Clinical Policy Title:	metronidazole vaginal gel
Policy Number:	RxA.241
Drug(s) Applied:	Nuvessa™
Original Policy Date:	02/07/2020
Last Review Date:	06/10/2021
Line of Business Policy Applies to:	All lines of business

Background

Metronidazole vaginal gel (Nuvessa™) is a nitroimidazole antimicrobial. It is indicated for the treatment of bacterial vaginosis in females 12 years of age and older.

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
metronidazole Vaginal Gel (Nuvessa™)	Bacterial vaginosis in non-pregnant women	One applicator of 5 g of gel (65 mg of metronidazole) administered intravaginally as a single dose at bedtime.	1 applicator/day

Dosage Forms

- Prefilled applicator: 1.3% gel (5 g of vaginal gel containing approximately 65 mg of metronidazole).

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 term 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. Bacterial Vaginosis (must meet all):

1. Diagnosis of bacterial vaginosis;
2. Age ≥ 12 years;
3. Member is not pregnant;
4. Documentation supports inability to use metronidazole 0.75% vaginal gel;
5. Dose does not exceed one applicator as a single dose.

Approval Duration

Commercial: 1 month (one dose)

Medicaid: 1 month (one dose)

II. Continued Therapy Approval

A. Bacterial Vaginosis:

1. Re-authorization is not permitted. Member must meet the initial approval criteria.

Approval Duration
Commercial: Not applicable
Medicaid: Not applicable

III. Appendices

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

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	Dose Limit/ Maximum Dose
metronidazole gel 0.75% (MetroGel- Vaginal, Vandazole)	One applicatorful (5 g of 0.75% metronidazole gel) intravaginally once daily to BID for 5 days	2 applicators/day

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

APPENDIX C: Contraindications/Boxed Warnings

- Contraindication(s):
  - History of hypersensitivity to metronidazole, parabens, other ingredients of the formulation, or other nitroimidazole derivatives.
  - Concomitant use of disulfiram or within 2 weeks of disulfiram.
  - Concomitant use of alcohol.

- Boxed Warning(s):
  - None reported

APPENDIX D: General Information

- Not Applicable

References

1. Micromedex® Healthcare Series [Internet database]. Greenwood Village, Colo: Thomson Healthcare. Updated periodically. Accessed March 8, 2021.
2. Nuvessa Prescribing Information. Florham Park, NJ: Exeltis USA, Inc.; August 2018. Available at: http://www.nuvessa.com . Accessed on March 8, 2021.

Review/Revision History	Review/Revised Date	P&T Approval Date
Policy established	01/2020	02/07/2020
Policy was reviewed: 1. Clinical Policy Title was updated. 2. Drug(s) Applied was updated. 3. Line of Business Policy Applies to was update to all lines of business.	07/20/2020	09/14/2020

4. Initial Approval criteria: Commercial and Medicaid approval duration were updated to 1 months. 5. References were updated. 6. Appendix B: Therapeutic Alternatives – updated dosing regimen by removing 37.5 mg and added 5 g of 0.75% metronidazole gel once daily to BID for 5 days		
Policy was reviewed: 1. APPENDIX B: Therapeutic Alternatives verbiage updated "Below are..." 2. References were updated.	03/08/2021	06/10/2021