# Complete Summary

## GUIDELINE TITLE

Omalizumab for severe persistent allergic asthma.

## BIBLIOGRAPHIC SOURCE(S)

National Institute for Health and Clinical Excellence (NICE). Omalizumab for severe persistent allergic asthma. London (UK): National Institute for Health and Clinical Excellence (NICE); 2007 Nov. 28 p. (Technology appraisal guidance; no. 133).

## GUIDELINE STATUS

This is the current release of the guideline.

## ** REGULATORY ALERT **

## FDA WARNING/REGULATORY ALERT

**Note from the National Guideline Clearinghouse**: This guideline references a drug(s) for which important revised regulatory and/or warning information has been released.

- February 21, 2007, Xolair (Omalizumab): New reports of serious and life-threatening allergic reactions (anaphylaxis) in patients after treatment with Xolair.

## COMPLETE SUMMARY CONTENT

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## SCOPE

### DISEASE/CONDITION(S)

Severe persistent immunoglobulin E (IgE) mediated allergic asthma

### GUIDELINE CATEGORY

Assessment of Therapeutic Effectiveness
Management
Treatment

### CLINICAL SPECIALTY

Allergy and Immunology
Family Practice
Internal Medicine
Pediatrics

### INTENDED USERS

Advanced Practice Nurses
Nurses
Physician Assistants
Physicians

### GUIDELINE OBJECTIVE(S)

To evaluate the clinical effectiveness and cost-effectiveness of omalizumab for the treatment of severe asthma

### TARGET POPULATION

Adults and adolescents (12 years and older) identified as having severe persistent allergic asthma

### INTERVENTIONS AND PRACTICES CONSIDERED

Omalizumab as add-on therapy for severe persistent allergic asthma

### MAJOR OUTCOMES CONSIDERED

- Clinical effectiveness
    - Clinically significant asthma exacerbations (severe and non-severe)
    - Hospitalization, emergency visits and unscheduled doctor's visits
    - Health-related quality of life
    - Clinical symptom score
    - Use of rescue medication
    - Patients and investigators Global Evaluations of Treatment Effectiveness (GETE)

    - Use of concomitant asthma medications
    - Pulmonary function tests
    - Adverse events
    - Mortality
- Cost-effectiveness

## METHODOLOGY

### METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Hand-searches of Published Literature (Secondary Sources)
Searches of Electronic Databases
Searches of Unpublished Data

### DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

**Note from the National Guideline Clearinghouse (NGC)**: The National Institute for Health and Clinical Excellence (NICE) commissioned an independent academic centre to perform a systematic literature review on the technology considered in this appraisal and prepare an assessment report. The assessment report for this technology appraisal was prepared by the Southampton Health Technology Assessment Centre (SHTAC), Wessex Institute for Health Research and Development (WIHRD), University of Southampton (see the "Availability of Companion Documents" field).

**Clinical Effectiveness**

**Description of Manufacturer's Search Strategy**

*Clinical Effectiveness Searches*

The manufacturer ran searches meeting the minimum database criteria as specified by NICE, i.e. Cochrane Database of Systematic Reviews (CDSR), Embase, Medline and Medline in process (MEIP). Additional databases that could have been searched to obtain clinical evidence include ISI proceedings, Biosis, and Cochrane CENTRAL (Cochrane Central Register of Controlled Trials.)

To identify on-going trials databases such as current controlled trials, www.clinicaltrials.gov or the National Research Register (NRR) could have been searched, although this was not a requirement by NICE. The manufacturer searched these databases following submission of the manufacturer's submission (MS) in response to a query from the Evidence Review Group (ERG). This search identified one on-going study in addition to the on-going study already reported in the MS. The additional study appears to be recruiting patients aligned with the European Union/United Kingdom (EU/UK) license, but results will not be available until 2008/2009 at the earliest.

The search included data up until the 30th of January 2006. As the submission was received by the ERG on the 1st of February, it is unclear if this is the original search date or an update of the original searches. No date restriction was

specified with the CDSR searches; other searches were restricted to 1996 onwards, but this is not unreasonable with omalizumab being a recently licensed drug. The search terms used and strategy appear to be appropriate, although a more complex wider search filter, encompassing free text terms, may have maximised the chance of finding randomized controlled trials (RCTs). ERG searches using an RCT filter identified an additional 53 references in Medline, and an additional 109 references in Embase. Additional results were identified in Cochrane CENTRAL and some other databases. Disparities could have arisen due to use of differing host systems. The host system utilised by Novartis (for Embase, Medline & MEIP) is Dialog/Datastar. The ERG uses an alternative host, Ovid. Consequently, head-to-head number comparison of results are not completely feasible, due to differing search syntax and different indexing lag times between the two host systems. The additional references identified by the ERG from searches of Medline and Embase were briefly scanned and do not appear to be relevant.

