TITLE: Omalizumab Treatment for Adults and Children with Allergic Asthma: Clinical Effectiveness, Cost-Effectiveness, and Guidelines

DATE: 29 November 2011

RESEARCH QUESTIONS

1. What is the clinical effectiveness of omalizumab for the treatment of allergic asthma in adults and children who are not responsive to other therapies?

2. What is the cost-effectiveness of omalizumab for the treatment of allergic asthma in adults and children who are not responsive to other therapies?

3. What are the international evidence-based guidelines regarding the use of omalizumab for the treatment of allergic asthma in adults and children?

KEY MESSAGE

Evidence suggests that omalizumab decreases the risk of asthma exacerbations in patients with allergic asthma inadequately controlled by standard therapies who are not responsive to other therapies; omalizumab was found by most studies to be cost-effective due to the health benefits achieved; and guidelines recommend that omalizumab be administered to patients older than twelve years of age for the treatment of severe persistent allergic asthma.

METHODS

A limited literature search was conducted on key resources including PubMed, OVID’s Medline, The Cochrane Library (November 2011), University of York Centre for Reviews and Dissemination (CRD) databases, Canadian and an abbreviated list of major international health technology agencies, as well as a focused Internet search. No filters were applied to limit the retrieval by study type. Where possible, retrieval was limited to the human population. The search was also limited to English language documents published between January 01 2005 and November 15 2011. Internet links were provided, where available.
The summary of findings was prepared from the abstracts of the relevant information. Please note that data contained in abstracts may not always be an accurate reflection of the data contained within the full article.

RESULTS

Rapid Response reports are organized so that the higher quality evidence is presented first. Therefore, health technology assessment reports, systematic reviews, and meta-analyses are presented first. These are followed by randomized controlled trials (RCT), economic evaluations, and evidence-based guidelines.

One systematic review and nine randomized controlled trials regarding the clinical effectiveness of omalizumab for the treatment of allergic asthma in adults and children who are not responsive to other therapies were identified. Two of the RCTs reported results from the INNOVATE study. One systematic review and five economic evaluations regarding the cost-effectiveness of omalizumab for the treatment of allergic asthma in adults and children were identified. Five evidence-based guidelines regarding the use of omalizumab for the treatment of allergic asthma in adults and children were identified. Additional references of potential interest are provided in the appendix.

OVERALL SUMMARY OF FINDINGS

In all included systematic reviews and RCTs, omalizumab was found to decrease the risk of asthma exacerbations in patients with allergic asthma inadequately controlled by standard therapies when compared to placebo. All studies included patients who were already taking corticosteroid therapy. One systematic review and two RCTs focused on children between six and twelve years old while the remainder of the studies focused on patients over the age of twelve. Further detail is included in Table 1.

