BSACI
Improving Allergy Care
through education, training and research

Standard Operating Procedure

Omalizumab for Urticaria

Omalizumab (Xolair, Novartis) is a biological monoclonal antibody that targets IgE. It is used in in adults and adolescent (12 years and above) patients with chronic spontaneous urticaria (CSU) who have not achieved sufficient symptom control using standard treatments (H_1-antihistamines and leukotriene antagonists). It acts by inhibiting the binding of IgE to receptors on mast cells and basophils, blocking the IgE-mediated secretion of inflammatory mediators. As it is an 'add-on' therapy, patients need to continue their standard treatment whilst receiving Omalizumab injections (NICE 2015).

Patient inclusion

Omalizumab is recommended as an option as add-on therapy only if:

- The diagnosis is confirmed as chronic spontaneous urticaria.
- The severity of condition is assessed objectively using a weekly urticaria activity score (UAS7); and the score is 28 or more.
- The patient fails to achieve symptom control despite high dose (4x recommended dose) non-sedating anti-histamines together with a trial on leukotriene receptor antagonists.
- Omalizumab is stopped at or before the fourth dose if the condition has not responded.
- Omalizumab is stopped at the end of the course of treatment (6 doses) to establish if the condition has gone into spontaneous remission, and is restarted only if the condition relapses.

Patients should be referred to and managed by secondary care specialists in allergy, dermatology or immunology.

Patient outcomes

The primary outcome for patients who respond to therapy is reduced frequency and severity of symptom flares, as measured by objectively assessed symptom severity scores (NICE, 2015).

Urticaria Activity Score 7 or 'UAS7' (Mathias et al 2012) is recommended for assessment in adults and adolescents (NICE, 2015).

Responsibilities for health care professional prior to commencement of Omalizumab

- Confirm diagnosis of CSU after discussion in local MDT meeting.
- Discussion with patient/family of mode of action of Omalizumab, possible side effects.
- Discuss dosage schedule of planned 4 injections at 4 weekly intervals; with options to discontinue treatment at or before 4th if there is no response, or offer 2 further doses in patients who do respond.
- Discussion of expectations of the patient/family i.e. to attend appointments, complete weekly UAS7 during treatment.
- Collate of UAS7 scores at each visit.
- Provide written information.
- Obtain written informed consent.
- Complete registration on HiCost /IFR database (Blueteq form).
- Arrange for responsible clinician to prescribe Omalizumab dose.
- Ensure that first dose(s) are given in a clinical setting with resuscitation facilities.
- Discuss possibility of home administration of Omalizumab in the future if suitable.
- Arrange follow up appointment in clinic to assess response to treatment

Considerations for initial dose

- Measure baseline observations before administering injections.
- Anaphylaxis to Omalizumab is very rare and the risk of anaphylaxis decreases with each dose. Precautionary measures are needed, such as extended observation period for initial dose(s) according to individual service practice. A 2-hour observation period with initial dose(s) has been recommended, followed by a minimum observation period of 30 mins for subsequent doses (British Association of Dermatologists, 2018).
- See manufacturer leaflet and trust guidance for information regarding method of administration.
- Observations should be taken prior to patient discharge, or before if patient reports feeling unwell. Patients must be assessed fit for discharge before leaving.
- Patient should book their next appointment in 4 weeks' time following local procedure.
- Complete nursing documentation in patient notes.

- Write GP letter to inform of commencement of course of treatment.

Subsequent Doses

- Continue treatment in compliance with NICE guidance i.e. do not continue beyond 4th dose if no improvement.
- Subsequent doses should be given at 4 week intervals. The duration between appointments may be extended/reduced if clinically appropriate thereafter. This would be decided by their prescribing specialist clinician.
- Patient should return UAS7 questionnaires at every visit; these should be scanned to or documented in their clinical notes as appropriate.