The MS states that the INNOVATE trial is the only study that recruited patients that matched the EU/UK licensed indication, and there are no other published or unpublished RCT data held by the manufacturer that fulfill the criteria for the license. However, no formal searches of company databases were reported in the MS. Following a query from the ERG, the manufacturer conducted a manual search of listings of omalizumab studies in their possession. They report that the results of this search confirm that there are no other relevant studies of omalizumab.

*Statement of the Inclusion/Exclusion Criteria Used in the Study Selection and Comment on whether They Were Appropriate*

The reporting of methods used by the manufacturer for screening references for inclusion was limited. It was not clear how many reviewers screened and assessed the references identified by the searches. This has implications for the reliability and reproducibility of the selection process. The manufacturer subsequently reported that inclusion/exclusion criteria were applied by one person, in response to a query from the ERG. The patient inclusion/exclusion criteria are clearly stated in the MS report, and are appropriate although they are extremely limiting, adhering strictly to the licensed indication. The MS specified the following inclusion criteria for the review of the literature:

- ≥12 years of age
- Severe persistent allergic asthma
- Currently treated with high dose inhaled corticosteroids (ICS) (>1000 micrograms/day beclometasone dipropionate [BDP] or equivalent) + long-acting beta 2 agonist (LABA) and experiencing:
    - Reduced lung function (forced expiratory volume in 1 second [FEV1] <80%)
    - Frequent daytime symptoms and night-time awakenings
    - Multiple documented severe asthma exacerbations
- Positive skin test or *in vitro* reactivity to a perennial aeroallergen
- Convincing immunoglobulin E (IgE) mediated asthma

Only RCTs reporting primary results, as well as fulfilling the specific criteria of the product license and the decision problem were included. The MS did not

specifically state whether systematic reviews would be considered, and neither is there discussion of whether conference abstracts would be included or excluded.

See Appendix A and section 3.1.2 in the Evidence Review Group Report [see the "Availability of Companion Documents" field] for more information).

The ERG did not identify any relevant studies that were not included in the submission from searches undertaken.

**Economic Evaluation**

The MS states that no formal search of data held by the manufacturer was conducted, but following a query from the ERG a search was undertaken (refer to Appendix A, response to question A1 in the Evidence Review Group Report [see the "Availability of Companion Documents" field]). No additional studies were identified. Studies were included in the review if they related to patient populations meeting the EU/UK license criteria. Two economic evaluations were identified by the searches, one of which was excluded as it referred to a different patient population. The one that was included was a cost-utility study of omalizumab add-on therapy in a Swedish setting. The manufacturer identified a further publication in press by Brown and colleagues, which reports a cost utility study from a Canadian perspective based on the IA-04 (ETOPA) study.

## NUMBER OF SOURCE DOCUMENTS

**Clinical Effectiveness**

Only one randomized controlled trial (RCT) met the inclusion/exclusion criteria and was included in the manufacturer's submission.

**Economic Evaluation**

- One published cost-utility study
- One publication in press

## METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Expert Consensus

## RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

## METHODS USED TO ANALYZE THE EVIDENCE

Review of Published Meta-Analyses
Systematic Review with Evidence Tables

## DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

**Note from the National Guideline Clearinghouse (NGC)**: The National Institute for Health and Clinical Excellence (NICE) commissioned an independent academic centre to perform a systematic literature review on the technology considered in this appraisal and prepare an assessment report. The assessment report for this technology appraisal was prepared by the Southampton Health Technology Assessment Centre (SHTAC), Wessex Institute for Health Research and Development (WIHRD), University of Southampton (see the "Availability of Companion Documents" field).

**Clinical Effectiveness**

The manufacturer applied the quality assessment criteria to the INNOVATE trial and an open-label "naturalistic" randomly controlled trial (RCT). Since the latter did not meet the inclusion criteria for the manufacturer's submission (MS), the Evidence Review Group (ERG) have not subjected it to critical appraisal. The manufacturer's quality assessment of the INNOVATE trial was not adequate for some parameters (refer to Table 2 of the Evidence Review Group Report [see the "Availability of Companion Documents" field]), and details of whether the process was performed by two independent reviewers were lacking. There is also uncertainty about the validity of including unpublished post hoc analysis for two subgroups.

