Tocilizumab - for moderate to severe Rheumatoid Arthritis

AREAS OF RESPONSIBILITY FOR THE SHARING OF CARE

This shared care agreement outlines suggested ways in which the responsibilities for managing the prescribing of Tocilizumab can be shared between the specialist and general practitioner or non-medical prescriber in primary care (GP). GPs are invited to participate. If the GP is not confident to undertake these roles, then he or she is under no obligation to do so. In that case, the total clinical responsibility for the patient for the diagnosed condition remains with the specialist.

If a specialist asks the GP to prescribe drugs for this treatment, the GP should reply to this request as soon as practicable.

Sharing of care assumes communication between the specialist, GP and patient. The intention to share care should be explained to the patient by the doctor initiating treatment. It is important that patients are consulted about treatment and are in agreement with it. Patients with active moderate to severe Rheumatoid arthritis are under regular specialist follow-up. This provides an opportunity to discuss and to monitor drug therapy.

The doctor who prescribes the medication legally assumes clinical responsibility for the drug and the consequences of its use.

RESPONSIBILITIES and ROLES

<table>
<thead>
<tr>
<th>Specialist responsibilities</th>
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<tr>
<td>• Initiate treatment (and continue, if responding) with Tocilizumab.</td>
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<td>• Discuss the benefits and side effects of treatment with the patient and inform GP this has occurred.</td>
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<td>• Ask the GP whether he or she is willing to participate in shared care, and agree with the GP as to who will discuss the shared care arrangement with the patient.</td>
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<td>• Review the patient's condition and monitor response to treatment regularly where indicated.</td>
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<td>• Advise GP if monitoring is needed, and the frequency.</td>
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<td>• Monitor any other parameters considered necessary, or advise GP on which to monitor.</td>
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<td>• Communicate promptly with the GP when treatment is changed or needs to be changed by the GP, any results of the monitoring undertaken, and assessment of adverse events.</td>
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<td>• Have a mechanism in place to receive rapid referral of a patient from the GP in the event of deteriorating clinical condition.</td>
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<td>• Advise GPs on when to stop treatment (if appropriate).</td>
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<td>• Report adverse events to the MHRA via Yellow Card Scheme.</td>
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<td>• Ensure that clear backup arrangements exist for GPs to obtain advice and support.</td>
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General Practitioner responsibilities

- Reply to the request for shared care as soon as practicable.
- Monitor any parameters considered necessary, if agreed with the specialist to do so.
- Report to and seek advice from the specialist on any aspect of patient care that is of concern and may affect treatment.
- Refer patient to specialist if his or her condition deteriorates.
- Stop treatment on the advice of the specialist or immediately if an urgent need to stop treatment arises.
- Report adverse events to the specialist and to the MHRA via the Yellow Card Scheme.

Patient’s role

1. Report to the specialist or GP if he or she does not have a clear understanding of the treatment.
3. Report any adverse effects to the specialist or GP.

BACK-UP ADVICE AND SUPPORT

<table>
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<tr>
<th>Contact details</th>
<th>Telephone No.</th>
<th>Email address:</th>
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<tbody>
<tr>
<td>Specialist:</td>
<td>01592 648193</td>
<td><a href="mailto:janegibson@nhs.net">janegibson@nhs.net</a></td>
</tr>
<tr>
<td>Rheumatology Dept</td>
<td>01592 265967 (fax)</td>
<td><a href="mailto:helenharris@nhs.net">helenharris@nhs.net</a>, <a href="mailto:johnmclaren@nhs.net">johnmclaren@nhs.net</a>, <a href="mailto:sharoncullinane@nhs.net">sharoncullinane@nhs.net</a></td>
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Other:
ADTC website - FRDU adverse drug reaction document

SUPPORTING INFORMATION (taken from the SPC)

Licensed indications
For use in patients with moderate to severe active Rheumatoid Arthritis.

In Fife it is used in FRDU algorithm after failure or contra-indication to an Anti-TNF therapy and / Rituximab. It is licensed in combination therapy with Methotrexate and as a monotherapy.

Dosage and Administration
By intravenous infusion at 8mg/kg once every 4 weeks within the day intervention unit.
Dose adjustments are made in some circumstances.

Contraindications and precautions for use
- Severe active infections, history of diverticulitis or Hepatitis (B and C)
- Neutropenia
- Monitor renal function closely in renal impairment, avoid in hepatic impairment.
Avoid pregnancy during treatment and up to 3 months following discontinuation. No information available on breast feeding.

The use of live vaccines is contra-indicated.

**Side Effects (also state any specific side-effects which require the consultant to be notified)**

- **Common:** Abdominal pain, mouth ulceration, gastritis, rash, headache, dizziness and hypertension.
- **Rare:** Gastro-intestinal ulceration and perforation.
- Infusion related reactions and anaphylaxis.
- Hypercholesterolaemia raised hepatic transaminases and neutropenia.
- **Patients who develop a new infection while undergoing treatment with Tocilizumab should be monitored closely. Administration of Tocilizumab should be discontinued if a patient develops a serious infection i.e. one that requires antibiotic therapy. Antibiotic therapy, where indicated, must be commenced promptly and only once the course completed and the infection has resolved should therapy with Tocilizumab be re-commenced.**

**ALL side effects should be reported to the Rheumatology Department**

For a complete list of side effects see BNF/Summary of product Characteristics.

**Monitoring (State specific monitoring to be undertaken by the GP / Consultant) see FRDU blood monitoring forms (ADTC website)**

**Rheumatologist responsibilities:**
- FBC, liver and renal function are within normal parameters to allow Tocilizumab to commence.
- Pulmonary fibrosis and latent TB (or active TB) have been excluded.
- Active Infection has been excluded.
- Checked for any risk factors for Hepatitis B and C.
- Checked for any history of diverticulitis.
- Checked lipids have been checked in last 6 months.
- Checked vaccinations are up to date.

**General Practitioner responsibilities:**
- FBC/CRP & Liver function: Every 4 weeks for the first 6 months after starting Tocilizumab and providing Methotrexate dose is stable, every 12 weeks thereafter.
- Cholesterol: Should be checked prior to first infusion (Rheumatology Dept.) and 4-8 weeks after commencing Tocilizumab.
- Renal function: 6 –12 monthly if normal.

**Drug Interactions**
- Avoid concomitant use of live vaccines.

For a complete list of drug interactions please see the BNF / Summary of Product Characteristics.

**Cost (March 2012)**

RoActemra concentrate for intravenous infusion:

- 80mg vial = £102.40; 200mg vial = £256.00; 400mg vial = £512.00.

The cost of Tocilizumab is met by the Rheumatology service. This product must not be prescribed by GPs.