Home therapy

- Omalizumab is licensed for home therapy and may be administered in accordance with the agreed local protocol.
- See appendix 1, 2 and 3 for example documents to support establishing home administration.

After 6 doses

- The patient should take a break in Omalizumab treatment to assess for spontaneous remission of symptoms.
- After the 6th injection, the patient is given a 3 month clinic follow up appointment. Patients should continue to take their standard treatment at agreed adjusted doses; and be asked to contact the service if they experience a flare up of symptoms prior to their follow up appointment.
- Patient should be asked to complete a weekly UAS7 score in advance of any subsequent appointment.
- Omalizumab treatment can be restarted if the urticaria flares (UAS7 >16) despite high dose anti-histamines.

How to administer Omalizumab therapy

Always wash hands before administering subcutaneous injections and prepare injection materials according to local trust policy.

PROCEDURE	RATIONALE
1. Omalizumab should be given in a controlled healthcare setting with access to emergency medications	There is a risk of anaphylaxis
2. Assess current health status. BP, pulse and oxygen saturations.	To reduce the risk of respiratory compromise in the event of an anaphylactic reaction
3. Patients should ensure they notify the team should they become pregnant during a course of Omalizumab.	Omalizumab is regarded as safe during pregnancy.
4. Remove Omalizumab dose(s) from the fridge 20 minutes before dose is to be administered	To allow medication to reach room temperature (product information) to reduce the viscosity.
5. Check expiry date and ensure the liquid in each prefilled syringe is clear and not discoloured	To ensure that the drug is safe to use
6. Dose should be limited to 150mg per injection site. Ensure skin is clear, unbroken and without bruising. Confirm the preferred site with the patient. Rotate sites where possible. If multiple injections are being given, no time gap is required between each being administered.	Due to the large volume of fluid. To prevent fat atrophy.
7. Topical anaesthesia may be used to numb the area as per manufacturer's guidelines	To numb the area and reduce discomfort
8. Administer subcutaneously.	To facilitate deep subcutaneous injection
9. Remove needle and ask patient to press with gauze or cotton wool for 30 seconds. Apply plaster if tolerated by patient.	To prevent drug leakage

10. Dispose of sharp safely	As per local infection control policy
11. Document procedure in patient records. Sign prescription chart and record dose, route, time, batch, expiry date and time of administration.	To maintain accurate documentation
12. Observe the patient following drug administration: a. For 2 hours following the first injection(s) b. For 30 minutes after subsequent injections.	Due to the risk of anaphylaxis
13. Prior to discharge check injection site and check patient observations again.	To ensure patient is well
14. Advise patient not to discontinue regular medications without medical advice	Omalizumab is an add-on therapy rather than replacement for usual preventer medications
15. Ensure patient has an appointment for the next dose and a point of contact for any queries.	For assistance with any concerns or queries

References

1. Lewis-Jones MS, Finlay AY. (1995) The Children's Dermatology Life Quality Index (CDLQI): Initial validation and practical use. *British Journal of Dermatology;* 132: 942-949.
2. Mathias SD, Crosby RD, Zazzali JL, Maurer M, Saini SS. (2012) Evaluating the minimally important difference of the urticaria activity score and other measures of disease activity in patients with chronic idiopathic urticaria. *Ann Allergy Asthma Immunol*, 108(1):20–24.
3. NICE (2015) *Omalizumab for previously treated chronic spontaneous urticaria, Technology appraisal guidance [TA339]* Accessed at https://www.nice.org.uk/guidance/ta339 on 1st July 2022.
4. Weller K, Groffik A, Church MK, et al. (2014) Development and validation of the Urticaria Control Test: A patient reported outcome instrument for assessing chronic urticaria. *J Allergy Clin Immunol*; 133:1365.

