Overview

This clinical protocol defines requirements and activities related to the ordering, scheduling and administration of infusion services.

PROTOCOL

1. Guidelines applicable to all infusion medications: The guidelines in this section apply to all infusion medications. Guidelines applicable for individual medications may be found in the section of this protocol for that particular medication.

   A. Prior to the initiation of services there must be a physician order. The order should not be accepted unless it contains all correct parameters (ie mg/kg, dose frequency, etc.).

   B. Prior to scheduling and the provision of infusion services, all prior authorization must be obtained, as required by the applicable third party payor.

   C. Prior to scheduling a patient for infusion services, each patient record must be screened to ensure that all prerequisites are met for the particular drug being administered. Check the requirements for the specific medication being infused as defined in this protocol.

   D. Infusion medications are acquired as vials that may only be utilized for a single patient. No single use vial shall be utilized for any patient other than the original patient for whom the vial was used. Any amount of medication that remains after the completion of the infusion process for a patient shall be disposed in the manner identified under the section for that particular medication.

   E. In order to perform infusion services, the provider must meet the qualifications as defined for the specific medicine being infused.

   F. The administration of infusion services shall be properly documented in the patient record, recordings, as a minimum, the items identified in the template established for the particular medication being infused. In addition, the provider is to complete the Therapeutic Injection section of the progress note. In addition, if there is a significant change in the medication regimen (ie. Change in the number of vials used), the reason for the change is to be documented in the patient record.

   G. Infusion medications shall be maintained under a system of inventory control that allows for a complete accounting of vials used. The inventory process shall ensure that each lot of a medication acquired is identified along with the count of vials for that lot. The inventory shall be declinated as vials are utilized. The number of vials utilized for a specific patient and the name of the patient and date used, shall be identified as part of the declination
documentation.

H. Infusion services may only be performed when a physician is in the office.

I. Schedule patient for next infusion date and necessary physician visits prior to patient’s departure form an infusion service, if possible.

2. Remicade: The following guidelines apply specifically to Remicade.

A. Prerequisites for scheduling and administration include:

   a. Presence of a CBC, CMP and SED rate.
   b. The completion of all other routine labs ordered by the referring physician
   c. No evidence of current infections
   d. No current antibiotic use
   e. The patient is current with scheduled visits with prescribing physician
   f. Presence of a negative TB screen and clear chest xray within the last year

   The prerequisites above shall be ascertained at the time of scheduling the appointment, and just prior to administration. The prescribing physician must be consulted prior to scheduling or administering an infusion procedure if the patient is missing any of the prerequisites identified above, or has an abnormal result with an ordered diagnostic test. The satisfactory attainment of prerequisites and the results of any consultation (if necessary) with the referring physician shall be documented in the patient record.

B. Prior to administration of Remicade, obtain the patient’s blood pressure, pulse and weight and document in the patient record.

C. Calculate dosing according to prescribing physician ordered dose based upon weight. Compare with Remicade Suggested Dosing Chart provided by manufacturer. Consult with prescribing physician if there are discrepancies. Document applicable discussion with prescribing physician.

D. Remicade dosing is to be rounded up to the nearest complete vial.

E. If unable to access venipuncture site after 2 attempts, notify Office Manager and seek assistance as required.

F. Mix medication and administer in accordance with manufacturer guidelines for drip rates and venipuncture location, unless prescribing physician orders alternate administration guidelines. Utilize a .22 micron filter in the IV line.

G. Monitor patient for any adverse response to treatment. Vitals should be taken at least every 30 minutes while infusion is in process. If an adverse response is detected, immediately stop administering the drug and seek assistance from an appropriate member of the medical staff. Document the adverse response and any treatment ordered and provided (Ex. Solumedrol, Benadryl and/or Tylenol).
H. Patient should remain in the treatment area for 20 minutes after the administration of infusion before leaving as a further precaution against adverse reaction. Take vital signs prior to patient departure.

I. In the event there is some Remicade that is not utilized during the infusion, the unused portion shall be disposed of in a biohazard container. Any amount so disposed shall be documented in the chart as wasted.

3. **Orencia:** The following guidelines apply specifically to Orencia.

