NHS
Greater Glasgow and Clyde

CLINICAL GUIDELINES

Omalizumab in Chronic Spontaneous Urticaria

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 Intranet 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.

NHS GGC Omalizumab Protocol for Chronic Spontaneous Urticaria

1. Omalizumab Indication:

Omalizumab is a recombinant DNA-derived humanised monoclonal antibody that binds to immunoglobulin E (IgE). It is licensed as an 'add on therapy for the treatment' of chronic spontaneous urticaria (CSU) in adults and adolescents (12 years and over) with inadequate response to H1 antihistamine treatment.

Evidence for omalizumab use in CSU comes from the randomized, double-blind, placebo-controlled phase III studies; GLACIAL[1], ASTERIA I[2] and ASTERIA II[3]. The ASTERIA studies reported significantly improved outcomes for itch severity score (ISS). In the GLACIAL study of 336 patients with CSU or chronic idiopathic urticaria who remained symptomatic despite H1 antihistamines (up to 4x licensed dose) plus H2 antihistamines or leucotriene receptor antagonist (LTRA) or both for at least 3 consecutive days before screening, significant improvements in both urticaria activity score over 7 days (UAS7 score) and weekly ISS were demonstrated.

Scottish Medicines Consortium (SMC) Advice:

Following SMC review, omalizumab has been accepted for restricted use in Scotland as add on therapy for the treatment of CSU in adults and adolescent patients with an inadequate response to combination therapy with H1 antihistamine treatment, LRTA and H2 antihistamines used according to current treatment guidelines[4].

For NHS GGC, the decision to initiate omalizumab therapy for CSU is restricted to a Consultant or Associate Specialist Dermatologist in accordance with the SMC restriction - Appendix: Protocol for omalizumab for chronic spontaneous urticaria.

2. Patient Assessment prior to starting omalizumab

- Patients will be given an appointment at a dermatology clinic for initial assessment (week 0).

- The number of wheals and the severity of itch much be assessed by completing weekly Urticarial Activity Scores (UAS7) and Dermatology Life Quality Index (DLQI) over at least 4 weeks before considering omalizumab.

- Patients with a UAS7 score ≥28 with an inadequate response to combination therapy with H1-antihistamines (up to 4 times licensed dose) and/or LTRA and/or H2-antihistamines are eligible for omalizumab.

- Patient to be given omalizumab information leaflet.

- Patients who meet criteria for starting omalizumab will require a medicine prescription chart (Kardex®) to be completed by a doctor/Nurse prescriber. Nursing staff in charge should be notified in advance of any new patients to allow time to order the first dose of medication. The patient should be booked to attend the Nurse-led outpatient clinic to receive treatment. The Kardex® should then be placed in a designated folder.

Drug Preparation

Pre-filled syringe of 1ml omalizumab 150mg

Dosage and Administration

Patient attendance at nurse-led clinic (week 0):

- Patient identification should be confirmed

- 300 mg of omalizumab (i.e. 2 syringes) to be administered by subcutaneous injection into deltoid area of arm, alternatively the thigh can be used.

- DO NOT give omalizumab by intravenous or intramuscular injection

- Omalizumab should only be given where full resuscitation equipment is available due to the anaphylactic risk. Most reactions are reported within the first 2 hours after injection.

- Subsequent dose to be ordered and prescribed at each visit (weeks 4, 8,12 & 16).

3. Patient monitoring whilst receiving Omalizumab

No routine blood tests are necessary.

Blood pressure, pulse and oxygen saturation should be monitored pre and post injection.

For the first injection, the patient should remain in department for 2 hours for observation. For subsequent injections, patient should remain in department for 30 minutes for observation. Patients require first three (3) doses of Omalizumab be given in hospital.
From fourth (4th) dose onwards some patients may be appropriate to self-inject. The decision which patients are suitable for self- injection is made by the doctor along with the patient.

