Introduction

The CDC published HIV Pre-Exposure Prophylaxis (PrEP) Guidelines for use of Truvada in 2012 and has championed its use as a way to help prevent HIV infections in populations at high risk for sex-related acquisition of the virus.

The CDC PrEP Fact Sheet states that “…for some individuals at very high risk for sexual exposure to HIV, PrEP may represent a much-needed additional prevention method…PrEP…requires strict adherence to daily medication and regular HIV testing. It is not intended to be used in isolation, but rather in combination with other HIV prevention measures.”

PrEP is not a “morning after” or other post-exposure remedy. There are separate guidelines for post-exposure prophylaxis which will not be discussed here.

Internet sources suggest the cost of PrEP with Truvada – not counting ongoing HIV testing and medical protocol supervision – costs $8,000-14,000 per year. Many health insurers are apparently covering the protocol cost if an insured is prescribed PrEP based on CDC recommendations. That said, Life and Disability insurers can expect to see applicants for life and/or disability insurance coverage(s) from individuals who include PrEP as a part of their health care regimen.

The Truvada PrEP Protocol

Truvada is a once-per-day combination of two well-known anti-retroviral medications (tenofovir and emtricitabine) in a single pill. It is frequently used to treat (i.e., suppress viral replication) in persons with HIV infection. For persons already infected with HIV, Truvada may be one key component within a multi-drug HIV treatment regimen.

Since 2012, Truvada alone can also be prescribed for use as a single, pre-exposure prophylactic (PrEP) pill to help prevent an HIV(–) individual from acquiring HIV infection if exposed to HIV via activities known to carry high risk for HIV transmission.

PrEP with Truvada is typically prescribed when an HIV(–) person is considered at higher than usual risk for acquiring HIV infection. Some example exposure situations might include being an HIV (–) intimate partner of an HIV (+) individual, an HIV (–) person providing regular complete care for a cognitively or psychiatically impaired individual with HIV infection, or an HIV (–) person anticipating higher risk activity with a person or persons of unknown HIV status.

According to the manufacturer, to be optimally effective, Truvada must be taken daily as prescribed. The drug is known to be highly effective at preventing infection with HIV but is not 100% effective. It is thus recommended by CDC and the manufacturer that those using this drug for PrEP: (a) take it only as prescribed; (b) begin the regimen well before HIV exposure is likely; (c) adhere to CDC recommended HIV transmission prevention guidelines (safer sex practices, blood and body fluid precautions, etc.) and (d) be followed routinely by the prescribing physician (see below).

The Truvada protocol requires routine medical follow-up – to be re-checked for HIV status every three months (since Truvada alone would be inadequate therapy if HIV acquisition has occurred) as well as be periodically monitored for renal function (serum BUN and creatinine) and serum cholesterol, etc. Periodic liver function testing (LFT’s) may also be indicated.

Truvada is generally well tolerated but, as with any medication, there is potential for side effects which affect a small percentage (<10%) of users. These may include GI upset (nausea, diarrhea), constitutional
symptoms (fatigue), headache, dizziness, depression, disordered sleep, etc. Abnormalities of cholesterol, liver and renal function tests can occur. Some persons can become allergic to a component of the drug. As with any medicine regimen, side effects as well as medication and follow-up costs may affect compliance or ability to tolerate or continue the medication.

A rare but serious illness – lactic acidosis with severe hepatomegaly (liver enlargement) and steatosis (severe fatty liver) has been reported (seen in a very small number of patients, mostly in obese females treated for actual HIV infection with this drug). To date, this syndrome has not been reported in persons taking Truvada on a prophylactic basis.

Truvada has not been around for very long thus possible effects of prolonged use for pre-exposure prophylaxis are unknown.

Potential Concerns for Life, Disability Insurers Associated with PrEP with Truvada

Use of Truvada PrEP indicates some real or perceived increased risk of acquiring HIV infection.

PrEP with Truvada, when taken as prescribed and coupled with compliance with other preventative measures, can be very effective in reducing the risk of HIV infection.

- **Acquisition of HIV while on PrEP treatment** – very low risk* but not zero (* if protocol-compliant, risk of HIV infection is presumably significantly lower than if not taking the medication)

- **Disabling side effect of medication** – low risk – most persons tolerate this medication and most side effects are reversible if medication is stopped; side effects might be problematic for DI coverage if side effects affect ability to carry out occupational duties and proposed insured continues to take the medication despite side effect

- **Medication discontinued or not taken as prescribed,** e.g., discontinuing or inability to tolerate or comply with the medication regimen – risk for HIV acquisition will depend on adherence to other HIV transmission prevention guidelines which can be quite effective, if properly applied and compliant.

Underwriting Applicants Utilizing PrEP with Truvada

**All Cases – Individual Consideration**

- Consult your Legal Department to ensure underwriting is consistent with the company’s guidelines and any applicable laws or regulations

- Review full medical records including current routine insurance labs (HIV, Creatinine, LFT’s, UA, etc.):

  - Consider no offer if indications of impaired renal or liver function, substance abuse, major depression, coincident chronic hepatitis B or C infection, ongoing participation in high risk activities without CDC recommended precautions, compliance issues (medication use, compliance with CDC recommendations for medical supervision and follow-up testing, etc.)

  - If PrEP medication recently started, suggest period of postponement for three-six months since starting Truvada to document that medication is being well tolerated (no/minimal side effects) and compliance with protocol can be demonstrated.

  - If PrEP medication recently discontinued (at time of app) due to side effects or other reasons, PP three-six months to document resolution of side effects before offering.

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