TOCILIZUMAB (ACTEMRA) & BIOSIMILARS

PATIENT INFORMATION / REFERRAL STATUS

Referral Status: □ New Referral □ Updated Order □ Order Renewal **Date:** _____

Patient Name: _____ DOB: _____

ICD-10 Code: _____ ICD-10 Description/Diagnosis: _____

Allergies: □ NKDA Allergies: _____ Weight: _____ □ lbs/□ kg Height: _____

Patient Status: □ New to Therapy □ Continuing Therapy Last Treatment Date: _____ Next Due Date: _____

PROVIDER / PRACTICE INFORMATION

Ordering Provider: _____ Provider NPI: _____

Referring Practice Name: _____ Phone: _____ Fax: _____

Practice Address: _____ City: _____ State: _____ Zip: _____

Referral Coordinator Name: _____ Email: _____ Alternative Phone Number: _____

REFERRING PROVIDER COMMUNICATIONS

□ I have reviewed the prescribing information and medication guide for Actemra/Avtozma/Tofidence/Tyenne (tocilizumab/tocilizumab-anoh,-bavi,-azzg).

- Avoid use of live vaccines during treatment. Prior to initiating therapy, complete all age appropriate vaccinations according to current immunization guidelines.
- Evaluate for active infection. Delay administration to patients with an active infection.
- Evaluate patients for tuberculosis (TB) prior to initiating treatment. Consider anti-tuberculosis therapy prior to therapy initiation in patients with a past history of latent or active tuberculosis. Monitor patients for signs and symptoms of active TB during and after treatment.
- Evaluate patients for viral hepatitis and treat them according to guidelines prior to initiating therapy. Consider periodic evaluation of patients who are hepatitis B carriers for signs/symptoms of active hepatitis B infection.
- Evaluate liver enzymes and bilirubin at baseline and periodically thereafter. Monitor for tocilizumab induced hepatic injury. Instruct patients to seek immediate medical attention if they experience symptoms suggestive of hepatic dysfunction. Initiation of therapy in patients with active hepatic disease or hepatic impairment or with the baseline ALT or AST elevation is usually not recommended.
- Treatment with tocilizumab was associated with a higher incidence of neutropenia and thrombocytopenia. It is not recommended to initiate treatment if ANC < 2000/mm^3 and/or Platelets < 100,000/mm^3.
- Use with caution in patients who may be at increased risk for gastrointestinal perforation. Promptly evaluate patients presenting with fever, new onset abdominal symptoms, and a change in bowel habits for early identification of gastrointestinal perforation.
- Monitor patients for signs and symptoms potentially indicative of demyelinating disorders.

NURSING PROTOCOL COMMUNICATIONS

☒ Provide nursing care, vital signs, monitoring according to Memorial Outpatient Procedures. Establish/maintain IV access and administer medication as ordered. Remove peripheral IV access after infusion completion if applicable. Follow infusion-related/hypersensitivity reactions management according to MHS Outpatient Adverse Reaction Protocol available for review on at mhs.net/services/pharmacy/infusion-services/outpatient-infusion.

☒ Discharge/Follow-up instructions according to Memorial Outpatient Procedures.

Memorial Healthcare System

TOCILIZUMAB (ACTEMRA) & BIOSIMILARS

LABORATORY ORDERS

☐ ***Pregnancy, Urine for females of childbearing potential who have not undergone a hysterectomy:***

☐ Once ☐ Every Visit ☐ Every ____ months

☒ ***CBC with Diff:*** Every 4-8 weeks for the first 6 months

☒ ***Comprehensive Metabolic Panel:*** Every 4-8 weeks for the first 6 months

☒ ***Lipid panel:*** Every 4-8 weeks for the first 6 months

☐ ***CRP:*** ☐ Once ☐ Every Visit ☐ Every ____ months

☐ ***Hep B surface antigen [HBsAg]:*** ☐ Once ☐ Every Visit ☐ Every ____ months

☐ ***Hep B surface antibody quantitative:*** ☐ Once ☐ Every Visit ☐ Every ____ months

☐ ***Hep B virus DNA:*** ☐ Once ☐ Every Visit ☐ Every ____ months

☐ ***Hep B core antibody [anti-HBc]:*** ☐ Once ☐ Every Visit ☐ Every ____ months

☐ ***Quantiferon (R) TB gold, draw site incubated:*** ☐ Once ☐ Every Visit ☐ Every ____ months