The submitted evidence generally reflects the decision problem defined in the submission.

There is uncertainty about some of the statistical methods used in the analysis because of post hoc adjustments to the data, and reporting of results for the primary intention to treat (PITT) (and not true intention to treat [ITT]) population. Confidence intervals are not presented consistently for all outcomes. There is also uncertainty about the quality of the INNOVATE trial as no information was provided in the MS on how treatment allocation was concealed, and some details were also lacking with regards the power calculation for the sample size. The INNOVATE trial paper did not report on either of these aspects. The ERG also noted some concern that personnel preparing and administering the injections were aware of the identity of the drug/placebo treatment and whether this may have potentially impacted on the blinding of the study.

No evidence synthesis in the form of a meta-analysis was possible as there was only one RCT.

Refer to Sections 3.1 to 3.4 of the Evidence Review Group Report (see the "Availability of Companion Documents" field) for more information.

**Economic Evaluation**

**Critical Appraisal of the Manufacturer's Submitted Economic Evaluation**

*Modelling Methods*

An outline critical review of modelling methods has been undertaken. The review has used the framework for good practice in modelling presented by Philips and

colleagues as a guide, addressing issues of model structure, structural assumptions, data inputs, consistency, and assessment of uncertainty.

Modelling Approach/Model Structure

The MS presents a Markov state transition model comprising five health states: day-to- day symptoms, clinically significant (CS) non severe exacerbation, CS severe exacerbation, asthma death and non asthma death. The modelling approach and health states used in the model seem reasonable to the ERG and the clinical experts consulted. The structural assumptions have been justified and seem reasonable.

Structural Assumptions

The MS provides little detail on the development of the model structure and makes no explicit reference to its clinical validation. The MS suggests that the model structure has been derived from observation of clinical trial findings and not from an underlying clinical model of the disease. The structure reflects the conception of asthma as a disease of fluctuating day-to-day symptoms and intermittent exacerbations. Thus patients' usual condition is one of impaired quality of life, due to the variable presence of day-to-day symptoms (such as wheezing, coughing or shortness of breath causing the patient to wake at night). Patients' movement between health states does not reflect progression of disease – as would be more typical of a Markov model of chronic disease – but temporary and reversible deterioration.

While noting the lack of detail on the development and validation of the model, it appears to be appropriate given the decision problem, the data available and the specified causal relationships.

One-way Sensitivity Analyses

The MS presents univariate sensitivity analyses for a limited range of methodological (discount rates), structural (time horizon) and parameter (treatment duration, asthma related fatality, health state utility, exacerbation cost and basis for estimating omalizumab drug cost) uncertainties. No rationale has been given for the choice of variables included in (or excluded from) this sensitivity analysis. In addition the analysis has been conducted by replacing base case values with alternative assumptions – no consideration has been given to variation around base case values using credible ranges or confidence intervals. Some key input parameters (such as proportion of responders, exacerbation rates or relative risk of exacerbation with omalizumab add-on therapy) which might be expected to be highly influential on the cost-effectiveness estimates have been omitted from the sensitivity analysis.

ERG Sensitivity Analysis

The ERG presents sensitivity analyses for these parameters in Table 13 of the Evidence Review Group Report (see the "Availability of Companion Documents" field). The ERG used the confidence intervals for the parameters as ranges in the sensitivity analyses. These were taken from the INNOVATE trial data, the

manufacturer's calculations on Excel sheet *'AP2-Model Parameters'*, or calculated using standard confidence interval calculations. The ranges for other parameters were chosen arbitrarily based on reasonable likely ranges.

Comment on Validity of Results Presented with Reference to Methodology Used

In general, the approach taken to modelling cost effectiveness in this patient group seems reasonable. A number of concerns have been raised by the ERG, with respect to the approach to costing omalizumab treatment, the appropriateness of the exacerbation fatality rate used and inadequate consideration of potential biases introduced by missing data. However the overall structure of the model seems reasonable and the significance of the concerns raised by the ERG can partly be determined through careful sensitivity analysis.

Refer to Sections 4.2 to 4.4 for more information on methods used to analyze cost-effectiveness.

## METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

## DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

### Considerations

Technology appraisal recommendations are based on a review of clinical and economic evidence.

### Technology Appraisal Process

The National Institute for Health and Clinical Excellence (NICE) invites 'consultee' and 'commentator' organisations to take part in the appraisal process. Consultee organisations include national groups representing patients and carers, the bodies representing health professionals, and the manufacturers of the technology under review. Consultees are invited to submit evidence during the appraisal and to comment on the appraisal documents.

Commentator organisations include manufacturers of the products with which the technology is being compared, the National Health Service (NHS) Quality Improvement Scotland and research groups working in the area. They can comment on the evidence and other documents but are not asked to submit evidence themselves.

NICE then commissions an independent academic centre to review published evidence on the technology and prepare an 'assessment report'. Consultees and commentators are invited to comment on the report. The assessment report and the comments on it are then drawn together in a document called the evaluation report.

An independent Appraisal Committee then considers the evaluation report. It holds a meeting where it hears direct, spoken evidence from nominated clinical experts, patients and carers. The Committee uses all the evidence to make its first recommendations, in a document called the 'appraisal consultation document' (ACD). NICE sends all the consultees and commentators a copy of this document and posts it on the NICE website. Further comments are invited from everyone taking part.

When the Committee meets again it considers any comments submitted on the ACD; then it prepares its final recommendations in a document called the 'final appraisal determination' (FAD). This is submitted to NICE for approval.

Consultees have a chance to appeal against the final recommendations in the FAD. If there are no appeals, the final recommendations become the basis of the guidance that NICE issues.

**Who is on the Appraisal Committee?**

NICE technology appraisal recommendations are prepared by an independent committee. This includes health professionals working in the NHS and people who are familiar with the issues affecting patients and carers. Although the Appraisal Committee seeks the views of organisations representing health professionals, patients, carers, manufacturers and government, its advice is independent of any vested interests.

## RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

## COST ANALYSIS

The manufacturer's submission presented an economic analysis comparing omalizumab add-on therapy to standard therapy with standard therapy alone using a Markov transition model with a lifetime horizon of 40 years.

The economic analysis was performed for the INNOVATE primary intent to treat (PITT) population and the high-risk hospitalisation subgroup. Base-case analysis for the INNOVATE PITT population produced an incremental cost effectiveness ratio (ICER) of 30,600 pounds sterling per quality adjusted life years (QALY) gained and an ICER of 26,500 pounds sterling per QALY gained for the high-risk hospitalisation subgroup. The manufacturer also presented an alternative base-case analysis using subpopulation data from the ETOPA (IA-04) trial that gave an ICER of 21,700 pounds sterling per QALY gained.

One-way sensitivity analyses presented in the manufacturer's submission suggested that the key drivers of the economic model were asthma mortality rate from clinically significant severe exacerbations, omalizumab treatment duration and time horizon. Notably, assuming an asthma mortality rate of 0% from clinically significant severe exacerbations, the base-case ICER increases to 73,200 pounds sterling per QALY gained. Assuming the asthma-related mortality rate is 2.478% gives an ICER of 33,500 pounds sterling per QALY gained. The

manufacturer's submission presented a probabilistic sensitivity analysis that showed a mean ICER of 31,700 pounds sterling per QALY gained. No probabilistic sensitivity analysis was performed for the high-risk hospitalisation subgroup.

The Evidence Review Group (ERG) noted uncertainties surrounding the following parameter assumptions: costing of omalizumab on a per milligram (mg) basis, utility values assigned to non-severe clinically significant exacerbations, clinically significant severe exacerbations and asthma mortality rate. The ERG therefore explored a number of scenario analyses on alternative assumptions for these parameters. The scenario analyses for the INNOVATE PITT population ranged from 33,300 pounds sterling to 40,900 pounds sterling per QALY gained while the scenario analyses for the high-risk hospitalisation subgroup ranged from 29,800 pounds sterling to 34,300 pounds sterling per QALY gained. The ERG performed an amended probabilistic sensitivity analysis that showed greater uncertainty around the ICERs for the INNOVATE PITT population than suggested in the manufacturer's economic analyses. The ERG's amended probabilistic sensitivity analysis showed a mean ICER of 38,900 pounds sterling per QALY gained. At a threshold willingness to pay of 30,000 per pounds sterling QALY, omalizumab add-on therapy was estimated to have a 23.6% probability of being cost effective. No probabilistic sensitivity analysis was performed for the high-risk hospitalisation subgroup.

