Clinical Policy: Metronidazole Vaginal Gel (Nuvessa)

Reference Number: ERX.NPA.126
Effective Date: 12.01.19
Last Review Date: 11.21
Line of Business: Commercial, Medicaid

Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description
Metronidazole 1.3% vaginal gel (Nuvessa™) is a nitroimidazole antimicrobial.

FDA Approved Indication(s)
Nuvessa is indicated for the treatment of bacterial vaginosis in females 12 years of age and older.

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

Health plan approved formularies should be reviewed for all coverage determinations. Requirements to use preferred alternative agents apply only when such requirements align with the health plan approved formulary.

It is the policy of health plans affiliated with Envolve Pharmacy Solutions™ that Nuvessa is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Bacterial Vaginosis (must meet all)**:**

1. Diagnosis of bacterial vaginosis;
2. Age ≥ 12 years;
3. Member must use metronidazole 0.75% vaginal gel, unless contraindicated, clinically significant adverse effects are experienced, or documentation supports necessity of metronidazole 1.3% vaginal gel;
4. Dose does not exceed one applicator as a single dose.

Approval duration: 1 month (one dose)

B. Other diagnoses/indications

1. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

A. Bacterial Vaginosis

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

Approval duration: Not applicable

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy.
   Approval duration: Duration of request or 1 month (whichever is less); or
2. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off-label use policy – ERX.PA.01 or evidence of coverage documents.

IV. Appendices/General Information

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

Appendix B: Therapeutic Alternatives
This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
metronidazole gel 0.75% (MetroGel-Vaginal®, Vandazole™)	One applicatorful (~37.5 mg) intravaginally QD 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

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Bacterial vaginosis	One applicator of 5 g of gel (65 mg of metronidazole) administered intravaginally as a single dose at bedtime	1 applicator/day

VI. Product Availability

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

VII. References

1. Micromedex® Healthcare Series [Internet database]. Greenwood Village, Colo: Thomson Healthcare. Updated periodically. Accessed July 2, 2021.
2. Nuvessa Prescribing Information. Florham Park, NJ: Exeltis USA, Inc.; August 2018. Available at: http://www.nuvessa.com. Accessed on July 2, 2021.
3. Paladine, H, Desai U. Vaginitis: diagnosis and treatment. March 2018. Am Fam Physician. 2018;97(5):321-329.
4. ACOG practice bulletin, number 215: Vaginitis in nonpregnant patients. Obstetrics and Gynecology. 2020; 135(1): 243-245.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created.	08.13.19	11.19
4Q 2020 annual review: no significant changes; references reviewed and updated.	07.29.20	11.20
4Q 2021 annual review: no significant changes; revised from “documentation supports inability” to “must use”; references reviewed and updated.	07.02.21	11.21

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of

physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members.

This policy is the property of Envolve Pharmacy Solutions. Unauthorized copying, use, and distribution of this Policy or any information contained herein is strictly prohibited. By accessing this policy, you agree to be bound by the foregoing terms and conditions, in addition to the Site Use Agreement for Health Plans associated with Envolve Pharmacy Solutions.

©2019 Envolve Pharmacy Solutions. All rights reserved. All materials are exclusively owned by Envolve Pharmacy Solutions and are protected by United States copyright law and international copyright law. No part of this publication may be reproduced, copied, modified, distributed, displayed, stored in a retrieval system, transmitted in any form or by any means, or otherwise published without the prior written permission of Envolve Pharmacy Solutions. You may not alter or remove any trademark, copyright or other notice contained herein.