Rituximab (Truxima) in Renal Patients - Full Clinical Guideline

Reference no.:CG-REN/2023/002

1. Introduction

Rituximab is indicated for the treatment of adult patients with ANCA-associated vasculitis, Membranous Nephropathy and SLE within specified criteria. The commissioning criteria for the use of Rituximab in induction and maintenance therapy for adult patients with vasculitis is set out in this policy document: https://www.england.nhs.uk/commissioning/wp-content/uploads/sites/12/2015/01/a13-ritux-anca-vascul.pdf

Rituximab has also been used, off license and sometimes uncommissioned, for a variety of glomerular diseases , minimal change disease and focal segmental glomerulosclerosis (FSGS). The use of Rituximab in these circumstances will need to be approved by the associate clinical director, service manager and the Drug and Therapeutic committee.

2. Aim and Purpose

To ensure that patients are receiving Rituximab (Truxima) in a safe and effective manner.

Rituximab is a monoclonal antibody directed against the CD20 antigen on B cells.

3. Keywords

Rituximab

Truxima

Glomerulonephriti

4. Guideline

Initiation of therapy should be by Consultant Nephrologist only.

Prior to treatment

- Counselling of the patient regarding possible side effects of Rituximab therapy and provision of information sheet to take place before first treatment. (10526 Truxima Patient Information 130x240 AW.indd (medicines.org.uk)

Prior to initiating Induction therapy, the following investigations / checks are required:

Use Renal pick list on Lorenzo “pre renal immunosuppression” for blood tests

- Full blood count (within 7 days)
- U&E (within 7 days)
- Liver function tests (within 7 days)
- CRP (within 7 days)
- Chest x-ray within the past 6 months
- Additional TB screening with IGRA test for high risk individuals
- Baseline immunoglobulins
- Viral Hepatitis and HIV screen (Hep B sAg, Hep BcAb, Hep B sAb, Hep C Ab, HIV)
- Vaccination Status (Pneumovax within 5 years, Flu, Covid) (need to have at least 4 weeks before treatment if not had unless it is emergency)
- VzV Ab levels
- Any other disease specific markers as baseline levels pre treatment (if relevant)

Prior to all subsequent treatments

- Full blood count (within 7 days)
- U&E (within 7 days)
- Liver function tests (within 7 days)
- CRP (within 7 days)
- Immunoglobulins should be checked within the month before the next infusion (if low to discuss with requesting consultant who should discuss at GN MDT if available and may delay or reduce dose depending on level and indication)
- Vaccination Status (Pneumovax, Flu, Covid)
- Consider annual CXR
- Any other disease specific markers (if relevant)

The prescribing Dr is responsible for completing the Dr's checklist prior to prescription/administration Rituximab (Truxima) in Renal Patients - Clinical Guidelines - Doctor's Checklist

Contraindications

- Active severe infection (including acute and chronic infections)
- Patients in a severely immunocompromised state
- History of hypersensitivity to the drug or any other components of the infusion or to murine proteins
- NYHA grade 4 congestive cardiac failure (CCF) or severe, uncontrolled cardiac disease

Treatment Schedule

Induction therapy is administered as two intravenous infusions of 1000mg at an interval of 2 weeks. For prescribing select renal truxima induction dose for both 1st and second doses

Maintenance Therapy

If indicated by disease activity, treatment can be repeated as maintenance therapy at a dose of 1000mg at a minimum of 6 monthly intervals. On occasions dose may be reduced to

500mg at consultants discretion. For maintenance select Truxima maintenance and choose either no previous reaction or previous reaction to select infusion rate. The faster rate should not be used in patients who have had previous serious infusions reactions to any previous biologic or in patients with clinically significant cardiovascular disease including arrhythmias.

