Palmetto Infusion Services COMPLIANCE

MRN:_____

Phone: 1-800-809-1265 Fax: 1-866-872-8920

DOB:_____

STANDARD Actemra® (tocilizumab) PLAN OF TREATMENT FOR RHEUMATOLOGY

(Re) Certification Period From_____to _____

NOTE: Patient ***may be ineligible*** to receive tocilizumab if receiving antibiotics for active infectious process, antifungal therapy, active fever and/or suspected infection, new-onset or deterioration neurological changes, new-onset abdominal symptoms, and/or surgery.

1. Patient Name: _____Height (inches): _____Weight (lbs):_____

2. Allergies:_____

3. Diagnosis: * Please complete the 2nd and 3rd digits to complete the ICD-10 code for billing

☐ **M05._____** Rheumatoid Arthritis with Rheumatoid factor ☐ **M06._____** Rheumatoid Arthritis without Rheumatoid factor

☐ Other **ICD-10 Code**: _____**diagnosis description:** _____

4. Pre-medications: ☐ None ***OR*** ***Administered 30 minutes prior to infusion as selected:***

**** Suggest caution with use of Diphenhydramine due to 60-minute infusion time and safety risks with driving.***

Acetaminophen:
- ☐ 650 mg PO
- ☐ 500 mg PO
- ☐ 325 mg PO

Diphenhydramine: ☐ 25 mg PO, ☐ 50 mg PO, ☐ 25 mg IVP, ☐ 50 mg IVP or
Fexofenadine ☐ 60 mg or ☐ 180 mg, ☐ Cetirizine 10 mg, ☐ Loratadine 10 mg
Methylprednisolone ☐ 40 mg IVP ☐ 125 mg IVP or other _____mg IVP
Famotidine: ☐ 20 mg PO, ☐ 40 mg PO, ☐ 20 mg IVP, ☐ 40 mg IVP

Pre-medicate with other: _____

5. Orders: Actemra® (tocilizumab) per 100ml Sodium Chloride 0.9% IV to infuse over at least 1 hour

☐ Induction dose of 4mg/kg and then maintenance dose of ☐ 4mg/kg or ☐ 8mg/kg every 4 weeks

☐ Maintenance dose of ☐ 4mg/kg or ☐ 8mg/kg every 4 weeks

**** ACTEMRA® dosing exceeding 800 mg are not recommended in RA patients and dosing should not be administered no less than every 28 days.***

Lab orders: (Initial labs should be drawn prior to first infusion and then routinely)

CBC with diff, Platelets, and LFT's to include ALT and AST: at 2nd infusion, and then every 12 weeks with infusions
Cholesterol level at 2nd infusion, and then every 6 months

Lab parameters for treatment: (Pharmacist to perform clinical lab monitoring)
If ANC>1000 cells/mm³ maintain dose. If ANC is 500 to 1000 cells/mm³, interrupt tocilizumab dosing. When ANC >1000 cells/mm³, resume tocilizumab at 4mg/kg and increase to 8mg/kg as clinically appropriate. If ANC < 500 cells/mm³, then discontinue tocilizumab.
If Platelet count 50,000 to 100,000 cells/ mm³, then interrupt tocilizumab dosing. When platelet count is > 100,000 cells/ mm³, resume treatment at tocilizumab at 4mg/kg and increase to 8mg/kg as clinically appropriate. If Platelet count is <50,000 cells/ mm³, then discontinue tocilizumab.
If Liver enzymes are > 3-5 x upper limit normal or ALT/AST are > 1.5x upper limit normal, then HOLD dose of tocilizumab.
If Cholesterol levels are elevated, notify referring MD for clinical evaluation and monitoring.

If adverse drug reaction occurs, utilize the ADVERSE DRUG REACTION GUIDELINES

If anaphylaxis or other hypersensitivity reaction occurs, stop administration immediately and discontinue permanently. Do not administer to patients with known hypersensitivity.