A. Prerequisites for scheduling and administration include:

   a. Presence of a CBC that is within acceptable range within the last 6 months
   b. The completion of all other routine labs ordered by the referring physician
   c. No evidence of current infections
   d. No current antibiotic use
   e. The patient is current with scheduled visits with prescribing physician
   f. Presence of a negative TB screen and clear chest xray within the last year

   The prerequisites above shall be ascertained at the time of scheduling the appointment, and just prior to administration. The prescribing physician must be consulted prior to scheduling or administering an infusion procedure if the patient is missing any of the prerequisites identified above, or has an abnormal result with an ordered diagnostic test. The satisfactory attainment of prerequisites and the results of any consultation (if necessary) with the referring physician shall be documented in the patient record.

B. Prior to administration of Orencia, obtain the patient’s blood pressure, pulse and weight and document in the patient record.

C. Calculate dosing according to prescribing physician ordered dose based upon weight. Compare with Orencia Suggested Dosing Chart provided by manufacturer. Consult with prescribing physician if there are discrepancies or suggested changes. Document applicable discussion with prescribing physician.

D. Orencia dosing is in full vials according to manufacturer’s guidelines per weight.

E. If unable to access venipuncture site after 2 attempts, notify Office Manager and seek assistance as required.

F. Mix medication and administer in accordance with manufacturer guidelines for drip rates and venipuncture location, unless prescribing physician orders alternate administration guidelines. Utilize a filter in the IV line.

G. Monitor patient for any adverse response to treatment. Vitals should be taken at least every 30 minutes while infusion is in process. If an adverse response is detected, immediately stop administering the drug and seek assistance from an appropriate member
of the medical staff. Document the adverse response and any treatment ordered and provided (Ex. Solumedrol, Benadryl and/or Tylenol).

H. Patient should remain in the treatment area for 20 minutes after the administration of infusion before leaving as a further precaution against adverse reaction. Take vital signs prior to patient departure.

I. In the event there is some Orencia that is not utilized during the infusion, the unused portion shall be disposed of in a biohazard container. Any amount so disposed shall be documented in the chart as wasted.

4. **Simponi Aria:** The following guidelines apply specifically to Simponi Aria.

A. Prerequisites for scheduling and administration include:

   a. Presence of a CBC and CMP (per Jean the FDA only requires a TB prior to starting therapy – not even annually. They recommend a HEP B screen prior to and periodic) that is within acceptable range within the last 6 months
   b. The completion of all other routine labs ordered by the referring physician
   c. No evidence of current infections
   d. No current antibiotic use
   e. The patient is current with scheduled visits with prescribing physician
   f. Presence of a negative TB screen and clear chest xray within the last year

   The prerequisites above shall be ascertained at the time of scheduling the appointment, and just prior to administration. The prescribing physician must be consulted prior to scheduling or administering an infusion procedure if the patient is missing any of the prerequisites identified above, or has an abnormal result with an ordered diagnostic test. The satisfactory attainment of prerequisites and the results of any consultation (if necessary) with the referring physician shall be documented in the patient record.

B. Prior to administration of Simponi Aria, obtain the patient’s blood pressure, pulse and weight and document in the patient record.

C. Calculate dosing according to prescribing physician ordered dose based upon weight. Compare with Simponi Aria Suggested Dosing Chart provided by manufacturer. Consult with prescribing physician if there are discrepancies. Document applicable discussion with prescribing physician.

D. Simponi Aria is not to be rounded up to the nearest vial. Use only exact dosing as calculated. Any remainder in the vial should be documented as waste and disposed of properly.

E. Simponi Aria is manufactured with liquid in vial, no reconstitution is required. Administer in accordance with manufacturer guidelines for drip rates and venipuncture location, unless prescribing physician orders alternate administration guidelines.

F. If unable to access venipuncture site after 2 attempts, notify Office Manager and seek
assistance as required.

G. Prepare medication and administer in accordance with manufacturer guidelines for drip rates and venipuncture location, unless prescribing physician orders alternate administration guidelines. Utilize a .22 micron filter in the IV line.

H. Monitor patient for any adverse response to treatment. Vitals should be taken at least every 30 minutes while infusion is in process. If an adverse response is detected, immediately stop administering the drug and seek assistance from an appropriate member of the medical staff. Document the adverse response and any treatment ordered and provided (Ex. Solumedrol, Benadryl and/or Tylenol).

