Clinical Policy Title:	vancomycin HCl
Policy Number:	RxA.537
Drug(s) Applied:	Vancocin®
Original Policy Date:	03/06/2020
Last Review Date:	09/14/2021
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:

- Parenteral administration of vancomycin is not effective for the above infections; therefore, Vancocin® must be given orally for these infections.
- 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 orally four times daily for 10 days. Pediatric (< 18 years): 40 mg/kg orally in 3 or 4 divided doses for 7 to 10 days.	2 gm/day
	Staphylococcal enterocolitis	Adult (≥ 18 years): 500 mg to 2 gm orally in 3 or 4 divided doses/day for 7 to 10 days. Pediatric (< 18 years): 40 mg/kg orally in 3 or 4 divided doses for 7 to 10 days.	2 gm/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. The provision of provider samples does not guarantee coverage under the terms of the pharmacy benefit administered by RxAdvance. All criteria for initial approval must be met in order to obtain coverage.

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. Member is 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
CDAD: C. difficile-associated diarrhea

APPENDIX B: Therapeutic Alternatives
Below are suggested therapeutic alternatives based on clinical guidance. Please check drug formulary for preferred agents and utilization management requirements.

Drug Name	Dosing Regimen	Maximum Dose
Zinplava®	10 mg/kg intravenously	10 mg/kg intravenously once
Dificid®	200 mg twice daily for 10 days	400 mg/day orally

Therapeutic alternatives are listed as generic (Brand name®) when the drug is available by both generic and brand, Brand name® when the drug is available by brand only and generic name when the drug is available by

generic only.

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 orally 125 mg four times daily for 10 to 14 days, then twice daily for 1 week, then once daily for 1 week, then every 2 or 3 days for 2 to 8 weeks.
  - For pediatrics: vancomycin orally 10 mg/kg (max 125 mg four times daily) for 10 to 14 days, then 10 mg/kg (max 125 mg twice daily) for 1 week, then 10 mg/kg (max 125 mg once daily) for 1 week, then 10 mg/kg (max 125 mg every 2 or 3 days) for 2 to 8 weeks.

References

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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. Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC127235/. Accessed July 02, 2021.
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Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	01/01/2020	03/06/2020
Policy was reviewed and updated: 1. Policy format was updated to the latest template; 2. Line of business was updated from “Commercial” to “all lines of business”; 3. Duration of therapy for both indications was added to Dosing Information table; 4. Criteria I.A.2 and I.B.2 were added; 5. Initial approval duration for C.diff associated diarrhea was updated from “up to 14 days” to “14 days”; 6. Initial approval duration for Staphylococcal enterocolitis was updated from “up to 10 days” to “14 days”; 7. Continued therapy approval duration was updated from “up to 12 weeks” to “3 months”; 8. References were reviewed and updated.	09/01/2020	09/14/2020
Policy was reviewed: 1. Clinical Policy Title was updated from “vancomycin oral” to “vancomycin HCl.” 2. Background was updated to include limitation of use, “Parenteral administration of vancomycin is not effective…”. 3. Statement about provider sample ‘‘The provision of provider samples does not guarantee coverage…” was added to Clinical Policy. 4. Continued Therapy Approval Criteria II.A.1 was rephrased to "Member is currently receiving medication that has been authorized by RxAdvance...". 5. Appendix A was updated to include abbreviation CDAD. 6. Appendix B: Therapeutic Alternatives verbiage was rephrased to "Below are suggested therapeutic alternatives based on clinical guidance..". 7. Appendix B: Therapeutic Alternatives was updated to remove generic drug name bezlotoxumab. 8. Appendix B: Therapeutic Alternatives was updated to include brand-name drugs Zinplava	07/02/2021	09/14/2021

and Dificid as well as their respective dosing regimens and maximum doses. 9. Statement about drug listing format in Appendix B is updated to "Therapeutic alternatives are listed as generic (Brand name®) when the drug is available by both generic and brand, Brand name® when the drug is available by brand only and generic name when the drug is available by generic only". 10. References were reviewed and updated.		