Protocol

Glatiramer acetate treatment of relapsing-remitting multiple sclerosis (MS)

1 Scope

Treatment of patients with a diagnosis of multiple sclerosis by the MS team at Cambridge University Hospitals NHS Foundation Trust.

2 Purpose

To ensure the safe use and monitoring of glatiramer acetate.

3 Introduction

Glatiramer acetate is indicated for treatment of people with active relapsing-remitting MS (but **not** highly active relapsing-remitting MS or rapidly evolving severe MS) if they have had at least two clinically significant relapses in the previous two years or women considering pregnancy or fertility treatment.

4 Undertaken by (staff groups)

Medical staff and nursing staff who are competent to prescribe and monitor beta interferons.

5 Treatment

5.1 Eligibility and screening

Patients are assessed as eligible for treatment by a consultant neurologist in the disease modifying therapy clinic. Risks and benefits of the treatment are discussed. Medications and co-morbidities are documented on Epic. NICE technology appraisal guidance: TA 527 Beta interferons and glatiramer acetate for treating multiple sclerosis (2018) https://www.nice.org.uk/guidance/ta527 will be followed when assessing eligibility.

Pre-treatment screening occurs in the outpatient clinic setting:

- Screening blood tests are sent as outlined in the Multiple Sclerosis (MS) disease modifying therapy (DMT) Initiation and Monitoring Standard Operating Procedure.

- Vaccine advice given as per Multiple Sclerosis (MS) disease modifying therapy (DMT) Initiation and Monitoring Standard Operating Procedure
- Baseline expanded disability status scale (EDSS)

5.2 Side effects

Common side effects:

- Injection site reactions – erythema, pain, mass, pruritis, oedema, inflammation and hypersensitivity.
- Short-lived injection reactions may occur within minutes of an injection: vasodilatation (flushing), chest pain, dyspnoea, palpitations or tachycardia. The majority of these symptoms are short-lived and resolve spontaneously without any sequelae.
- Infections – vaginal candidiasis
- Nausea and vomiting, rash, headache
- Anxiety and depression

Rare side effects:

- Anaphylactoid reactions
- Drug induced liver injury and toxic hepatitis

5.3 Cautions and contraindications

- Hypersensitivity to the active substance or any of the excipients.

5.4 Prescription

- When the patient rings with medication choice the MS nurse/ admin passes information to consultant neurologist to complete Blueteq form and write the prescription.
- Prescriptions are generated on the appropriate homecare private prescription form, an electronic version of which is kept on the network drive.
- Prescriptions are collected by the pharmacy homecare team and processed.
- Homecare companies supply the medication (these products are not stocked at CUH).
- MS nurse sees patient in MS nurse clinic for training and for the patient to self-administer the first dose under supervision.
- If the patient cannot be seen in clinic for training, the MS nurses have prepared a training video available at: https://youtu.be/Irze8sYM7Oc

5.5 Follow up and monitoring

Outpatient appointments to assess side-effects, medication compliance and disease activity:

- Reviewed by MS nurse at month 3 and 12 if well.
- Reviewed by MS nurse or consultant neurologist annually (alternates).

5.6 Stopping criteria

- Development of secondary progression
- EDSS 7.0 ie loss of ambulation for greater than six months
- Unacceptable adverse effects*
- Allergic reaction to glatiramer acetate*
- Pregnancy and breast feeding
- Persistent failure to keep booked appointments. At the discretion of the clinical team a standard DNA letter will be sent to the patient informing them that further deliveries will cease pending their contacting the department.

  *Patients who relapse on treatment may be eligible for alternative DMTs (eg fingolimod, alemtuzumab, natalizumab). Patients who have an allergic reaction or other unacceptable side effects will either need to stop treatment or switch (e.g. dimethyl fumarate) depending on the clinical situation.

6 Monitoring compliance with and the effectiveness of this document

6.1 Process for monitoring compliance and effectiveness

- Patients will be assessed at 3 and 12 months in the first year then annually for continued eligibility for treatment by consultant neurologist or MS specialist nurse.
- Patients will agree, before starting treatment, to comply with treatment protocol, keep appointments and contact relevant health professionals in the event of changes in their underlying MS condition or suspected side-effects.
- Ongoing maintenance of database of patients offered treatment, undergoing treatment and stopping treatment, including reason for stopping treatment, will be kept by the MS specialist nurses and neurology consultants to audit against NICE guidelines.

6.2 Standards/ key performance indicators

- The audit department will request evidence of compliance with NICE guideline.
- Internal checks on safety, compliance and efficacy will be undertaken by the MS team.

7 References

NICE TA 527 Beta interferons and glatiramer acetate for treating multiple sclerosis (2018) https://www.nice.org.uk/guidance/ta527

Association of British Neurologists: revised (2015) guidelines for prescribing disease-modifying treatments in multiple sclerosis *Pract Neurol* doi:10.1136/practneurol-2015-001139 http://pn.bmj.com/content/early/2015/06/20/practneurol-2015-001139

Clinical Commissioning Policy: disease modifying therapies for patients with multiple sclerosis. NHS England. May 2014. https://www.england.nhs.uk/wp-content/uploads/2013/10/d04-p-b.pdf

National Institute for Health and Care Excellence (2002). Beta interferon and glatiramer acetate for the treatment of multiple sclerosis: https://www.nice.org.uk/guidance/ta32

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This document complies with the Cambridge University Hospitals NHS Foundation Trust service equality and diversity statement.

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Document management

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