Belimumab IV - Systemic Lupus Erythematosus (SLE) - Summary Clinical Guideline

Reference no.: CG-RHEUM/2018/009

Belimumab is a monoclonal antibody which inhibits the activity of B lymphocyte stimulator (BLyS).

Indications for Treatment

Belimumab in combination with other non-biologic immunosuppressant treatment and corticosteroids is indicated for the treatment of adult patients with severe active SLE who have had an inadequate response or intolerance to other disease modifying drugs and corticosteroids. Patients must have a positive dsDNA antibody and low complement.

Belimumab will be given as add on therapy to patients on a stable dose of immunosuppressant treatment plus corticosteroids.

Prior to treatment

* Counselling of the patient regarding possible side effects of Belimumab therapy and provision of information sheet to take place before first treatment.

* Patients should have a BILAG and SELENASLEDAI documented. A SELENASLEDAI score >10 indicates active disease eligible for treatment.

* Patients should have positive dsDNA antibodies and a low complement level

Contraindications

* Active severe infection

* Women who are breast feeding or pregnant (discontinue for 12 months in males and females before conception)

* History of hypersensitivity to the drug or any other components of the infusion

* Hepatitis B C or HIV disease

* Patients with severe active lupus nephritis or CNS lupus

* Hypogammaglobulinaemia

* Organ or bone marrow transplant

Treatment Schedule

Initiation of therapy should be by Consultant Rheumatologist only.

Belimumabimab is administered as an intravenous infusions of 10mg/ kg body weight at week 0, week 2 and week 4 and at 4 weekly intervals thereafter. Patients should also be pre-treated 1 hour before with paracetamol 1g orally and chlorpheniramine (piriton) 4mg oral

Prior to initiating therapy check the following:

* BILAG and SELENASLEDAI score

* Full blood count, ESR

* Initial profile and Liver function tests

* CRP

* urinalysis

* Chest x-ray within the past 6 months and TB screening as per guidelines

* Baseline immunoglobulins

* Hepatitis screen

* Pneumovax status (need to have at least 4 weeks before treatment if not had)

Preparation

Belimumab is normally prepared in a 250ml bag of normal saline (fluid will have been withdrawn such that the volume to be infused is 250mls).

A Peripheral Catheter needs to be inserted on the day of the infusion. A 500ml bag of normal saline should be hanging by the patient's bed in case of hypotension.

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

Before each administration

Measure and record: weight, blood pressure, temperature, urinalysis

Collect: Full blood count, ESR

IP and LFT CRP

NB. If these 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.

Paracetamol, chlorpheniramine 10 mg IV and Adrenaline 0.5ml 1 in 1000 IM should be readily available (as per anaphylaxis protocol).