University Hospitals of Derby and Burton NHS Foundation Trust

Omalizumab in Chronic Spontaneous Urticaria - Full Clinical Guideline - DERBY

Reference no.: CG-DERM/2023

1. Introduction

Omalizumab (Xolair) is a monoclonal antibody that targets IgE. It has a UK marketing authorisation as an add-on therapy for the treatment of chronic ordinary urticaria in adult and adolescent (12 years and above) patients with an inadequate response to H_1 -antihistamines.

2. Aim and Purpose

This guideline outlines the role of Omalizumab in Chronic Ordinary Urticaria.

3. Definitions, Keywords

a) Urticaria
Urticaria is characterised by transient, itchy, raised lesions known as wheals with or without angioedema.

b) Chronic Urticaria
Urticaria occurring most days lasting over 6 weeks.

c) Chronic Spontaneous Urticaria or Chronic Ordinary Urticaria
The two terms are used interchangeably for urticaria occurring most days lasting more than 6 weeks without any underlying recognisable cause and not inducible by any specific stimulus.

d) Urticaria Activity Score (UAS)
This is a composite score to assess disease severity in patients with chronic ordinary urticaria on a scale of itch severity and hive count. Patients record the severity of their itch and the number of hives once a day. Each component of the UAS is scored between 0 to 3; the 2 scores are added together for a daily total of 0 to 6. The UAS7 is the sum of daily scores over 7 days and ranges from 0 to 42.

Urticaria Activity Score (UAS)		
Score	Itch severity	Number of hives
0	None	None
1	Mild	1-6
2	Moderate	7-12
3	Severe	>12

4. Protocol

Antihistamines are the first line treatment for all patterns of urticaria. It has become common practice to titrate-up second generation antihistamines to fourfold in patients who respond poorly to licensed doses.

Targeted second line treatments, such as short courses of oral corticosteroids, may be given for patients who do not respond to higher doses of H1 antihistamines. After that, Montelukast can be added. Immunosuppressive therapies (especially ciclosporin or methotrexate) are used for patients with severe and disabling chronic ordinary urticaria.

There remain, however, a small group of patients with severe ordinary urticaria who do not respond adequately to antihistamines, second line or immunosuppressive therapies that may be considered for Omalizumab provided their urticarial assessment scores and/or health related quality of life scores exceed the predetermined criteria detailed in this guideline despite ongoing standard therapies.

A small subgroup of patients with histological evidence of small vessel vasculitis but with clinical features of chronic urticaria (normocomplementaemic urticarial vasculitis) may also be considered for treatment with Omalizumab when all standard treatments, including long term oral corticosteroids, sulphonamide derivatives and immunosuppressive agents, have failed to provide adequate control or have resulted in unacceptable side effects, such as diabetes or osteoporosis.

Omalizumab can be started after discussion at Dermatology Consultants' Meeting for Specialist Initiation only (Appendix A). It is indicated in patients over 12 years of age with severe chronic ordinary urticaria with UAS score of 28 or more for at least 2 weeks in a period of 4 weeks. It is administered at a dose of 300 mg s.c. every 4 weeks by a doctor or nurse in an acute hospital setting for 4 doses. Courses should be clearly identified as Course 1, Course 2 etc to avoid long term usage. Treatment is to be stopped if there is no response after 4 doses or if after 6 doses the disease is cleared i.e. UAS score of 6 or less. If there is a UAS score of 16 prior to 5th dose, it may be continued if baseline score was > 40 and current score is between 16-27 with steroid or the patient is immunosuppression dependent or has a large angioedema component. In case of relapses with UAS score > 16, retreatment may be required.

Patients with no known history of anaphylaxis can be considered for self-administration of the Omalizumab injection from the 4th dose onwards. Alternatively,

a caregiver may administer the injection. These patients or their caregivers must be trained in injection technique and the recognition of serious allergic reactions.

5. Important contact details

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6. References

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7. Documentation Controls

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8. Appendix A Derby Chronic Ordinary Urticaria pathway