Complete Summary

GUIDELINE TITLE

Dual-chamber pacemakers for symptomatic bradycardia due to sick sinus syndrome and/or atrioventricular block.

BIBLIOGRAPHIC SOURCE(S)

National Institute for Clinical Excellence (NICE). Dual-chamber pacemakers for symptomatic bradycardia due to sick sinus syndrome and/or atrioventricular block. London (UK): National Institute for Clinical Excellence (NICE); 2005 Feb. 36 p. (Technology appraisal; no. 88).

GUIDELINE STATUS

This is the current release of the guideline.

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SCOPE

DISEASE/CONDITION(S)

Symptomatic bradycardia due to sick sinus syndrome and/or atrioventricular block

GUIDELINE CATEGORY

Assessment of Therapeutic Effectiveness
Treatment

CLINICAL SPECIALTY

Cardiology
Internal Medicine

INTENDED USERS

Advanced Practice Nurses
Physician Assistants
Physicians

GUIDELINE OBJECTIVE(S)

To assess the effectiveness and cost-effectiveness of dual-chamber pacemakers for symptomatic bradycardia due to sick sinus syndrome and/or atrioventricular block

TARGET POPULATION

Patients with symptomatic bradycardia due to sick sinus syndrome and/or atrioventricular block

INTERVENTIONS AND PRACTICES CONSIDERED

Dual chamber pacemakers as compared to single-chamber pacemakers (atrial, ventricular, or both)

MAJOR OUTCOMES CONSIDERED

- Clinical effectiveness
    - Mortality (all cause and cardiovascular)
    - Incidence of stroke
    - Incidence of atrial fibrillation
    - Incidence of heart failure
    - Exercise capacity
    - Symptoms of breathlessness, fatigue, chest pain, dizziness, palpitations and sleep disturbance
    - Functional status
    - Quality of life
    - Adverse events of implantation (peri-operative mortality and non-fatal complications)
    - Incidence of pacemaker syndrome
- 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Searches of Unpublished Data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 Peninsula Technology Assessment Group (see the "Companion Documents" field).

Search Strategy

A range of electronic databases were searched for published studies of effectiveness and cost-effectiveness or cost-benefit of dual chamber pacing, encompassing completed or ongoing research: Medline, Cochrane Library (Central, CDSR), Embase, ISI-Web of Knowledge, Web of Science Proceedings, BIOSIS, DARE, HTA, Biomed Central. In addition, the Web sites of the National Research Register, Current Controlled Trials and US Food and Drug Administration (FDA) were searched. The full search strategy is detailed in Appendix 11.2 of the systematic literature review companion document.

Bibliographies were searched for further relevant publications. Members of the Advisory Group were asked to identify additional published or unpublished studies. Submissions to the National Institute for Health and Clinical Excellence (NICE) by technology sponsors as part of the NICE appraisal process were checked for additional published and unpublished literature. The specialized registry of the Cochrane Heart Group was searched by a member of the Cochrane Heart Group.

Inclusion and Exclusion Criteria

Population

Adults and children recruited in secondary and tertiary centres with a primary diagnosis of acquired symptomatic bradycardia, secondary to sick sinus syndrome, atrioventricular (AV) block, or chronic bifascicular block, and individuals with symptomatic bradycardia were included. People at any stage of disease progression were considered, subject to their eligibility for permanent pacing.

Exclusion Criteria

Studies were excluded if they reported on the following populations:

- People with carotid sinus syndrome and malignant vasovagal syncope
- People with a primary diagnosis of congestive heart failure or cardiomyopathy
- People with a primary diagnosis of atrial fibrillation, or atrial fibrillation from other causes without concomitant sick sinus syndrome or atrioventricular block
- People with a primary diagnosis of isolated tachycardia or tachycardia from other causes without concomitant sick sinus syndrome or atrioventricular block

Intervention

Studies of dual chamber pacemakers compared to single chamber pacemakers (ventricular, atrial or both, separately reported) for the treatment of symptomatic bradycardia in eligible population groups.

