

Contraceptive Coverage Medical Necessity Letter

Patient Information	
Name	
Date of Birth	
Pharmacy Insurance	
Pharmacy Insurance ID Number	
Prescriber Information	
Name	
NPI/DEA	
Address	
Phone Number	

To whom it may concern:

I am prescribing Phexxi for my patient _____ for the prevention of pregnancy.

As the patient’s medical provider, I am confirming that Phexxi is medically appropriate for my patient.

Per the January 10th, 2022 Frequently Asked Questions (FAQs) about the Affordable Care Act (Implementation 51):

“This FAQ makes clear that all FDA-approved cleared, or granted contraceptive products that are determined by an individual’s medical provider to be medically appropriate for such individual must be covered without-cost sharing, whether or not specifically identified in the current FDA Birth Control Guide.”

“The FAQ makes clear that the plan or issuer must defer to the attending provider.”

Prescriber signature _____

Date: _____

If you have any further questions regarding this matter, or need additional information, please do not hesitate to contact my office.

INDICATIONS AND USAGE

Phexxi (lactic acid, citric acid, and potassium bitartrate) vaginal gel 1.8%, 1%, 0.4% is indicated for the prevention of pregnancy in females of reproductive potential for use as an on-demand method of contraception.

LIMITATIONS OF USE

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

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

Few cases (0.36%) of adverse reactions of cystitis, pyelonephritis and other upper urinary tract infection (UTI) have been reported in Phexxi clinical studies. Of these, one case of pyelonephritis was considered serious and required hospitalization. Avoid use of Phexxi in females of reproductive potential with a history of recurrent urinary tract infection or urinary tract abnormalities.

ADVERSE REACTIONS Most common adverse reactions were vulvovaginal burning sensation, vulvovaginal pruritus, vulvovaginal mycotic infection, urinary tract infection, vulvovaginal discomfort, bacterial vaginosis, vaginal discharge, genital discomfort, dysuria, and vulvovaginal pain. 9.8% of male partners reported local discomfort.

Patients should be counseled on the following:

- **To contact and consult with their healthcare provider for severe or prolonged genital irritation or if experiencing urinary tract symptoms.**
- **To discontinue Phexxi if they develop a local hypersensitivity reaction.**
- **That Phexxi does not protect against HIV infection or other sexually transmitted infections.**
- **To avoid Phexxi use with vaginal rings.**

To report **SUSPECTED ADVERSE REACTIONS**, contact Evofem at toll-free phone 1-833-EVFM BIO or you may contact FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Please see full [Prescribing Information](#) for Phexxi.

1. FAQs ABOUT AFFORDABLE CARE ACT IMPLEMENTATION PART 51, FAMILIES FIRST CORONAVIRUS RESPONSE ACT AND CORONAVIRUS AID, RELIEF, AND ECONOMIC SECURITY ACT IMPLEMENTATION. <https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-51.pdf> Accessed 1.19.2022