PHARMACY FRIDAY PEARLS

A PHARMACY EDUCATIONAL SERIES

PHARMACYFRIDAY.COM

Non-Occupational Post-Exposure Prophylaxis (nPEP) and Cost Considerations

Introduction

1. Many medications for treatment and prophylaxis of are brand-name only and can come with a significant cost for both insured and uninsured patients. Price may be a significant barrier for appropriate treatment and patient compliance.
    a. Patient Assistance Programs (PAP) are valuable resources that may help physicians make therapy decisions when cost is a significant barrier
    b. Not all guideline recommended therapies have patient assistance programs, and newer combination products designed to improve adherence that do not have FDA-indications for nPEP are being considered as alternative therapies, although data to support their use is lacking

Pharmacotherapy				
	Truvada + Isentress or Tivicay* (first-line)	**Truvada + Prezista + Norvir**	**Stribild (guideline alternative)**	**Genvoya**
Generic Combination	tenofovir DF 300mg / emtricitabine 200mg + raltegravir 400mg or dolutegravir 50mg	tenofovir DF 300mg / emtricitabine 200mg + darunavir 800mg + Ritonavir 100mg	tenofovir DF 300mg / emtricitabine 200mg / elvitegravir 150mg / cobicistat 150mg	Tenofovir alafenamide 10mg / emtricitabine 200mg / elvitegravir 150mg / cobicistat 150mg
Mechanism	Nucleoside reverse transcriptase inhibitor (x 2) + integrase inhibitor	Nucleoside reverse transcriptase inhibitor (x 2) + protease inhibitor (x 2)	Nucleoside reverse transcriptase inhibitor (x 2) + integrase inhibitor + cytochrome P450 inhibitor	Nucleoside reverse transcriptase inhibitor (x 2) + integrase inhibitor + cytochrome P450 inhibitor
Administration	Truvada daily + Isentress BID or Tivicay daily (2-3 tabs per day)	Truvada, Prezista, and Norvir daily (3 tabs per day)	Daily (1 tab per day)	Daily (1 tab per day)
Length of Therapy	28 Days			
Considerations	All regimens require adjustments for renal dysfunction. Not all products are safe for pregnancy			
Price for treatment course (with GoodRx coupon)	Truvada: $1,825.63 Isentress: $1,639.03 Tivicay: $1,810.03	Truvada: $1,825.63 Prestiza: $1,750.12 Norvir (generic): $53.11	$3,359.20	$3,202.66
PAP available?	Truvada: YES: Gilead Advancing Access Isentress: YES Merck Tivicay: YES ViiV Connect	Truvada: YES: Gilead Advancing Access Prestiza: Possible through outside organization Ritonavir: NO	POSSIBLY Through hospital-specific programs	YES Gilead Advancing Access

***It is important to note that many patients will not meet requirements for a PAP, especially if they have any type of primary insurance coverage**
***Even if patient has insurance coverage, brand-name medications may not be covered by plan and alternatives may need to be considered**

Jlpruitt@gmh.edu; kmfifer@gmh.edu

CDC 2016 Guidelines Recommendations

Table 5. Preferred and alternative antiretroviral medication 28-day regimens for nPEP[a,b]

Age group	Preferred/ alternative	Medication
Adults and adolescents aged ≥ 13 years, including pregnant women, with normal renal function (creatinine clearance ≥ 60 mL/min)	**Preferred**	A 3-drug regimen consisting of tenofovir DF 300 mg ***and*** fixed dose combination emtricitabine 200 mg (Truvada[c]) once daily ***with*** raltegravir 400 mg twice daily ***or*** dolutegravir 50 mg once daily
	Alternative	A 3-drug regimen consisting of tenofovir DF 300 mg ***and*** fixed dose combination emtricitabine 200 mg (Truvada) once daily ***with*** darunavir 800 mg (as 2, 400-mg tablets) once daily ***and*** ritonavir[b] 100 mg once daily
Adults and adolescents aged ≥ 13 years with renal dysfunction (creatinine clearance ≤59 mL/min)	**Preferred**	A 3-drug regimen consisting of zidovudine ***and*** lamivudine, with both doses adjusted to degree of renal function ***with*** raltegravir 400 mg twice daily ***or*** dolutegravir 50 mg once daily
	Alternative	A 3-drug regimen consisting of zidovudine ***and*** lamivudine, with both doses adjusted to degree of renal function ***with*** darunavir 800 mg (as 2, 400-mg tablets) once daily ***and*** ritonavir[b] 100 mg once daily

Overview of Evidence

Author, year	Design/ sample size	Intervention & Comparison	Outcome
Valin 2016	Prospective cohort N = 234	Stribild tolerability in PEP	92% of patients completed 28 days of therapy. 60% reported at least one ADR but were mild to moderate, with only 3 people switching regimens.
Mayer 2017	Historical Control Comparison N =100	Completion rates of daily Stribild vs. historical treatment (BID)	71% completed the course in the Stribild group vs. 57% and 39% in both historical control group regimens. No participants became HIV infected.
Inciarte 2017	Prospective open randomized trial N = 157	Truvada + lopinavir/ritonavir or elvitegravir/cobicistat	The lopinavir/ritonavir group had a higher PEP non-completion rate (33%), poor adherence (47%), and ADR rate (90%) than the elvitegravir/cobicstat group (15%, 9% and 49%, respectively). 1 seroconversion was observed in the elvitegravir/cobicstat group in a patient with multiple high-risk exposures before and after PEP.

Conclusions

1. Any patient experiencing possible HIV exposure should be evaluated for appropriateness of nPEP
    a. Prophylaxis is only recommended if initiated within 72 hours of exposure
    b. Rapid Ag/Ab or antibody blood should be tested. Patients should not receive nPEP if HIV status is positive.
    c. All Patients should be treated with a minimum of a 3-drug antiviral regimen if they meet criteria for prophylaxis
2. Patients' financial situation should always be considered prior to prescribing therapy to ensure patients will be able to obtain access to treatment and prophylaxis. Addressing cost concerns prior to discharge may aid in patient compliance, even if alternative therapies need to be utilized.

References

1. CDC. 2016 nPEP Guideline Update.
2. Mayer KH, et al. *J Acqur Immune Defic Syndr*. 2017;15:75(5):535-39.
3. Valin N, et al. *BMC Infect Dis*. 2016. doi: 10.1186/s12879-016-2056-3.
4. Inciarte A, et al. *J Antimicrob Chemother*. 2017;72:2857-61.
5. Micromedex [Electronic version].Greenwood Village, CO: Truven Health Analytics. Retrieved June 5, 2020, from http://www.micromedexsolutions.com/

Jlpruitt@gmh.edu; kmfifer@gmh.edu