Clinical Pathways

HIV PEP (Post-Exposure Prophylaxis)

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Connecticut Children's

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What is a Clinical Pathway?

An evidence-based guideline that decreases unnecessary variation and helps promote safe, effective, and consistent patient care.

Objectives of Pathway

- Ensure that all patients who are potentially exposed to HIV receive prompt and appropriate anti-retroviral therapy to decrease their risk of becoming infected with the virus and developing HIV/AIDS
- Ensure that all patients potentially exposed to HIV have the appropriate baseline laboratory testing
- To ensure appropriate follow up and monitoring for patients potentially exposed to HIV

Why is Pathway Necessary?

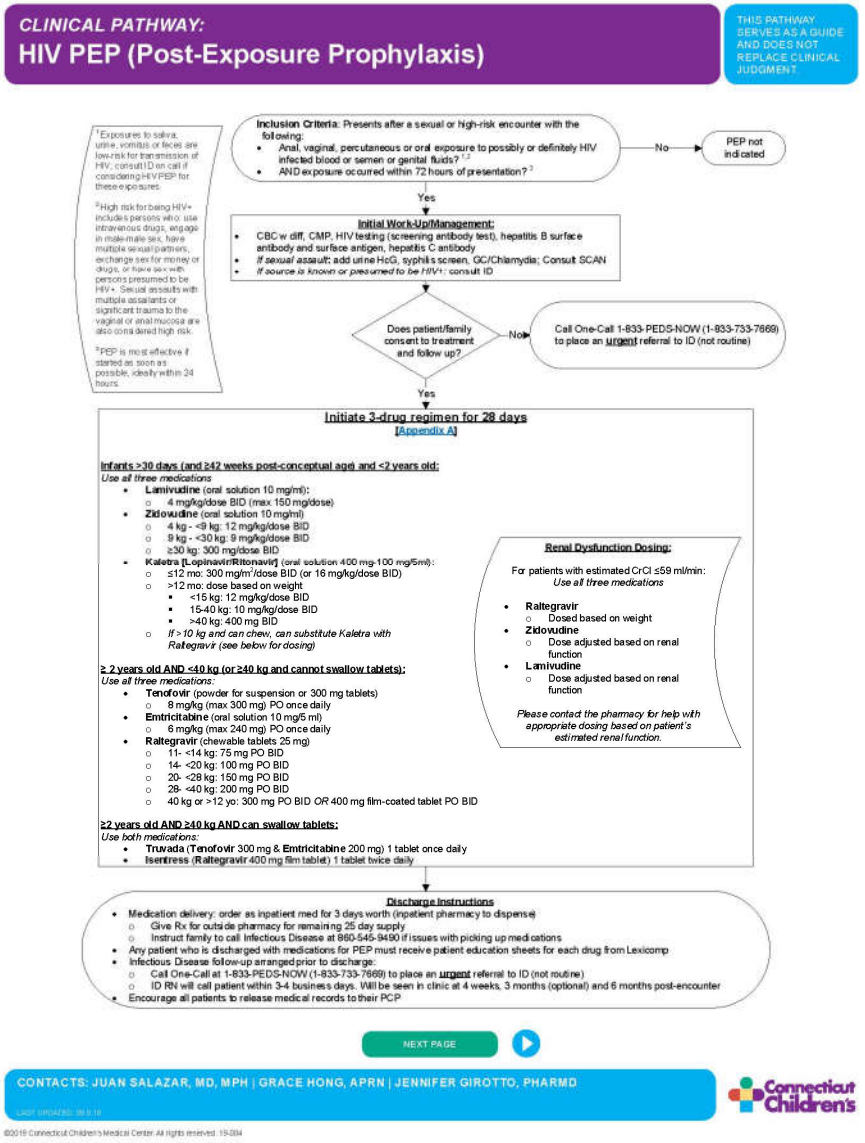
- Timely and appropriate anti-HIV regimens can decrease the risk of patients acquiring HIV
- Many anti-HIV medications may not be readily available at local pharmacies (especially pediatric dosage forms) – ensuring patients have an adequate supply of medication is crucial
- Ensure that patients have appropriate treatment and necessary work up
- Ensure that patients have appropriate follow up in place
- In 2016, CDC published new guidelines for non-occupational HIV PEP

Background

- In 2016, CDC updated their guidelines for Antiretroviral Post-Exposure Prophylaxis for Non-Occupational HIV exposures [1]
  - Outlines specific parameters for starting HIV PEP
  - Outlines specific baseline laboratory work up
  - Outlines only using a 3-drug regimen when HIV PEP is indicated
- 3 drug regimens are preferred because of:
  - Maximal suppression of viral replication
  - Greater protection against acquiring resistant virus
  - Increased likelihood of successful prophylaxis with resistance mutations
  - More likely to limit emergence of resistance
  - Ensures maximal protection for the population who may have poor follow up

This is the HIV PEP Clinical Pathway.

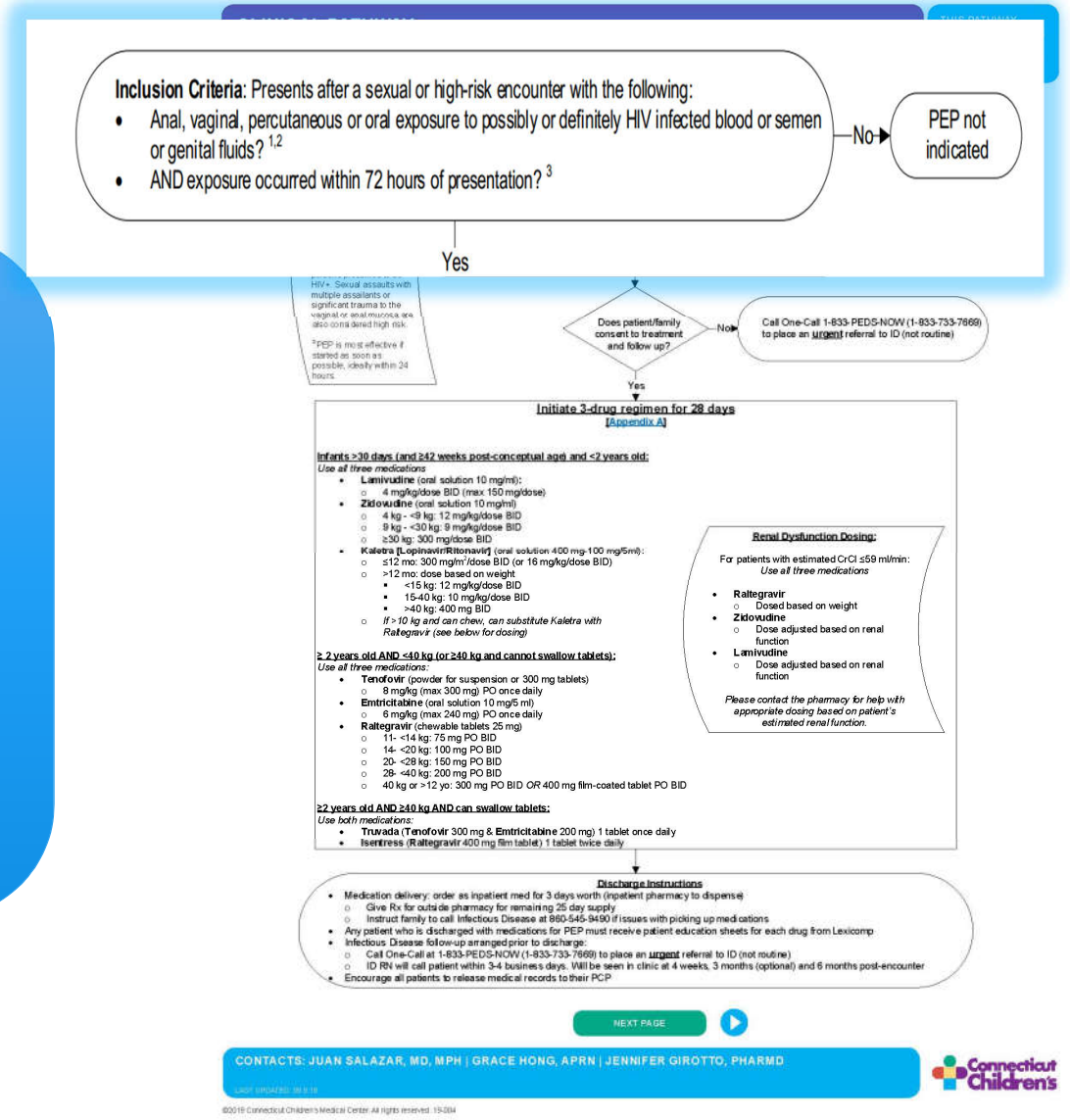
We will be reviewing each component in the following slides.