Exclusion Criteria

Studies will be excluded if reporting on the following pacing types:

- Bi-ventricular
- Bi-atrial
- Triple chamber
- Any type of temporary or diagnostic pacing

Studies on dual chamber, therapeutic, permanent pacemakers with any of the above were excluded when results were not reported separately.

Outcomes

See the "Major Outcomes Considered" field.

Composite outcomes made up of the above were also included.

Type of Studies

Systematic reviews or randomised, controlled parallel or crossover trials were included in the assessment of effectiveness.

Exclusion Criteria

- Non-randomised studies of effectiveness, case series and case reports, n of 1 trials, case-control studies, and cohort studies
- Studies in which insufficient methodological detail were reported to allow critical appraisal
- Studies of less than 48 hours duration
- Studies on patients with clinical indications for pacing other than those considered in this Technology Assessment review (TAR)
- Pre-clinical studies, models, or electrophysiology experimentation on human or other biological material
- Studies in animal models
- Studies not published in English, and for which translation in English is not available

In the review of cost effectiveness studies, reviews of economic studies were included.

Individual studies were considered only if they were full economic evaluations (i.e., those which considered costs and outcomes).

Identification

Studies identified from the literature search were independently assessed by two researchers for inclusion, with disagreement resolved by discussion. Full papers were retrieved and screened independently by two researchers for inclusion, with disagreement resolved by discussion.

Data Extraction Strategy

A data extraction sheet was developed by one researcher and piloted on a small subsample of papers. Data were extracted by one researcher and checked by another. Data were extracted retaining actual numbers where provided, or other summary measures as detailed in the published study.

Quality Assessment Strategy

Methodological quality of randomized controlled trials (RCTs) was assessed using the criteria detailed in Table 6 of the systematic literature review companion document.

The framework established by the QUORUM statement was used for the critical appraisal of systematic reviews.

The quality of cost-effectiveness and cost-utility studies were assessed using the frameworks published by in Sculpher and colleagues and Drummond and colleagues.

Where subgroup analyses were reported, the group considered their methodological quality using the following framework:

- Sample size, with two possibilities, all participants were included in the subanalysis or some were excluded based on pre-selection criteria
- Whether the analysis was preplanned
- Whether the baseline equality of groups was maintained in the subgroup
- Whether blinding was maintained
- Whether the power calculation in the original trial included the subgroup analysis
- Whether the subgroup was analysed on an intention to treat basis
- Whether loss to follow up was reported and how this compared to loss to follow-up in the main study

NUMBER OF SOURCE DOCUMENTS

The searches retrieved a systematic review of effectiveness and cost effectiveness published in 2002; 4 parallel group randomised controlled trials and 28 cross over trials. The quality of the systematic review was good and it was used as the basis for reporting the existing published economic literature as no additional studies were identified.

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

Meta-Analysis of Randomized Controlled Trials
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 Peninsula Technology Assessment Group (see the "Companion Documents" field).

Data Synthesis

The results of individual trials were pooled using random effects meta-analysis, carried out in Review Manager Software version 4.2. The summary statistic was, by default, the odds ratio. Standard test for heterogeneity was carried out in each case and the proportion of variation due to heterogeneity as opposed to chance reported using the I^2 statistic. Limited exploration of heterogeneity was carried out by stratification.

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

Literature searches identified one systematic review of the cost effectiveness of dual-chamber pacing in patients with sick sinus syndrome, sick sinus syndrome with atrioventricular block, or unspecified bradycardia, who were eligible for dual-chamber or single-chamber pacing. The studies included in this review were of limited relevance because they did not incorporate effectiveness data from the recent large parallel-group randomised controlled trials (RCTs), because results were not presented as cost per quality-adjusted life year (QALY), and because of the technological developments in dual chamber pacing.

