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

Reference Number: PA.CP.PMN.251
Effective Date: 11/2022
Last Review Date: 10/2023

Coding Implications
Revision Log

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 PA Health & Wellness® 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: 12 months

B. Other diagnoses/indications

1. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53

II. Continued Therapy

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

1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;
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: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.LTSS.PHAR.01) applies.
   Approval duration: Duration of request or 12 months (whichever is less); or
2. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53

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 – PA.CP.PMN.53

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.; February 2022. Available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/208352s002lbl.pdf. Accessed July 30, 2023.
2. Micromedex® Healthcare Series [Internet database]. Greenwood Village, Colo: Thomson Healthcare. Updated periodically. Accessed July 30, 2023.
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 July 30, 2023.
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
Policy created	10/2022
4Q 2023 annual review: no significant changes; references reviewed and updated.	10/2023