This pathway focuses on non-occupational exposure to HIV.

Exposure to saliva, urine, vomitus or feces is actually low-risk for transmission of HIV. You can consult ID if considering PEP for these exposures.

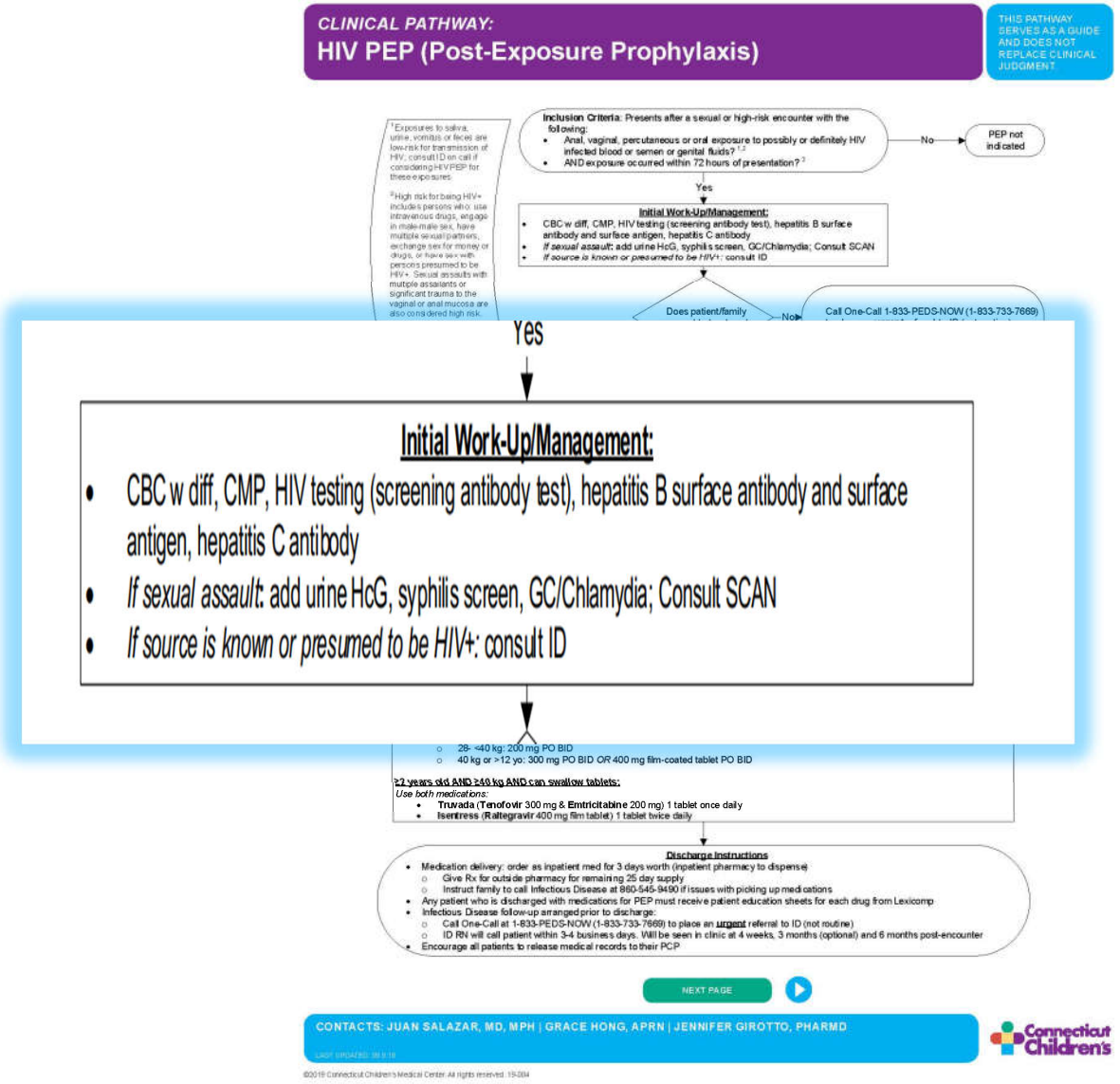
HIV PEP is the most effective within 72 hours of encounter (it is the best within 24 hours). Beyond this period, HIV PEP is unlikely to prevent HIV transmission.



The initial work up includes baseline laboratory tests.

