

Phexxi® Letter of Medical Necessity

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 _____.
 Phexxi is the only hormone-free, prescription vaginal gel approved for the prevention of pregnancy.

Please accept this request for medical necessity for insurance coverage with no cost sharing on behalf of my patient. Per the Affordable Care Act, a patient does not have to meet step edit or prior authorization requirements if a letter of medical necessity is completed.

Medication		
Phexxi		
<input type="checkbox"/> 1 box (12 applicators) X 11 refills	<input type="checkbox"/> 2 boxes (24 applicators) X 6 refills	<input type="checkbox"/> 3 boxes (36 applicators) X 4 refills
<input type="checkbox"/> Other: Refills:		

Diagnosis code

<input type="checkbox"/>	Z30.018 Encounter for initial prescription of other contraceptives
<input type="checkbox"/>	Z30.019 Encounter for initial prescription of contraceptives, unspecified
<input type="checkbox"/>	Z30.49 Encounter for surveillance of other contraceptives
<input type="checkbox"/>	Z30.8 Encounter for other contraceptive management
<input type="checkbox"/>	Z30.0 Encounter for contraceptive management, unspecified

Medical Necessity Rationale

<input type="checkbox"/>	Patient contraindicated to use hormones
<input type="checkbox"/>	Patient is intolerant to hormones or the severity of associated side effects
<input type="checkbox"/>	Patient and prescriber preference for non-hormonal contraception option
<input type="checkbox"/>	Ability to adhere to contraception
<input type="checkbox"/>	Provider and patient decision that individual is not a candidate for or not interested in a daily oral contraceptive, vaginal ring, patch or long-term reversible method

<input type="checkbox"/>	Intolerance or failure of spermicide use
<input type="checkbox"/>	Spermicide is not appropriate for this patient due to the black box warning of increased risk of HIV/STIs
<input type="checkbox"/>	Patient and provider do not want to disrupt current successful therapy on Phexxi
<input type="checkbox"/>	Other:

Rationale for Treatment with Phexxi

Phexxi is approved as vaginal gel for the prevention of pregnancy in females of reproductive potential for use as an on-demand method of contraception. Phexxi is a non-hormonal, on-demand, vaginal pH modulator contraceptive designed to maintain vaginal pH within the normal range of 3.5 to 4.5 – an acidic environment that is inhospitable to sperm.

Per the Health Resources and Services Administration (HRSA) guidelines, women should have access to the full range of FDA-approved contraceptive methods including, but not limited to, barrier methods, hormonal methods, and implanted devices, as well as patient education and counseling, as prescribed by a healthcare provider. ²Based on the Affordable Care Act Implementation (Part XXVI):²

- If utilizing reasonable medical management techniques within a specified method of contraception, plans and issuers must have an easily accessible, transparent, and sufficiently expedient exceptions process that is not unduly burdensome on the individual or provider.
- If an individual’s attending provider recommends a particular service or FDA-approved item based on a determination of medical necessity with respect to that individual, the plan or issuer must cover that service or item without cost sharing. The plan or issuer must defer to the determination of the attending provider.
- The Departments of Labor and Health and Human Services and the Treasury released a set of “Frequently Asked Questions” which affirmed that under the ACA’s women’s preventives services, plans cannot limit their coverage of contraceptives to only oral contraceptives. The FAQs state, “The HRSA Guidelines ensure women’s access to the full range of FDA-approved contraceptive methods including, but not limited to, barrier methods, hormonal methods, and implanted devices, as well as patient education and counseling, as prescribed by a health care provider.”
- Furthermore, the FAQs affirmed that the ACA’s women’s preventive services requirement requires plans to provide coverage of all brand-name forms of contraception that do not have a generic equivalent. The FAQ says, “If, however, a generic version is not available,...then a plan or issuer must provide coverage for the brand name drug in accordance with the requirements of the interim final regulations (that is, without cost-sharing, subject to reasonable medical management).” Phexxi is a brand name drug without a generic equivalent, thus my patients plan must provide coverage of Phexxi without cost sharing.

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

Prescriber signature_____

1. Phexxi [Prescribing Information]. Evofem Biosciences, Inc.: San Diego, CA; May 2020.
2. FAQs about Affordable CareAct implementation (Part XXVI). Centers for Medicare and Medicaid Services website. https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/aca_implementation_faqs26.pdf. Published May 11, 2015. Accessed January 9, 2020.

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.

EVFM-US-001283

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