Republic of the Philippines
Department of Health
OFFICE OF THE SECRETARY

28 April 2022

HON. FRANCISCO T. DUQUE III, MD, MSc
Secretary of Health

Dear **Secretary Duque:**

Greetings!

This has reference to the Health Technology Assessment Council (HTAC) recommendation on tocilizumab dated 10 May 2021 which is an interim recommendation for the use of tocilizumab as an investigational drug for COVID-19 and is not indicative of the inclusion of tocilizumab in the Philippine National Formulary (PNF) for government financing. Specifically, it is recommended in addition to systemic steroids, in patients showing respiratory deterioration and/or requiring high doses of oxygen and with elevated markers of inflammation; and was not recommended among patients with COVID-19 infection who do not require oxygen supplementation. The HTAC recommendation was based on the review of evidence, specifically the evidence review on the safety and efficacy of tocilizumab by the Philippine Living Clinical Practice Guidelines (Philippine COVID-19 Living CPG) in February 2021.

The HTAC, however, did not recommend the inclusion of tocilizumab in the PNF as the listing requires CPR with an indication that is specific for the treatment of COVID-19. At the time of the review, the available regulatory authorization issued by the Philippine Food and Drug Administration (FDA) for tocilizumab is a Drug under Emergency Use (DEU) as it already has a CPR indicated for rheumatoid arthritis pursuant to FDA Circular No. 2020-012 *[Guidelines for the Registration of Drug Products under Emergency Use (DEU) for the Coronavirus Disease 2019 (COVID-19)]* and 2021-0008 *[Updated Guidelines for the Registration of Drug Products under Emergency Use (DEU) for COVID-19]*, and FDA Advisory No. 2021-2223 *[List of Drugs under Emergency Use]* and 2022-0006 *[Updated List of Drugs under Emergency Use]*.

In view of this, the HTAC recommended that the DOH secure appropriate regulatory authorization for tocilizumab from the Philippine FDA for the procurement and/or reimbursement by DOH and PhilHealth.

On 15 March 2022, the Philippine FDA issued a CPR of tocilizumab for the treatment of COVID-19 in adults who are receiving systemic corticosteroids and require supplemental oxygenation or mechanical ventilation.

In light of this development, the HTAC assessed the updated review of the Philippine COVID-19 Living CPG (October 2021). While there were six new studies in the updated review, there are **no changes** in the latest Philippine COVID-19 Living CPG recommendations *[i.e., tocilizumab is recommended in addition to systemic steroids in patients showing rapid respiratory deterioration and/or requiring high doses of oxygen (high-flow nasal cannula, noninvasive or invasive mechanical ventilation) and with the elevated biomarkers of inflammation (Moderate quality of evidence; Strong recommendation); and tocilizumab is not recommended among patients with COVID-19 infection who do not require oxygen (Very low quality of evidence; Strong recommendation)]*.

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Moreover, in the most recent WHO Guidelines on Therapeutics and COVID-19 (March 2022) which focused only on **intravenous** administration of tocilizumab, it is currently recommended for patients with severe or critical COVID-19 *(Strong recommendation)*. This is in line with the existing HTAC recommendation in May 2021 and with the updated Philippine COVID-19 Living CPG recommendation for tocilizumab.

Regarding the drug regimen cost of using tocilizumab, the following are the updated drug regimen costs incurred per patient for each preparation of tocilizumab IV, based on unit costs from the DOH purchase request cost *(400mg/20mL IV formulation)* and government list price from the manufacturer (i.e., Roche) *(200mg/10mL and 80mg/4mL IV formulations)*:

Tocilizumab IV Preparation	**2022 Updated Drug Cost of Tocilizumab IV per patient per regimen**	**2021 Cost of Tocilizumab IV per patient per regimen**
400mg/20mL (20mg/mL)	PhP 18,100.00 *source of unit cost:* ***DOH purchase request cost***	PhP 46,102.44 *source of unit cost: DOH-Pharmaceutical Division, median of procurement costs from DOH hospitals*
200mg/10mL (20mg/mL)	PhP 41,162.80 *source of unit cost: government list price from the manufacturer*	PhP 46,560.00 *source of unit cost: DOH-Pharmaceutical Division, median of procurement costs from DOH hospitals*
80mg/4mL (20mg/mL)	PhP 41,162.50 *source of unit cost: government list price from the manufacturer*	PhP 67,405.00 *source of unit cost: DOH-Pharmaceutical Division, median of procurement costs from DOH hospitals*

Important information considered by the HTAC are found in the following annexes:

- Annex A: Product quality based on the Certificate for Post-Approval Changes issued by the Philippine FDA;
- Annex B: Summary of recommendations from the Philippine COVID-19 Living CPG;
- Annex C: Summary of new studies in the updated review of the Philippine COVID-19 Living CPG on tocilizumab; and
- Annex D: Costing Analysis for tocilizumab IV formulations

Relative thereto, the **HTAC affirms that the previous recommendation on tocilizumab (10 May 2021) still stands** based on the new studies and updated recommendations of the WHO and Philippine COVID-19 Living CPG.

- HTAC recommends the use of tocilizumab in addition to systemic steroids, in patients showing respiratory deterioration and/or requiring high doses of oxygen and with elevated markers of inflammation.
    - The recommended indication by HTAC matched with the approved therapeutic indication for COVID-19 of tocilizumab as shown in *Annex A*.
      "Treatment of coronavirus disease 2019 (COVID-19) in adults who are receiving systemic corticosteroids and require supplemental oxygen or mechanical ventilation"

- HTAC recommends against the use of tocilizumab among patients with COVID-19 infection who do not require oxygen supplementation.

Following the issuance of the post-approval changes to the CPR of tocilizumab to include a therapeutic indication for COVID-19 (IV formulations only), the **HTAC recommends the inclusion of tocilizumab with the following formulations in the PNF:**

- Tocilizumab 80mg/4mL (20mg/mL) Concentrate for Solution for IV Infusion
- Tocilizumab 200mg/10mL (20mg/mL) Concentrate for Solution for IV Infusion
- Tocilizumab 400mg/20mL (20mg/mL) Concentrate for Solution for IV Infusion

This recommendation will not undergo an appeals process as it is classified under the expedited track as related to the COVID-19 public health emergency.

We remain grateful for the opportunity to work with you. Thank you very much and best regards.

Respectfully yours,

For the Health Technology Assessment Council
(HTAC):

Marita V. T-Reyes

MARITA V. TOLENTINO-REYES, MD
Chair, HTAC

Approval of the HTAC Recommendation:

FRANCISCO T. DUQUE III, MD, MSc
Secretary of Health

CC: OIC- Undersecretary Charade B. Mercado-Grande