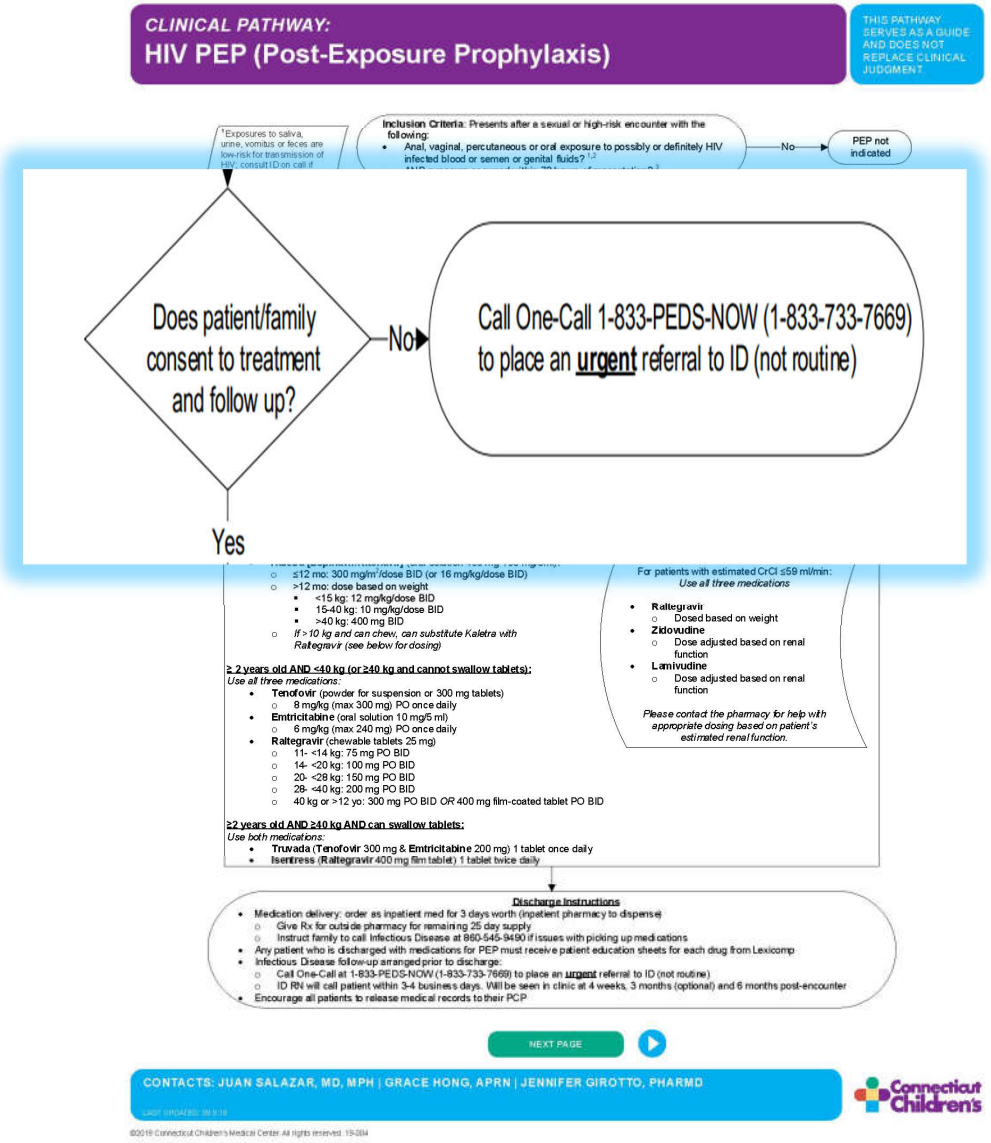
If we know there is a sexual assault – remember to consult SCAN team.

If source is known or presumed to be HIV+: consult ID to help determine optimal regimen.



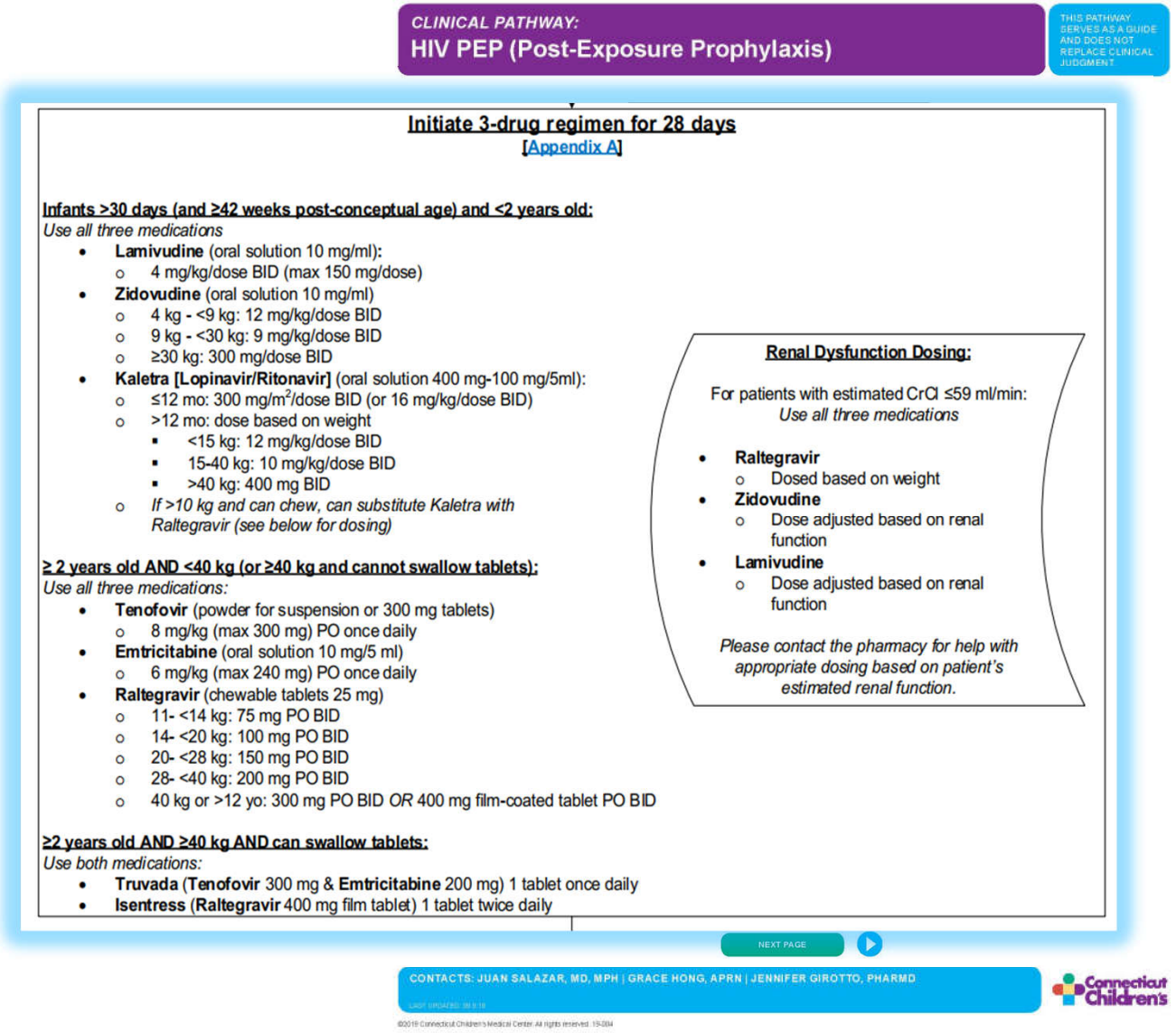
If the family does not consent to treatment, place an URGENT referral to ID via One-Call.

The outpatient ID team will ensure appropriate education and testing.



The new CDC guidelines point to a 3 drug regimen for HIV PEP (instead of the previously recommended 2 drug regimen that was based on risk stratification).

The recommended medications are divided out based on age, weight, and ability to swallow tablets. It no longer differentiates between puberty classification.