The Committee considered the mortality rate associated with clinically significant severe exacerbations and noted that this was one of the key drivers of the model. In the manufacturer's base-case, cost per QALY gained for the INNOVATE trial population was 30,600 pounds sterling assuming a 3.1% mortality rate, but this increased to 36,400 pounds sterling with an assumption of 2% mortality (ERG sensitivity analysis), and 73,200 pounds sterling assuming no effect on mortality. The Committee heard from the clinical specialists that asthma-related mortality is rare and tends to occur in patients with poorly controlled asthma and low adherence to treatment. Such patients would not usually be considered appropriate for omalizumab therapy on the basis of the marketing authorisation, because they could not fulfill the requirement for full optimisation of therapy. Additionally, the Committee considered that the assumption of a 2% mortality rate for this group of severe asthmatics may be an overestimate. Therefore the Committee considered the ICER of 30,500 pounds sterling (corresponding to a 2% asthma mortality rate) for the high-risk hospitalisation subgroup to be an underestimate of the true cost per QALY gained unless a subgroup of patients at a higher risk was defined. The Committee considered that the cost effectiveness evidence relating to the economic analysis of the high-risk hospitalisation subgroup from the INNOVATE trial was the most appropriate of those presented by the manufacturer.

## METHOD OF GUIDELINE VALIDATION

External Peer Review

## DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Consultee organizations from the following groups were invited to comment on the draft scope, Assessment Report and the Appraisal Consultation Document

(ACD) and were provided with the opportunity to appeal against the Final Appraisal Determination.

- Manufacturer/sponsors
- Professional/specialist and patient/carer groups
- Commentator organisations (without the right of appeal)

In addition, individuals selected from clinical expert and patient advocate nominations from the professional/specialist and patient/carer groups were also invited to comment on the ACD.

## RECOMMENDATIONS

### MAJOR RECOMMENDATIONS

Omalizumab is recommended, within its licensed indication, as an option for the treatment of severe persistent allergic (immunoglobulin E [IgE] mediated) asthma as add-on therapy to optimised standard therapy, only in adults and adolescents (12 years and older) who have been identified as having severe unstable disease.

For the purposes of this guidance, optimised standard therapy is defined as a full trial of, and documented compliance with, inhaled high-dose corticosteroids and long-acting beta-2 agonists in addition to leukotriene receptor antagonists, theophyllines, oral corticosteroids and beta-2 agonist tablets, and smoking cessation where clinically appropriate.

Omalizumab add-on therapy should only be initiated if the patient fulfils the following criteria of severe unstable allergic asthma.

- Confirmation of IgE mediated allergy to a perennial allergen by clinical history and allergy skin testing.
- Either two or more severe exacerbations of asthma requiring hospital admission within the previous year, or three or more severe exacerbations of asthma within the previous year, at least one of which required admission to hospital, and a further two which required treatment or monitoring in excess of the patient's usual regimen, in an accident and emergency unit.

Omalizumab add-on therapy should be initiated and monitored by a physician experienced in both allergy and respiratory medicine in a specialist centre.

Omalizumab add-on therapy should be discontinued at 16 weeks in patients who have not shown an adequate response to therapy. Response to treatment should be defined on the basis of a full clinical assessment comprising: degree of asthma control, quality of life, control of exacerbations, avoidance of unscheduled healthcare utilisation; spirometry and peak expiratory flow measures and a global evaluation of treatment effectiveness, as assessed by the physician.

### CLINICAL ALGORITHM(S)

None provided

## EVIDENCE SUPPORTING THE RECOMMENDATIONS

### TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of evidence supporting the recommendations is not specifically stated.

## BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

### POTENTIAL BENEFITS

Appropriate use of omalizumab for the treatment of severe persistent allergic asthma in adults and adolescents

### POTENTIAL HARMS

- The most common side effects of omalizumab treatment are bruising, erythema and pain at the site of injection. Rare side effects include increased risk of parasitic infections, anaphylaxis, usually within 2 hours of the first injection and possible drug-induced malignancies.
- The prescribing information has been revised based on post marketing surveillance data and indicates that allergic reactions, including anaphylaxis and anaphylactic shock, may occur beyond 2 hours and sometimes beyond 24 hours of first injection. Patients should be informed that such reactions are possible and prompt medical attention should be sought if allergic reactions occur.

