RXADVANCE
2 Park Central Drive
Southborough, MA 01772

Clinical Policy Title:	vancomycin oral
Policy Number:	RxA.537
Drug(s) Applied:	Vancocin®
Original Policy Date:	03/06/2020
Last Review Date:	09/14/2020
Line of Business Policy Applies to:	All lines of business

Background

Vancomycin oral (Vancocin®) is a glycopeptide antibiotic. It is indicated for the treatment of:

- *Clostridium difficile*-associated diarrhea
- Enterocolitis caused by *Staphylococcus aureus* (including methicillin-resistant strains)

Limitation(s) of use: Orally administered Vancocin is not effective for other types of infections.

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
vancomycin oral (Vancocin®)	*C. difficile*-associated diarrhea	Adult (≥ 18 years): 125 mg PO QID for 10 days. Pediatric (< 18 years): 40 mg/kg PO in 3 or 4 divided doses for 7 to 10 days.	2 g/day
	Staphylococcal enterocolitis	Adult (≥ 18 years): 500 mg to 2 g PO in 3 or 4 divided doses/day for 7 to 10 days. Pediatric (< 18 years): 40 mg/kg PO in 3 or 4 divided doses for 7 to 10 days.	2 g/day

Dosage Forms

- Capsules: 125 mg, 250 mg

Clinical Policy

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

I. Initial Approval Criteria

A. *Clostridium difficile*-Associated Diarrhoea (must meet all):

1. Diagnosis of *Clostridium difficile*-associated diarrhea;

2. One of the following (a or b):
   a. Member is allergic to an inactive ingredient of the generic vancomycin oral capsule (125 mg or 250 mg);
   b. The generic vancomycin of the requested strength is currently unavailable in the market;
3. Dose does not exceed 2 g per day.

Approval Duration
Commercial: 14 days
Medicaid: 14 days

B. Staphylococcal Enterocolitis (must meet all):
1. Diagnosis of staphylococcal enterocolitis;
2. One of the following (a or b):
   a. Member is allergic to an inactive ingredient of the generic vancomycin oral capsule (125 mg or 250 mg);
   b. The generic vancomycin of the requested strength is currently unavailable in the market;
3. Dose does not exceed 2 g per day.

Approval Duration
Commercial: 14 days
Medicaid: 14 days

II. Continued Therapy Approval

A. All Indications in Section I (must meet all):
1. Currently receiving medication that has been authorized by RxAdvance or member has previously met initial approval criteria;
2. If request is for a dose increase, new dose does not exceed 2 g per day.

Approval Duration
Commercial: 3 months
Medicaid: 3 months

III. Appendices

APPENDIX A: Abbreviation/Acronym Key
FDA: Food and Drug Administration

APPENDIX B: Therapeutic Alternatives
Not applicable

APPENDIX C: Contraindications/Boxed Warnings
- Contraindication(s):
  - hypersensitivity
- Boxed Warning(s):
  - none reported

APPENDIX D: General Information
- Oral vancomycin is not absorbed systemically and is not effective for other types of infection.

- Per 2017 IDSA guidelines for C. difficile-associated diarrhoea, vancomycin and fidaxomicin are preferred first-line treatments for non-severe, recurrent, and severe disease in adults. Metronidazole is recommended as an alternative agent, if vancomycin and fidaxomicin are unavailable.
- FDA labelling and guidelines recommend duration of therapy to be 10 days. However, the guidelines recommend considering extending treatment to up to 14 days for patients with delayed response to treatment.
- For recurrence, a second course of vancomycin for 10 to 14 days is a dosing regimen option per guidelines.
- For recurrence, tapered and pulsed regimens of vancomycin are alternative dosing regimens to the standard vancomycin regimen per guidelines. Examples of the regimen include:
  - For adults: vancomycin PO 125 mg QID for 10 to 14 days, then BID for 1 week, then QD for 1 week, then every 2 or 3 days for 2 to 8 weeks.
  - For pediatrics: vancomycin PO 10 mg/kg (max 125 mg QID) for 10 to 14 days, then 10 mg/kg (max 125 mg BID) for 1 week, then 10 mg/kg (max 125 mg QD) for 1 week, then 10 mg/kg (max 125 mg every 2 or 3 days) for 2 to 8 weeks.

References

1. Vancocin Prescribing Information. Baudette, MN: ANI Pharmaceuticals, Inc.; August 2020. Available at: file:///C:/Users/vicky.zhang/Downloads/20200820_a078d9c2-f89c-4f9f-8ded-60ffb2983c3f.pdf. Accessed September 1, 2020.
2. Pelaez T, Alcala L, Rodriguez-Creixems M, et al. Reassessment of Clostridium difficile susceptibility to metronidazole and vancomycin. Antimicob Agents Chemother. 2002;46:1647-1650.
3. Joyce AM, Burns, DL. Recurrent Clostridium difficile colitis: Tackling a tenacious nosocomial infection. Postgradmed. 2002:112(5):53-54, 57-58, 65.
4. Musher DM, Logan N, Hamill RJ et al. Nitazoxanide for the treatment of Clostridium difficile colitis. Clin Infec Dis. 2006;43(4):421-427.
5. McDonald LC, Gerding DN, Johnson S, et al. Clinical practice guidelines for Clostridium difficile infection in adults and children: 2017 updated by the Infectious Diseases Society of America (IDSA) and Society for Healthcare Epidemiology of America (SHEA). Clin Infect Dis. March 2018;66(7):987-994.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	01/01/2020	03/06/2020
Policy was reviewed and updated: - Policy format was updated to the latest template; - Line of business was updated from “Commercial” to “all lines of business”; - Duration of therapy for both indications was added to Dosing Information table; - Criteria I.A.2 and I.B.2 were added; - Initial approval duration for	09/01/2020	09/14/2020

C.diff associated diarrhea was updated from “up to 14 days” to “14 days”; - Initial approval duration for Staphylococcal enterocolitis was updated from “up to 10 days” to “14 days”; - Continued therapy approval duration was updated from “up to 12 weeks” to “3 months”; - References were reviewed and updated.		