6. Physician's Signature: _____/ _____Date: _____

No Stamp Signatures (Dispense as written) (Substitution permitted)

Printed Physician's Name with Credentials: _____NPI: _____

7. Fax updated supporting clinical MD notes with each order renewal or change in orders

Infusion order forms and Adverse Drug Reaction Guidelines are available at www.palmettoinfusion.com

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Guidelines for Prescribing Actemra ® (tocilizumab)

(Required documentation with all initial referrals)

Patient Name: _____ Referral Date:_____

___ Include signed and completed **Plan of Treatment**. *(MD must complete sections 1-7)*
(Infusion order forms & Standard Adverse Reactions orders are available at www.palmettoinfusion.com under Agency/MD tab)

___ Include patient demographic information and insurance information. (Copy of insurance cards if available)

___ **Supporting clinical MD notes to include any past tried and/or failed therapies, intolerance, outcomes or contraindications to conventional therapy. Include any lab results and/or tests to support diagnosis.**

- ACTEMRA® (tocilizumab) is indicated for the treatment of adult patients with moderately to severely active rheumatoid arthritis who have had an **inadequate response to one or more Disease-Modifying Anti-Rheumatic Drugs (DMARDs).** May be used alone or in combination with methotrexate or other DMARDs.

___ If patient is switching biological therapies, then MD must specify wash-out period prior to starting Actemra® as specified of _____ weeks. Last known biological therapy: _____ and last date received:_____. (Include copy of last ACTEMRA® infusion record if available and currently on therapy)

___ Other as requested: _____
_____
_____

Pre-Screening: **(TB and Hepatitis screening results must be available prior to start of therapy and within last 12 months.)**

___ **Required TB screening results: PPD or QuantiFERON Gold Test.**
(* If screening results are positive or indeterminate, then a negative CXR result is required.)

___ **Required Hepatitis screening to include: Hepatitis B Surface Antigen results.**

___ **Lab results within last 30-60 days: CBC with diff, Platelets, both AST and ALT, and Cholesterol level.**
(It is recommended that tocilizumab not be initiated in patients with an ANC of less than 2000/mm^3, platelet count below 100,000/mm^3, or who have ALT or AST greater than 1.5 x the upper limit of normal.)

** Warnings/Precautions: **Hypersensitivity Reactions, Including Anaphylaxis:** If anaphylaxis or other hypersensitivity reaction occurs, stop administration immediately and discontinue permanently. Do not administer to patients with known hypersensitivity. **Serious infections**: leading to hospitalization or death including tuberculosis (TB), bacterial, invasive fungal, viral, and other opportunistic infections have occurred in patients receiving ACTEMRA®. Pre-screening for TB prior to starting ACTEMRA. Safety and efficacy has not been studied in patients with hepatic impairment, including patients with positive HBV and HCV serology. Consider interrupting therapy with Actemra® if patients develop a new infection during treatment. Most patients who developed these infections were taking concomitant immunosuppressants such as methotrexate or corticosteroids. Actemra ® has not been studied in combination with other biologics. **Gastrointestinal (GI) perforation:** Events of gastrointestinal perforation have been reported in clinical trials, primarily as complications of diverticulitis in RA patients. Use caution in patients who may be at increased risk or history of diverticulitis/GI Bleed. Evaluate patients presenting with new onset abdominal symptoms for early identification of gastrointestinal perforation. ***Laboratory monitoring*** – recommended due to potential consequences of treatment-related changes in neutrophils, platelets, lipids, and liver function tests. Evaluation of immunizations should be completed prior to and live vaccines should not be given before or concurrently with Actemra ®. See full prescribing information

Palmetto Infusion Services will complete insurance verification and submit all required clinical documentation to the patient's insurance company for eligibility. Our office will notify you if any further information is required. We will review financial responsibility with the patient and refer them to any available Co-pay assistance as required. Thank you for the referral.

Please fax all information to 1-866-872-8920 or call 1-800-809-1265 for assistance.

Revised 8/31/18, ref. PI 5/2018