**Instructions:** Complete staff initials next to procedures completed. Do not initial for other staff members. If other staff members are not available to initial checklist items themselves, initial and date a note on the checklist documenting who completed the procedure, e.g., “done by {name}” or “done by nurse.” If a procedure listed on the checklist is not performed, enter “ND” for “not done” or “NA” for “not applicable” beside the item and record the reason why (if not self-explanatory); initial and date this entry. If any procedures are not conducted on the date recorded above, ensure the date procedure conducted is included in the comments section.

| **Procedure** | | | **Staff Initials** |
| --- | --- | --- | --- |
|  | Confirm identity, age and PTID. | |  |
|  | Check for co-enrollment   * NOT enrolled in another study 🡪 CONTINUE. * Enrolled in another study 🡪 STOP. Consult the PSRT regarding ongoing product use and safety considerations. | |  |
|  | Explain procedures to be performed at today’s visit. | |  |
|  | Review/update locator information. | |  |
|  | Provide available test results from previous visit(s), if not already provided. Treat and/or refer for care as required. | |  |
|  | Log into Medidata Rave and select the appropriate PTID. Begin visit by opening the applicable Visit folder. | |  |
|  | Complete **Follow-up Visit YN** and **Follow-up Visit Summary eCRFs.** | |  |
|  | *If clinically indicated*, collect mid-stream catch urine (15-60 mL) and perform tests:   * *Qualitative hCG (pregnancy) if applicable* * *NAAT for GC/CT/TV* * *Dipstick urinalysis and/or culture per site SOP*   Document GC/CT/TV test results on the STI Test Results eCRF. For individuals who can get pregnant, document pregnancy test results on local testing log and the Pregnancy Test Results eCRF, when *applicable*. If pregnant→ STOP. Refer to SSP and site-specific SOPs | |  |
|  | Review/update medical history to verify and/or update all information previously recorded. Document all updates as needed on the **Adverse Event Summary/Log eCRFs** and **Concomitant Medications Summary/Log eCRFs**.  *Note: A participant with a current unresolved pelvic, genital or anorectal AE Grade 3 or higher* ***OR*** *any other AE that in the opinion of the investigator is judged to be related to study product and would preclude the participant from continuing to the next product use period may not proceed to the next scheduled regimen, without prior PSRT consultation. Submit PSRT Query Form, complete* ***Product Hold eCRF*** *and Study Product Request Slip marked “HOLD;” deliver the top (white) copy to the pharmacy. Retain yellow copy of prescription in participant’s binder.* | |  |
|  | *If clinically indicated, provide and document HIV pre-test and HIV/STI risk reduction counseling, including offering male condoms, using the HIV Pre/Post Test and Risk Reduction Counseling Worksheet.* | |  |
|  | *If clinically indicated, collect the following amounts of blood and send to lab for testing:*   * *HIV 1/2* * *[X] mL [color] top [additive/no additive] tube* * *Syphilis serology* * *[X] mL [color] top [additive/no additive] tube*   Document syphilis results on the Syphilis Serology eCRF, if applicable | |  |
|  | *If clinically indicated, perform and document HIV test (s) per site SOPs and in accordance with HIV Testing Algorithm.*  *The following applies to sites running one EIA:*   * If negative 🡪 UNINFECTED 🡪 CONTINUE. * If positive or indeterminate 🡪HOLD PRODUCT→ Perform HIV confirmation test actions per HIV testing algorithm. * POSITIVE→COLLECT SAMPLE 2 for HIV confirmation test actions per HIV testing algorithm. * POSITIVE→ STOP→PERMANENTLY DISCONTINUE PRODUCT * NEGATIVE OR INDETERMINATE→CONSULT LC   *The following applies to sites running two rapid tests:*   * If both tests negative → UNINFECTED → CONTINUE. * If both tests positive → HOLD PRODUCT→ Perform HIV confirmation test actions per HIV testing algorithm. * POSITIVE→COLLECT SAMPLE 2 for HIV confirmation test actions per HIV testing algorithm. * POSITIVE→ STOP→PERMANENTLY DISCONTINUE PRODUCT * NEGATIVE OR INDETERMINATE→CONSULT LC * If one test positive and one test negative → DISCORDANT →Perform HIV confirmation test actions per HIV testing algorithm. * POSITIVE→COLLECT SAMPLE 2 for HIV confirmation test actions per HIV testing algorithm. * POSITIVE→ STOP→PERMANENTLY DISCONTINUE PRODUCT * NEGATIVE OR INDETERMINATE→CONSULT LC   Document results on **HIV Test Results eCRF.** If a HOLD or DISCONTINUATION is initiated, complete **Study Product Request Slip** and the **Product Hold Log** or **Discontinuation of Study Product CRF**. | |  |
