

Mandell Center Medication Protocol: Rituxan/Truxima (Rituximab)

Indications and Usage:

- At provider's discretion.

Prior to initiating Rituxan/ Truxima, the following are required:

Labwork: (within two months prior to initiating treatment)

- CBC with differential
- Liver profile
- BUN
- Creatinine
- Hep B Surface Antigen
- Hep B Core AB, IGM
- Immunoglobulins (IgG, IgM, IgA)
- VZV Antibody IgG

Imaging:

- MRI Brain (with or without contrast per provider)– to be performed in the 3 months prior or within 2 months of starting Rituxan/Truxima for relapsing-remitting patients (may also be performed at provider discretion).

*For patients transitioning from Tysabri, MRI brain with and without contrast to be performed for JCV positive patients upon discontinuing Tysabri and at 6 months after discontinuing Tysabri.

- MRI Brain (with or without contrast) to be performed at provider discretion for patients with progressive forms of MS.

Vaccination:

- Patients should, if possible, be brought up to date with all immunizations in agreement with current immunization guidelines prior to initiating Rituxan/Truxima and administer non-live vaccines at least 4 weeks prior to a course of Rituxan/Truxima.

Contraception:

- Advise females of reproductive potential to use effective contraception during treatment with Rituxan/Truxima and for at least 12 months after the last dose.



Preparation before/during infusion:

- A driver is required for patients receiving IV/PO Benadryl or any sedating medication for Rituxan/Truxima infusions.
- Infection assessment: Prior to every infusion of Rituxan/Truxima determine whether there is an active infection. In case of active infection, delay infusion of Rituxan/Truxima until the infection resolves.
- RN to assess patient each visit; any change in patient status or abnormal vital signs are to be reported to the provider prior to administration to determine if drug is to be administered. Vital signs including systolic BP > 160, diastolic BP > 100, pulse > 100, temperature > 100 degrees Fahrenheit, and pulse oximetry < 95% are to be reported to provider before initiating treatment.
- Vital signs to be performed upon admission, 30 minutes after start of Rituxan/ Truxima, PRN during infusion, and upon completion of infusion.

Pre-infusion medications as follows:

- 0.9% Normal Saline 500mL IV @ 999mL/hr; saline to be administered prior to first 1000mg Rituxan/Truxima doses (2 weeks apart) and the first subsequent dose of Rituxan/ Truxima.
- Solu-Medrol 125mg IVP, administer over 2 minutes (for severe intolerance to Solumedrol, omit).
 - If intolerant to Solu-Medrol, administer Decadron 4mg IVP over 2-3 minutes.
- Diphenhydramine (Benadryl) 50mg IVP over 2-3 minutes; if intolerant to IV Benadryl, may substitute with Benadryl 50mg PO.
 - If intolerant to Benadryl, administer Famotidine (Pepcid) 20mg/2mL (vial) (dilute in 5mL NS) IVP over 3-5 minutes.
- Acetaminophen 975mg PO.

Recommended Dosing and Administration:

First infusion: Rituxan/Truxima 1000mg in 500mL 0.9% NS (2mg/mL), start at 50mg/hr, increase by 50mg/hr every 30 minutes to a maximum of 400mg/hr.

Second infusion (2 weeks later): Rituxan/Truxima 1000mg in 500mL 0.9% NS (2mg/mL), start at 50mg/hr, increase by 50mg/hr every 30 minutes to a maximum of 400mg/hr.

Subsequent infusion (6 months after first infusion): Rituxan/Truxima 1000mg in 500mL 0.9% NS (2mg/mL), start at 100mg/hr, increase by 100mg/hr every 30 minutes to a maximum of 400mg/hr.

- One-hour observation period after each Rituxan/Truxima infusion (IV to be left intact until observation period is completed)
- If patient desires to leave prior to one hour, they must sign out AMA.



Delayed or Missed Doses:

- If a planned infusion of Rituxan/ Truxima is missed, administer as soon as possible; do not wait until the next scheduled dose. Reset the dose schedule to administer the next sequential dose 6 months after the missed dose is administered.
 - *If dose is delayed > 9 months refer to provider for dosing.*
- Doses of Rituxan/ Truxima must be separated by at least 5 months.

