● **NATIONAL FUNDING/ACCESS DECISIONS**

NICE decisions

▸ **Omalizumab for severe persistent allergic asthma (April 2013)** NICE TA278

Omalizumab is recommended as an option for treating severe persistent confirmed allergic IgE-mediated asthma as an add-on to optimised standard therapy in patients aged 6 years and over:

- who need continuous or frequent treatment with oral corticosteroids (defined as 4 or more courses in the previous year), **and**
- only if the manufacturer makes omalizumab available with the discount agreed in the patient access scheme.

Optimised standard therapy is defined as a full trial of and, if tolerated, documented compliance with inhaled high-dose corticosteroids, long-acting beta$_2$ agonists, leukotriene receptor antagonists, theophyllines, oral corticosteroids, and smoking cessation if clinically appropriate.

Patients currently receiving omalizumab whose disease does not meet the criteria should be able to continue treatment until they and their clinician consider it appropriate to stop.

www.nice.org.uk/guidance/ta278

▸ **Omalizumab for previously treated chronic spontaneous urticaria (June 2015)** NICE TA339

Omalizumab is an option as add-on therapy for the treatment of severe chronic spontaneous urticaria in patients 12 years and over, only if:

- the severity of the condition is assessed objectively, for example, using a weekly urticaria activity score of 28 or more,
- the patient's condition has not responded to standard treatment with H_1-antihistamines and 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 a course of treatment (6 doses) if the condition has responded and is restarted only if the condition relapses,
- omalizumab is administered under the management of a secondary care specialist in dermatology, immunology or allergy,
- the manufacturer provides omalizumab with the discount agreed in the patient access scheme.

Patients currently receiving omalizumab whose disease does not meet the above criteria should have the option to continue treatment until they and their clinician consider it appropriate to stop.

www.nice.org.uk/guidance/ta339

Scottish Medicines Consortium (SMC) decisions

The *Scottish Medicines Consortium* has advised (January 2015) that omalizumab (*Xolair*®) is accepted for restricted use within NHS Scotland for the treatment of chronic spontaneous urticaria in patients aged 12 years and over, who have had an inadequate response to combination therapy with H_1-antihistamines, leukotriene receptor antagonists and H_2-antihistamines, used according to current treatment guidelines.

● **MEDICINAL FORMS** There can be variation in the licensing of different medicines containing the same drug.

Solution for injection

▸ **Xolair** (Novartis Pharmaceuticals UK Ltd)

Omalizumab 150 mg per 1 ml Xolair 150mg/1ml solution for injection pre-filled syringes | 1 pre-filled disposable injection PoM £256.15 DT = £256.15

Xolair 75mg/0.5ml solution for injection pre-filled syringes | 1 pre-filled disposable injection PoM £128.07 DT = £128.07

Reslizumab

01-Nov-2017

● **DRUG ACTION** Reslizumab is a humanised monoclonal antibody that interferes with interleukin-5 receptor binding, thereby reducing the survival and activity of eosinophils.

● **INDICATIONS AND DOSE**

Severe eosinophilic asthma (adjunctive therapy when inadequately controlled by high-dose corticosteroids plus another standard treatment) (specialist use only)

▸ BY INTRAVENOUS INFUSION

▸ Adult: (consult product literature)

PHARMACOKINETICS

▸ The half-life of reslizumab is approx. 24 days.

● **CAUTIONS** Hypersensitivity reactions · pre-existing helminth infection

CAUTIONS, FURTHER INFORMATION

▸ Helminth infection Manufacturer advises to treat pre-existing helminth infections before starting reslizumab—consider temporarily discontinuing reslizumab if patient becomes infected during therapy and does not respond to anti-helminth treatment.

▸ Hypersensitivity reactions Serious hypersensitivity reactions, including life-threatening anaphylaxis, can occur and manufacturer advises to monitor closely during treatment and for at least 20 minutes after completion of infusion; in the event of a hypersensitivity reaction, treatment should be permanently discontinued.

● **SIDE-EFFECTS**

▸ **Uncommon** Anaphylactic reaction · myalgia

▸ **Frequency not known** Secondary malignancy

● **PREGNANCY** Manufacturer advises avoid—limited information available.

● **BREAST FEEDING** Manufacturer advises avoid during first few days after birth—risk of transfer of antibodies to infant cannot be excluded; present in milk in *animal* studies.

● **DIRECTIONS FOR ADMINISTRATION** For *intravenous infusion*, manufacturer advises give intermittently in Sodium chloride 0.9%; administer over 20–50 minutes through an in-line 0.2 micron filter.

● **HANDLING AND STORAGE** Manufacturer advises store in a refrigerator (2–8°C); consult product literature for storage conditions after preparation of infusion.

● **PATIENT AND CARER ADVICE** Manufacturer advises patients and their carers should be instructed to seek medical advice if their asthma remains uncontrolled or if symptoms worsen after initiation of treatment.

● **NATIONAL FUNDING/ACCESS DECISIONS**

NICE decisions

▸ **Reslizumab for treating severe eosinophilic asthma (October 2017)** NICE TA479

Reslizumab, as an add-on therapy, is recommended as an option for the treatment of severe eosinophilic asthma that is inadequately controlled in adults despite maintenance therapy with high-dose inhaled corticosteroids plus another drug, only if:

- the blood eosinophil count has been recorded as 400 cells per microlitre or more, **and**
- the person has had 3 or more severe asthma exacerbations needing systemic corticosteroids in the past 12 months, **and**
- the manufacturer provides reslizumab with the discount agreed in the patient access scheme.

At 12 months, stop reslizumab if the asthma has not responded adequately or continue reslizumab if the asthma has responded adequately and assess response each year.

Patients whose treatment was started within the NHS before this guidance was published should have the option