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through education, training and research

Nurses in Allergy

# Standard Operating Procedure

## Omalizumab Therapy

Omalizumab (Xolair) is a biological monoclonal antibody used in the management of severe, persistent asthma in adults and children aged 6 years and above.[1] It is a treatment option for selected individuals with difficult-to-control asthma and a strong allergic component, whose symptoms are inadequately controlled on Step 5 of the BTS Guidelines.[2] Omalizumab specifically binds to circulating IgE in the blood and interstitial fluid, and primarily prevents the binding of IgE to high-affinity FcεRI receptors on mast cells and basophils or the low-affinity FcεRII (CD23) receptors on B cells resulting in down-regulation of these receptors.

**Inclusion criteria:**

- A positive skin prick or specific IgE test to a perennial aeroallergen
- Serum total IgE concentration between 30-1500 IU/mL
- Body weight between 20-150kg, although the weight limit may be lower depending on total IgE level
- Reduced lung function (FEV1 <80% in adolescents >12 years and adults)
- Frequent day-time symptoms *or* nocturnal awakenings *despite* full trial of high-dose inhaled corticosteroids with good compliance and adequate inhaler technique, LABA medications, leukotriene receptor antagonists and oral corticosteroids
- Multiple documented severe exacerbations despite daily inhaled high-dose inhaled corticosteroids plus a long-acting inhaled beta2 agonist.[3]
- Continuous or frequent oral prednisolone courses (>3 courses per year)
- Smoking cessation measures

The primary benefits to patients who respond to therapy are reduced disease exacerbations requiring fewer unplanned medical visits and fewer hospitalisations with resulting improvement in quality of life. Lung function may also improve, while some patients are able to reduce or discontinue systemic corticosteroids. Approximately 1 in 5 eligible patients fail to respond to a 16 week trial of therapy.

**Assessments:**

A formal assessment should occur before therapy is initiated (baseline) and after 16 weeks of treatment (decision point).

**Key Response Indicator Assessments**

- Mini-PAQLQ or (Asthma QoL)[4]
- Asthma Control Test (ACT)[5]

**Supportive Assessment**

- Recording of number of unscheduled healthcare episodes including GP visits and telephone calls, unplanned escalation of therapy, ED visits and admissions
- A PEF diary additionally documenting use of reliever therapy

*Responders must achieve improvement in the Key Response Indicators at 16 weeks:*

- **Mini-Paediatric Asthma Quality of Life Questionnaire (PAQLQ): ≥0.5 improvement**
- **Asthma Control Test (ACT)**
- **Physician Global Evaluation of Treatment Effectiveness (GETE)*:** Excellent or Good **(The GETE is a clinical judgement made by the responsible Respiratory Physician based on all available information** to evaluate how much improvement in asthma control the child has experienced compared with baseline)

    - **Excellent:** complete control of asthma
    - **Good**: marked improvement of asthma
    - **Moderate**: discernible, but limited improvement in asthma
    - **Poor**: no appreciable change in asthma
    - **Worsening:** overall deterioration in asthma control



Production date: May 2014 Review Date: May 2016

**Omalizumab Safety:**

Ensure that written, informed consent has been taken from the patient (or parent). The dose of omalizumab should have determined and prescribed by the asthma doctor using a recently measured serum total IgE concentration and patient weight. Ensure you have identified the correct patient by name and date of birth and checked against the prescription.

Omalizumab should be initiated and monitored in a specialist centre. Omalizumab is administered subcutaneously via prefilled syringe every 2-4 weeks with the dose dependent upon the individual's weight and total serum IgE concentration. IgE concentrations cannot be re-measured during omalizumab therapy because the drug "holds" IgE in the circulation, although dose changes can be made to accommodate significant changes in body weight (assuming that the serum IgE concentration at the commencement of therapy is unchanged). The maximum recommended dose is 600mg every 2 weeks.

