

# ACE Guidance

## Plain English Summary



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### Omalizumab for treating antihistamine-resistant chronic spontaneous urticaria (CSU or hives)

#### WHAT DOES THE GUIDANCE SAY?

Omalizumab is recommended for listing on the Medication Assistance Fund (MAF) for government subsidy for people aged 12 years and over with severe CSU if their condition has not improved with antihistamine treatment.

#### WHAT IS CSU?

Urticaria, also called hives, is a raised itchy rash. The rash can affect one part of the body or can spread across large areas. It is considered chronic if it happens repeatedly for at least six weeks. For half of all people with CSU, symptoms may clear within six months.

#### WHAT IS OMALIZUMAB?

You may know omalizumab as Xolair, a drug that blocks immunoglobulin E, which is a substance that plays a part in the immune system, and is thought to cause the symptoms of CSU.

#### HOW MUCH OMALIZUMAB CAN I TAKE?

Your doctor will usually prescribe one 300 mg injection every four weeks. Unless your doctor advises otherwise, you will also continue taking your current medication for CSU.

#### HOW LONG SHOULD I TAKE IT?

If this is your first treatment course, you can take omalizumab for up to 24 weeks. You can receive subsequent treatment courses if your condition responded well to the previous course and:

- Your condition worsens significantly after stopping omalizumab, even with high doses of non-sedating antihistamines; and
- Your doctor confirms that taking omalizumab has improved your CSU.

## Omalizumab for treating antihistamine-resistant chronic spontaneous urticaria (CSU or hives)

### WHO CAN HAVE OMALIZUMAB?

People can apply for omalizumab through MAF if they:

- Have severe CSU, confirmed with the Urticaria Activity Score (UAS) test by a doctor specialised in immunology, allergy, or dermatology;
- Are 12 years and older; and
- Are currently taking high doses of a non-sedating antihistamine, but their condition has not improved or they are unable to tolerate antihistamine treatment.

Your doctor can advise if omalizumab is a suitable treatment for you.

### WHY WAS OMALIZUMAB RECOMMENDED FOR MAF?

ACE evaluates how well a treatment works in relation to how much it costs compared to other treatments. Omalizumab was recommended because its benefit in relieving symptoms and improving quality of life for certain patients justifies its cost.

### WHAT DOES LISTING ON THE MAF MEAN FOR ME?

The MAF helps people pay for expensive treatments that are clinically necessary. If your doctor prescribes omalizumab for you, and you meet the MAF criteria, your treatment cost will be subsidised by 40% to 75%.

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