<table>
<thead>
<tr>
<th>Authors, study design</th>
<th>Included studies, population, duration</th>
<th>Intervention and comparators</th>
<th>Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rodrigo 2011, SR¹</td>
<td>Placebo-controlled studies Children and adults with asthma taking corticosteroid therapy</td>
<td>Omalizumab Placebo</td>
<td>Patients taking omalizumab showed decreased risk of asthma exacerbations at the end of the stable and adjustable-steroid phases.</td>
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<td>Busse 2011, RCT³</td>
<td>Inner-city children, adolescents, and young adults with persistent asthma 60 weeks</td>
<td>Omalizumab Placebo</td>
<td>Omalizumab significantly reduced the number of days with asthma symptoms. Omalizumab significantly reduced the proportion of participants who had one or more exacerbations.</td>
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<td>Henania 2011, RCT⁴</td>
<td>Patients with inadequately controlled severe asthma who are receiving high-dose</td>
<td>Omalizumab Placebo</td>
<td>Omalizumab significantly reduced the rate of protocol-defined asthma exacerbations compared with placebo.</td>
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<td>Omalizumab Treatment for Adults and Children with Allergic Asthma</td>
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<td><strong>Table 1: Omalizumab for the treatment of allergic asthma in adults and children</strong></td>
<td><strong>Clinical effectiveness</strong></td>
<td><strong>Authors, study design</strong></td>
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<td></td>
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<td>ICS and LABA</td>
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<td>Kulus 2010, RCT</td>
<td>Children (6 to &lt;12 years) with inadequately controlled severe allergic asthma, specifically perennial</td>
<td><strong>Omalizumab</strong></td>
<td><strong>Placebo</strong></td>
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<td>Lanier 2009, RCT</td>
<td>Children (6 to &lt;12 years) with inadequately controlled severe allergic asthma</td>
<td><strong>Omalizumab</strong></td>
<td><strong>Placebo</strong></td>
</tr>
<tr>
<td>Massanari 2009, RCT</td>
<td>Patients with moderate to severe persistent asthma and cat allergen sensitivity Pooled analysis of 2 RCTs</td>
<td><strong>Omalizumab</strong></td>
<td><strong>Placebo</strong></td>
</tr>
<tr>
<td>Ohta 2009, RCT</td>
<td>Asian patients with moderate to severe persistent asthma despite receiving corticosteroids and other standard therapies</td>
<td><strong>Omalizumab</strong></td>
<td><strong>Placebo</strong></td>
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<tr>
<td>Niven 2008, RCT</td>
<td>Patients with inadequately controlled severe persistent allergic asthma despite high-dose ICS and LABA</td>
<td><strong>Omalizumab</strong></td>
<td><strong>Placebo</strong></td>
</tr>
<tr>
<td>Sthoeger 2007, RCT</td>
<td>Patients (12 to 75 years) with severe persistent asthma despite high-dose ICS and LABA</td>
<td><strong>Omalizumab</strong></td>
<td><strong>Placebo</strong></td>
</tr>
</tbody>
</table>
Table 1: Omalizumab for the treatment of allergic asthma in adults and children—clinical effectiveness

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<tr>
<td>Humbert 2005, RCT111</td>
<td>Patients (12 to 75 years) with inadequately controlled severe persistent allergic asthma despite high-dose ICS and LABA</td>
<td>Omalizumab Placebo</td>
<td>Omalizumab significantly reduced severe asthma exacerbation rate and emergency department visit rate.</td>
</tr>
</tbody>
</table>

ICS = inhaled corticosteroids; LABA = long-acting beta(2)-agonist; RCT = randomized controlled trial; SR = systematic review

One systematic review2 and five economic evaluations12-16 on the cost-effectiveness of omalizumab for the treatment of allergic asthma in adults and children who are not responsive to other therapies were identified. The included systematic review2 found omalizumab to be cost-effective, however, authors identified the high proportion of manufacturer-funded economic evaluations included as a study weakness. Two studies12,13 found that omalizumab increased health care costs but provided health benefits to justify the higher costs. One study14 merged published data on clinical and economic outcomes to project 10-year costs and did not find omalizumab to be cost-effective and recommended that clinicians explore alternative options first. Two studies15,16 based their economic models on data from specific RCTs. One study15 found that add-on omalizumab therapy is cost-effective in patients with severe persistent allergic asthma while the other16 found that omalizumab provides cost offsets and may have an attractive incremental cost-effectiveness ratio.

Five evidence-based international guidelines17-21 regarding the use of omalizumab for the treatment of allergic asthma in adults and children were identified. The guidelines made the following recommendations regarding omalizumab use in allergic asthma:

- not recommended for children aged six to eleven as the clinical benefit does not justify the high cost of treatment;17
- recommended for patients older than 12 years of age who have had at least two asthma attacks requiring hospital admission within the past year;18
- should be considered for patients older than 12 years of age with allergies and persistent asthma, however, clinicians should be prepared and equipped for potential anaphylaxis.20,21

The British Guideline on the Management of Asthma19 specifies the amount of omalizumab that can be safely administered to children between six and twelve years of age.
Omalizumab Treatment for Adults and Children with Allergic Asthma

REFERENCES SUMMARIZED

Health Technology Assessments
No literature identified.

Systematic Reviews and Meta-analyses


Randomized Controlled Trials


PubMed: PM18657960

PubMed: PM17642399

PubMed: PM15679715

**Economic Evaluations**

PubMed: PM21608372

PubMed: PM20148804

PubMed: PM17904628

PubMed: PM17298423

PubMed: PM16968580
Guidelines and Recommendations


   Note: See Persistent Asthma, Step 5, Long-Term Control Medications


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APPENDIX – FURTHER INFORMATION:

Guidelines and Recommendations – in development


Non-Randomized Studies


Review Articles


Additional references
