| **Visit 3 (Single Dose Administration 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 treatment and/or referral as needed. |  |
|  | If clinically indicated, perform and document targeted physical exam using Physical Exam CRF. |  |
|  | Obtain vitals (if indicated) and document on Vital Signs CRF.  |  |
|  | Review/update medical, medication, and for female participants, menstrual history, as needed. Complete/update AE Log CRF(s), and Concomitant Medications Log CRF, if applicable. |  |
|  | Complete the Sexual Lubricant CRF.  |  |
|  | Complete the **MTN-026 Study Gel Prescription**. Send the white original copy to the pharmacy. File the yellow copy (bottom) 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]
 |  |
|  | Obtain study product and lubricant Note: Staff should evaluate safety prior to administration of product.  |  |
|  | Administer/apply dose application. Document date and time of dose application on Directly Observed Dosing Log CRF |  |
|  | Collect blood samples for:* Blood for PK:
	+ 30-60 minutes \_\_\_ mL [tube type] OR
	+ 120 minutes \_\_\_ mL [tube type]

Document PK blood collection on Timed Specimen Storage CRF and LDMS Specimen Tracking Sheet 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 Hematology CRF, Local Laboratory Results CRF and/or STI Test Results CRF*,* if indicated once available. |  |
|  | Perform and document anorectal exam, per participant PK/PD assignment. Collect 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. |  |
|  | Administer appropriate Follow-up CASI Behavioral Questionnaire. Document administration on the CASI Summary and CASI Tracking CRFs. |  |
|  | 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 Adherence Counseling worksheet |  |
|  | Confirm/Schedule Visit 4 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. |  |
|  | Perform QC1: while participant is still present, review the following for completion:* Visit checklist
* Follow-up Visit Summary
* Sexual Lubricant
* LDMS Specimen Tracking Sheets and Timed Specimen Storage CRF
* Anorectal Exam
* Concomitant Medications Log (as applicable)
* Adverse Event Log (if, at this visit, new AEs are reported or previously reported AEs are updated)
* Physical Exam (if indicated)
* Vital Signs (if indicated)
* Pelvic Exam (if indicated)
* Pelvic Exam Diagrams (if indicated)
* Supporting chart notes, as needed
 |  |
|  | 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 CRFs: * Follow-up Yes/No
* Follow-up Visit Summary
* CASI Summary and CASI Tracking
* Sexual Lubricant
* Anorectal Exam
* Timed Specimen Storage
* Additional Study Procedures (for pregnancy testing)
* Pregnancy Test Results (female participants only)
* Pharmacy Dispensation (completed by and accessible to site pharmacists only)

If Indicated CRFs:* Physical Exam
* Vital Signs
* Hematology
* Local Laboratory Results
* STI Tests
* Pelvic Exam (female participants only)
* Pelvic Exam Diagrams (female participants only)
* Study Discontinuation
* Participant Replacement Assessment

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

**Additional Notes/Comments/Referrals:**