

# Antiretroviral Therapy (ART) for HIV Post-Exposure Prophylaxis (HIV PEP)

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The human immunodeficiency virus (HIV) post-exposure prophylaxis (PEP) starter kits are provided by the Saskatchewan Ministry of Health. Human immunodeficiency virus PEP starter kits are located in a variety of health care facilities throughout Saskatchewan (see [Appendix 2 – Saskatchewan Post-Exposure Prophylaxis \(PEP\) Kit Sites](#)).

If HIV PEP is indicated, it is recommended the antiretroviral therapy (ART) medications be initiated as soon as possible.

***Initiation of all medications in the HIV PEP ‘starter kit’\* should not be delayed:***

- HIV PEP should start as soon as possible, *preferably within 2 hours* of the exposure and is unlikely to be of benefit if more than 72 hours post-exposure.
- Adherence to HIV PEP medications is critical for prevention of infection.

\*Refer to [Appendix 5 – Antiretrovirals in HIV PEP Kits](#)

**NOTE:** Genotypic resistance testing of the source patient’s virus at the time of the exposure to confirm the most appropriate HIV PEP regimen is impractical as it may take two or more weeks to obtain the results.

An infectious diseases (ID) Specialist will authorize the remainder of the 28 days course of HIV PEP. A prescription for the balance of the therapy should be given by the attending physician/ID Specialist/RN(NP) to the exposed person if required. This section provides the details for obtaining the balance of HIV PEP medications.

## **Provision of HIV PEP Kit**

The physician or RN(NP) will make the determination if an HIV PEP Kit is recommended. When the ER physician or RN(NP) requires a second opinion on the results of the Risk Assessment, the Medical Health Officer (MHO) or ID Specialist can be consulted to assist in decision-making. When the situation is questionable and access to an ID Specialist is delayed, it is better to start HIV PEP and ensure quick assessment by an ID Specialist to determine the need to continue therapy.

Before dispensing the HIV PEP Kit, the current list of medications the exposed person is on must be reviewed to determine if there are any contraindications. It is ideal to view the prescription history in the Saskatchewan Drug Plan’s electronic Pharmaceutical Information Program (PIP). Refer to [Appendix 5 – Antiretrovirals in HIV PEP Kits](#) for medications and drug interactions.

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## Determine Necessity of Ongoing HIV PEP

The ER physician or RN(NP) doing the initial assessment is required to have a timely phone consultation (within 24 hours) with an ID Specialist so authorization for ongoing HIV PEP can occur (see note below). If the initial or ongoing risk assessment indicates that HIV PEP should be continued, the full treatment period is 28 days.

The HIV PEP Kit includes 3 days of medication.<sup>8</sup> The remaining course for HIV PEP medications can be obtained with a prescription. Access to HIV PEP medications from a community pharmacy, if the pharmacy does not have the medication in stock, may take approximately 2 days.

### Decision for Ongoing HIV PEP

The final determination for ongoing HIV PEP is made in consultation with an ID Specialist at the time of the exposure.

The ID Specialist will provide recommendations on the appropriate HIV PEP medications.

### Accessing HIV PEP Medications to Complete 28 Day Course

If ongoing HIV PEP is recommended by the ID Specialist, the attending physician or RN(NP) will write a prescription for the client.

### Timely Access to Ongoing HIV PEP Medications

It may take up to 2 days for the community pharmacies to obtain the medications for HIV PEP and it is imperative no doses are missed in the interim, therefore:

- Review the medications the exposed person is currently taking<sup>9</sup> to determine if there are any contraindications or potential for severe drug interactions. Refer to [Appendix 5 – Antiretrovirals in HIV PEP Kits](#) for medications and drug interactions.
- Fax the prescription to the client’s pharmacy of choice as soon as written and indicate it is for “PEP” and the name of the ID Specialist who authorized it.

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<sup>8</sup> PEP Kits located in sites north of Prince Albert contain 5 days of medications.

<sup>9</sup> The Saskatchewan Pharmacy Information Program (PIP) is a recommended reference for this information.

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The ongoing HIV PEP medications will be provided to the client free of charge:

- **Saskatchewan Drug Plan**

The Saskatchewan Drug Plan authorizes Exception Drug Status (EDS)<sup>10</sup> for the client when the physician or pharmacist requests it. The pharmacist needs to know the EDS criteria requested is 'HIV PEP' and the name of the ID Specialist authorizing ongoing HIV PEP so they can inform the Drug Plan.