I. Patient should remain in the treatment area for 20 minutes after the administration of infusion before leaving as a further precaution against adverse reaction. Take vital signs prior to patient departure.

J. In the event there is some Simponi Aria that is not utilized during the infusion, the unused portion shall be disposed of in a biohazard container. Any amount so disposed shall be documented in the chart as wasted.

5. **Zolendronic Acid / Reclast**: The following guidelines apply specifically to (Zoledronic Acid) and Reclast

A. Prerequisites for scheduling and administration include:
   
a. Presence of a Vitamin D and CMP that is within acceptable range within last 6 months

b. Dental exam to rule out osteonecrosis of the gums by either a Doctor or Dentist within the past year.

c. No current infections.

d. No current antibiotic use.

e. Women that are nursing or pregnant or suspect being pregnant should not take treatment.

f. Determine if patient plans to have dental surgery or teeth removed. Inform prescribing physician if there are such plans.

g. Determine if patient has some sort of renal impairment before starting treatment. Inform prescribing physician is such is the case.

h. Infusion should not be scheduled until on or after 365 days (1 year anniversary) from receiving a previous zolendronic acid/reclast infusion.
The prerequisites above shall be ascertained at the time of scheduling the appointment, and just prior to administration. The prescribing physician must be consulted prior to scheduling or administering an infusion procedure if the patient is missing any of the prerequisites identified above, or has an abnormal result with an ordered diagnostic test. The satisfactory attainment of prerequisites and the results of any consultation (if necessary) with the referring physician shall be documented in the patient record.

**B.** Prior to the administration of Reclast (Zoledronic Acid), obtain patient’s blood pressure, pulse and weight and document in the patient record.

**C.** Reclast (Zoledronic Acid) is provided in a pre-packaged 5mg per 100 ml IV Bag or similar container, dependent on Manufacturer.

**D.** Infuse patient with 100mg IV bag of Sodium Chloride before starting treatment. Utilize a .22 micron filter during infusion.

**E.** Administer in accordance with manufacturer’s recommendations and document in patient’s record.

**F.** Monitor patient for any adverse response to treatment. Vitals should be taken at least every 30 minutes while infusion is in process. If an adverse response is detected, immediately stop administering the drug and seek assistance from an appropriate member of the medical staff. Document the adverse response and any treatment ordered and provided (Ex. Solumedrol, Benadryl and/or Tylenol).

**G.** Patient should remain in the treatment area for 20 minutes after the administration of infusion before leaving as a further precaution against adverse reaction. Take vital signs prior to patient departure.

**H.** In the event there is some (Zoledronic Acid) or Reclast that is not utilized during the infusion, the unused portion shall be disposed of in the biohazard container. Any amount so disposed shall be documented in the chart as wasted.

**6. Actemra:** The following guidelines apply specifically to Actemra.

**A.** Prerequisites for scheduling and administration include:

a. Lipids (4-8) weeks following the initiation; every 24 weeks thereafter
b. Liver function tests (ALT/AST): 4-8 weeks following initiation; every 3 months thereafter
c. Neutrophils: 4-8 weeks following initiation; every 3 months thereafter
d. Platelets: 4-8 weeks following initiation; every 3 months thereafter
e. The completion of all other routine labs ordered by the prescribing physician
f. No evidence of current infections
g. No current antibiotics use
h. The patient is current with scheduled visits with prescribing physician
i. Presence of a negative TB screening within the last year
j. Vaccinations, not administer concurrently with Actemra as clinical safety has not been established. No data are available on the secondary transmission of infection from persons receiving live vaccines to patients receiving Actemra, or on the effectiveness of vaccination in patients receiving Actemra.
k. Demyelinating Disorders, the impact of Actemra on demyelinating disorders is not known, but multiple sclerosis and chronic inflammatory demyelinating polyneuropathy were reported rarely in RA clinical Trials.
l. Gastrointestinal perforations, events of gastrointestinal perforations have been reported in clinical trials, primarily as complications or diverticulitis. Use Actemra with caution in patients who may be at increased risk for gastrointestinal perforation. Promptly evaluate patients presenting with new onset of abdominal symptoms for early identification of gastrointestinal perforation.