Patients will be educated how to self-inject by the nurses giving the first three doses of Omalizumab. They will supply an information leaflet with written instructions also. Patients suitable for self-injection will be identified by the Urticaria clinic staff. The sharps boxes will be supplied by the nurses also. They are found in dermatology outpatient department. Delivery of Omalizumab via homecare services will be initiated in patients self-injecting at home.

Side effects of treatment

The treatment is usually very well tolerated and has relatively few side effects. There can be a small reaction at the site of injection (itch, pain, redness or swelling) shortly after it is given. Anaphylaxis has been reported in Asthma patients receiving Omalizumab.

Headaches, sore throat, 'flu like symptoms', arthralgia, sinusitis. Fever and abdominal pain have been reported in children.

Contraindications

- Omalizumab should not be given to patients with known hypersensitivity to active ingredients or any excipients. Anaphylaxis due to the treatment would usually contraindicate further injections.

- Omalizumab should not be given during breastfeeding or pregnancy.

(Avoided unless necessary after careful consideration of its benefits in relation to any known/unknown risks, although there is currently no evidence that it is harmful to a baby)

Interaction with other medications

There are no known interactions with other medications. Medications such as steroids and other immunosuppressives which are used for urticaria should normally be possible to stop.
Antihistamines should be continued throughout the course of treatment.

4. Monitoring of Omalizumab Treatment Response

All patients receiving omalizumab should be recorded on a drug-disease register.

After the 4th injection of omalizumab (week 12), the patient will have a telephone consultation carried out by a specialist nurse/ pharmacist to assess response to treatment using UAS7 and DLQI score.

Treatment will be discontinued after 4th injection for non-responders (UAS7 >16).

In exceptional cases it may be appropriate to continue Omalizumab in patients:
-with a UAS7 16-27 if the baseline score was in excess of 40
- Who are steroid or immunosuppressive-dependent and unable to stop their treatment without severe symptom relapse and should be changed to omalizumab to minimize long term risks of therapy
- with a large angio- oedema component since this is not recorded on UAS7[5]

Patients demonstrating improvement of at least 50% in UAS7 and DLQI score for CSU will continue for a further 2 months of treatment (weeks 20 & 24), therefore completing a full 6-month course of omalizumab.

Treatment relapse

UAS7 scores should be carried out monthly after completing a full course of omalizumab to assess if symptoms have relapsed despite taking antihistamines. A decision to start another 6-month course of omalizumab will be based upon a qualifying UAS7 score as described in section 2. Patients may require multiple courses of Omalizumab.

Communication

Please inform the patient's GP that this medicine is being prescribed by Acute and, where relevant, supplied to the patient via a hospital prescription for community pharmacy dispensing. Within General Practice it is beneficial for patient and prescriber safety to ensure that a patient's medicine record includes medicines that may be prescribed and supplied outwith the GP practice.

5. References

1. Kaplan A, Ledford D, Ashby M, et al. Omalizumab in patients with symptomatic chronic Idiopathic/spontaneous urticaria despite standard combination therapy. J Allergy Clin Immunol 2013;132:101-9.

2. Saini SS, Bindslev-Jensen C, Maurer M, et al. Efficacy and safety of omalizumab in patients with chronic idiopathic/spontaneous urticaria who remain symptomatic on H1-antihistamines: A randomized, placebo-controlled study. J Investigative Dermatology 2014; doi 10.1038/jid.2014.306

3. Maurer M, Rosen K, Hsieh HJ, et al. Omalizumab for the treatment of chronic idiopathic or spontaneous urticaria. N Engl J Med 2013;368:924-35.

4. Scottish Medicines Consortium (SMC) (2015). Omalizumab 150mg solution for injection (Xolair®) SMC No. (1017/14). Glasgow: SMC.
[Online] http://www.scottishmedicines.org.uk/SMC_Advice/Advice/1017_14_omalizumab_Xolair/omalizumab_Xolair
[Accessed 19/06/17
5. Nice Technology Appraisal339: Omalizumab for previously treated chronic spontaneous Urticaria.]