| **Visits 7-12 (Study Product Administration Visits) Checklist** |
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| **Procedures:** | **Staff Initials** |
|  | Confirm identity and PTID |  |
|  | Check for co-enrollment in other studies:* NOT enrolled in another study ==> CONTINUE.
* Enrolled in another study ==> STOP. Immediately contact PSRT and Management Team for further guidance.
 |  |
|  | Explain procedures to be performed at today’s visit. |  |
|  | Review elements of informed consent as needed.  |  |
|  | Review/update locator information. |  |
|  | Provide available test results from previous visit. Provide and document treatment and/or referral as needed. |  |
|  | If clinically indicated, perform and document targeted physical examination on the Physical Exam CRF and Vital Signs CRF.  |  |
|  | Review/update medical, medication, and for female participants, menstrual histories. Complete/update AE Log CRF(s), and Concomitant Medications/Summary Log CRF, if applicable. |  |
|  | At Visit 7, complete Sexual Lubricant CRF.  |  |
|  | Required at Visit 7 (if indicated at Visits 8-12): Provide HIV pre-test and risk reduction counseling using HIV and Risk Reduction Counseling Worksheet, if applicable. |  |
|  | Complete the **MTN-026 Study Gel Request Slip**. Send the white original copy to the pharmacy, and file the yellow copy (bottom) in the participant’s file. |  |
|  | At Visit 7, collect urine for: * Qualitative hCG (for female participants)

Enter results onto Pregnancy Test Result CRF once available. If clinically indicated:* Dipstick urinalysis
* Urine culture
* NAAT for GC/CT

Enter results onto STI Test Results once available.  |  |
|  | Collect blood samples for:* At Visit 7:
	+ Plasma for PK\_\_\_ mL [tube type]
	+ Plasma for storage \_\_\_ mL [tube type]
	+ HIV serology \_\_\_ mL [tube type]
* At Visit 8:
	+ Plasma for PK\_\_\_ mL [tube type]

Document PK collection and plasma for storage on Specimen Storage CRF and applicable LDMS Tracking Sheet. Enter results onto HIV Test Results CRF once available. If clinically indicated: * CBC with differentials and platelets \_\_\_ mL [tube type]
* AST, ALT \_\_\_ mL [tube type]
* Creatinine \_\_\_ mL [tube type]
* Syphilis \_\_\_ mL [tube type]

Transcribe results onto Hematology CRF, Local Laboratory Results CRF and/or STI Test Results once available. |  |
|  | Provide product, relevant product use instructions, and lubricant |  |
|  | Required at Visit 7 and 8 (if indicated at all other visits): Perform and document anorectal exam. Collect Visit 7 (hour 0) or Visit 8 (24 hour after Visit 7 application) rectal samples (See Genital Exam Checklist).  |  |
|  | If clinically indicated, for female participants, perform and document pelvic exam on the Pelvic Exam CRF and Pelvic Exam Diagrams form. |  |
|  | Provide and explain all available findings and results. Refer for findings as indicated. |  |
|  | If STI/RTI/UTI is diagnosed, provide or refer for treatment. Document in chart notes |  |
|  | Observe dose application. Document date and time of dose application on Directly Observed Dosing Log CRF. |  |
|  | Provide available test results.  |  |
|  | At Visit 7 (if indicated at Visits 8-12) provide post-test counseling and document on HIV Pre/Post Test and Risk Reduction Counseling Worksheet  |  |
|  | Provide and document protocol counseling per Protocol Counseling worksheet. |  |
|  | Confirm/Schedule next study visit and advise participant of potential length of the visit. Provide contact information and instructions to report symptoms and/or request information, counseling before next visit. |  |
|  | At Visit 7: Provide one-dose application for at-home use, if needed, and lubricant. Document dispensation on Product Dispensation and Returns CRF. |  |
|  | Perform QC1: while participant is still present, review the following for completion if completed:* Follow-up Visit Summary
* Anorectal Exam
* Directly Observed Dosing Log
* Product Dispensation and Returns
* Sexual Lubricant
* LDMS Specimen Tracking Sheets and Specimen Storage
* Concomitant Medications (as applicable)
* Adverse Event Log (if, at this visit, new AEs are reported or previously reported AEs are updated)
* Physical Exam, Vital Signs, Pelvic Exam, Pelvic Exam Diagrams (if indicated)
* Supporting chart notes, as needed
 |  |
|  | Provide reimbursement |  |

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| **POST-VISIT PROCEDURES** |
|  | Ensure that data is entered into the study database (and perform QC2 review, if applicable) ensuring all data entered into the study database is accurate and complete.Visit Forms: * Follow-up Y/N
* Follow-up Visit Summary
* Required at Visit 7 Only:
	+ Pregnancy Test (female participants only)
	+ HIV Test Results
	+ Sexual Lubricant
	+ Product Dispensation and Returns
* Required at Visit 7 and 8 Only:
	+ Anorectal Exam
	+ Specimen Storage

If Indicated:* Physical Exam
* Vital Signs
* Hematology
* Local Laboratory Results
* STI Tests
* Pelvic Exam and Pelvic Exam Diagrams
* HIV Confirmatory Results
* Missed Visit
* Treatment Discontinuation
* Study Discontinuation
* Participant Replacement
* Additional Study Procedures
* Pregnancy Report and History (female participants only)

Log CRFs (if newly-completed or updated):* Adverse Event Summary/Log
* Concomitant Medications Summary/Log
* Protocol Deviations Summary/Log
* Directly Observed Dosing Log
* Pregnancy Outcome Summary/Log (female participants only)
 |  |

**Additional Notes/Comments/Referrals:**