CLINICAL PATHWAY:
HIV PEP (Post-Exposure Prophylaxis)

THIS PATHWAY SERVES AS A GUIDE AND DOES NOT REPLACE CLINICAL JUDGMENT

Initiate 3-drug regimen for 28 days
[Appendix A]

Infants >30 days (and ≥42 weeks post-conceptual age) and <2 years old:
Use all three medications

- **Lamivudine** (oral solution 10 mg/ml):
  - 4 mg/kg/dose BID (max 150 mg/dose)
- **Zidovudine** (oral solution 10 mg/ml)
  - 4 kg - <9 kg: 12 mg/kg/dose BID
  - 9 kg - <30 kg: 9 mg/kg/dose BID
  - ≥30 kg: 300 mg/dose BID
- **Kaletra [Lopinavir/Ritonavir]** (oral solution 400 mg-100 mg/5ml):
  - ≤12 mo: 300 mg/m^2/dose BID (or 16 mg/kg/dose BID)
  - >12 mo: dose based on weight
    - <15 kg: 12 mg/kg/dose BID
    - 15-40 kg: 10 mg/kg/dose BID
    - >40 kg: 400 mg BID
  - *If >10 kg and can chew, can substitute Kaletra with Raltegravir (see below for dosing)*

≥ 2 years old AND <40 kg (or ≥40 kg and cannot swallow tablets):
Use all three medications:

- **Tenofovir** (powder for suspension or 300 mg tablets)
  - 8 mg/kg (max 300 mg) PO once daily
- **Emtricitabine** (oral solution 10 mg/5 ml)
  - 6 mg/kg (max 240 mg) PO once daily
- **Raltegravir** (chewable tablets 25 mg)
  - 11- <14 kg: 75 mg PO BID
  - 14- <20 kg: 100 mg PO BID
  - 20- <28 kg: 150 mg PO BID
  - 28- <40 kg: 200 mg PO BID
  - 40 kg or >12 yo: 300 mg PO BID *OR* 400 mg film-coated tablet PO BID

≥2 years old AND ≥40 kg AND can swallow tablets:
Use both medications:

- **Truvada** (**Tenofovir** 300 mg & **Emtricitabine** 200 mg) 1 tablet once daily
- **Isentress** (**Raltegravir** 400 mg film tablet) 1 tablet twice daily

Renal Dysfunction Dosing:

For patients with estimated CrCl ≤59 ml/min:
Use all three medications

- **Raltegravir**
  - Dosed based on weight
- **Zidovudine**
  - Dose adjusted based on renal function
- **Lamivudine**
  - Dose adjusted based on renal function

Please contact the pharmacy for help with appropriate dosing based on patient's estimated renal function.

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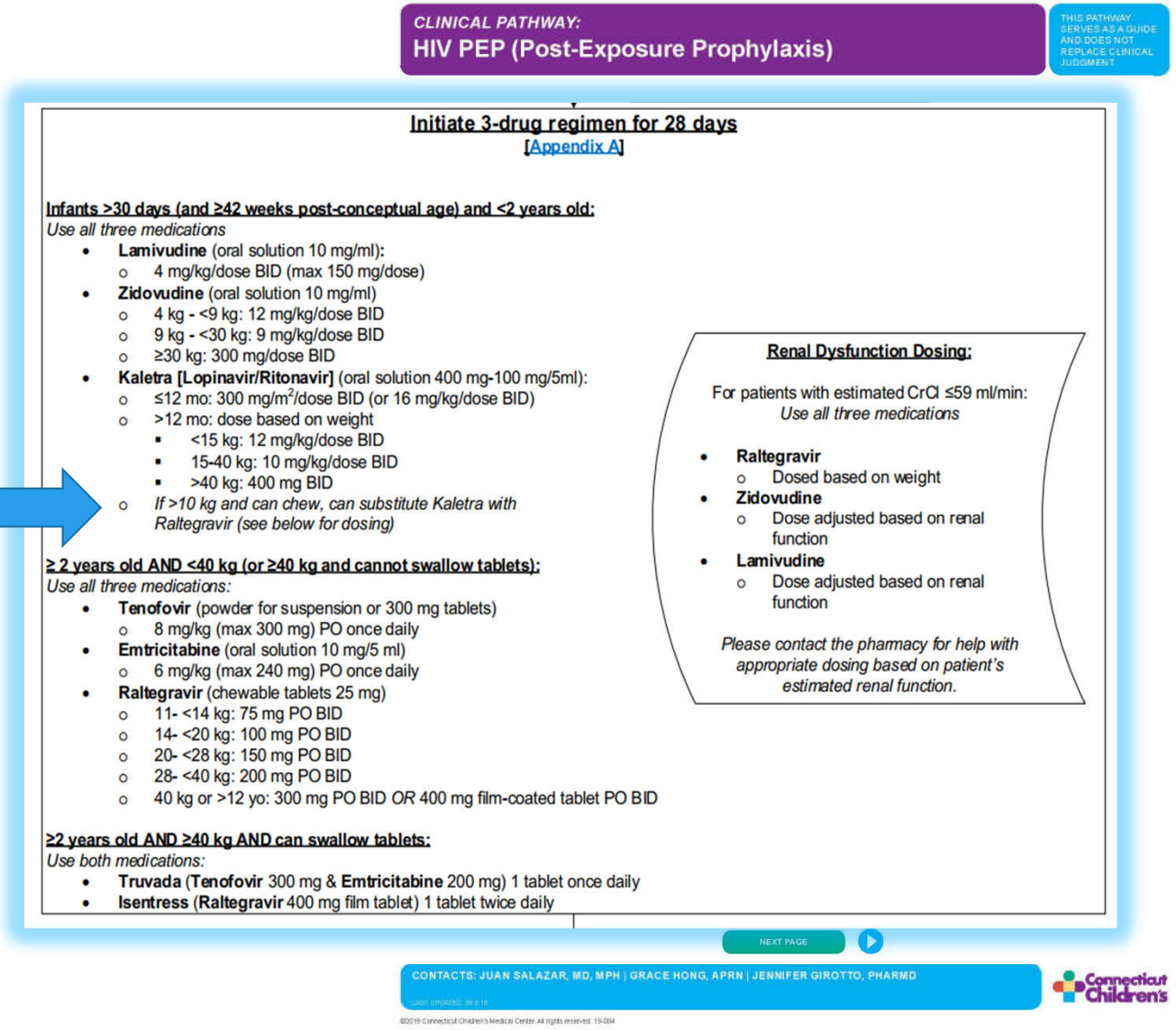
For those <2 years old and >10 kg and can chew: using raltegravir is much more tolerable than Kaletra.



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≥2 years old AND ≥40 kg AND can swallow tablets:
Use both medications:

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- **Isentress** (**Raltegravir** 400 mg film tablet) 1 tablet twice daily

Renal Dysfunction Dosing:

For patients with estimated CrCl ≤59 ml/min:
Use all three medications

- **Raltegravir**
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- **Zidovudine**
  - Dose adjusted based on renal function
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Please contact the pharmacy for help with appropriate dosing based on patient's estimated renal function.

