Appendix C – NYS Department of Health Updated Clinical Guidelines for HIV Post-Exposure Prophylaxis

In May 2018, the New York State Department of Health (2018b) updated its recommendations on HIV post-exposure prophylaxis following an occupational exposure.

What's New – May 2018 Update

Language regarding potential increased risk of neural tube defects with dolutegravir (DTG)-based ART regimens was added throughout the guideline (for clarity, some changes in blue):

ART Regimens for oPEP

Change 1. Recommendation: The preferred PEP regimen is tenofovir disoproxil fumarate + emtricitabine (lamivudine may be substituted for emtricitabine) plus either raltegravir or dolutegravir* (see text for dosing and Antiretroviral Agents Recommended for PEP for additional information). Zidovudine is no longer recommended in the preferred PEP regimen. The first dose should be given as soon as possible after exposure, ideally within 2 hours. The recommended duration of PEP is 28 days.

*On May 18, 2018, the U.S. Food and Drug Administration and the DHHS Antiretroviral Guidelines Panels issued statements in response to preliminary results from a study that reported increased risk of neural tube defects in babies born to mothers were taking dolutegravir (DTG)-based antiretroviral (ARV) drug regimens at the time of conception. For exposed women who are pregnant, considering pregnancy, or not using effective contraception, dolutegravir-containing regimens should be avoided until more data are available. If there are no alternatives for dolutegravir in women of childbearing potential, clinicians should strongly advise the use of effective contraception and should obtain a pregnancy test before initiating treatment (see PEP for Exposed Workers Who Are Pregnant or Breastfeeding for drugs to avoid in exposed workers who are pregnant or breastfeeding) (cited AIDSinfo as reference 13 and U.S. Food and Drug Administration as reference 14).

Change 2. Added the following note for recommended PEP regimen following occupational exposure: Preliminary results from an ongoing observational study reported increased risk of neural tube defects in babies born to mothers were taking dolutegravir (DTG)-based antiretroviral (ARV) drug regimens at the time of conception. For exposed women who are pregnant, considering pregnancy, or not using effective contraception, dolutegravir-containing regimens should be avoided until more data are available. If there are no alternatives for dolutegravir in women of childbearing potential, clinicians should strongly advise the use of effective contraception and should obtain a pregnancy test before initiating treatment.

Change 3. Under Antiretroviral Drugs to Avoid as PEP Components, revised text to state that Efavirenz is not recommended as part of an initial PEP regimen for several reasons (reasons enumerated in text).

PEP for Exposed Workers Who are Pregnant or Breastfeeding

Change 4. Added the following note at the beginning of the section:

⇨ Note: Potential Increased Risk of Neural Tube Defects with Dolutegravir (DTG)-based ART Regimens

On May 18, 2018, the U.S. Food and Drug Administration and the DHHS Antiretroviral Guidelines Panels issued statements in response to preliminary results from a study that reported increased risk of neural tube defects in babies born to mothers were taking dolutegravir (DTG)-based antiretroviral (ARV) drug regimens at the time of conception [1,2]. For exposed workers who are pregnant, considering pregnancy, or not using effective contraception, dolutegravir-containing regimens should be avoided until more data are available. If there are no alternatives for

dolutegravir in individuals of childbearing potential, clinicians should strongly advise the use of effective contraception and should obtain a pregnancy test before initiating treatment (cited AIDSinfo as reference 1 and U.S. Food and Drug Administration as reference 2).

Change 5. Recommendation: The preferred PEP regimen for pregnant individuals is tenofovir disoproxil fumarate + emtricitabine (lamivudine may be substituted for emtricitabine) plus raltegravir (see text for dosing and Antiretroviral Agents Recommended for PEP for additional information). The recommended duration of PEP is 28 days. (AII)

Change 6. With the exception of dolutegravir, the agents listed below are non-preferred agents for use in PEP regimens and are not likely to be used; however, clinicians should be aware that these agents should not be prescribed in exposed workers who are pregnant.

Change 7. Added dolutegravir to the list of drugs to avoid during pregnancy:
Dolutegravir: Teratogenicity; preliminary reports of increased risk of neural tube defects

Source: HIV Clinical Resource, *PEP for Occupational Exposure to HIV Guideline.* Updates to this Guideline. May 2018.

The full NYS Department of Health (2018a) clinical guidelines for HIV post-exposure prophylaxis for healthcare workers can be found at: https://www.hivguidelines.org/pep-for-hiv-prevention/occupational/#