PRIOR AUTHORIZATION POLICY

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

REVIEW DATE: 05/08/2024

INSTRUCTIONS FOR USE

THE FOLLOWING COVERAGE POLICY APPLIES TO HEALTH BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. CERTAIN CIGNA COMPANIES AND/OR LINES OF BUSINESS ONLY PROVIDE UTILIZATION REVIEW SERVICES TO CLIENTS AND DO NOT MAKE COVERAGE DETERMINATIONS. REFERENCES TO STANDARD BENEFIT PLAN LANGUAGE AND COVERAGE DETERMINATIONS DO NOT APPLY TO THOSE CLIENTS. COVERAGE POLICIES ARE INTENDED TO PROVIDE GUIDANCE IN INTERPRETING CERTAIN STANDARD BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. PLEASE NOTE, THE TERMS OF A CUSTOMER'S PARTICULAR BENEFIT PLAN DOCUMENT [GROUP SERVICE AGREEMENT, EVIDENCE OF COVERAGE, CERTIFICATE OF COVERAGE, SUMMARY PLAN DESCRIPTION (SPD) OR SIMILAR PLAN DOCUMENT] MAY DIFFER SIGNIFICANTLY FROM THE STANDARD BENEFIT PLANS UPON WHICH THESE COVERAGE POLICIES ARE BASED. FOR EXAMPLE, A CUSTOMER'S BENEFIT PLAN DOCUMENT MAY CONTAIN A SPECIFIC EXCLUSION RELATED TO A TOPIC ADDRESSED IN A COVERAGE POLICY. IN THE EVENT OF A CONFLICT, A CUSTOMER'S BENEFIT PLAN DOCUMENT ALWAYS SUPERSEDES THE INFORMATION IN THE COVERAGE POLICIES. IN THE ABSENCE OF A CONTROLLING FEDERAL OR STATE COVERAGE MANDATE, BENEFITS ARE ULTIMATELY DETERMINED BY THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT. COVERAGE DETERMINATIONS IN EACH SPECIFIC INSTANCE REQUIRE CONSIDERATION OF 1) THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT IN EFFECT ON THE DATE OF SERVICE; 2) ANY APPLICABLE LAWS/REGULATIONS; 3) ANY RELEVANT COLLATERAL SOURCE MATERIALS INCLUDING COVERAGE POLICIES AND; 4) THE SPECIFIC FACTS OF THE PARTICULAR SITUATION. EACH COVERAGE REQUEST SHOULD BE REVIEWED ON ITS OWN MERITS. MEDICAL DIRECTORS ARE EXPECTED TO EXERCISE CLINICAL JUDGMENT AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. COVERAGE POLICIES RELATE EXCLUSIVELY TO THE ADMINISTRATION OF HEALTH BENEFIT PLANS. COVERAGE POLICIES ARE NOT RECOMMENDATIONS FOR TREATMENT AND SHOULD NEVER BE USED AS TREATMENT GUIDELINES. IN CERTAIN MARKETS, DELEGATED VENDOR GUIDELINES MAY BE USED TO SUPPORT MEDICAL NECESSITY AND OTHER COVERAGE DETERMINATIONS.

CIGNA NATIONAL FORMULARY COVERAGE:

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.

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is(are) covered as medically necessary when the following criteria is(are) met for FDA-approved indication(s) or other uses with supportive evidence (if applicable):

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 COVERED

- **Phexxi™ (lactic acid, citric acid, and potassium bitartrate vaginal gel – Evofem)**

is(are) considered experimental, investigational or unproven for ANY other use(s) including the following (this list may not be all inclusive; criteria will be updated as new published data are available):

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 or other sexually transmitted infections.[1]

REFERENCES

1. Phexxi™ vaginal gel [prescribing information]. San Diego, CA: Evofem; June 2023.
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.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	05/17/2023
Annual Revision	No criteria changes.	05/08/2024