Clinical Policy: Lactic Acid/Citric Acid/Potassium Bitartrate (Phexxi)

Reference Number: CP.PMN.251
Effective Date: 12.01.20
Last Review Date: 11.24
Line of Business: Commercial, Medicaid

Revision Log

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

Description

Lactic acid/citric acid/potassium bitartrate vaginal gel (Phexxi®) is an on-demand method of contraception.

FDA Approved Indication(s)

Phexxi is indicated for the prevention of pregnancy in females of reproductive potential for use as an on-demand method of contraception.

Limitation(s) of use: Phexxi is not effective for the prevention of pregnancy when administered after intercourse.

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.

It is the policy of health plans affiliated with Centene Corporation® that Phexxi is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Contraception (must meet all)**:**

1. Prescribed for prevention of pregnancy;
2. Medical justification supports inability to use vaginal spermicide (active ingredient nonoxynol-9) (e.g., member is contraindicated or has experienced clinically significant adverse effects) (*see Appendix B*);
3. Phexxi is not prescribed concurrently with vaginal ring products;
4. Dose does not exceed 5 grams (one pre-filled applicator) before each act of vaginal intercourse.

Approval duration:
Medicaid – 12 months
Commercial – 12 months or duration of request, whichever is less

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

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):

a. For drugs on the formulary (commercial) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial and CP.PMN.255 for Medicaid; or
b. For drugs NOT on the formulary (commercial) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial and CP.PMN.16 for Medicaid; or

2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial and CP.PMN.53 for Medicaid.

II. Continued Therapy

A. Contraception (must meet all)**:**

1. Member meets one of the following (a or b):
   a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
   b. Member is currently receiving medication and is enrolled in a state and product with continuity of care regulations (*refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B);*
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed 5 grams (one pre-filled applicator) before each act of vaginal intercourse.

Approval duration:
Medicaid – 12 months
Commercial – 12 months or duration of request, whichever is less

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

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial and CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial and CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial and CP.PMN.53 for Medicaid.

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 policies – CP.CPA.09 for commercial and CP.PMN.53 for Medicaid 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 for all relevant lines of business and may require prior authorization.

Drug Name*	Dosing Regimen	Dose Limit/ Maximum Dose
Examples of vaginal spermicide products (active ingredient nonoxynol-9 - gel, film, foam)		
• nonoxynol-9 vaginal gel (Options Conceptrol 4%, Options Gynol II Contraceptive 3%, VCF Vaginal Contraceptive 4%) • nonoxynol-9 vaginal film 28% and foam 12.5% (VCF)	See product directions	See product directions

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.
**OTC*

Appendix C: Contraindications/Boxed Warnings
None reported

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Pregnancy prevention	Administer one pre-filled applicator (5 grams) vaginally immediately before or up to one hour before each act of vaginal intercourse. If more than one act of vaginal intercourse occurs within one hour, an additional dose must be applied.	See dosing regimen

VI. Product Availability

Pre-filled single-dose vaginal applicators with vaginal gel, supplied as a box of 12 individually wrapped applicators in sealed foil pouches along with a plunger: 5 g containing lactic acid (1.8%), citric acid (1%), and potassium bitartrate (0.4%)

VII. References

1. Phexxi Prescribing Information. San Diego, CA: Evofem, Inc.; June 2023. Available at https://www.phexxi.com/. Accessed July 19, 2024.
2. Micromedex® Healthcare Series [Internet database]. Greenwood Village, Colo: Thomson Healthcare. Updated periodically. Accessed August 1, 2024.
3. Birth Control: Free Publications for Women. U.S. Food and Drug Administration. Content current as of June 18, 2021. Available at: https://www.fda.gov/consumers/free-publications-women/birth-control. Accessed August 1, 2024.
4. Trussell, J. (2011). Contraceptive failure in the United States. Contraception 83(5):397-404.

5. Nelson AL. An overview of properties of Amphora (Acidform) contraceptive vaginal gel. Expert Opinion on Drug Safety. 2018, VOL. 17, NO. 9, 935–943. https://doi.org/10.1080/14740338.2018.1515197.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	07.07.20	11.20
4Q 2021 annual review: no significant changes; removed HIM LOB as drug is on preventive tier; references reviewed and updated.	08.09.21	11.21
Revised approval duration for Commercial line of business from length of benefit to 12 months or duration of request, whichever is less	10.18.21	02.22
4Q 2022 annual review: no significant changes; references reviewed and updated. Template changes applied to other diagnoses/indications and continued therapy section.	07.21.22	11.22
4Q 2023 annual review: no significant changes; references reviewed and updated.	07.30.23	11.23
4Q 2024 annual review: no significant changes; references reviewed and updated.	07.19.24	11.24

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. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions, and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a

discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment, or medical care. It is not intended to dictate to providers how to practice medicine. 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 clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members, and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note:
For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.