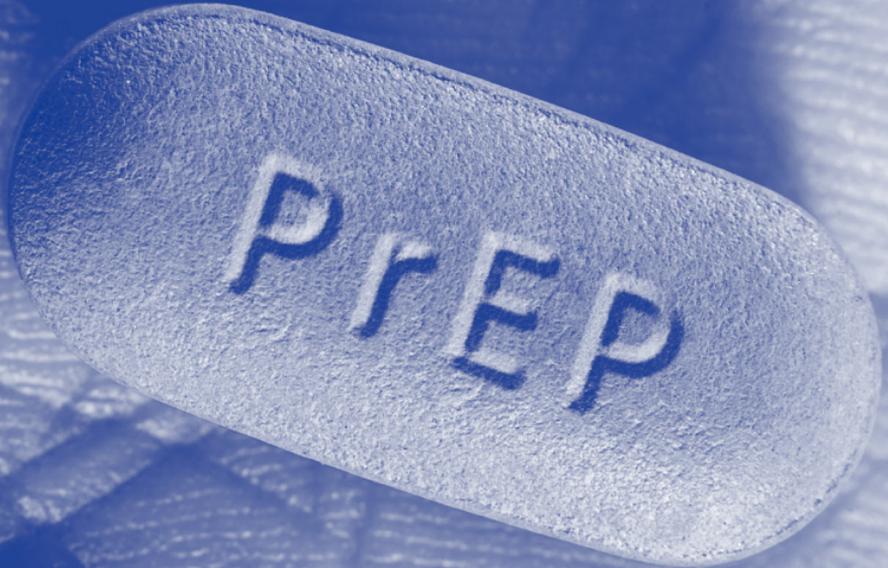


Pre-exposure Prophylaxis for HIV

**(PrEP)** and Special Populations



## Cisgender (non-transgender) women

*Tenofovir disoproxil fumarate-emtricitabine (TDF-FTC) for PrEP is efficacious in cisgender women.* PrEP efficacy among cisgender women in randomized controlled trials varied based on adherence; in one study in which participants were highly adherent, PrEP was highly efficacious<sup>1</sup>, but in two studies of young women with poor adherence, PrEP showed no benefit.<sup>2-3</sup> Tenofovir takes longer to reach maximal tissue concentrations in the cervicovaginal tissue as compared to the rectal tissue, so it is possible that inconsistent medication adherence may diminish efficacy more for cisgender women engaging in vaginal sex than for men who have sex with men (MSM) engaging in anal sex.<sup>4</sup> PrEP does not decrease the efficacy of hormonal contraception, and vice versa.<sup>5-6</sup>

## Transgender women

*PrEP probably reduces the risk of HIV infection in transgender women, but data for this population are limited.* No randomized trials of PrEP have focused on transgender women, despite the high risk for HIV infection in this population. However, PrEP effectively reduces HIV transmission from both vaginal and anal sex and is thus anticipated to be effective among transgender women. A post-hoc analysis of a small group of transgender women in one PrEP trial found no benefit to TDF-FTC; however, most transgender women in the study were not adherent to the medication.<sup>7</sup> No transgender women who had tenofovir drug levels consistent with taking 4 doses of PrEP per week contracted HIV, suggesting that PrEP reduces HIV infection in transgender women with good adherence. Many transgender women take hormonal treatments (estradiol and anti-androgens such as spironolactone) for gender affirmation, and some have raised concerns about the possibility of interactions between PrEP and hormones.<sup>8</sup> However, there are no known or anticipated interactions between TDF-FTC and either estradiol or anti-androgens.<sup>7</sup> Clinicians should consider PrEP for transgender women who have a high risk of infection.

## People who are trying to conceive or who are pregnant

*PrEP may benefit people who are pregnant and at high risk of HIV infection or who are in a serodifferent relationship and attempting to conceive.* PrEP is one option to help reduce the risk of HIV transmission for HIV-serodifferent, heterosexual couples attempting conception in which the male partner is HIV-infected and the female partner is not<sup>4</sup>, although the utility of PrEP in this setting is likely low if the male partner is virologically suppressed on antiretroviral therapy and condomless sex is limited to the time of ovulation.<sup>9</sup> In addition, PrEP can be used by pregnant women who have a high, ongoing risk of HIV infection.<sup>4</sup> Clinicians should counsel patients who are pregnant or who are trying to become pregnant that no major safety concerns with TDF-FTC for PrEP in pregnancy have been identified<sup>10</sup> but that experiences with the medication in this context are limited.



## Adolescents

*Clinicians can consider prescribing PrEP to adolescents at high risk of HIV infection.* In 2018, TDF-FTC for PrEP was approved by the Food and Drug Administration for adolescents weighing at least 35 kilograms. Some adolescents, especially young MSM of color, are at very high risk of HIV infection and might thus benefit from PrEP.<sup>11</sup> Two observational studies of young MSM showed that PrEP was generally safe and well-tolerated but that medication adherence was poor.<sup>12-13</sup> Concerns have also been raised about the effect of TDF-FTC on bone mineral density in young people who are still growing. Use of PrEP in adolescents requires careful consideration of the benefits and risks of the medication, knowledge of local laws as they apply to parental consent for interventions such as PrEP, and, in many cases, intensive adherence support.

## People with HIV-infected sexual partners

*The benefit of PrEP may be minimal for people who are in monogamous sexual relationships with HIV-infected but virologically suppressed partners.* PrEP can help protect the HIV-uninfected partner in a serodifferent relationship from contracting HIV, especially when the HIV-infected partner is not virologically suppressed on antiretroviral therapy.<sup>1</sup> Whether or not PrEP would benefit an HIV-uninfected person who is in a monogamous sexual relationship with an HIV-infected partner who is virologically suppressed on antiretroviral therapy is not known. However, a large randomized controlled trial of people in heterosexual serodifferent relationships<sup>14</sup>, as well as a large observational study of both heterosexual and MSM serodifferent couples<sup>15</sup>, indicated that people living with HIV who are virologically suppressed are not sexually infectious. However, PrEP may still be indicated for the HIV-uninfected partner in such couples if that person engages in sexual activity with people outside of the partnership.

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