For full details of side effects and contraindications, see the summary of product characteristics (SPC) available at http://emc.medicines.org.uk/.

## QUALIFYING STATEMENTS

### QUALIFYING STATEMENTS

- This guidance represents the view of the Institute, which was arrived at after careful consideration of the available evidence. Healthcare professionals are expected to take it fully into account when exercising their clinical judgement. The guidance does not, however, override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.
- Areas of uncertainty:

  There is uncertainty about some of the statistical methods used in the analysis of the INNOVATE trial because of post hoc adjustments to the primary outcome to correct for suggested clinically relevant imbalances in baseline exacerbation history between trial arms. The manufacturer's submission (MS) reports that such adjustment was recommended by the Committee for Medicinal Products for Human Use (CHMP). The validity of post hoc adjustments has to be viewed with caution, particularly as the difference

in favour of omalizumab in the primary outcome only became statistically significant following adjustment.

The validity of including unpublished post hoc analysis for two sub-groups ("high-risk" previously hospitalised patients, and omalizumab responders) is also questionable as both are likely to be underpowered.

Long term published data on the effectiveness and safety of omalizumab are not yet available. The economic model extrapolates efficacy data from the 28 week INNOVATE trial over a 5 year period, and assumes full compliance. In practice compliance is likely to vary with factors such as the standard of care, which may not be as optimal as within the context of a clinical trial.

There is no discussion in the MS of possible bias introduced due to missing response data on 14 omalizumab-treated patients. There is no discussion of the characteristics of these patients and the MS does not report the number of exacerbations for these patients separately.

Refer to the Evidence Review Group Report (see the "Availability of Companion Documents" field) for additional information on areas of uncertainty and key issues of MS.

## IMPLEMENTATION OF THE GUIDELINE

### DESCRIPTION OF IMPLEMENTATION STRATEGY

- The Healthcare Commission assesses the performance of National Health Service (NHS) organisations in meeting core and developmental standards set by the Department of Health in "Standards for better health" issued in July 2004. The Secretary of State has directed that the NHS provides funding and resources for medicines and treatments that have been recommended by National Institute for Health and Clinical Excellence (NICE) technology appraisals normally within 3 months from the date that NICE publishes the guidance. Core standard C5 states that healthcare organisations should ensure they conform to NICE technology appraisals.
- "Healthcare standards for Wales" was issued by the Welsh Assembly Government in May 2005 and provides a framework both for self-assessment by healthcare organisations and for external review and investigation by Healthcare Inspectorate Wales. Standard 12a requires healthcare organisations to ensure that patients and service users are provided with effective treatment and care that conforms to NICE technology appraisal guidance. The Assembly Minister for Health and Social Services issued a Direction in October 2003 which requires Local Health Boards and NHS Trusts to make funding available to enable the implementation of NICE technology appraisal guidance, normally within 3 months.
- NICE has developed tools to help organisations implement this guidance (listed below). These are available on the NICE website (www.nice.org.uk; see also the "Availability of Companion Documents" field).
    - Costing report and costing template to estimate the savings and costs associated with implementation
    - Audit criteria to monitor local practice

### IMPLEMENTATION TOOLS

Audit Criteria/Indicators
Patient Resources
Quick Reference Guides/Physician Guides
Resources

For information about availability, see the "Availability of Companion Documents" and "Patient Resources" fields below.

## INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

### IOM CARE NEED

Getting Better
Living with Illness

### IOM DOMAIN

Effectiveness
Patient-centeredness

## IDENTIFYING INFORMATION AND AVAILABILITY

### BIBLIOGRAPHIC SOURCE(S)

National Institute for Health and Clinical Excellence (NICE). Omalizumab for severe persistent allergic asthma. London (UK): National Institute for Health and Clinical Excellence (NICE); 2007 Nov. 28 p. (Technology appraisal guidance; no. 133).

### ADAPTATION

Not applicable: The guideline was not adapted from another source.

### DATE RELEASED

2007 Nov

### GUIDELINE DEVELOPER(S)

National Institute for Health and Clinical Excellence (NICE) - National Government Agency [Non-U.S.]

