PRIOR AUTHORIZATION POLICY

POLICY: Contraceptives – Phexxi Prior Authorization Policy
- Phexxi™ (lactic acid, citric acid, and potassium bitartrate vaginal gel – Evofem)

REVIEW DATE: 05/04/2022; selected revision 6/29/2022

OVERVIEW

Phexxi is indicated for the **prevention of pregnancy** in females of reproductive potential for use as an on-demand method of contraception.[1] Limitation of Use: Phexxi is not effective for the prevention of pregnancy when administered after intercourse.

Phexxi contains lactic acid, citric acid, and potassium bitartrate; *in vitro* studies show that a pH lowering effect and sperm motility reduction contribute to the activity of the product in the vagina.[1] Phexxi has been previously known under multiple names, such as Amphora, Acidform, and was historically available as an over-the-counter (OTC) personal lubricant.[2] The recommended dose of Phexxi is one pre-filled applicator (5 grams) vaginally administered immediately before or up to one hour before each act of vaginal intercourse.[1] If more than one act of vaginal intercourse occurs within one hour, an additional dose must be used.

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Phexxi. All approvals are provided for the duration noted below. In cases where the approval is authorized in months, 1 month is equal to 30 days.

Note: When compliance with the Affordable Care Act, HRSA Guidelines, and PHS Act section 2713 is required and the conditions for coverage listed under the Recommended Authorization Criteria are not met, approval is granted for the prevention of pregnancy if, according to the prescriber, other barrier methods of contraception would not be as medically appropriate for the patient as the requested drug.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

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

FDA-Approved Indication

1. **Prevention of Pregnancy.** Approve for 6 months if the patient has tried THREE other barrier methods of contraception (i.e., diaphragms, condoms, spermicides, or sponges).

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Phexxi is not recommended in the following situations:

1. **As a Personal Lubricant.** The ingredients in Phexxi were previously available and marketed as an OTC personal lubricant.[2] Phexxi is currently only indicated for prevention of pregnancy.[1]

2. **Acute Episodes of Bacterial Vaginosis.** Low vaginal pH may provide a measure of protection against specific organisms.[2] In a pilot clinical study comparing Acidform gel with metronidazole gel for the treatment of symptomatic bacterial vaginosis, Acidform gel was significantly less effective.[3]

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.[1]

4. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Phexxi™ vaginal gel [prescribing information]. San Diego, CA: Evofem; February 2022.
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.