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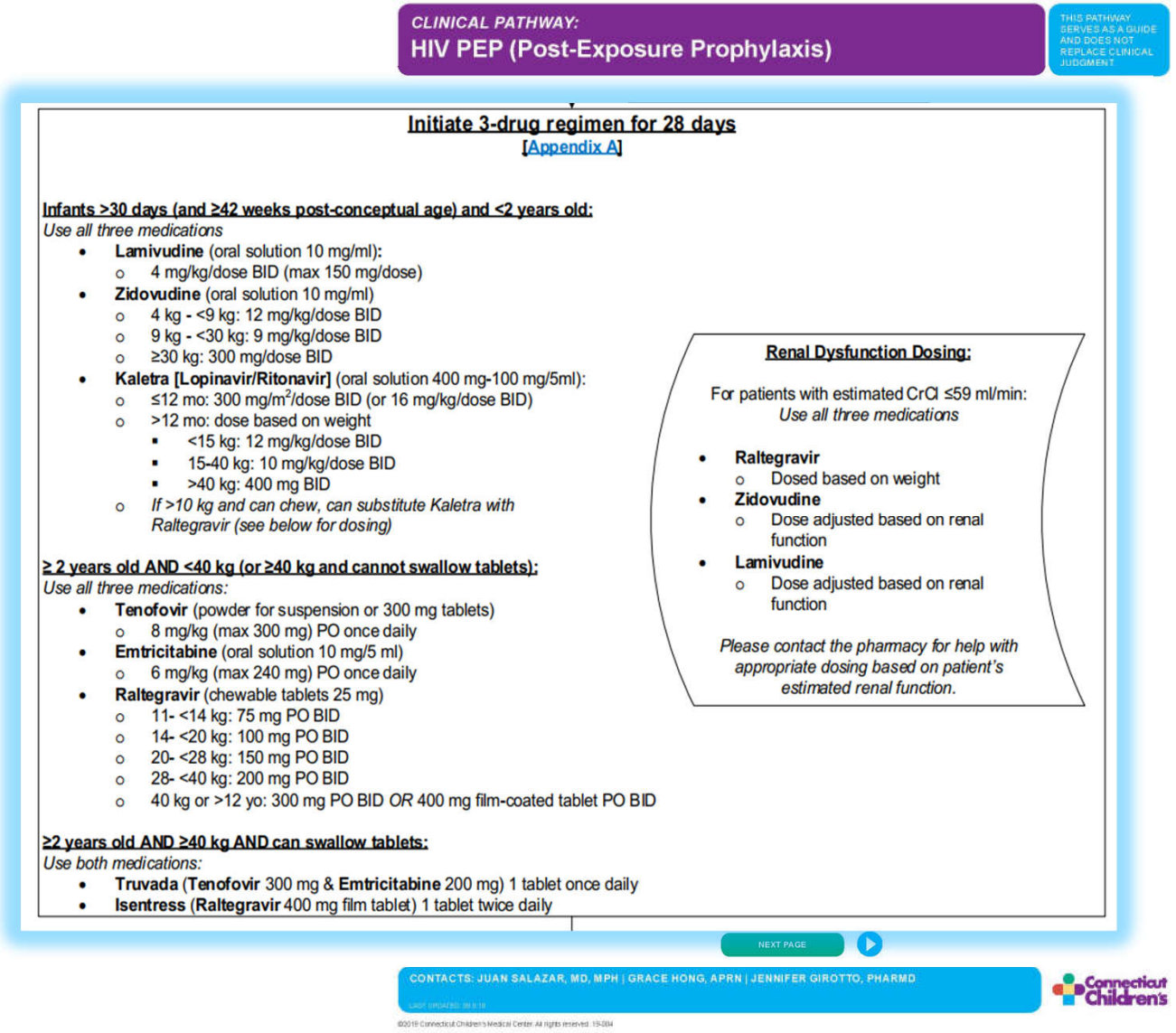
If there is renal dysfunction noted (CrCl ≤59 ml/min), the 3 drug regimen is outlined on the pathway.

It is important to contact the pharmacy for help to determine the appropriate dosing as it is based on the individual patient's estimated renal function.



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Use both medications:

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Renal Dysfunction Dosing:

For patients with estimated CrCl ≤59 ml/min:
Use all three medications

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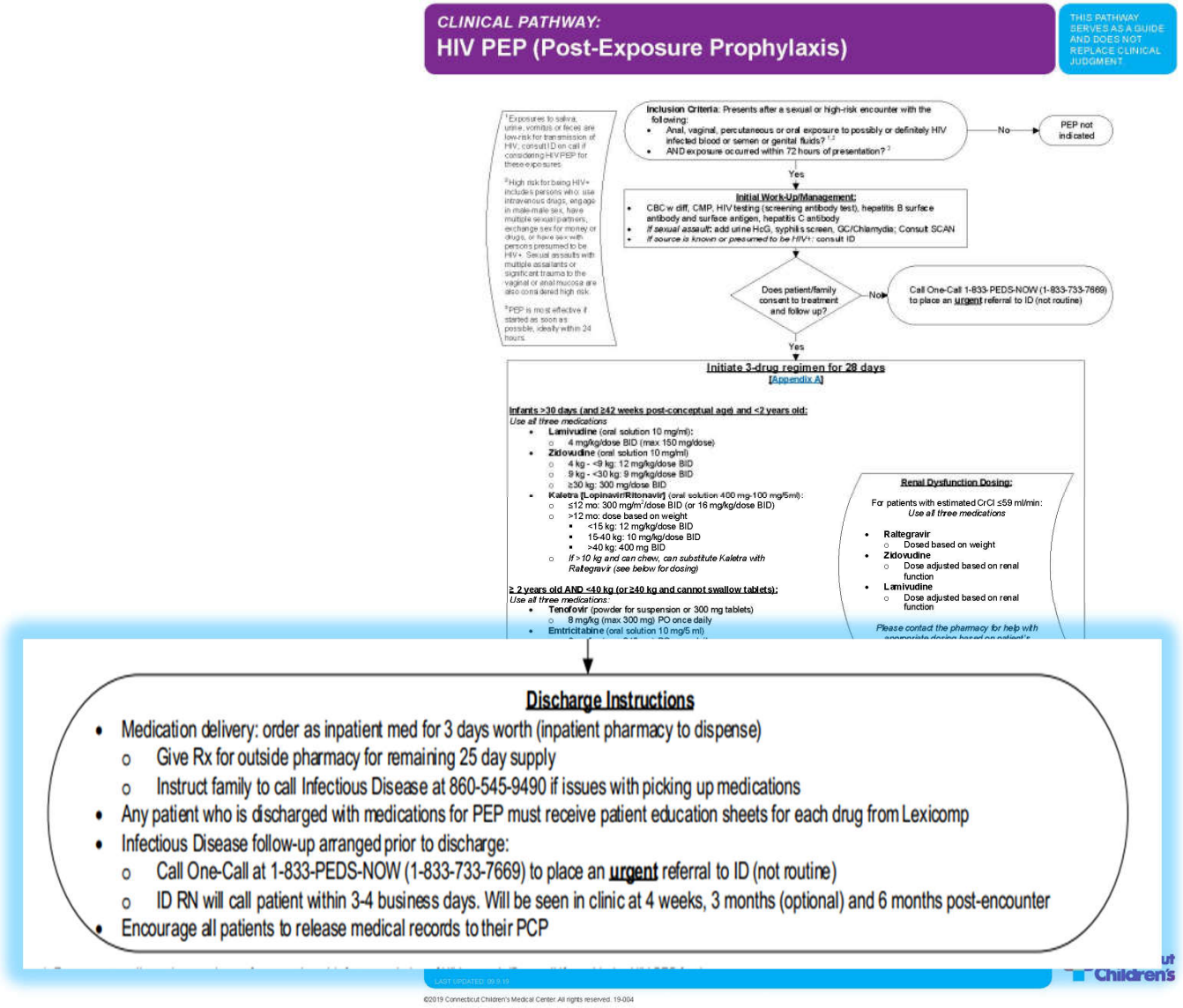
It is often difficult to find an appropriate supply for HIV PEP medications at outside pharmacies.

