

APPLICATION FOR SUBSIDY BY SPECIAL AUTHORITY

APPLICANT (stamp or sticker acceptable) **PATIENT** NHI: **REFERRER** Reg No:

Reg No: First Names: First Names:

Name: Surname: Surname:

Address: DOB: Address:

..... Address:

.....

Fax Number: Fax Number:

Omalizumab

INITIAL APPLICATION - severe asthma

Applications only from a respiratory specialist or clinical immunologist. Approvals valid for 6 months.

Prerequisites (tick boxes where appropriate)

- 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

See also: **INITIAL APPLICATION** - severe chronic spontaneous urticaria p2 , **RENEWAL** - severe asthma p2 and **RENEWAL** - severe chronic spontaneous urticaria p3

I confirm the above details are correct and that in signing this form I understand I may be audited.

Signed: Date:

Post application to Ministry of Health, Private Bag 3015, Wanganui – Fax: 0800 100 131

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Omalizumab - continued

INITIAL APPLICATION - severe chronic spontaneous urticaria

Applications only from a clinical immunologist or dermatologist. Approvals valid for 6 months.

Prerequisites (tick boxes where appropriate)

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

or

Patient has a Urticaria Control Test (UCT) of 8 or less

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

RENEWAL - severe asthma

Current approval Number (if known):.....

Applications only from a clinical immunologist or respiratory specialist. Approvals valid for 2 years.

Prerequisites (tick boxes where appropriate)

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

See also: **RENEWAL** - severe chronic spontaneous urticaria p3

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Omalizumab - continued

RENEWAL - severe chronic spontaneous urticaria

Current approval Number (if known):.....

Applications only from a clinical immunologist or dermatologist. Approvals valid for 6 months.

Prerequisites (tick boxes where appropriate)

Patient has previously adequately responded* 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.

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