The prerequisites above shall be ascertained at the time of scheduling the appointment, and just prior to administration. The prescribing physician must be consulted prior to scheduling or administering an infusion procedure if the patient is missing any of the prerequisites identified above, or has an abnormal result with an ordered diagnostic test. The satisfactory attainment of prerequisites and the results of any consultation (if necessary) with the referring physician shall be documented in the patient record.

B. Prior to administration of Actemra, obtain the patient’s blood pressure, pulse and weight and document in the patient record.

C. Calculate dosing according to prescribing physician ordered dose based upon weight. Compare with Actemra Suggested Dosing Chart provided by manufacturer. Consult with prescribing physician if there are discrepancies. Document applicable discussion with prescribing physician.

D. Document total dosage delivered in the patient’s record. Utilize vial combinations that result in the least amount of waste between the dosage per weight calculation and the total dosage in the vials. Document amount delivered and the amount discarded in the patient record and utilize appropriate billing codes.

E. If unable to access venipuncture site after 2 attempts, notify Office Manager and seek assistance as required.

F. Mix medication and administer in accordance with manufacturer guidelines for drip rates and venipuncture location, unless prescribing physician orders alternate administration guidelines.

G. Monitor patient for any adverse response to treatment. Vitals should be taken at least every 30 minutes while infusion is in process. If an adverse response is detected, immediately stop administering the drug and seek assistance from an appropriate member of the medical staff. Document the adverse response and any treatment ordered and provided (Ex. Solumedrol, Benadryl and/or Tylenol).
H. Patient should remain in the treatment area for 20 minutes after the administration of infusion before leaving as a further precaution against adverse reaction. Take vital signs prior to patient departure.

I. In the event there is some Actemra that is not utilized during the infusion, the unused portion shall be disposed of in a biohazard container. Any amount so disposed shall be documented in the chart as wasted.

7. **Rituxin**: The following guidelines apply specifically to Rituxin.

   A. Prerequisites for scheduling and administration include:
      
      a. The completion of routine labs ordered by the prescribing physician
      b. No evidence of current infections
      c. No current antibiotics use
      d. The patient is current with scheduled visits with prescribing physician
      e. Presence of a negative TB screening within the last year

      The prerequisites above shall be ascertained at the time of scheduling the appointment, and just prior to administration. The prescribing physician must be consulted prior to scheduling or administering an infusion procedure if the patient is missing any of the prerequisites identified above, or has an abnormal result with an ordered diagnostic test. The satisfactory attainment of prerequisites and the results of any consultation (if necessary) with the referring physician shall be documented in the patient record.

   B. Prior to administration of Rituxan, obtain patient’s blood pressure, pulse and weight and document in the patient record.

   C. Premedicate the patient per physician order at least 30 minutes prior to infusion or as ordered by physician.

   D. Rituxan does not need to be reconstituted but allow the vials to warm up to room temperature before mixing.

   E. Prepare the Rituxin solution per manufacturer’s guidelines.

   F. Document total amount administered as well as amount discarded in patient’s record. Any amount not used is to be discarded in biohazard container.

   G. On the first day of infusion, follow rate of administration indicated by manufacturer’s guidelines. Utilize dial flow tubing.

   H. If patient tolerates the first day’s infusion without adverse reaction, then administer subsequent infusions in accordance with manufacturer’s guidelines.

   I. During infusion, monitor patient for any adverse response to treatment. Vitals should be
taken at least every 30 minutes while infusion is in process.

J. If an adverse response is detected, immediately stop administering the drug and seek assistance from an appropriate member of the medical staff.

K. Document the adverse response and any treatment ordered and provided.

L. Patient should remain in the treatment area for 20 minutes after the administration of infusion before leaving as a further precaution against adverse reaction. The IV should remain in place at a KVO rate. Take vital signs and ensure that patient is stable prior to departure.

M. Advise the patient and family members to contact the infusion center for any questions or concerns. Advise the patient and family members to seek immediate medical attention for any symptoms of adverse reaction or complications.

<table>
<thead>
<tr>
<th>DATE</th>
<th>REVIEW/APPROVAL SIGNATURE</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>