PRE-MEDICATION ORDERS (30-60 Minutes Prior to Therapy)

☐ Acetaminophen (Tylenol) 650 mg PO

☐ Diphenhydramine (Benadryl) ☐ 25 mg ☐ 50 mg ☐ PO ☐ IV **OR**

☐ Cetirizine (Zyrtec) or Loratadine (Claritin) 10 mg PO

☐ Methylprednisolone (Solu-Medrol) ☐ 40 mg ☐ 125 mg IV **OR**

☐ Dexamethasone (Decadron) ☐ 8 mg ☐ 20 mg PO

☐ Other: _____ Dose: _____ Route: _____ Frequency/Timing: _____

Memorial Healthcare System

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THERAPY PLAN

Select Product (Check one):

☐ Tocilizumab (Actemra) ☐ Tocilizumab-anoh (Avtozma)
☐ Tocilizumab-bavi (Tofidence) ☐ Tocilizumab-aazg (Tyenne)

Dose: ☐ 4 mg/kg ☐ 6 mg/kg ☐ 8 mg/kg ☐ Other:_____

Frequency: ☐ Every 4 weeks ☐ Other:_____

Route: ☒ IV ☐ SQ ☐ IM

Infuse over: ☐ 30 minutes ☒ 1 Hour ☐ 2 Hours ☐ Other:_____

Diluent/Volume/Concentration/Special tubing/Filters will be in accordance with the product package insert.*

☒ Flush with 0.9% sodium chloride at completion per protocol or medication-specific instructions

Additional Administration Instructions:

Patients less than 30 kg, use a 50 mL infusion bag. Patients at or above 30 kg weight, use a 100 mL infusion bag. Do not infuse with other agents. Do not administer IV push or IV bolus. Monitor patient for infusion-related reaction.

Note to Pharmacy/Comments:

_____

_____

Refills: ☐ Zero ☐ for 12 months ☐ Other:_____

(if not indicated, order will expire one year from date signed)

_____ _____ _____

Provider Name (Print) ***Provider Signature*** ***Date***

Memorial Healthcare System

Adverse Reaction Management Protocol (Adult)

Observe patient for infusion related and hypersensitivity reactions such as fever, chills, rigors, pruritus, rash, cough, sneezing, throat irritation, nausea, vomiting.

If reaction occurs:

- Stop infusion and assess patient.
- Maintain or establish vascular access if needed
- **Administer emergency medication(s) according to symptoms:**

☒ Acetaminophen 650 mg PO once PRN headache, pain, fever >100.4F, chills or rigors.

☒ Diphenhydramine 50 mg IV once PRN itching, allergies, infusion reaction, hives, pruritic and other nonspecific symptoms of allergic reaction **OR**

☒ Diphenhydramine 50 mg IM once PRN itching, allergies, infusion reaction, hives, pruritic and other nonspecific symptoms of allergic reaction (if no IV access)

☒ Dexamethasone 10 mg IV once PRN shortness of breath or wheezing **OR**

☒ Dexamethasone 10 mg IM once PRN shortness of breath or wheezing (if no IV access)

☒ Ondansetron 4 mg IV once PRN nausea, vomiting **OR**

☒ Ondansetron 4 mg IM once PRN nausea, vomiting (if no IV access)

- May re-start therapy if appropriate when symptoms resolve. Resume infusion at 50% of the previous rate and increase per manufacturer's guidelines.

If a severe allergic/anaphylactic reaction occurs

- Symptoms are rapidly progressing or continuing after administration of PRN medications and/or signs and symptoms of severe allergic/anaphylactic reaction (angioedema, swelling of the mouth, tongue, lips, or airway, dyspnea, bronchospasm with or without hypotension or hypertension)

☒ Notify the Rapid Response / Rescue Alert Team / Blue Alert / 911.

☒ Initiate BLS/ Cardiopulmonary resuscitation if necessary.

☒ Administer Epinephrine 0.3 mg intramuscularly, every 5 MIN PRN rapidly progressing or continuing after administration of PRN medication or signs and symptoms of severe allergic/anaphylactic reaction. Administer every 5-15 minutes as needed preferably in the outer thigh.

☒ Place the patient in a recumbent position, elevate lower extremities.

☒ Continuously monitor vital signs (blood pressure, pulse oximetry, and heart rate).

☒ Contact and notify the referring provider on the day of occurrence once patient is stabilized.

☒ Document reaction in the medical record and complete an incident report once patient is stabilized.