Western Cape Government

Department of Health
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TO: CHIEF DIRECTORS / DIRECTORS
HEADS OF INSTITUTIONS
MANAGER: CAPE MEDICAL DEPOT
HEAD OF HEALTH: CITY OF CAPE TOWN
RESPONSIBLE PHARMACIST: CHRONIC DISPENSING UNIT

N.B. FOR CIRCULATION TO ALL MEDICAL, PARAMEDICAL, PHARMACEUTICAL AND NURSING PERSONNEL

ORAL BARICITINIB FOR THE TREATMENT OF HOSPITALISED ADULT PATIENTS WITH CONFIRMED COVID-19 ON HIGH FLOW NASAL OXYGEN (HFNO) WITH A GOOD PROGNOSIS

Baricitinib is an oral selective Janus Kinase 1 and 2 inhibitor with anticytokine effects which is approved in South Africa for the treatment of Covid-19 in hospitalised patients requiring supplemental oxygen.

The MAC NEMLC COVID-19 therapeutics committee has reviewed baricitinib and suggested that it be used in hospitalised patients with confirmed COVID-19 and meeting specified criteria.

The updated NDoH EML Rapid Review for baricitinib, dated 19 November 2021, is available on the NDoH website: *http://www.health.gov.za/covid-19 -rapid reviews/*

The Provincial Pharmacy and Therapeutics Committee (PPTC) reviewed and approved the use of baricitinib in the Western Cape as follows:

1. Use is restricted to adult patients with confirmed COVID-19 requiring HFNO with a good prognosis who are identified as a RED 1 patient as per the WCGH Critical Care Triage Tool (Circular H83/2020).
2. Baricitinib must be initiated by a specialist.
3. Inflammatory markers do not need to be quantified routinely for baricitinib initiation. Per clinical experience from the previous "waves", patients who require HFNO will invariably have raised inflammatory markers. Routine inflammatory marker quantification before initiation of baricitinib is therefore an unnecessary cost.
4. Duration of treatment is 14 days or until discharge, whichever comes first.
   - If the patient progresses to ventilation, then stop baricitinib.
   - If the patient improves and no longer requires HFNO then continue baricitinib to complete the 14-day course or until discharge, whichever comes first.

A Provincial Patient Registry should be implemented in the pharmacy to monitor appropriate use, outcomes, and adverse effects.

Until a provincial registry has been implemented, information should be captured on the online MS Office Form. It is suggested that dedicated persons per hospital are made responsible for capturing the data online.

The link for access to the baricitinib online form is available from:
Yasmina Johnson: Email: Yasmina.Johnson@westerncape.gov.za

For more detail on clinical and registry information refer to:

- **Annexure A**: Additional clinical information on baricitinib
- **Annexure B**: Requirements for the baricitinib registry

This decision was supported by the Operations Executive Committee (OPEXCO)on 11 January 2022. The current cost per course per patient for 14 days is R4 220.00, (Eli Lilly SA Pty Ltd; quotation received from NDoH).

Baricitinib may be procured through the Cape Medical Depot (CMD) as a direct delivery voucher (DDV): ICN: 4748027

Yours faithfully

DR SAADIQ KARIEM
DDG: CHIEF OF OPERATIONS
DATE: 08/02/2022

ANNEXURE A

BARICITINIB: ADDITIONAL INFORMATION

(Ref: NDOH Clinical Management Guidelines for COVID-19: Module 5 – Drug therapy v7, 21 Dec 2021)

Usual adult dose is 4mg daily. However, baricitinib requires dose modification for patients with renal failure, and is contraindicated in patients with eGFR <15 ml/min (including those on dialysis):

eGFR	Dose
30-59ml/min	Decrease to 2mg daily
15-29ml/min	Decrease to 1mg daily
<15ml/min	Not recommended

Remarks:

1. Baricitinib is not an alternative to corticosteroids, which should be given in addition to baricitinib.

2. Baricitinib should not be given with tocilizumab or other potent immunosuppressives (apart from corticosteroids) as the combined immunosuppressive effect may cause more harm than good.

3. For patients unable to swallow (e.g. intubated patients), baricitinib can be crushed, mixed with liquid, and given via nasogastric tube. Before administering baricitinib, flush nasogastric tube.

4. Baricitinib can predispose patients to serious infections. If a serious infection other than COVID-19 is present, or develops, we suggest conducting an individualized risk/benefit assessment to assess whether treatment with baricitinib should be discontinued.

5. There is insufficient data to assess the risk of baricitinib in pregnant or breastfeeding women, and in patients with severe hepatic disease. A risk/benefit assessment needs to be made on an individual case-by-case basis.

6. Baricitinib can be associated with cytopenias. A risk/benefit assessment needs to be made for patients whose absolute neutrophil count is <1000 cells/mm2, or whose lymphocyte count is <200 cells/mm3, or whose haemoglobin is <8 g/dL.

ANNEXURE B

INFORMATION TO BE CAPTURED ON THE BARICITINIB REGISTER

ELEMENT / MEASURE	CRITERIA	OPTIONS
Location / hospital	Hospital	Name
	District / Sub-structure, Regional or Central hospital	Name
Patient details	Patient's initials	Free text
	Folder number	number
	Date of birth	date
	Sex	• Male • Female
	COVID-19 Vaccination Status	• Fully (1xJ&J or 2xPfizer) • Fully, with booster • Partially • Not vaccinated • Not known
Criteria for commencing treatment	On HFNO	• Yes • No • Not known
	RED 1 patient	• Yes • No • Not known
Treatment information	Start date	Date
	End date	Date
	Dose & frequency	• 4mg daily • 2mg daily • 1mg daily • Other: specify
	Reason for stopping	• Completion of course • Progress to invasive mechanical ventilation • Discharge • Death • Severe renal impairment (eGFR <15ml/min) • Severe adverse drug reaction • Referral to other hospital • Severe infection other than COVID-19 • Other, specify:
Patient outcome	Outcome	• Discharge • Death • Referral to other hospital (name of hospital)
	Date of outcome	Date
Suspected adverse drug reaction	List suspected adverse drug reaction(s)	Free text