Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Omalizumab

INITIATION – severe asthma
Re-assessment required after 6 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a clinical immunologist or respiratory specialist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ Patient must be aged 6 years or older

and

- ○ Patient has a diagnosis of severe asthma

and

- ○ Past or current evidence of atopy, documented by skin prick testing or RAST

and

- ○ Total serum human immunoglobulin E (IgE) between 76 IU/mL and 1300 IU/ml at baseline

and

- ○ Proven adherence with optimal inhaled therapy including high dose inhaled corticosteroid (budesonide 1,600 mcg per day or fluticasone propionate 1,000 mcg per day or equivalent), plus long-acting beta-2 agonist therapy (at least salmeterol 50 mcg bd or eformoterol 12 mcg bd) for at least 12 months, unless contraindicated or not tolerated

and

- ○ Patient has received courses of systemic corticosteroids equivalent to at least 28 days treatment in the past 12 months, unless contraindicated or not tolerated

or

- ○ Patient has had at least 4 exacerbations needing systemic corticosteroids in the previous 12 months, where an exacerbation is defined as either documented use of oral corticosteroids for at least 3 days or parenteral steroids

and

- ○ Patient has an Asthma Control Test (ACT) score of 10 or less

and

- ○ Baseline measurements of the patient's asthma control using the ACT and oral corticosteroid dose must be made at the time of application, and again at around 26 weeks after the first dose to assess response to treatment

CONTINUATION – severe asthma
Re-assessment required after 6 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a respiratory specialist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ An increase in the Asthma Control Test (ACT) score of at least 5 from baseline

and

- ○ A reduction in the maintenance oral corticosteroid dose or number of exacerbations of at least 50% from baseline

I confirm that the above details are correct:

Signed: ..... Date: .....

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PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Omalizumab *- continued*

INITIATION – severe chronic spontaneous urticaria
Re-assessment required after 6 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a clinical immunologist or dermatologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ Patient must be aged 12 years or older

and

- ○ Patient is symptomatic with Urticaria Activity Score 7 (UAS7) of 20 or above

and

- ○ Patient has a Dermatology life quality index (DLQI) of 10 or greater

and

- ○ Patient has been taking high dose antihistamines (e.g. 4 times standard dose) and ciclosporin (> 3 mg/kg day) for at least 6 weeks

or

- ○ Patient has been taking high dose antihistamines (e.g. 4 times standard dose) and at least 3 courses of systemic corticosteroids (> 20 mg prednisone per day for at least 5 days) in the previous 6 months

or

- ○ Patient has developed significant adverse effects whilst on corticosteroids or ciclosporin

and

- ○ Treatment to be stopped if inadequate response* following 4 doses

or

- ○ Complete response* to 6 doses of omalizumab

CONTINUATION – severe chronic spontaneous urticaria
Re-assessment required after 6 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a clinical immunologist or dermatologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ Patient has previously had a complete response* to 6 doses of omalizumab

or

- ○ Patient has previously had a complete response* to 6 doses of omalizumab

and

- ○ Patient has relapsed after cessation of omalizumab therapy

Note: *Inadequate response defined as less than 50% reduction in baseline UAS7 and DLQI score, or an increase in Urticaria Control Test (UCT) score of less than 4 from baseline. Patient is to be reassessed for response after 4 doses of omalizumab. Complete response is defined as UAS7 less than or equal to 6 and DLQI less than or equal to 5; or UCT of 16. Relapse of chronic urticaria on stopping prednisone/ciclosporin does not justify the funding of omalizumab.

I confirm that the above details are correct:

Signed: ..... Date: .....