Certolizumab Pegol - for control of active joint inflammation

AREAS OF RESPONSIBILITY FOR THE SHARING OF CARE
This shared care agreement outlines suggested ways in which the responsibilities for managing the prescribing of Certolizumab Pegol 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 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 (and continue, if responding) treatment with Certolizumab Pegol, which will be supplied by homecare provider.</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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</thead>
<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></td>
</tr>
<tr>
<td></td>
<td></td>
<td><a href="mailto:johnmclaren@nhs.net">johnmclaren@nhs.net</a></td>
</tr>
<tr>
<td></td>
<td></td>
<td><a href="mailto:sharoncullinane@nhs.net">sharoncullinane@nhs.net</a></td>
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**ADTC website - FRDU adverse drug reaction document**

**SUPPORTING INFORMATION (taken from the SPC)**

**Licensed indications**

Certolizumab Pegol is currently licensed for the management of rheumatoid arthritis.

**Dosage and Administration**

Certolizumab Pegol is administered by subcutaneous injection, either by the patient themselves or by a designated person (carer/relative). The dose of Certolizumab Pegol is 200mg every other week (occasionally weekly).

Some patients will require practice or district nurse input for administration. If this is not going to be possible please let the Rheumatology Department know as soon as possible.

**Contraindications and precautions for use**

- The use of live vaccines with Certolizumab Pegol is contra-indicated.
- Patients taking Certolizumab Pegol are more susceptible to serious infections (see below).
- Tuberculosis may be activated by Certolizumab Pegol, the patient will be appropriately screened by the rheumatologist as part of the initial decision-making process.
- Certolizumab Pegol is contraindicated in moderate to severe heart failure (NYHA class III/IV).
- Certolizumab Pegol must not be continued in patients who develop new or worsening symptoms of heart failure.
- The use of Certolizumab Pegol in pregnant women is not recommended, and women of child-bearing potential should be advised not to get pregnant during Certolizumab Pegol therapy. They should use effective contraception to prevent pregnancy during therapy and for at least 5 months after discontinuation of therapy. As human immunoglobulins are excreted in milk, women must not...
breast feed during Certolizumab Pegol therapy or for at least 5 months after Certolizumab Pegol therapy is discontinued.
- It is also recommended that male partners receiving Certolizumab Pegol should use effective contraception for the time periods stated above.

**Side Effects (also state any specific side-effects which require the consultant to be notified)**
- Headache, cough, nasopharyngeal pain, rash, pruritis, lower respiratory infections, viral infections (influenza, herpes), candidiasis, bacterial infections (including urinary tract infections), upper respiratory infection, injection site reaction (including pain, swelling, redness or pruritus), hepatic enzymes increased, diarrhoea, abdominal pain, stomatitis and mouth ulceration, nausea.
- Rare: pulmonary oedema, pancreatitis, parasthesia, hypertension, pneumonitis.

- Certolizumab Pegol can cause leucopenia and neutropenia. Patients who develop a new infection while undergoing treatment with Certolizumab Pegol should be monitored closely.
- **Administration of Certolizumab Pegol 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 Certolizumab Pegol be re-commenced.

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

**Treatment should be withheld and the Rheumatology Department contacted if:**
- **NEUTROPHILS < 1.5 \times 10^9 ,**
- **PLATELETS < 100 \times 10^9**
- **>2 fold increase in ALT (from upper limit of reference range)**
- **RASH, EXCESS BRUISING OR ORAL ULCERATION**
- **Sepsis**
- **New / increasing dyspnoea or cough**

**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 Certolizumab Pegol to commence.
- Pulmonary fibrosis and latent TB (or active TB) have been excluded.

**General Practitioner responsibilities:**
- While taking Certolizumab Pegol patients require: fortnightly FBC for 3 months, and monthly FBC thereafter.
- Liver function monthly.
- Renal function if normal should be checked every 6-12 months.

**Consider pneumonitis in any patient on Certolizumab Pegol who develops new or worsening dyspnoea.**

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

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

**Cost (July 2012)**
- 200mg prefilled syringe = £357.50
- The cost of Certolizumab Pegol is met by the Rheumatology service.
- Certolizumab Pegol is supplied directly to patients using a homecare provider, which is organised by the Rheumatology service.