Criteria for use for Inhaled Budesonide for Adult Outpatients with COVID-19

Horizon ID/Med Micro Advisory Group **April 28, 2021**

Background

- The criteria for use for inhaled budesonide for treatment of symptomatic COVID-19 are based on the results and inclusion criteria from the PRINCIPLE and STOIC trials.
- Criteria for use will be adapted as new evidence and recommendations become available.
- Click here to access the STOIC trial.
- Click here to access the PRINCIPLE trial (pre-print).

Recommendation

- The Horizon ID/Med Micro Advisory Group supports consideration for the use of inhaled budesonide on a case-by-case basis for ambulatory adult patients with symptomatic COVID-19 meeting criteria for use as outlined in this document.
- Treatment should be initiated as soon as possible if prescribed.
- Informed consent should be obtained given the uncertainty of benefit and off-label use of the product. Discuss with the patient potential benefit; risk of adverse effects and recommended self-monitoring while at home (see GNB COVID19 self-assessment).

Eligible Criteria

Consider early use of inhaled budesonide if:

- Patient with confirmed COVID-19 with presence of symptoms; **AND**
- Age 40 and over

  OR

  Patient with risk factors for complications or severe disease (e.g. diabetes; hypertension; cardiovascular disease including heart failure; chronic lung disease; cerebrovascular disease or other neurologic condition; chronic kidney disease; chronic liver disease or hepatic impairment; immunosuppression due to illness or medication; cancer; obesity (BMI ≥30 kg/m^2); smoker).

Exclusion Criteria

- Almost recovered (generally much improved and symptoms now mild or almost absent).
- Patient currently prescribed inhaled or systemic corticosteroids.
- Known hypersensitivity or contraindication to budesonide or other inhaled corticosteroids.
- Unable to use an inhaler (even with assistance or reasonable adjustments).
- Admitted to hospital with COVID-19 requiring supplemental oxygen therapy.

Dose

- Budesonide 800 mcg inhaled twice daily for 14 days.

Available dose formats:

Dosage Form	Strength
Dry powder for inhalation (DPI) – turbuhaler (PULMICORT TURBUHALER)	100 mcg/inhalation 200 mcg/inhalation 400 mcg/inhalation
Nebules (PULMICORT NEBUAMP; Teva-budesonide)	**Use not recommended**

Patient Instruction – How to Use a Turbuhaler

- Click here to access English Instructions
- Click here to access French Instructions