Management of Mild to Moderate Infusion Reactions (most commonly to include symptoms of itching in ears, throat, extremities; rash – most commonly face/neck, headache, complaints of muscle tightness/spasticity):

- Stop infusion and restart as per resolution of patient's symptoms.
- 500mL 0.9% NS, IV run to gravity.
- Diphenhydramine (Benadryl) 25mg IVP over 2-3 minutes, PRN for rash or itching; may administer an additional 25mg IVP if no change in symptoms after 10 minutes; once.
 - Famotidine (Pepcid) 20mg/2mL (vial) IVP over 3-5 minutes, if intolerant to Diphenhydramine or if symptoms persist after Benadryl is administered; may repeat once if Pepcid was not used in pre-medications.
- Solu-Medrol 125mg IVP; administer over 2 minutes; once.
 - If intolerant to Solu-Medrol, administer Decadron 4mg IVP, over 2-3 minutes; once.
- Re-start infusion at one half the dose rate when the reaction started and increase by 50mg/hr every 30 minutes for first infusions (2 weeks apart). Increase by 100mg/hr every 30 minutes for subsequent Rituxan/Truxima infusions.
- If patient continues to present with infusion reaction after above treatment, contact provider for further instruction.

For severe infusion reaction or suspected allergic reaction (most commonly to include SOB, hypotension or hypertension, tachycardia, bradycardia, tongue or throat swelling):

- **STOP INFUSION, Initiate Rapid Response**
- Call 911
- Sodium Chloride 0.9% (NS) IV Bolus, 500mL, to gravity.
- Notify provider
- Per provider, the following may be used while waiting for transport:
 - Atropine 0.5mg IV push, every 3-5 minutes up to 3mg maximum dosage prn for S/S bradycardia
 - Epinephrine 0.1mg IV push, prn for S/S anaphylaxis, may repeat every 5-15 minutes up to max of 0.5mg.
- Monitor with code cart until EMS arrives for transport

Patient Counseling/Discharge Instructions:

1. Tylenol 1000mg may be used for post infusion fever, headache, throat irritation, and/or flu-like symptoms. Do not exceed 4,000 mg in a 24-hour period; be sure to include the Tylenol that was administered during the infusion today.
 - a. Patients may alternate with Ibuprofen 800 mg every 8 hours.
2. Benadryl 50mg PO may be used every 4-6 hours as needed for itchy skin, rash, hives, or flushing.
3. Pepcid (Famotidine) 20mg may be used for treatment of nausea (maximum of two doses in a 24-hour period).
4. Call 911 to be transported to the emergency room if you experience any discomfort or swelling in your mouth or throat, trouble breathing, weakness, fast/slow/irregular heartbeat, or chest pain.
5. Stay hydrated – drink plenty of water following your infusion.
6. Fatigue and lightheadedness may be experienced after your infusion. Please take precautions to protect yourself from falls or injury.
7. If you have an allergy or medical concern with use of any of the above listed medications, please avoid usage and follow up with the medical provider.
8. A driver is required for patients receiving IV Benadryl or any as needed sedating medication for Rituxan/Truxima infusions.



Follow-up monitoring for Rituxan/ Truxima:

Labwork: (to be completed within 1-2 months prior to each subsequent 6-month infusion*)

- CBC with differential
 - Liver profile
 - BUN
 - Creatinine
 - Immunoglobulins (IgG, IgM, IgA)
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- *May be drawn of day of infusion without holding infusion unless clinically warranted.
 - Monitor the levels of quantitative serum immunoglobulins during Rituxan/Truximatreatment and after discontinuation of treatment, until B-cell repletion, and especially in the setting of recurrent serious infections.
 - Referral to Immunology for decreased immunoglobulins in the setting of recurrent Serious Infection or Opportunistic infection.

Imaging:

- Annual brain and cervical MRI (without contrast) to be performed for monitoring of relapsing-remitting patients.

Follow-up:

- Follow-up appointment with provider at the MS Center within 2-4 months after infusion; if follow up appointment is already scheduled; this appointment will suffice for monitoring.
- Annual EDSS examination.

Dr. Mary A. Bailey, Regional Director

Mandell Multiple Sclerosis Center

Date

Reference: Rituxan PI revision 08/2020

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