Administration

Before each administration

- Collect Bloods if not already available*:* FBC, U&E, LFT and CRP
- Measure and record on Patientrack: weight, pulse, blood pressure, temperature.
- Rituximab should only be administered in an environment with immediately available full resuscitation facilities.
- A bed or reclinable chair is required for all infusions.
- A doctor should be readily available in case of reaction.
- A Peripheral canula needs to be inserted on the day of the infusion. Blood results within a week must be reviewed prior to prescription/ administration. See Rituximab (Truxima) in Renal Patients - Clinical Guidelines for Nursing checklist.

NB. If above bloods have not been done within a week of the infusion these should be done as urgent samples and the results checked prior to prescribing treatment. Do not proceed if no immunoglobulin results available within the previous month. (results take around 5 days)

Pre-Medication to be given 1 hour pre infusion

Methylprednisolone 125mg IV in 100mls sodium chloride 0.9% infused over 30 minutes,
Paracetamol 1g orally
Chlorphenamine (Piriton) 10mg intravenously.

Preparation

Rituximab is not cytotoxic and requires no special precautions or procedures in case of spillage

Rituximab 1000mg (in 350ml of sodium chloride 0.9%) is available as a ready-made bag which is supplied from the pharmacy department. Other strengths are made in the pharmacy aseptics satellite and the infusion may be prepared in advance if the patient is able to be assessed within the week before the infusion.

Do not give other IV fluids or drugs through the same line. A filter is not required

During infusion

- A 500ml bag of normal saline should be hanging by the patient's bed in case of hypotension.
- Check BP, pulse and temperature every 30 minutes during the infusion and for 1 hour post infusion.

- This infusion must be given via a Volumetric Infusion pump and an infusion Pump Checklist completed.
- A rituximab infusion rate calculator chart will be provided from by the pharmacy department describing the administration rate for the infusion..

Infusion reactions

Infusion reactions occur in 15% of patients following the first infusion and in 2% in the second infusion. Infusion reactions may include pruritis, fever, urticaria/ rash, chills, pyrexia, rigors, sneezing, angioneurotic oedema, throat irritation, cough and brochospasm, with or without hypotension or hypertension. Premedication with IV steroids significantly reduces the incidence and severity of these events

If **minor infusion reactions** occur slow the infusion, stop if necessary and restart at half the previous rate
If **severe reactions** occur **(bronchospasm, severe breathlessness, hypoxia).** Stop infusion. Treat in accordance with the current anaphylaxis guidelines.

After infusion

Giving set is disconnected after a saline flush, but the cannula is left in situ until after observation period is complete.

Patient should be started on pneumocystis pneumonia prophylaxis to continue for at least 6 months after receiving Rituximab induction therapy.

For patients who are receiving maintenance therapy pneumocystis pneumonia prophylaxis should continue until at least 6 months after cessation of therapy.

Co trimoxazole is 1st line with Atovaquone as second line if Co trimoxazole is not tolerated.

Patient can go home 1 hour after infusion if they are well and observations have been satisfactory.
Inform patient of follow up plans

Further Doses

The timing of future doses is the responsibility of the requesting consultant, normally if there has been **no** clinical or biological response at 6 months (12 months for membranous nephropathy), then further doses are unlikely to produce a response and should not be given.

5. References (including any links to NICE Guidance etc.)

- Truxima summary of product characteristics January 2022

- Clinical Commissioning Policy: Rituximab for the treatment of ANCA-associated vasculitis in adults.

6. Documentation Controls

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CG-REN/2023/002</td><td colspan="2">Version:

2</td><td>Status

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<tr><td rowspan="3">Version / Amendment History</td><td>Version</td><td>Date</td><td>Author</td><td colspan="2">Reason</td></tr>
<tr><td>2</td><td>8.6.23</td><td>Dr Pittman</td><td colspan="2">Update and inclusion of checklists</td></tr>
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<tr><td colspan="6">Training and Dissemination: Via the ward and clinical educators. Medical Dr departmental induction</td></tr>
<tr><td colspan="6">Development of Guideline: Dr Zoe Pittman
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7. Appendices (see separate documents in Koha)