Infliximab - Rheumatology - Full Clinical Guideline

Reference no.: CG/Rheum/2023/004

Infliximab is a Monoclonal antibody used in the treatment of Rheumatoid Arthritis, Ankylosing Spondylitis and Psoriasitic arthritis

Purpose

To ensure that patients are receiving infliximab in a safe and effective manner. Infliximab is a chimeric monoclonal antibody that binds with high affinity to TNFα, thereby neutralising its activity. It is licensed for use in rheumatoid arthritis (in combination with methotrexate), ankylosing spondylitis and psoriatic arthritis. It will be prescribed according to originator or biosimilar brand name (Remicade or Remsima). They both have the same licensed indications and are delivered the same way.

Indications for treatment:

Patients should be treated in accordance with National Institute of Clinical Effectiveness (NICE), local commissioning and British Society of Rheumatology (BSR) guidelines. The decision to use the agent should be by Consultant Rheumatologist only.

Rheumatoid arthritis (RA)Infliximab in combination with methotrexate is indicated for the treatment of adult patients with severe active RA who have had an inadequate response or intolerance to other disease modifying drugs.

Psoriatic arthritis (PsA): Infliximab is indicated for treatment of active and progressive psoriatic arthritis in adult patients when the response to previous DMARD therapy has been inadequate.

Ankylosing spondylitis (AS) **:**Infliximab is indicated for treatment of severe, active ankylosing spondylitis, in adult patients who have responded inadequately to conventional therapy**.**

Contraindications

- Hypersensitivity to the active substance, to other murine proteins, or to any of the excipients
- Patients with active tuberculosis or other severe infections such as sepsis, abscesses, and opportunistic infections.
- Patients with moderate or severe heart failure (NYHA class III/IV)

Cautions

- Demyelinating disorders (risk of exacerbation)
- hepatitis B virus—monitor for active infection
- history of dysplasia (in inflammatory bowel disease)
- history of malignancy or increased risk of malignancy
- history of prolonged immunosuppressant or PUVA treatment in patients with psoriasis
- mild heart failure (discontinue if symptoms develop or worsen)
- predisposition to infection (discontinue if new serious infection develops)
- risk of delayed hypersensitivity reactions if drug-free interval exceeds 16 weeks

Possible Adverse effects

Patient information: Patient should be familiar with the information available in the Versus Arhtritis Patient Information booklet: Infliximab information booklet (versusarthritis.org)

Patients should be reminded about the need to stop medication if they have an infection and to ensure they are up t o date with vaccines, especially Covid and flu

Immediate: Hypersensitivity (see below)

Other: see SPC: Remicade 100mg powder for concentrate for solution for infusion - Summary of Product Characteristics (SmPC) - (emc) (medicines.org.uk)

Treatment Schedule

Prior to treatment:

Counselling of the patient regarding possible side effects of Infliximab therapy and provision of information sheet should take place before first treatment, usually by a Rheumatology Clinical Nurse Specialist

Prior to initiating therapy please check the following has been done:

- Relevant baseline assessment of disease activity (DAS 28, PsARC or BASDAI)
- Full blood count, ESR
- Urea and electrolytes, Liver function tests CRP
- Urinalysis
- Chest x-ray within the past 12 months and T-spot screening
- Hepatitis and HIV screen
- Vaccines as follows:

- Flu and Covid vaccination if available (depending on season)
- Pneumovax vaccine
- Shingles **vaccine** if eligible

Dose

Rheumatoid arthritis: (Needs to be in combination with weekly methotrexate)

Intravenous : Initially 3 mg/kg, then 3 mg/kg to be taken at week 2 and 6 after initial dose, then 3 mg/kg every 8 weeks.

IV infusion then SC maintenance: Initially intravenous 3 mg/kg, and further 3 mg/kg after 2 weeks; then after 4 weeks (by subcutaneous injection) maintenance 120 mg sc every 2 weeks

Ongoing: Response should be assessed at 12 weeks. Consider discontinuation if inadequate response or consider increasing dose to 3 mg/kg intravenous every 4 - 6 weeks, or alternatively increasing steps of 1.5 mg/kg every 8 weeks (max. per dose 7.5 mg/kg every 8 weeks). Again assess response at 12 weeks and discontinue if inadequate response.

Ankylosing spondylitis and Psoriatic arthritis

Intravenous: Initially 5 mg/kg, then 5 mg/kg, to be taken at week 2 and 6 after initial dose, then 5 mg/kg every 6–8 weeks.

IV infusion then SC maintenance: Initially 5 mg/kg, followed by (by intravenous infusion) 5 mg/kg after 2 weeks; then, (by subcutaneous injection) maintenance 120 mg every 2 weeks, subcutaneous maintenance dosing to be started 4 weeks after the second of the initial intravenous infusions.

Directions for Intravenous administration

Before each administration

- Measure and Record: Weight, pulse, BP, temperature and urinalysis (only if urinary symptoms)
- Check recent FBC , U&E and LFT are acceptable

Administration

- Intravenous treatment, including initial IV loading will be on a Medical Day Case unit
- Reconstitution technique should be as per pharmacy instruction
- Give over 2 hours through a low protein-binding filter (1.2 micron or less);

- Adults who have tolerated 3 initial 2-hour infusions may be given subsequent infusions of up to 6 mg/kg over at least 1 hour. Start infusion within 3 hours of reconstitution.

Monitoring of infusion

- Infliximab has been associated with acute infusion related reactions including anaphylactic shock. Acute infusion reactions may develop within seconds or within a few hours following infusion.
- A doctor should be readily available for the entire infusion.
- Check BP, pulse and temperature every 30 minutes during the infusion.
- If an acute reaction occurs stop the infusion immediately.
- If severe reactions occur (bronchospasm, severe breathlessness, hypoxia) treat with Adrenaline, chlorphenamine and intravenous steroids in accordance with the current anaphylaxis guidelines

- Infusion 1st -4th : administer over 2 hours and patient must wait for 2 hours after infusion
    - Patients who have tolerated at least 4 initial 2 hour infusions may be considered for shortened infusion times as follows:
        - Infusions 5-9 administer over 1 hour and the patient must wait for 1 hour after infusion
        - Infusions ≥10 administer over 30 minutes and the patient does not need to wait

Self-administration (With subcutaneous use)

Patients may self-administer Remsima® pre-filled syringes or pens following training in subcutaneous injection technique. Alert card should be provided to the patients.

References:

https://www.medicines.org.uk/emc/product/3831/smpc#gref

https://cks.nice.org.uk/topics/rheumatoid-arthritis/management/confirmed-ra/#drug-treatments

https://bnf.nice.org.uk/drugs/infliximab/#indications-and-dose

1. Documentation Controls

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2. Appendices