

CONDOMS

External (Male) Condoms, FC2 Female Condom

RATIONALE FOR INCLUSION IN PA PROGRAM

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).

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.

Summary

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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.