- **Non-Insured Health Benefits (NIHB)**

Health Canada NIHB provides coverage for registered First Nations and recognized Inuit individuals in Canada with a limited range of medically necessary health-related goods and services not provided through private or provincial/territorial health insurance plans. A link to the drug benefit list is found at: <http://www.hc-sc.gc.ca/fniah-spnia/nihb-ssna/provide-fournir/pharma-prod/med-list/index-eng.php>. Most medications are an open benefit and do not require prior approval. If prior approval is required, the pharmacist will call the Drug Exception Centre at 1-800-580-0950 to initiate the exception process. The prescriber will be faxed a form to complete so a decision can be made.

- **Workers' Compensation Board (WCB)**

In the instance of occupational exposures where WCB provides coverage, the usual WCB process should be followed.<sup>11</sup> If the claim is not yet set up through WCB, options for payment include:

- a. The employer may pay for the prescription and submit the bill to WCB for coverage once the claim is set up.
- b. The employee can pay for the prescription and submit the bill to WCB for coverage once the claim is set up.
- c. The employee can request the prescription be filled for one week at a time to reduce upfront costs and to allow time for WCB to set the claim up.

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<sup>10</sup> For immediate EDS approval during Monday to Friday office hours call (306) 787-8744. When after hours approval is sought, call 1-800-667-2549. Requests received in this manner may take longer to process.

<sup>11</sup> <http://www.wcsask.com/WCBPortalWeb/appmanager/WCBPortalWeb/WCBPortalWeb> OR [http://www.wcsask.com/WCBPortalPage/book\\_forms\\_pubs.html](http://www.wcsask.com/WCBPortalPage/book_forms_pubs.html).

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Should WCB deny coverage, but the ID Specialist determines the exposure requires HIV PEP, the medications would be covered by the Ministry of Health. To facilitate coverage:

- a. The Saskatchewan Drug Plan will approve the EDS for the HIV PEP medications.
- b. The pharmacy will submit a manual pharmacy claim to the Drug Plan for the medications if there is a patient co-pay portion.
- c. The Drug Plan will pay the pharmacy for the full cost of the prescription.

## Potential Adverse Effects of One Month of Antiretroviral Therapy

The following provides a rough estimate of frequency of adverse effects to assist discussion between the physician and the exposed person in deciding about use of HIV PEP.

- Minor Reactions – nausea, fatigue, etc. (70% of patients).
- Serious Reactions – are rare. Due to the frequency of minor reactions, individuals may be unable to work for the month of therapy (30 – 60% of patients); however, this risk is probably lower with the newer regimens.
- Long Term Effects – are poorly defined:  $\approx 1:5,000$ .
- Risk of Death – is unknown, but estimated to be 1:15,000 to 1:150,000 (BC Centre for Excellence in HIV/AIDS, 2009).

## Special Considerations

Considerations should be given to individuals with **renal insufficiency** and those on other medications. Significant drug interactions and dosing adjustments are highlighted in [Appendix 5 – Antiretrovirals in HIV PEP Kits](#).

### Pregnant/Breastfeeding Clients

The antiretroviral medications contained in the provincial HIV PEP kit are **1<sup>st</sup> line choices for treating pregnant HIV patients** and as such may be used if HIV prophylaxis required. Do not deny HIV PEP solely on the basis of pregnancy. As with all HIV exposures where HIV PEP is initiated, expert consultation with an ID Specialist should be sought as soon as possible.

HIV PEP is **indicated at any time during pregnancy** when a significant exposure to HIV has occurred. Before administering to a pregnant woman, the clinician should discuss the potential benefits and risks to her and the fetus.

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It should be noted there has been no evidence of human teratogenicity for Combivir® or Kaletra® (i.e., well-tolerated, short-term safety demonstrated in Phase I/II studies; both rated FDA pregnancy category C [Panel on Treatment of HIV-Infected Pregnant Women and Prevention of Perinatal Transmission, 2011]).

**Avoid breastfeeding** while on HIV PEP and for 3 months after the exposure or until HIV transmission has been ruled out. The risk of breastfeeding is related to the risk of transmission of the virus through the breastmilk, not because of risks from the medications.

## Children

The antiretroviral medications contained in the provincial HIV PEP kit are also **1<sup>st</sup> line choices for treating HIV positive children**, though oral solution formulations should be obtained as soon as possible to ensure optimal doses of each agent and avoid the need to split tablets. (See [Appendix 5 – Antiretrovirals in HIV PEP Kits](#) for recommendations to accommodate pediatric dosing using a HIV PEP Kit).