Our inpatient pharmacy will give 3 days worth of medication to the patient, with the remaining 25 day supply being sent to the outside pharmacy (so that they have a few days to fill the medication).

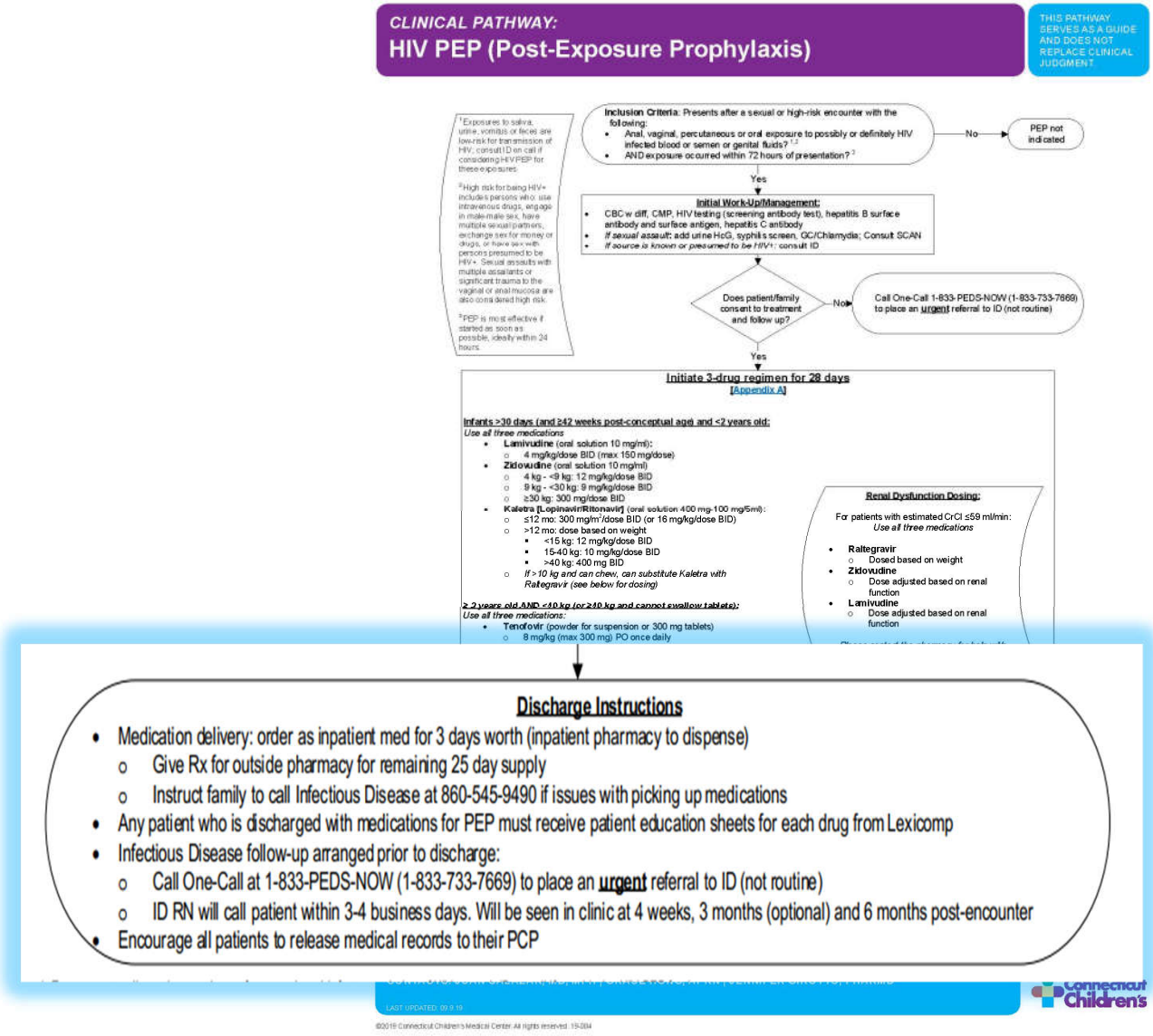
If there are issues with the outpatient medications, the family should be instructed to contact ID for help.



ID follow up MUST be arranged prior to discharge. This is imperative – patients who start on HIV PEP often get lost to follow up.

Place an URGENT referral to ID via the One-Call system. This will put them on top of ID's patient queue and allow our staff to arrange follow up appropriately. ID will coordinate care with their PCP and SCAN as appropriate.

It is helpful if the ED can encourage all patients to release medical records to their PCP in case the patient is lost to follow up here.



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[1]Exposures to saliva, urine, vomitus or feces are low-risk for transmission of HIV; consult ID on call if considering HIV PEP for these exposures.

[2]High risk for being HIV+ includes persons who: use intravenous drugs, engage in male-male sex, have multiple sexual partners, exchange sex for money or drugs, or have sex with persons presumed to be HIV+. Sexual assaults with multiple assailants or significant trauma to the vaginal or anal mucosa are also considered high risk.

[3]PEP is most effective if started as soon as possible, ideally within 24 hours.