|  | *If clinically indicated, provide HIV test results in the context of post-test counseling and document on HIV Pre/Post Test and HIV/STI Risk Reduction Counseling Worksheet. Provide referrals for care and treatment, if applicable, per site SOPs.* | |  |
|  | *If clinically indicated, perform a targeted physical exam and complete the Vital Signs eCRF and Physical Exam eCRF* | |  |
|  | *If clinically indicated, collect pharyngeal sample for NAAT for GC/CT and complete STI Test Results eCRF.* | |  |
|  | *If clinically indicated, for individuals with a natural phallus or neo-phallus, perform genital examination per Genital Exam Checklist and document findings on the Genital Exam eCRF.* | |  |
|  | *If clinically indicated, for individuals with a natural vagina or neo-vagina, perform pelvic examination and/or collect vaginal swab per Pelvic Exam Checklist. Document results on STI Test Results eCRF and exam findings on the Pelvic Exam Diagrams Form and Pelvic Exam eCRF.* | |  |
|  | *If clinically indicated, perform anorectal exam per Anorectal Exam Checklist and document findings on the Anorectal Exam eCRF* | |  |
|  | *If indicated, evaluate findings identified during rectal (if applicable, genital and pelvic) and physical examinations and medical history review. Determine whether participant has current RTI/STI/UTI symptoms:*   * *No symptoms 🡪 CONTINUE.* * *Symptom(s) present 🡪 evaluate per site SOPs.*   *If symptomatic and diagnosed with an RTI/STI/UTI, treat or refer for treatment if indicated, per site SOP.* |  | |
|  | Provide and explain all available findings and results. Refer for other findings as indicated. |  | |
|  | Document referral in chart notes and update **Concomitant Medications Log eCRF**, if treatment provided or prescribed. Document relevant conditions on the **Adverse Event Log** **eCRF**. |  | |
|  | Complete a **Study Prescription** for assigned product sequence. Deliver the top (white) copy [along with the site-specific form, if applicable] to the pharmacy. Retain yellow copy of prescription in participant’s binder. | |  |
|  | Provide written product use instructions, review instructions on how to use and store assigned product. Provide assigned product (and lubricant if needed) and have participant self-administer first dose for Period 2 or 3. | |  |
|  | Program/initiate short message service SMS/IM Reporting System. Review instructions and training on how to receive and respond to SMS/IM. | |  |
|  | Perform QC1 with participant still present. Review the following for completion and clear documentation:   * This visit checklist to ensure all required procedures were completed. * **Adverse Event Summary/Log eCRFs** and **Concomitant Medications Log eCRF** to ensure all medications and AEs are captured consistently and updated. * **Chart notes** to ensure completeness and accuracy based on participant responses and clinical findings. * All CRFs for completeness and accuracy, based on participant responses and clinical findings. | |  |
|  | Schedule next visit and provide condoms (if needed) and any other study informational materials, site contact information, and instructions to contact the site for additional information, study product and/or counseling if needed before the next visit: [add site-specific list if desired] | |  |
|  | Provide reimbursement. | |  |
|  | Perform QC2. Review participant chart contents, paper forms and EDC data:  Required CRFs   * Follow-up Visit Y/N * Follow-up Visit Summary   Paper Forms:   * Study Prescription * Protocol Counseling Worksheet * Pelvic Exam Diagram, *if applicable* * Pelvic Exam Checklist, *if applicable* * Anorectal Exam Checklist, *if applicable* * Genital Exam Checklist, *if applicable* * HIV Pre/Post-Test and HIV/STI Risk Reduction Counseling Worksheet, *if applicable*   *If indicated/applicable CRFs*   * Adverse Event Summary/Log * Medical History Summary/Log (if newly reported baseline conditions) * Concomitant Medications Summary/Log * Vital Signs * Physical Exam * Pregnancy Test Results * Anorectal Exam * Genital Exam * Pelvic Exam * Social Impact Y/N * Social Impact Log * STI Test Results * Syphilis Serology * Pelvic Exam * HIV Test Results * Protocol Deviations Log * Product Hold Log * Social Impact Log * Discontinuation of Study Product * Study Termination * Additional Study Procedures | |  |
| **Comments:** | | | |
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