Provider Workflow for Tocilizumab (Actemra) for the Treatment of COVID-19

The U.S. Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EUA) for the emergency use of tocilizumab (Actemra) for the treatment of coronavirus disease 2019 (COVID-19). Actemra is FDA-approved for several indications, however, it is not approved for the treatment of COVID-19. To support CMH's providers ordering these medications and satisfy FDA requirements, providers should follow the workflow outline below.

Patient Candidate for Actemra Therapy
See Inclusion/Exclusion Criteria Checklist

Step 1: Contact ID Provider for Approval
Use is restricted to ID approval

Step 2. Complete Patient's Inclusion / Exclusion Checklist

Step 3. Review medication information consistent with the FDA "Fact Sheet for Patients, Parents and Care Givers" with patient / care giver. A written copy must also be provided**.**

Step 4. Obtain patient / care givers' written consent to receive drug
Using CMH drug specific Consent form

Step 5. Documentation in patient medical record

Documentation that (Dot phrase is available: /actemra_treat_covid)

- The FDA "Fact Sheet for Patients, Parents and Care Givers" has been reviewed and copy provided
- Patient / care giver was informed of alternatives to receiving Actemra.
- Patient / care giver was Informed that Actemra is an approved drug that is authorized for the unapproved use of the treatment of COVID-19 under this Emergency Use Authorization

Complete drug order

Step 6. Pharmacy notification

- **Fax copy of the completed Inclusion / Exclusion Criteria Checklist and signed consent to Pharmacy. (FAX 795-5675)**

Step 7. Monitor the patient for adverse events.

- Monitor ALT, AST, neutrophils and platelet counts, signs and symptoms of infection (prior to, during, and after therapy), signs and symptoms of CNS demyelinating disorders, new onset abdominal symptoms, hypersensitivity reactions, including anaphylaxis

Step 8. Prescribing Physician is responsible for reporting all potentially medication error or adverse event to the FDA and Genentech within 7 days

- Clinical Research Coordinators will assist with follow-up documentation and FDA submissions regarding patient reactions, etc.

Tocilizumab (Actemra) for the Treatment of COVID-19
Inclusion/Exclusion Criteria Checklist

(Fax to Pharmacy: 795-5675)

Apply Patient Sticker Here

Date:	Prescribing Provider:
Patient Name/FIN (if no sticker):	Hospital: CMMC RH BH

Inclusion criteria (Check all that Apply) Must meet all Criteria:

☐	Confirmed COVID-19 via laboratory testing (per EUA)	☐	ID provider approved use
☐	Hospitalized Adult or pediatric patient (2 years of age and older) (per EUA)	☐	Not receiving concurrent Baricitinib therapy
☐	Receiving systemic corticosteroids (per EUA)	☐	≥1 elevated inflammatory marker **CRP, D-dimer, LDH, ferritin ***
☐	Require supplemental oxygen, non-invasive or invasive mechanical ventilation, or ECMO (per EUA)	☐	No known hypersensitivity to Actemra or any of its ingredients (per EUA)
☐	No active non-SARS-CoV-2 Infection: ACTEMRA should not be administered if patients have any other concurrent active non-SARS-CoV-2 infection, including localized infection. Serious and potentially fatal infections have been reported in patients receiving Actemra	☐	Laboratory Parameters Checked: Use is not recommended in patients with an absolute neutrophil count (ANC) less than 1000 per mm^3, platelet count below 50,000 per mm^3, or ALT or AST above 10 times the upper limit of the reference range (Per EUA)
☐	Exhibiting rapid respiratory decompensation due to COVID-19 ** Studies suggest Actemra use may be more beneficial in people with early rapidly progressive disease; NIH COVID-19 Treatment guidelines recommend use within 3 days of admission to the hospital or within 24 hours of admission to the ICU***		

If all the above Inclusion Criteria are met, check that you have assessed the following for risk vs benefit

☐	Immunosuppression: Actemra should be avoided in patients who are significantly immunosuppressed, particularly in those with recent use of other biologic immunomodulating drugs	☐	Demyelinating Disorder: Use with caution in patients with preexisting or recent onset CNS demyelinating disorders. The impact of treatment with Actemra on demyelinating disorders is not known, but multiple sclerosis and chronic inflammatory demyelinating polyneuropathy were reported rarely in rheumatoid arthritis clinical studies
☐	Tuberculosis: Tuberculosis (pulmonary or extrapulmonary) has been reported in patients receiving tocilizumab; both reactivation of latent infection and new infections have been reported.	☐	Active hepatic disease and hepatic impairment: not recommended in patients with active hepatic disease or hepatic impairment. Serious cases of hepatic injury have been observed
☐	Gastrointestinal perforation: Use with caution in patients who may be at increased risk for gastrointestinal perforation (for example diverticulitis)		

**Pediatric Patients: While approved for patients 2 years or older, Actemra has not been studied in pediatrics for the treatment of COVID-19. It is recommended that there be a discussion with a Pediatric ID specialist before using. The outpatient on-call provider at Maine Medical Partners Pediatric Specialty Care can be reached at 207-662-5522

- The FDA "Fact Sheet for Patients, Parents and Care Givers" has been reviewed and copy provided to patient/care giver
- Patient / care giver was informed of alternatives to receiving Actemra.
- Patient / care giver was Informed that Actemra is an approved drug that is authorized for the unapproved use of the treatment of COVID-19 under this Emergency Use Authorization

Provider Name: _____ Provider Signature: _____ Date:_____

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