northern health
the northern way of caring

COVID-19 Non-Formulary Medication

baricitinib (Olumiant®) 2 mg oral tablets

An Intensivist or Internist working in ICU must be consulted in order to ensure judicious use and conserve supply for COVID-19

General Information:
Baricitinib belongs to a class of medications called Janus Kinase Inhibitors, which are typically used as disease modifying agents for treatment of rheumatoid arthritis. New evidence (primary COV-BARRIER and COV-BARRIER addendum trials) regarding the use of baricitinib in patients with COVID-19 has emerged and the BC COVID-19 Therapeutics Committee (BCCTC) has released new recommendations for the use of this medication in specific COVID-19 populations as an alternative to IL-6 inhibitor therapy. Based on this new information, Northern Health (NH) has developed an order set to facilitate baricitinib prescribing that aligns with the BCCTC recommendations and specifies inclusion and exclusion criteria with dosing options according to renal function.

Indication (Off Label):
For the treatment of suspected or confirmed COVID-19 in adult patients within 24 hours of requiring life support measures when an *interleukin-6 inhibitor is not available* (i.e. tocilizumab or sarilumab):

Known Side Effects
- Increased hepatic enzymes (ALT and AST), thrombocythemia, increased creatinine kinase, secondary infection (frequency and type undefined), thrombosis
- Report all adverse drug reactions to Health Canada via the NH PSLS site.

Special Precautions
- Pregnancy: limited data available, to be reviewed on a case-by-case basis with patients
- Elevated hepatic enzymes: caution if ALT or AST 3 to 5 times upper limit of normal
- Thrombosis: in hospitalized patients with COVID-19, prophylaxis for VTE is recommended unless contraindicated, monitor patients for clinical features of VTE while taking baricitinib
- GI perforations: caution in patients at increased risk of GI perforation (e.g. history of diverticulitis)
- Serious adverse effects: black box warning about cardiovascular-related events (stroke, heart attack), cancer, and death related to patients on chronic JAK inhibitor therapy (i.e. tofacitinib)

Contraindications
- Patients with hypersensitivity to baricitinib (e.g. anaphylaxis, angioedema) or any of its components
- Abnormal laboratory values:
  - ANC less than 1 X 10^9/L
  - Lymphocyte count less than 0.2 X 10^9/L
  - ALT or AST greater than 5 times upper limit of normal
  - eGFR less than 15 mL/min (or receiving renal replacement therapy)
- Known condition or treatment resulting in ongoing immune suppression including neutropenia prior to hospitalization
  - Receipt of one or more doses of interferon, riTUXimab, anakinra, tocilizumab, or sarilumab during the current hospitalization or on long-term therapy
- Previous use of convalescent plasma or intravenous immunoglobulin for COVID-19
- Active serious infection other than COVID-19 (e.g. suspected or confirmed TB)

References:
1. Baricitinib (Olumiant®) Eli Lilly Product Monograph 2020
2. Baricitinib Drug Information Monograph UpToDate® 2021
3. Marconi VC et al. Efficacy and safety of baricitinib for the treatment of hospitalised adults with COVID-19 (COV-BARRIER): a randomised, double-blind, parallel-group, placebo-controlled phase 3 trial. Lancet Respir Med. Sept 1, 2021.
4. Ely EW et al. Baricitinib plus Standard of Care for Hospitalised Adults with COVID-19 on Invasive Mechanical Ventilation or Extracorporeal Membrane Oxygenation: Results of a Randomised, Placebo-Controlled Trial (COV-BARRIER Addendum). https://www.medrxiv.org/content/10.1101/2021.10.11.21263897v1

Manufacturer: Eli Lilly

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