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**5.99.025**

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<b>Section:</b>	Prescription Drugs	<b>Effective Date:</b>	April 1, 2024
<b>Subsection:</b>	Miscellaneous Products	<b>Original Policy Date:</b>	November 12, 2021
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**Last Review Date:** March 8, 2024

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## Condoms

### Description

#### External (Male) Condoms, FC2 Female Condom

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#### Background

Condoms, both internal female condoms and external male condoms, can be used by anyone engaging in penetrative sexual intercourse. Condoms used for the prevention of pregnancy and the transmission of sexually transmitted infections (STIs), including HIV. Condoms are for one-time use; a new condom should be used for each sexual encounter. Due to possible problems with condom use (e.g., breakage, or condoms slipping off), there may be a need to use more than one condom for each sexual encounter (1-3).

Since condoms are used as needed, the quantity limits for these products are based upon coital frequency from studies of data analysis. According to the Predictors of Adult Sexual Activity in The United States survey, men and women between the ages of 25 and 45 have sex a mean 5.7 and 6.4 times per month, respectively. A Study of Declines in Sexual Frequency among American adults found that age had a strong effect on sexual frequency: Americans in their 20s had sex an average of about 80 times per year, declining to about 20 times per year by age 65. Among the studies, the highest average coital frequency reported amongst age groups is approximately 6 times per month, but there is a very wide range associated with this average. Therefore, the Pre-PA Allowance for these products is 16 condoms per month (1-2).

Due to numerous reasons (e.g., increased sexual activity, problems associated with condom use, socioeconomic factors), patients may choose to have multiple condoms available for use. Therefore, the PA quantity limit is set for twice the initial limit, or 32 condoms per month (1-2).

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## Regulatory Status

FDA-approved indication: The FC2 Female Condom is indicated for vaginal use for the prevention of unplanned pregnancy and the transmission of sexually transmitted infections (STIs), including HIV (3).

External condoms are used for prevention of unplanned pregnancy and the transmission of sexually transmitted infections (STIs), including HIV.

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## Related policies

### Policy

*This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.*

Internal condoms may be considered **medically necessary** for patients with a clinical need for more than the Pre-PA allowance.

## Prior-Approval Requirements

### Diagnosis

Patient must have the following:

1. Patient has a clinical need for more than 48 condoms in 90 days, such as increased sexual activity, condom breakage, etc.

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## Prior – Approval *Renewal* Requirements

Same as above

### Policy Guidelines

## Pre - PA Allowance

**Quantity** 48 internal **OR** external condoms per 90 days

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## Prior - Approval Limits

**Quantity** 96 internal **OR** external condoms per 90 days

**Duration** 12 months

## Prior – Approval *Renewal* Limits

Same as above

## Rationale

### Summary

Condoms are used to prevent STIs and to prevent unplanned pregnancy. According to studies done in the United States, the mean coital frequency is about 6 times per month, depending on age and other factors. The Pre-PA Allowance is set for 16 condoms per month. This PA criteria was created in order to allow for up to 32 condoms per month in patients with a clinical need, such as increased sexual activity or condom breakage (1-2).

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of internal condoms while maintaining optimal therapeutic outcomes.

### References

1. Eisenberg M, Shindel A, Smith J, et al. Socioeconomic, Anthropomorphic, and Demographic Predictors of Adult Sexual Activity in The United States: Data from the National Survey of Family Growth. J Sex Med. 2010; 7:50-58.
2. Twenge JM, Sherman RA, Wells BE. Declines in sexual frequency among American adults, 1989–2014. Arch Sex Behav. 2017;46(8):2389-2401.
3. FC2 Female Condom Leaflet. Miami, FL: Veru Inc.; September 2019. Available at: [https://fc2.us.com/wp-content/uploads/2020/01/Female-Condom\\_USA-Leaflet\\_G0066\\_SEPT2019.pdf](https://fc2.us.com/wp-content/uploads/2020/01/Female-Condom_USA-Leaflet_G0066_SEPT2019.pdf).

## Policy History

Date	Action
November 2021	Addition to PA
March 2022	Annual review

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December 2022 Annual editorial review. Added external (male) condoms to criteria. Per FEP, increased quantity limits to 48 per 90 days and 96 per 90 days for Pre-PA and PA respectively

March 2023 Annual review

March 2024 Annual review

## [Keywords](#)

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**This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 8, 2024 and is effective on April 1, 2024.**