### SOURCE(S) OF FUNDING

National Institute for Health and Clinical Excellence (NICE)

## GUIDELINE COMMITTEE

Appraisal Committee

## COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

*Committee Members*: Professor David Barnett, Professor of Clinical Pharmacology, University of Leicester; Dr David W Black, Director of Public Health, Chesterfield PCT; Professor Mike Campbell, Professor of Medical Statistics, University of Sheffield; Dr Carol Campbell, Senior Lecturer, University of Teesside; Mr Peter Clarke, Consultant Medical Oncologist, Clatterbridge Centre for Oncology, Merseyside; Ms Jude Cohen, Chief Executive, Womens Nationwide Cancer Control Campaign; Dr Christine Davey, Senior Researcher, North Yorkshire Alliance R&D Unit; Dr Mike Davies, Consultant Physician, Manchester Royal Infirmary; Mr Richard Devereaux-Phillips, Public Affairs Manager, Medtronic Ltd; Dr Rachel A Elliott, Clinical Senior Lecturer, The University of Manchester; Mrs Eleanor Grey, Lay member; Dr Dyfrig Hughes, Senior Research Fellow in Pharmacoeconomics, Centre for the Economics of Health and Policy in Health, University of Wales; Dr Catherine Jackson, Clinical Lecturer in Primary Care Medicine, Alyth Health Centre; Dr Peter Jackson, Clinical Pharmacologist, the University of Sheffield; Professor Peter Jones, Professor of Statistics & Dean Faculty of Natural Sciences, Keele University; Ms Rachel Lewis, Nurse Adviser to the Department of Health; Dr Damien Longson, Consultant in Liaison Psychiatry, Manchester Mental Health and Social Care Trust; Professor Jonathan Michaels, Professor of Vascular Surgery, University of Sheffield; Dr Eugene Milne, Deputy Medical Director, North East Strategic Health Authority; Dr Simon Mitchell, Consultant Neonatal Paediatrician, St Mary's Hospital, Manchester; Dr Richard Alexander Nakielny, Consultant Radiologist, Royal Hallamshire Hospital, Sheffield; Dr Katherine Payne, Health Economics Research Fellow, The University of Manchester; Dr Martin J Price, Head of Outcomes Research, Janssen-Cilag Ltd; Mr Miles Scott, Chief Executive, Bradford Teaching Hospitals NHS Foundation Trust; Professor Mark Sculpher, Professor of Health Economics, University of York; Professor Andrew Stevens (Chair) Professor of Public Health, University of Birmingham

## FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Committee members are asked to declare any interests in the technology to be appraised. If it is considered there is a conflict of interest, the member is excluded from participating further in that appraisal.

## GUIDELINE STATUS

This is the current release of the guideline.

## GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) format from the National Institute for Health and Clinical Excellence (NICE) Web site.

## AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

- Omalizumab for severe persistent allergic asthma. Quick reference guide. London (UK): National Institute for Health and Clinical Excellence (NICE); 2007 Nov. 2 p. (Technology appraisal 133). Available in Portable Document Format (PDF) from the National Institute for Health and Clinical Excellence (NICE) Web site.
- Omalizumab for severe persistent allergic asthma. Audit criteria. London (UK): National Institute for Health and Clinical Excellence (NICE); 2007 Nov. 11 p. (Technology appraisal 133). Available in Portable Document Format (PDF) from the NICE Web site.
- Costing template and report: omalizumab for severe persistent allergic asthma. London (UK): National Institute for Health and Clinical Excellence (NICE); 2007 Nov. Various p. (Technology appraisal 133). Available in Portable Document Format (PDF) from the NICE Web site.
- Omalizumab for severe persistent allergic asthma. Evidence Review Group Report commissioned by the NHS R&D HTA Programme on behalf of NICE. 2007 Mar. 93 p. Available in Portable Document Format (PDF) from the NICE Web site.

Print copies: Available from the National Health Service (NHS) Response Line 0870 1555 455. ref: N1404. 11 Strand, London, WC2N 5HR.

## PATIENT RESOURCES

The following is available:

- Omalizumab for severe persistent allergic asthma. Understanding NICE guidance - Information for people who use NHS services. London (UK): National Institute for Health and Clinical Excellence (NICE); 2007 Nov. 4 p. (Technology appraisal 133).

Electronic copies: Available in Portable Document Format (PDF) from the National Institute for Health and Clinical Excellence (NICE) Web site.

Print copies: Available from the NHS Response Line 0870 1555 455. ref: N1405. 11 Strand, London, WC2N 5HR.

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

## NGC STATUS

This NGC summary was completed by ECRI Institute on January 25, 2008.

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