

SASKATCHEWAN FORMULARY BULLETIN

Interim Measures Related to Exception Drug Status (EDS) During COVID-19 Pandemic

The Drug Plan and Extended Benefits Branch is aligning access to certain medications with input from the Saskatchewan Health Authority (SHA) and the infectious disease clinicians to avoid inappropriate use of these medications as a result of the current COVID-19 pandemic.

Currently, there are no antiviral agents that have been demonstrated to have clinical activity against COVID-19, and the foundation of treatment for all patients with COVID-19 remains supportive care, commensurate with degree of illness.

Pharmacists have a central role in protecting the supply of critical medications. The SHA as well as provincial infectious disease clinicians are concerned about inappropriate use of antiretroviral medications, including lopinavir/ritonavir (Kaletra), and/or hydroxychloroquine or chloroquine to treat and/or prevent COVID-19 illness. These medications have no clear evidence to support their use in managing COVID-19 illness, and may have a variety of unintended adverse effects. Use of these medications can be considered for critically ill patients on a case-by-case basis in consultation with an infectious disease specialist. This message is being communicated to physicians and nurses as well.

To protect access to these medications for appropriate patients, the following changes are **effective immediately**.

Revised from Full Formulary listing to an Exception Drug Status benefit according to the following criteria:

- chloroquine phosphate, tablet, 250mg (Teva-Chloroquine)
- AS WELL AS**
- hydroxychloroquine SO₄, tablet, 200mg (Plaquenil-AVT and listed generics)
 - a) For continuation or initiation of therapy when prescribed by a rheumatologist.
 - b) For use under the direction of an infectious disease specialist.

Revised Exception Drug Status listing according to the following criteria:

- lopinavir/ritonavir, tablet, 100mg/25mg; 200mg/50mg; oral solution, 80mg/20mg(mL) (Kaletra-ABV) (possible OEA)
 - a) For management of HIV disease.
This drug, as with other antivirals in the treatment of HIV, should be prescribed by an Infectious Disease specialist.
 - b) When prescribed by, or on the advice of an Infectious Disease specialist familiar with HIV treatment for post-exposure prophylaxis (PEP). Please refer to the HIV PEP Treatment document on the Formulary website.

The duration of these changes will be informed by the timeframe of pandemic resolution in Saskatchewan. Any interim EDS changes will be noted in [Appendix A of the Saskatchewan Formulary](#), as well as through Formulary Bulletins to prescribers and pharmacists.

Saskatchewan clinicians are also advised that any potential access to remdesivir is only possible through Health Canada's Special Access Programme and applications should be initiated under the direction of an infectious disease specialist.

Furthermore, the World Health Organization guidelines indicate that investigational anti-COVID-19 therapies should only be used in approved, randomized controlled trials.

In addition, the Drug Plan would like to advise Saskatchewan health care professionals of the following information after receiving communication from the Division of Infectious Diseases in the Regina and Saskatoon integrated service area as well as a recent Health Canada MedEffect:

Non-steroidal anti-inflammatory drugs (NSAIDs)

- There is no scientific evidence that establishes a link between ibuprofen (and other NSAIDs) and the worsening of COVID-19 symptoms.
- At this time, there are no current recommendations advising discontinuation of NSAIDs amongst patients who currently use these medications to treat their chronic diseases.
- The recent Health Canada MedEffect regarding ibuprofen and COVID-19 may be helpful: <https://healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2020/72633a-eng.php>.

Antivirals and antibiotics

- **No antivirals** (including oseltamivir and ribavirin) have been demonstrated to have clinical activity against COVID-19. The cornerstone of management is supportive care. However, oseltamivir should be considered for initial treatment of symptoms while seasonal influenza continues to circulate but can be discontinued if influenza testing is negative.
- **Antibiotics** do not have activity against viruses and have no benefit in viral infections. However, secondary bacterial infection can occur, and empiric antibiotics should be considered if secondary bacterial infection is suspected or sepsis is identified.

Please continue to monitor the Formulary website and bulletins for additional EDS updates during the COVID-19 pandemic.

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