| **Visit 13 (Last Study Product Administration Visit/Early Termination Visit) Checklist** |
| --- |
| **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. |  |
|  | Complete the **MTN-026 Study Gel Request Slip**. The white original copy will be delivered to the pharmacy, and the yellow copy (bottom) stored in the participant’s file. |  |
|  | Collect urine for: * Qualitative hCG (for female participants)

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

Enter results onto STI Tests CRF once available.  |  |
|  | Collect blood samples for PK:* + 0 hour (pre-dose) \_\_\_ mL [tube type]
 |  |
|  | Collect unused dose provided to be administered at home, if applicable. Document on Product Dispensation and Returns CRF. |  |
|  | Complete Sexual Lubricant CRF.  |  |
|  | Provide product, relevant product use instructions, and lubricant |  |
|  | Observe dose application. Document date and time of dose application on Directly Observed Dosing CRF.  |  |
|  | Collect blood samples for:* PK:
	+ 30-60 minutes \_\_\_ mL [tube type] OR
	+ 120 minutes \_\_\_ mL [tube type]

Document PK blood collection on LDMS Tracking Sheet and Timed Specimen Storage Collection CRF. If clinically indicated: * CBC with differentials and platelets \_\_\_ mL [tube type]
* AST, ALT \_\_\_ mL [tube type]
* Creatinine \_\_\_ mL [tube type]
* Syphilis \_\_\_ mL [tube type

Enter results onto Local Laboratory Results CRF and/or Hematology CRF and/or STI Tests CRF, if indicated once available. |  |
|  | If indicated, perform and document targeted physical examination on the Physical Exam CRF and Vital Signs CRF.  |  |
|  | Perform and document anorectal exam. Collect rectal samples (See Genital Exam Checklist).  |  |
|  | Female participants: Perform and document pelvic exam. Collect pelvic samples (See Genital Exam Checklist).  |  |
|  | Review/update medical, medication, and for female participants, menstrual histories. Complete/update AE Log CRF(s), and Concomitant Medications Log CRF, if applicable. Document menstrual information on Cervical Specimen Storage CRF. |  |
|  | Provide and explain all available findings and results. Refer for findings as indicated. |  |
|  | If STI/RTI/UTI is diagnosed, provide or refer for treatment. |  |
|  | *If Early Termination Visit:* Administer appropriate Follow-up CASI Behavioral Questionnaire. Document administration on CASI Summary and CASI Tracking CRFs.  |  |
|  | *If Early Termination Visit:* Have participant complete the in-depth interview with remote interviewer at the agreed upon time. Document administration on the CASI Tracking CRF.  |  |
|  | 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, study product, or condoms before next visit. |  |
|  | *If Early Termination Visit:* * Determine participant preference for post-study contact.
* If applicable, schedule a final study contact for disclosure of all remaining exam and lab test results.
* If applicable, schedule clinically indicated follow-up for all unresolved grade 2 and higher AEs and related AEs at this visit.
* Inform the participant of planned methods and timeframes for dissemination of study results.
* Determine and document whether participant is willing to be contacted about future studies for which s/he may be eligible.
 |  |
|  | Perform QC1: while participant is still present, review the following for completion:* Follow-up Visit Summary
* Anorectal Exam
* Product Dispensation and Returns
* Directly Observed Dosing
* LDMS Specimen Tracking Sheets and Timed Specimen Storage
* Pelvic Exam and Pelvic Exam Diagrams
* Physical Exam and Vital Signs (if indicated)
* Adverse Event Log (if, at this visit, new AEs are reported or previously reported AEs are updated)
* Concomitant Medications Log (as applicable)
* Supporting chart notes, as needed
* Visit Checklist
 |  |
|  | Provide reimbursement |  |
| **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.Required Visit Forms: * Follow-up Y/N
* Follow-up Visit Summary
* Sexual Lubricant
* Anorectal Exam
* Product Dispensation and Returns
* Timed Specimen Storage
* Treatment Discontinuation
* Additional Study Procedures (for pregnancy testing)
* Pregnancy Test Results (female participants only)
* Pelvic Exam (female participants only)
* Pelvic Exam Diagrams (female participants only)
* Cervical Specimen Storage (female participants only)

*Required if Early Termination:** CASI Summary and CASI Tracking
* Study Discontinuation

If Indicated:* Physical Exam
* Vital Signs
* Missed Visit
* Hematology
* Local Laboratory Results
* STI Tests
* Participant Replacement

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

**Additional Notes/Comments/Referrals:**