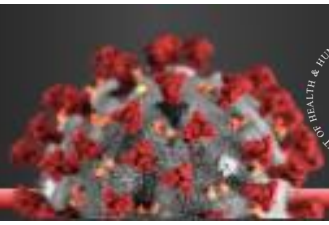
Indian Health Service
National Pharmacy and Therapeutics Committee

COVID-19 Emerging Treatments Update



April 7, 2023

Emergency Use Authorization
FDA authorizes GOHIBIC (vilobelimab) injection for the treatment of COVID-19

Background & Current Status[1,5]:

On April 4, 2023, the U.S. Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) for the use of GOHIBIC (vilobelimab) injection **for the treatment of COVID-19 in hospitalized adults when initiated within 48 hours of receiving invasive mechanical ventilation or extracorporeal membrane oxygenation (artificial life support)**.

The treatment targets a part of the immune system that is thought to play a role in the inflammation that leads to COVID-19 disease progression. The clinical trial supporting the authorization showed that patients treated with Gohibic had a lower risk of death by day 28 and day 60 of treatment compared to placebo.

Dosage, Administration, and Common Adverse Reactions[3]:

The recommended dosage of GOHIBIC is 800 mg administered by intravenous infusion after dilution, given up to six times over the treatment period. The most common adverse reactions with use of GOHIBIC are pneumonia, sepsis, delirium, pulmonary embolism, hypertension, pneumothorax, deep vein thrombosis, herpes simplex, enterococcal infection, bronchopulmonary aspergillosis, hepatic enzyme increased, urinary tract infection, hypoxia, thrombocytopenia, pneumomediastinum, respiratory tract infection, supraventricular tachycardia, constipation, and rash. Serious infections due to bacterial, fungal, or viral pathogens have been reported in patients with COVID-19 receiving GOHIBIC.

Current EUA Fact Sheets[3,4]:

As a convenience, Fact Sheets for GOHIBIC are accessible below:

- Healthcare Providers
- Patients, Parents and Caregivers

Conditions of Authorization for Healthcare Facilities under the Emergency Use Authorization[2]:

- Ensure that healthcare facilities are aware of the letter of authorization, and the terms herein, and that the authorized Fact Sheets are made available to healthcare providers and to patients and caregivers, respectively, through appropriate means, prior to administration of GOHIBIC.
- Track all serious adverse events and medication errors potentially related to GOHIBIC and report these to FDA. Complete and submit a MedWatch form or complete and submit FDA Form 3500 by fax (1-800-FDA-0178). Submitted reports must state, “GOHIBIC use for COVID-19 under EUA” at the beginning of the question “Describe Event” for further analysis. ***Federal, Tribal, and Urban programs are all encouraged to put “IHS” into field #26 of the form.***
- Ensure that appropriate storage is maintained until the product is administered consistent with the terms of this letter and the authorized labeling.
- Maintain records regarding the dispensing and administration of GOHIBIC for the use authorized in this letter (i.e., lot numbers, quantity, receiving site, receipt date), product storage, and maintain patient information (e.g., patient name, age, disease manifestation, number of doses administered per patient, other drugs administered)
- Ensure that any records associated with this EUA are maintained until notified by InflaRx (manufacturer) and/or FDA. Such records will be made available to InflaRx, HHS, and FDA for inspection upon request.
- Report therapeutics information and utilization data as directed by HHS.

References:

1. Food and Drug Administration. FDA authorizes GOHIBIC (vilobelimab) injection for the treatment of COVID-19. Released April 4, 2023.
2. Food and Drug Administration. GOHIBIC Letter of Authorization. Issued April 4, 2023.
3. Food and Drug Administration. GOHIBIC: FACT SHEET FOR HEALTHCARE PROVIDERS. Released April 4, 2023.
4. Food and Drug Administration. GOHIBIC: FACT SHEET FOR PATIENTS, PARENTS & CAREGIVERS. Released April 4, 2023.
5. ClinicalTrials.gov, Randomized, Controlled Study of IFX-1 in Patients With Severe COVID-19 Pneumonia (PANAMO)