Drug Coverage Policy

Effective Date……09/15/2025
Coverage Policy Number……IP0729
Policy Title……Phexx

Contraceptives – Phexx

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

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 where appropriate and have discretion in making individual coverage determinations. Where coverage for care or services does not depend on specific circumstances, reimbursement will only be provided if a requested service(s) is submitted in accordance with the relevant criteria outlined in the applicable Coverage Policy, including covered diagnosis and/or procedure code(s). Reimbursement is not allowed for services when billed for conditions or diagnoses that are not covered under this Coverage Policy (see "Coding Information" below). When billing, providers must use the most appropriate codes as of the effective date of the submission. Claims submitted for services that are not accompanied by covered code(s) under the applicable Coverage Policy will be denied as not covered. 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.

Overview

Phexx 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: Phexx is not effective for the prevention of pregnancy when administered after intercourse.

Phexx 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] Phexx 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 Phexx 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.

In May 2025, Phexxi had a name change to Phexx.[1]

Coverage Policy

Policy Statement
Prior Authorization is required for benefit coverage of Phexx. 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 medically necessary criteria are not met, approval is granted for the prevention of pregnancy or for the improvement of birth outcomes if, according to the prescriber, other barrier methods of contraception would not be as medically appropriate for the patient as the requested drug.

Phexx is considered medically necessary when the following is met:

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).

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Receipt of sample product does not satisfy any criteria requirements for coverage.

Conditions Not Covered

Phexx for any other use is considered not medically necessary, 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 Phexx were previously available and marketed as an OTC personal lubricant.[2] Phexx 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 Phexx labeling, it does not protect against HIV infection or other sexually transmitted infections.[1]

References

1. Phexx® vaginal gel [prescribing information]. San Diego, CA: Evofem; May 2025.
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.

Revision Details

Type of Revision	Summary of Changes	Date
New	New policy	07/01/2025
Selected Revision	Updated policy statement to include the wording: "or for the improvement of birth outcomes."	09/15/2025

The policy effective date is in force until updated or retired.