

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

Reg No: .....      First Names: .....      First Names: .....

Name: .....      Surname: .....      Surname: .....

Address: .....      DOB: .....      Address: .....

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**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

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

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

Post application to Health New Zealand, Private Bag 3015, Wanganui – email: [customerservice@health.govt.nz](mailto:customerservice@health.govt.nz)

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**Omalizumab** - continued

**Initial application — severe chronic spontaneous urticaria**

Applications only from a clinical immunologist or dermatologist. Approvals valid for 7 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

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

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Fax Number: .....	.....	Fax Number: .....

**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)

<b>or</b>	<input type="checkbox"/> Patient has previously adequately responded* to 6 doses of omalizumab		
	<table border="1"> <tr> <td rowspan="2" style="vertical-align: middle;"><b>and</b></td> <td><input type="checkbox"/> Patient has previously had a complete response* to 6 doses of omalizumab</td> </tr> <tr> <td><input type="checkbox"/> Patient has relapsed after cessation of omalizumab therapy</td> </tr> </table>	<b>and</b>	<input type="checkbox"/> Patient has previously had a complete response* to 6 doses of omalizumab
<b>and</b>	<input type="checkbox"/> Patient has previously had a complete response* to 6 doses of omalizumab		
	<input type="checkbox"/> 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 the above details are correct and that in signing this form I understand I may be audited.**

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