| **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:**