

## Positive Quality Intervention: Non-hormonal Birth Control Alternative with Lactic acid/Citric acid/Potassium Bitartrate (Phexxi®)

**Description:** The purpose of this PQI is to provide proper identification and management of patients who may benefit from the use of non-hormonal contraception using lactic acid/citric acid/potassium bitartrate (Phexxi), a novel non-hormonal, vaginal pH modulator.

**Background:** Lactic acid/citric acid/potassium bitartrate is indicated for the prevention of pregnancy in females of reproductive potential for use as an on-demand method of contraception.<sup>1</sup> In a single arm, multicenter, open label, phase 3 study, Lactic acid/citric acid/potassium bitartrate was evaluated for cumulative pregnancy prevention in women ages 18 - 35 years old and considered at risk for pregnancy.<sup>2</sup> Women enrolled in this study recorded use of the medication, coital frequency, symptoms experienced, and overall satisfaction with the product. The study found 86.3% contraceptive effectiveness with typical use and 93% contraceptive effectiveness when used as directed, with minimal side effects, and high satisfaction (up to 90%).<sup>2</sup> For decades we have known that hormones play an active role in cancer.<sup>3</sup> For women specifically, endometrial, breast, and ovarian cancers can be highly dependent on hormone driven oncogenesis. Although studies differ on the risk associated with the use of oral contraceptives and a woman's overall risk of cancer development, it is evident that women who used oral contraceptives have an increased risk of breast cancer and cervical cancer.<sup>4,5</sup> For this reason, alternative non-hormonal contraceptive methods may be warranted during and after treatment of cancer.

### PQI Process:

- Identify patients that may need non-hormonal contraception
  - Women of child bearing potential
    - Breast or cervical cancer patients
      - Other cancer patients may be considered as well
    - Female partners of cancer patients
- Screen for precautions and contraindications
  - Should not be used with vaginal ring
  - Cystitis
  - Pyelonephritis
  - Chronic UTI infections

### Patient Centered Activities:

- Discuss the pros and cons of lactic acid/citric acid/potassium bitartrate
  - Non-hormonal
    - Works by maintaining acidic vaginal pH in presence of semen and reduces sperm motility
    - Safe to use in cancer treatment
    - No systemic absorption
  - On demand usage/administration
    - Only used when needed as opposed to daily dosing with traditional oral contraceptives

**Important notice:** NCODA has developed this Positive Quality Intervention platform. This platform represents a brief summary of medication uses and therapy options derived from information provided by the drug manufacturer and other resources. This platform is intended as an educational aid and does not provide individual medical advice and does not substitute for the advice of a qualified healthcare professional. This platform does not cover all existing information related to the possible uses, directions, doses, precautions, warning, interactions, adverse effects, or risks associated with the medication discussed in the platform and is not intended as a substitute for the advice of a qualified healthcare professional. The materials contained in this platform are for informational purposes only and do not constitute or imply endorsement, recommendation, or favoring of this medication by NCODA, which assumes no liability for and does not ensure the accuracy of the information presented. NCODA does not make any representations with respect to the medications whatsoever, and any and all decisions, with respect to such medications, are at the sole risk of the individual consuming the medication. All decisions related to taking this medication should be made with the guidance and under the direction of a qualified healthcare professional.

### Patient Centered Activities Continued:

- Must be used *before* every act of intercourse - not effective if used after
- Due to the thickness of the product, there will be limited vaginal discharged
- Provide counseling on potential side effects
  - Burning sensation of vulva (18%)<sup>1</sup>
  - Pruritus of genital organs (14.5%)<sup>1</sup>
  - Vulvovaginal infections
    - Mycotic infection (9.1%)
    - Bacterial vaginosis (8.4%)
  - Urinary tract infections (9.0%)
- Counsel the patient on the intravaginal administration and the timing of administration
  - Immediately before each act of vaginal intercourse
  - Up to 1 hour before each act of vaginal intercourse
  - Repeat before each vaginal intercourse act takes place

### Supplemental Information

#### How to write prescription

- Medication – Phexxi Vaginal Gel 5g applicator
- Directions – Administer 1 application intravaginally immediately before or up to 1 hour before EACH act of vaginal intercourse as needed
- Quantity/refills – 12 applicators/11 refills

#### Copay Card (for commercially insured patients)

- <https://phexxi.copaysavingsprogram.com/>

#### References:

1. Phexxi® (lactic acid, citric acid, and potassium bitartrate) [prescribing information]. San Diego, CA; Evofem Biosciences, INC: 2020.
2. Michael A. Thomas, B. Todd Chappell, Bassem Maximos, Kelly R. Culwell, Clint Dart, Brandon Howard. A novel vaginal pH regulator: results from the phase 3 AMPower contraception clinical trial. *Contraception X*, Elsevier, 2020.
3. Key, T. (1995, December). Hormones and cancer in humans. Retrieved March 02, 2021, from <https://www.sciencedirect.com/science/article/abs/pii/0027510795001328?via%3Dihub>.
4. Collaborative Group on Hormonal Factors in Breast Cancer. Breast cancer and hormonal contraceptives: collaborative reanalysis of individual data on 53,297 women with breast cancer and 100,239 women without breast cancer from 54 epidemiological studies. *Lancet* 1996; 347(9017):1713–1727.
5. Smith JS, Green J, Berrington de Gonzalez A, et al. Cervical cancer and use of hormonal contraceptives: a systematic review. *Lancet* 2003; 361(9364):1159-1167.
6. Glossary. (2017, April 07). Retrieved March 02, 2021, from <https://www.cdc.gov/biomonitoring/glossary.html>.

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