CLINICAL GUIDELINE

Tocilizumab for the treatment of Giant Cell Arteritis

A guideline is intended to assist healthcare professionals in the choice of disease-specific treatments.

Clinical judgement should be exercised on the applicability of any guideline, influenced by individual patient characteristics. Clinicians should be mindful of the potential for harmful polypharmacy and increased susceptibility to adverse drug reactions in patients with multiple morbidities or frailty.

If, after discussion with the patient or carer, there are good reasons for not following a guideline, it is good practice to record these and communicate them to others involved in the care of the patient.

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Important Note:

The online version of this document is the only version that is maintained.
Any printed copies should therefore be viewed as 'Uncontrolled' and as such, may not necessarily contain the latest updates and amendments.

Guidance for the use of Tocilizumab in the Treatment of Giant Cell Arteritis

Giant Cell Arteritis (GCA) is a systemic, granulomatous arteritis of the aorta and its major branches (large vessel vasculitis) with a predilection for the extra cranial branches of the carotid arteries.

A recent phase III study of patients recently diagnosed, or with relapsing GCA, reported superiority in terms of 52- week steroid free remission in those treated with Tocilizumab plus a 26 week steroid taper compared to placebo plus a 26 week steroid taper.

Who should receive Tocilizumab?
Tocilizumab should be considered in all patients with a new or relapsing diagnosis of GCA, including cranial and extra-cranial GCA/ large vessel vasculitis (LVV). Where possible the diagnosis of GCA should be confirmed by means of temporal artery ultrasound (US) where available (local provision of US varies), temporal artery biopsy (TAB) or other imaging modalities such as PET CT in cases of extra-cranial GCA/ LVV.

Dose, Preparation and Supply of Tocilizumab?
Subcutaneous Tocilizumab 162mg once weekly alongside a proposed 26-week glucocorticoid tapering regime; it is acknowledged that glucocorticoid tapering may vary between patients. Tocilizumab should be continued as monotherapy upon discontinuation of glucocorticoids.

Glucocorticoids and Tocilizumab.
Tocilizumab monotherapy should not be used to treat an acute relapse and should be co-prescribed with glucocorticoids.

A 26-week glucocorticoid tapering regime should be followed, if possible, guided by disease activity and physician discretion (*Appendix 1*)

Who should prescribe Tocilizumab?
The prescription of Tocilizumab should be limited to Rheumatologists and Ophthalmologists with experience managing GCA and other large vessel vasculitides.

Duration of Tocilizumab Treatment?
Efficacy of Tocilizumab should be assessed at 3 and 6 months of treatment. Lack of efficacy would be defined as persistent or relapsing features of GCA despite treatment and precluding glucocorticoid tapering. In patients in whom Tocilizumab is ineffective, withdrawal should be considered and alternate immunosuppressant therapy instituted.

If effective, treatment with Tocilizumab should be continued for 12 months. Following withdrawal at 12 months, alternate immunosuppressant agents such as Mycophenolate Mofetil and Methotrexate can be considered at physician's discretion.

Re-treatment with Tocilizumab?
Consideration can be given, at physician's discretion, to re-prescribing Tocilizumab in the event of a disease flare after Tocilizumab had been withdrawn, providing Tocilizumab was deemed effective during the prior 12 month treatment period. In the event of relapse and the need for re-treatment, Tocilizumab should be accompanied with tapering glucocorticoids as per initial treatment schedule.

Are there any contraindications to Tocilizumab prescription?
Prescriber should refer to the Summary of Product Characteristics (available from www.medicines.org.uk) for a full list of cautions and contraindications.

Baseline pre-treatment screening
Secondary care screening to include: -

- FBC, ESR, UEs, LFTs, Lipids
- Hepatitis serology: Hepatitis B surface antigen (HBsAg) and antibodies to Hepatitis B core antigen (anti-HBc), Hepatitis C and HIV serology.
- Latent tuberculosis screening (CXR and Quantiferon)

Tocilizumab monitoring
Secondary care monitoring including: -

- 4- weekly FBC, LFTs for 6 months and 3-monthly thereafter.
- Baseline and 3-month lipid profile. Treatment of high cholesterol should be initiated based on local guidance.

Additional points

- Secondary care prescriber should ensure a timely clinic letter is issued to GP notifying when Tocilizumab is started and stopped to ensure Primary Care medication records are up to date.
- Influenza, Pneumococcal, Covid and Herpes Zoster (>18 years) vaccination is recommended in all patients receiving Tocilizumab, assuming no contraindications.
- Live and attenuated vaccines are contraindicated.
- Major elective surgery should be deferred to 2 weeks after last subcutaneous injection.
- Tocilizumab information leaflet should be provided to patients

Appendix 1: 26-Week glucocorticoid tapering regime.

Taper week	Prednisolone Dose mg/ day
1	60
2	50
3	40
4	35
5	30
6	25
7	20
8	15
9	12.5
10	12.5
11	10
12	9
13	8
14	7
15	6
16	6
17	5
18	5
19	4
20	4
21	3
22	3
23	2
24	2
25	1
26	1
27	0
28	0