Appendix 1: OMALIZUMAB HOME COMPETENCY

Allergy & Immunology Team

Date of assessment: ____ / ____ / _____

Name of nurse/assessor: _____

Patient name: _____

Patient hospital number: _____

Element of competence to be achieved	Patient observed Date/Signed	Patient observed Date/Signed	Patient competent Date/Signed
Demonstrate knowledge of use of Omalizumab in chronic spontaneous urticaria (CSU)			
Describe Omalizumab storage and transportation conditions (bring cool bag to hospital)			
Area preparation			
Hand washing			
Check the product (including sealed packaging, dose and expiry date)			
Demonstrate correct procedure for subcutaneous injection			
Describe common side effects of Omalizumab and how to manage them			
Refer to the patient information leaflet (PIL) in the injection box / Novartis PIL			
Demonstrate knowledge, importance of, and			

procedure for reporting side effects and adverse events			
Demonstrates how to dispose of clinical waste and sharps correctly and action to take if a needle- stick injury is sustained			
Demonstrates and understands the importance of keeping records (batch numbers and expiry dates)			
Records Urticaria Activity Score (UAS7)			
Will monitor and document fridge temperature			

I agree to complete the necessary documents and attend clinical appointments as advised. I understand the home therapy can be withdrawn if I am not compliant.

I declare that I feel confident to self-administer Omalizumab at home.

I have obtained a clinical waste sharps bin from the GP

Signature: _____ Date: _____ / _____ / _____

Print name:_____

I declare that I have assessed the above patient and/or carer and found them/him/her to be competent according to the above criteria.

Signature: _____ Date: _____ / _____ / _____

Print name:_____ Date: _____ / _____ / _____

For any queries or advice contact the Allergy & Immunology Nurse Specialists on:-

01234567890

Allergy & Immunology Team

Appendix 2: PATIENT AGREEMENT FOR OMALIZUMAB AT HOME

Omalizumab (Xolair) is a man-made protein that is used as an “add on” treatment for patients with Chronic Spontaneous Urticaria who remain symptomatic despite high dose antihistamines +/- Montelukast as assessed by elevated UAS7 scores (NICE criteria).
Omalizumab works by blocking a substance called Immunoglobulin E (IgE) which is produced by the body.
Omalizumab is now licensed for home therapy.
Your Allergy Team have identified that you could be a candidate for home Omalizumab therapy. This is on the proviso that you meet the following:-

- You achieve Trust competencies on home administration.
- You follow the competencies on safe medication handling, storage and administration.
- If you feel at any time you are not happy to self-administer Omalizumab, contact the allergy team who will arrange a clinic appointment.
- You comply with your treatment regime i.e. administer every 4 – 6 weeks according to your prescription.
- You will document batch numbers and expiry dates on the sheet provided and bring the record to your appointments.
- You will record your Urticaria Activity Score 7 (UAS7).
- If you fail to collect/administer Omalizumab you will be asked to come for hospital administration.
- You will be supplied with enough Omalizumab for months; after that, you will come to hospital for a review. If you are managing well at home, then a further prescription for months will be issued.
- If the allergy team have any clinical concerns, then home therapy will be withdrawn.

Date discussed: _____ / _____ / _____

Name: _____ Designation: _____

Patient name: _____ Signature: _____

Appendix 3: OMALIZUMAB HOME THERAPY RECORD

Allergy & Immunology Nurse Specialists: 01234 567890 (Mon - Fri 8am – 4pm)
Allergy Coordinator: 01234 567890 (Mon – Fri 8:30am – 4:30pm)

Print name:_____ Weight: _____

Hospital number: _____ Date of birth: _____ / _____ / _____

Competencies checked: Y [ ] N [ ]
Package leaflet for user provided (Novartis) Y [ ] N [ ]
Patient has sharps bin arranged Y [ ] N [ ]

Date	Injection site	Batch number	Expiry date	Sign	Urticaria Activity Score 7	Fridge temperature

Authors:

Hannah Kramer, Rebecca Batt, Deborah Hughes with support from the BSACI Nurses in Allergy Committee.