MEDICAL MUTUAL®

Drug Policy

Policy:	**Phexxi (lactic acid, citric acid and potassium bitartrate)**	**Annual Review Date: 12/16/2021** **Last Revised Date: 12/16/2021**

OVERVIEW

Phexxi is indicated for the prevention of pregnancy in females of reproductive potential as an on-demand method of contraception up to an hour before intercourse. Phexxi is a vaginal gel and has comparable efficacy to barrier contraceptive methods but is less effective than intrauterine devices and hormonal contraceptives. Phexxi adds to a diverse range of products available for pregnancy prevention.

POLICY STATEMENT

This policy involves the use of Phexxi. Prior authorization is recommended for pharmacy benefit coverage of Phexxi. Approval is recommended for those who meet the conditions of coverage in the **Criteria and Initial/Extended Approval** for the diagnosis provided. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

Because of the specialized skills required for evaluation and diagnosis of patients treated with Phexxi as well as the monitoring required for adverse events and long-term efficacy, initial approval requires Phexxi be prescribed by or in consultation with a physician who specializes in the condition being treated. All approvals for initial therapy are provided for the initial approval duration noted below; if reauthorization is allowed, a response to therapy is required for continuation of therapy unless otherwise noted below.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Phexxi is recommended in those who meet the following criteria:

1. **Pregnancy Prevention**
   Criteria. Approve if the patient meets the following criteria (A or B):
   A. Approve for 6 months if the patient has tried THREE other barrier methods of contraception (i.e., diaphragms, condoms, spermicides, or sponges); OR
   B. According to the prescriber, these alternatives would not be as medically appropriate for the patient as the requested drug.

Initial Approval/ Extended Approval.

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A) *Initial Approval:* 6 months (180 days)
B) *Extended Approval:* 6 months (180 days)

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Phexxi has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval).

1. **As a Personal Lubricant**. The ingredients in Phexxi were previously available and marketed as an OTC personal lubricant. Phexxi is currently only indicated for prevention of pregnancy
2. **Acute Episodes of Bacterial Vaginosis.** Low vaginal pH may provide a measure of protection against specific organisms. In a pilot clinical study comparing Acidform gel with metronidazole gel for the treatment of symptomatic vaginosis, Acidform gel was significantly less effective.
3. **For Protection Against Human Immunodeficiency Virus (HIV) or any other Sexually Transmitted Infections.** Per Phexxi labeling, it does not protect against HIV infection and other sexually transmitted infections.
4. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

REFERENCES

1. Phexxi™ vaginal gel [prescribing information]. San Diego, CA: Evofem Biosciences, Inc.; May 2020.
2. Nelson AL. An overview of properties of Amphora (Acidform) contraceptive vaginal gel. *Expert Opin Drug Saf.* 2018;17(9):935-943.
3. Simoes JA, Bahamondes LG, Camargo R, et al. A pilot clinical trial comparing an acid-buffering formulation (Acidform gel) with metronidazole gel for the treatment of symptomatic bacterial vaginosis. *Br J Clin Pharmacol.* 2006;61(2):211-17.