Inclusion Criteria: Presents after a sexual or high-risk encounter with the following:
- Anal, vaginal, percutaneous or oral exposure to possibly or definitely HIV infected blood or semen or genital fluids? [1,2]
- AND exposure occurred within 72 hours of presentation? [3]

No → PEP not indicated

Yes

Initial Work-Up/Management:
- CBC w diff, CMP, HIV testing (screening antibody test), hepatitis B surface antibody and surface antigen, hepatitis C antibody
- *If sexual assault:* add urine HcG, syphilis screen, GC/Chlamydia; Consult SCAN
- *If source is known or presumed to be HIV+:* consult ID

Does patient/family consent to treatment and follow up? No → Call One-Call 1-833-PEDS-NOW (1-833-733-7669) to place an **urgent** referral to ID (not routine)

Yes

Initiate 3-drug regimen for 28 days
[Appendix A]

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Use all three medications
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  - *If >10 kg and can chew, can substitute Kaletra with Raltegravir (see below for dosing)*

≥ 2 years old AND <40 kg (or ≥40 kg and cannot swallow tablets):
Use all three medications:
- **Tenofovir** (powder for suspension or 300 mg tablets)
  - 8 mg/kg (max 300 mg) PO once daily

Renal Dysfunction Dosing:
For patients with estimated CrCl ≤59 ml/min:
Use all three medications
- **Raltegravir**
  - Dosed based on weight
- **Zidovudine**
  - Dose adjusted based on renal function
- **Lamivudine**
  - Dose adjusted based on renal function

Discharge Instructions
- Medication delivery: order as inpatient med for 3 days worth (inpatient pharmacy to dispense)
  - Give Rx for outside pharmacy for remaining 25 day supply
  - Instruct family to call Infectious Disease at 860-545-9490 if issues with picking up medications
- Any patient who is discharged with medications for PEP must receive patient education sheets for each drug from Lexicomp
- Infectious Disease follow-up arranged prior to discharge:
  - Call One-Call at 1-833-PEDS-NOW (1-833-733-7669) to place an **urgent** referral to ID (not routine)
  - ID RN will call patient within 3-4 business days. Will be seen in clinic at 4 weeks, 3 months (optional) and 6 months post-encounter
- Encourage all patients to release medical records to their PCP

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Appendix A is a chart derived from the CDC guidelines.

It reviews all of the medications recommended for HIV PEP, including available formulations, side effects, contraindications, cautions, and dose adjustments.

Formulations, cautions, and dose adjustments for antiretroviral medications in preferred and alternative nPEP regimens

Drug	Formulation	Side effects, contraindications, and cautions	Dose adjustments
Tenofovir disoproxil fumarate (TDF) (Viread) Also available as component of fixed-dose combination, Truvada (200 mg emtricitabine + 300 mg TDF)	300 mg tablet 40 mg/gm powder	**Side effects:** Asthenia, headache, diarrhea, nausea, vomiting **Contraindications:** Nephrotoxicity; for nPEP, should not be administered to persons with acute or chronic kidney injury or those with eCrCl < 60 mL/min **Cautions:** TDF can be used in nPEP regimens for patients with chronic hepatitis B infection, but hepatic function tests should be closely monitored when regimen is stopped because withdrawal of this drug may cause an acute hepatitis exacerbation.	**Children aged 2–11 years (powder)** • 8 mg/kg body weight • Not to exceed adult dose (300 mg daily) • **Children aged 2–11 years (tablet), per body weight** • 17 to < 22 kg: 150 mg tablet once daily • 22 to < 28 kg: 200 mg tablet once daily • 28 to < 35 kg: 250 mg tablet once daily • ≥ 35 kg: 300 mg tablet once daily • Not to exceed adult dose (300 mg once daily)
Emtricitabine (FTC) (Emtriva) Also available as component of fixed-dose combination, Truvada (200 mg FTC + 300 mg TDF)	200 mg capsule 10 mg/mL oral solution	**Side effects:** Hyperpigmented rash or skin discoloration **Cautions:** FTC can be used in nPEP regimens for patients with chronic hepatitis B infection, but hepatic function tests should be closely monitored when regimen is stopped because withdrawal of this drug might cause an acute hepatitis exacerbation. **Contraindications:** Do not administer with lamivudine	**Children aged 1–3 months (oral solution)** • 3 mg/kg once daily • Not to exceed 240 mg once daily **Children aged 3 months–17 years, per body weight** • 6 mg/kg once daily (oral solution) • ≥ 33 kg: 200 mg tablet once daily • Not to exceed 240 mg once daily
Raltegravir (RAL) (Isentress)	25 mg chewable tablet 100 mg chewable, scored tablet 400 mg tablet	**Side effects:** Insomnia, nausea, fatigue, headache; severe skin and hypersensitivity reactions have been reported **Cautions:** Dosage adjustment required if co-administered with rifampin (800 mg twice daily for adults). Co-administration with antacids, laxatives, or other products containing polyvalent cations (Mg, Al, Fe, Ca, Zn), including iron, calcium, or magnesium supplements; sucralfate; buffered medications; and certain oral multivitamins can reduce absorption of RAL. RAL should be administered ≥ 2 hours before or ≥ 6 hours after administration of cation-containing medications or products, however, RAL can be co-administered with calcium carbonate-containing antacids. **Contraindications:** None	**Children aged 2–12 years (chewable tablets), per body weight** • 11 to < 14 kg: 75 mg twice daily • 14 to < 20 kg: 100 mg twice daily • 20 to < 28 kg: 150 mg twice daily • 28 to < 40 kg: 200 mg twice daily • ≥ 40 kg: 300 mg twice daily **Children aged 6–12 years and weighing > 25 kg** • 400 mg-tablet twice daily **Or** • Chewable tablets twice daily. See table above or chewable tablet dose.

Appendix A is a chart derived from the CDC guidelines.

It reviews all of the medications recommended for HIV PEP, including available formulations, side effects, contraindications, cautions, and dose adjustments.

Drug	Formulation	Side effects, contraindications, and cautions	Dose adjustments
Lopinavir (LPV)/ritonavir (RTV) (Kaletra)	200/50 mg tablets 80/20 mg/mL oral solution	**Side effects:** Nausea, vomiting, diarrhea **Cautions:** PR and QT interval prolongation have been reported. Use with caution with patients at risk for cardiac conduction abnormalities or receiving other drugs with similar effect. Do not administer to neonates before a postmenstrual age (first day of the mother's last menstrual period to birth plus the time elapsed after birth) of ≥ 42 weeks and a postnatal age of ≥ 14 days. **Contraindications:** Co-administration of ritonavir with certain sedative hypnotics, antiarrhythmics, sildenafil, or ergot alkaloid preparations is contraindicated and might result in potentially life-threatening adverse events.	**Children aged 14 days–12 months, per body weight** Suspension (lopinavir/ritonavir) • 16/4 mg/kg or 300/75 mg/m^2 twice daily **Children aged > 12 months–18 years, per body weight** Suspension (lopinavir/ritonavir) • < 15 kg: 12/3 mg/kg twice daily • ≥ 15 kg to 40 kg: 10/2.5 mg/kg twice daily • > 40 kg: 400/100 mg twice daily • Not to exceed the recommended adult dose (400/100 mg [5 mL] twice daily **Children aged > 12 months–18 years** Tablet, weight-based dosing (lopinavir/ritonavir) • 15 to 25 kg: 2 100/25-mg tablets twice daily • > 25 to 35 kg: 3 100/25-mg tablets twice daily • > 35 kg: 4 100/25 mg tablets twice daily or 2 200/50 mg tablets twice daily
Lamivudine (3TC) (Epivir)	150 mg scored tablet 10 mg/mL oral solution	**Side effects:** Headache, nausea, malaise and fatigue, nasal signs and symptoms, diarrhea, and cough **Cautions:** 3TC may be used in nPEP regimens for patients with chronic hepatitis B infection, but hepatic function tests should be closely monitored when regimen is stopped since withdrawal of this drug may cause an acute hepatitis exacerbation. **Contraindications:** Do not administer with emtricitabine	**Children, aged ≥ 4 weeks** Oral solution • 4 mg/kg (maximum dose 150 mg) twice daily **Children aged < 16 years and weighing ≥ 14 kg** Scored 150 mg tablet • 14 to < 20 kg, 75 mg (1/2 tablet) AM + 75 mg (1/2 tablet) PM • 20 to < 25 kg, 75 mg (1/2 tablet) AM + 150 mg (1 tablet) PM • ≥ 25 kg, 150 mg tablet twice daily **Adolescents (aged ≥ 16 years) and adults, per body weight** • < 50 kg: 4 mg/kg (up to 150 mg) twice daily • ≥ 50 kg: 150 mg twice daily or 300 mg once daily

