

QUANTITY LIMIT PRIOR AUTHORIZATION CRITERIA

DRUG CLASS

CONDOMS

BRAND NAME*
(generic)

FEMALE CONDOMS (OTC)

Status: CVS Caremark® Criteria

Type: Quantity Limit; Post Limit Prior Authorization

Ref # 4702-HJ

**Drugs that are listed in the target drug box include both brand and generic and all dosage forms and strengths unless otherwise stated. OTC products are not included unless otherwise stated.*

INDICATIONS AND USES

Female (internal) condoms are used for the prevention of pregnancy. Female condoms can also effectively protect against sexually transmitted infections (STIs) and human immunodeficiency virus (HIV) transmission.²⁻³ Specifically, the FC2 Female Condom is indicated for preventing pregnancy, HIV/AIDs and other sexually transmitted infections(STIs).¹

INITIAL QUANTITY LIMIT**

INITIAL LIMIT QUANTITY

Limits should accumulate across all drugs and strengths up to highest quantity listed depending on the order the claims are processed.

PLEASE NOTE: Since manufacturer package sizes may vary, it is the discretion of the dispensing pharmacy to fill quantities per package size up to these quantity limits. In such cases the filling limit and day supply may be less than what is indicated.

Drug

1 Month Limit*

3 Month Limit*

Female Condoms

12 condoms / 25 days

36 condoms / 75 days

** The duration of 25 days is used for a 30-day fill period and 75 days is used for a 90-day fill period to allow time for refill processing.*

**If the patient is requesting more than the initial quantity limit, the claim will reject with a message indicating that a prior authorization is required. The prior authorization criteria would then be applied to requests submitted for evaluation to the PA unit.

COVERAGE CRITERIA

Authorization may be granted for the requested drug when the following criteria is met:

- The patient requires more than 12 condoms per month due to a clinical need (e.g., increased sexual activity, condom breakage, or other need to have multiple condoms available for each sexual encounter)

QUANTITY LIMITS APPLY

24 condoms / 25 days* or 72 condoms / 75 days*

Female Condoms Limit, Post PA 4702-HJ UDR 04-2024.docx

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*The duration of 25 days is used for a 30-day fill period and 75 days is used for a 90-day fill period to allow time for refill processing.

DURATION OF APPROVAL (DOA)

- 4702-HJ: DOA: 12 months

REFERENCES

1. FC2 Female Condom Leaflet. Miami, FL: Veru Inc.; November 2021. Available at: <https://fc2.us.com/wp-content/uploads/2022/04/FC2-Female-Condom-Product-Leaflet-G0073-1.pdf> . Accessed February 27, 2024.
2. Lexicomp Online, Patient Education – Disease and Procedure Online. Waltham, MA: UpToDate, Inc.; 2024. <https://online.lexi.com>. Accessed February 27, 2024.
3. Colquitt CW, Martin TS. Contraceptive Methods: A Review of Nonbarrier and Barrier Products. *Journal of Pharmacy Practice*. 2017;30(1):130-135.
4. Eisenberg ML, Shindel AW, Smith JF, 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(1):50-58.
5. Twenge JM, Sherman RA, Wells BE. Declines in Sexual Frequency Among American Adults, 1989–2014. *Arch Sex Behav*. 2017;46(8):2389-2401.
6. Ueda P, Mercer CH, Ghaznavi C, et al. Trends in Frequency of Sexual Activity and Number of Sexual Partners Among Adults Aged 18-44 Years in the US, 2000-2018. *JAMA Network Open*. 2020 June 12; 3(6): e203833.

Written by: UM Development (CJH/SF)
 Date Written: 05/2021
 Revised: (CJH) 09/2021 (no clinical changes); (RZ) 03/2022 (no clinical changes), (VLS) 03/2023 (no clinical changes), (DFW) 03/2024 (no clinical changes)
 Reviewed: Medical Affairs (MD Committee) 06/2021, (CHART) 06/10/2021, 09/30/2021, 03/31/2022, 03/30/2023, 03/28/2024
 External Review: 06/2021 (MD Subcommittee), 12/2021 (MD Subcommittee), 06/2022 (MD Subcommittee), 06/2023 (MD Subcommittee), 06/2024 (MD Subcommittee)

CRITERIA FOR APPROVAL

- | | | | |
|---|---|-----|----|
| 1 | Does the patient require more than 12 condoms per month due to a clinical need (e.g., increased sexual activity, condom breakage, or other need to have multiple condoms available for each sexual encounter)?
[If Yes, then go to 2. If No, then no further questions.] | Yes | No |
| 2 | Does the patient require more than the plan allowance of 24 condoms per month?
[No further questions] | Yes | No |

RPh Note: If yes, then deny and enter a partial approval for 24 condoms / 25 days or 72 condoms / 75 days.

Mapping Instructions			
	Yes	No	DENIAL REASONS
1.	Go to 2	Deny	We have denied your request because it is for more than the amount your plan covers (quantity limit). Your plan only covers more of this product (additional quantities) when you meet the criteria for additional quantities. Your plan covers up to 12 condoms per month. We reviewed the information we had. Your request for more product has been denied. Your doctor can send us any new or missing information for us to review. For this product,

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			<p>you may have to meet other criteria. You can request the product policy for more details. You can also request other plan documents for your review.</p> <p>[Short Description: Quantity, Post limit criteria not met]</p>
2.	Deny	<p>[PA approved for 12 month(s), 24 condoms/25 days* OR 72 condoms/75 days*]. Approve, 12 Months</p>	<p>We have denied your request because it is for more than the amount your plan covers (quantity limit). We reviewed the information we had. We have partially approved your request for this product up to the amount your plan covers (24 condoms per 30 days). Your request for more product has been denied. Your doctor can send us any new or missing information for us to review. For this product, you may have to meet other criteria. You can request the product policy for more details. You can also request other plan documents for your review.</p> <p>[Short Description: Quantity, Exceeds max limit, Partial denial]</p>