**Dosing Table**

| | **Total Serum IgE concentration** | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| **Body Weight** | **20-25** | **>25-30** | **>30-40** | **>40-50** | **>50-60** | **>60-70** | **>70-80** | **>80-90** | **>90-125** | **>125-150** |
| **29-100** | 75 | 75 | 75 | 150 | 150 | 150 | 150 | 150 | 300 | 300 |
| **>100-200** | 150 | 150 | 150 | 300 | 300 | 300 | 300 | 300 | 450 | 600 |
| **>200-300** | 150 | 150 | 225 | 300 | 300 | 450 | 450 | 450 | 600 | 375 |
| **>300-400** | 225 | 225 | 300 | 450 | 450 | 450 | 600 | 600 | 450 | 525 |
| **>400-500** | 225 | 300 | 450 | 450 | 600 | 600 | 375 | 375 | 525 | 600 |
| **>500-600** | 300 | 300 | 450 | 600 | 600 | 375 | 450 | 450 | 600 | |
| **>600-700** | 300 | 225 | 450 | 600 | 375 | 450 | 450 | 525 | ***Do not administer*** | |
| **>700-800** | 225 | 225 | 300 | 375 | 450 | 450 | 525 | 600 | | |
| **>800-900** | 225 | 225 | 300 | 375 | 450 | 525 | 600 | | | |
| **>900-1000** | 225 | 300 | 375 | 450 | 525 | 600 | | | | |
| **>1000-1100** | 225 | 300 | 375 | 450 | 600 | | | | | |
| **>1100-1200** | 300 | 300 | 450 | 525 | 600 | | | | | |
| **>1200-1300** | 300 | 375 | 450 | 525 | | | | | | |
| **>1300-1500** | 300 | 375 | 525 | 600 | | | | | | |

Novartis (2012). XOL12 – C035: Xolair (Omalizumab) UK Abbreviated Prescribing Information

# Standard Operating Procedure

## How to administer Omalizumab therapy

Always wash hands before administering subcutaneous injections and prepare injection materials according to 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. Check the patient's current weight with the prescribed dose. Check total IgE before 1st dose only | To ensure that an effective dose will be administered |
| 3. Assess current health status. Record PEF, BP, P & $Sp0_2$. | To reduce the risk of respiratory compromise in the event of an anaphylactic reaction |
| 4. Ensure female patients are aware of the need for effective contraception | The safety profile of Omalizumab in pregnancy has not yet been established |
| 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. Several sites may be needed. Ensure skin is clear, unbroken and without bruising. Confirm the preferred site with the patient. Rotate sites where possible. | Due to the large volume of fluid |
| 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. Pinch the skin together. | To facilitate deep subcutaneous injection |
| 9. Remove needle and ask patient to press with gauze or cotton wool for 30 seconds. Apply plaster | To prevent drug leakage |
| 10. Dispose of sharp safely | As per local infection control policy |
| 11. Maintain accurate documentation. 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:<br>a) For 2 hours following the first three injections<br>b) For 1 hour after subsequent injections | Due to the risk of anaphylaxis |
| 13. Prior to discharge check injection site. Repeat Peak Flow measurement | 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 & Bibliography:

1. Normansell R et al (2014) Omalizumab for asthma in adults and children. Cochrane Database Syst Review 13(1)
2. NICE (2013) Omalizumab for the treatment of severe persistent allergic asthma in children aged 6 and over and adults (review of TA133 and TA201). Available at: guidance.nice.org.uk/TA133
3. Summary of product characteristics, Xolair. http://emc.medicines.org.uk/emc/industry/default.asp?page=displaydoc.asp&documentid+17029
4. Novartis (2012). XOL12 – C035: Xolair (Omalizumab) UK Abbreviated Prescribing Information
5. Juniper EFet al (1996) Measuring quality of life in children with asthma. Qual Life Res 1996; 5: 35 -46
6. Nathan RA et al (2004). JACI. 2004; 113:59-65.