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Drug	Formulation	Side effects, contraindications, and cautions	Dose adjustments
Zidovudine (ZDV; AZT) (Retrovir, ViiV Healthcare, Brentford, Middlesex, United Kingdom)	100-mg capsule 300-mg tablet 10-mg/mL oral syrup	**Side effects:** Nausea, vomiting, headache, insomnia, and fatigue **Cautions:** Can cause anemia and neutropenia	**Infants aged birth–41 days** **Full term (aged ≥ 35 weeks gestation at birth), per body weight** Syrup • 4 mg/kg orally twice daily Intravenous[c] • 3.0 mg/kg, infused over 30 minutes, every 12 hours **Premature (aged ≥ 30 to 35 weeks gestation at birth; from birth through day 14 of life; switch to full term infant dose at 15 days of life), per body weight** Syrup • 2 mg/kg orally twice daily Intravenous[c] • 1.5 mg/kg, infused over 30 minutes, every 12 hours **Premature (aged < 30 weeks gestation at birth; day 14–28 of life; switch to full term infant dose at 29 days[a] of life), per body weight** Syrup • 2 mg/kg orally twice daily Intravenous[c] • 1.5 mg/kg, infused over 30 minutes, every 12 hours **Infants and children aged ≥35 weeks post-conception and at least 4 weeks post-delivery, per body weight** Syrup or Capsules • 4 to < 9 kg, 12 mg/kg twice daily • 9 to < 30 kg, 9 mg/kg twice daily Tablet • ≥ 30 kg, 300-mg tablet twice daily [a] Note: Premature infants exposed to HIV after day 1 of life are switched to full-term infant dose at 29 days of life.

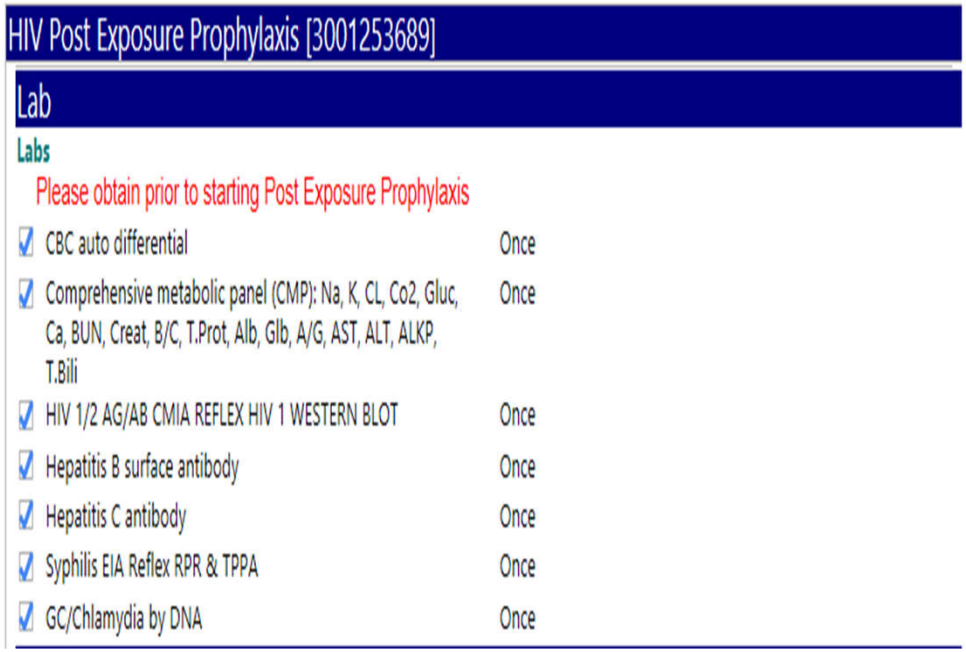
Review of Key Points

- HIV PEP is best started within 72 hours of high-risk exposure.
- Baseline testing should be obtained on all patients.
- A 3-drug regimen is recommended for all patients starting HIV PEP – regardless of risk stratification.
- An URGENT referral to ID outpatient is required for all patients as adequate follow up is needed.

Use of Order Set

This is the order set associated with the HIV PEP Pathway.

It will list all of the recommended labs and medications.



HIV Post Exposure Prophylaxis [3001253689]

Lab

Labs

Please obtain prior to starting Post Exposure Prophylaxis

☑ CBC auto differential	Once
☑ Comprehensive metabolic panel (CMP): Na, K, CL, Co2, Gluc, Ca, BUN, Creat, B/C, T.Prot, Alb, Glb, A/G, AST, ALT, ALKP, T.Bili	Once
☑ HIV 1/2 AG/AB CMIA REFLEX HIV 1 WESTERN BLOT	Once
☑ Hepatitis B surface antibody	Once
☑ Hepatitis C antibody	Once
☑ Syphilis EIA Reflex RPR & TPPA	Once
☑ GC/Chlamydia by DNA	Once

Quality Metrics

- Percentage of patients prescribed the appropriate type medication
- Percentage of patients prescribed medications in the correct dosage
- Percentage of patients all PEP patients having obtained baseline HIV, and Hepatitis B and C testing
- Percentage of patients with sexual assault having obtained Syphilis, Chlamydia, Gonorrhea and HcG (if appropriate) testing
- Percentage of patients with Infectious Disease clinic follow up within 2 months of exposure
- Average length of stay in ED (minutes)

Pathway Contacts

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References

- [1]The Centers for Disease Control and Prevention, U.S. Department of Health and Human Services. Updated Guidelines for Antiretroviral Postexposure Prophylaxis After Sexual, Injection Drug Use, or Other Nonoccupational Exposure to HIV – United States, 2016.

Thank You!

About Connecticut Children's Pathways Program

Clinical pathways guide the management of patients to optimize consistent use of evidence-based practice. Clinical pathways have been shown to improve guideline adherence and quality outcomes, while decreasing length of stay and cost. Here at Connecticut Children's, our Clinical Pathways Program aims to deliver evidence-based, high value care to the greatest number of children in a diversity of patient settings. These pathways serve as a guide for providers and do not replace clinical judgement