterologist;
3. Trial and failure of a 4-week trial of aminosalicylates(e.g. sulfasalazine, mesalamine), unless contraindicated or clinically significant adverse effects are experienced;
4. Trial and failure of generic Uceris (budesonide 9 mg extended release tablet);

Approval Duration

All Lines of Business (except Medicare): 12 months

II. **Continued Therapy Approval**

A. **All Indications in Section I** (must meet all):

Member is currently receiving or has been treated with this medication within the past 90 days, excluding manufacturer samples. **Approval Duration**

All Lines of Business (except Medicare): 12 months

References

1. Ko CW, Singh S, Feuerstein JD, et al. American Gastroenterological Association (AGA) Clinical Practice Guidelines on the Management of Mild-to-Moderate Ulcerative Colitis. Gastroenterology 2019; 156(3):748-764. Available at: https://www.aecp-es.org/images/site/documentos/GUIAS/16.pdf. Accessed April 18, 2023.
2. Nguyen GC, Smalley WE, Vege SS, et al. American Gastroenterological Association institute guideline on medical management of microscopic colitis. Gastroenterology 2016; 150(1):242-246. Available at: https://repositorio.uchile.cl/bitstream/handle/2250/136561/American-Gastroenterological-Association-Institute-Guideline.pdf;jsessionid=476B8D90FF08754CC4A6B3331FAB0DB6?sequence=1. Accessed April 18, 2023.

Review/Revision History	Review/Revised Date	P&T Approval Date
Policy established.	01/2020	02/07/2020
Policy was reviewed: 1. Clinical policy title updated 2. Line of Business Policy Applies to was updated to all lines of business.	08/25/2020	09/14/2020

This clinical policy has been developed to authorize, modify, or determine coverage for individuals with similar conditions. Specific care and treatment may vary depending on individual need and benefits covered by the plan. This policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. This document may contain prescription brand name drugs that are trademarks of pharmaceutical manufacturers that are not affiliated with RxAdvance.

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3. Initial approval criteria I.B.4-one criteria added. 4. Continued Therapy criteria II.A.1 was rephrased to "Currently receiving medication that has been authorized by RxAdvance..." 5. Reference reviewed and updated		
Policy was reviewed: 1. Clinical policy title updated. 2. Reference reviewed and updated.	04/07/2021	06/10/2021
Policy was reviewed: 1. Initial Approval Criteria I.B.4 was updated from," Request is for tablets" to "Request is for extended-release tablets". 2. Initial Approval Criteria I.B.5 and I.C.5 was updated from," Medical justification supports inability to use budesonide capsules" to," Medical justification supports inability to use budesonide extended-release capsules". 3. Continued Approval Criteria II.A.3 was updated from," For microscopic colitis, request is for tablets" to "For microscopic colitis request is for extended-release tablets.	12/21/21	01/17/2022
Policy was reviewed: 1. Initial Approval Criteria, I.A.4: Updated to include new drug request criteria Request is for Uceris®. 2. References were reviewed and updated.	01/10/2022	04/18/2022
Policy was reviewed: 1. RxA.286.Uceris_Entocort_Ortikos, Drug(s) Applied: Updated to remove drug that no longer requires PA – Entocort EC. 2. Initial Approval Criteria, I.A.6, I.B.5, and I.C.5: Verbiage updated to "Trial and failure of…" from "Medical justification supports…"	6/25/2022	7/18/2022
Policy was reviewed: 1. Initial Approval Criteria, I.B.: Updated to remove approval criteria for Microscopic colitis (off-label). 2. Continued Therapy Approval Criteria II.A.3: Updated to remove criteria for microscopic colitis "For microscopic colitis, request is for extended release tablets".	04/18/2023	07/13/2023

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3. References were reviewed and updated.		
Policy was reviewed.	10/19/2023	10/19/2023
Policy was reviewed: 1. Revised phrasing, removed at up to maximally indicated doses 2. Revised statement for continued therapy approval 3. Removed criteria for Oritkos (d/c)	4/1/2024	4/1/2024

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