Three economic models were submitted to the Institute by consultees, and the Assessment Group also developed two separate Markov models that compared

dual-chamber with single-chamber pacing according to whether the underlying cause of bradycardia was sick sinus syndrome or atrioventricular block. A summary of the findings is provided below. Please refer to section 4.2 of the original guideline document and to section 5 of the systematic review companion document for full details.

Summary of the Cost Effectiveness of Dual versus Single Chamber Pacing

- Published economic analyses were reviewed in 2001 and no further informative evaluations have been published since.
- Three evaluations carried out on behalf of sponsors of dual chamber pacing were reviewed. One is of poor quality. The other two (Guidant and Association of British Healthcare Industries [ABHI]) are of reasonable quality in terms of structure.
- The sponsor models suggest that benefits accrue in dual chamber pacing at relatively low cost and, in many cases, will be accompanied by cost saving. The differences between the PenTAG and sponsor models are accounted for by choice of inputs. The apparently large differences in cost effectiveness reflect the small incremental benefits and costs associated with dual chamber pacing, making the incremental cost effectiveness ration (ICER) subject to considerable variation for small changes, particularly in predicted benefits.
- The modelling undertaken by the assessment group is more conservative and suggests that, over five years, dual chamber pacing is likely to give additional QALYs, compared to single ventricular pacing, at a cost of around 8,500 pounds sterling in atrioventricular block (AVB) and 9,500 pounds sterling in sick sinus syndrome (SSS). This estimate is subject to considerable uncertainty although stochastic analysis shows that dual chamber pacing is likely to be considered cost effective at levels of willingness to pay generally considered acceptable by National Health Service (NHS) decision makers.
- The PenTAG model predicts that dual chamber pacing will become more cost effective as a longer time horizon is taken. At 10 years, the cost effectiveness is estimated to be around 5,500 pounds sterling per QALY in both AVB and SSS.
- These estimates are particularly sensitive to assumptions regarding the incidence, duration, and severity of pacemaker syndrome which drives both costs and benefits. Incremental benefits and costs are small. Where conservative assumptions are made regarding the persistence of mild pacemaker syndrome, the incremental cost effectiveness of dual chamber pacing is in the region of 27,000 to 35,000 pounds sterling per QALY over five years and 11,000 to 18,000 pounds sterling over ten years.
- The cost of implant is a more predictable determinant of cost effectiveness.
- Compared to atrial pacing, dual chamber devices appear to be less effective and more costly in SSS under all the assumptions modelled. This reflects the influence of a single small trial on the analysis, in which a large protective effect on atrial fibrillation was shown. The apparent benefits of atrial pacing are not offset by upgrades to dual chamber pacing due to the development of AV block until the risk of this event approaches 10% per year.

METHOD OF GUIDELINE VALIDATION

External Peer Review
Internal 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

This guidance refers only to pacing for the primary indications of sick sinus syndrome and/or atrioventricular block, and does not cover more complex pacing indications.

Dual-chamber pacing is recommended for the management of symptomatic bradycardia due to sick sinus syndrome, atrioventricular block, or a combination of sick sinus syndrome and atrioventricular block, except:

- In the management of sick sinus syndrome in patients in whom, after full evaluation, there is no evidence of impaired atrioventricular conduction; in this situation, single-chamber atrial pacing is appropriate.
- In the management of atrioventricular block in patients with continuous atrial fibrillation; in this situation, single-chamber ventricular pacing is appropriate.
- In the management of atrioventricular block (atrioventricular block alone, or in combination with sick sinus syndrome), when patient-specific factors, such as frailty or the presence of comorbidities, influence the balance of risks and benefits in favour of single-chamber ventricular pacing.

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 dual chamber pacemakers in patients with symptomatic bradycardia due to sick sinus syndrome and/or atrioventricular block, resulting in improved quality of life and minimal adverse effects of pacemaker implantation.
- Dual chamber pacing is associated with lower rates of atrial fibrillation, particularly in sick sinus syndrome, than ventricular pacing and prevents pacemaker syndrome.

POTENTIAL HARMS

Adverse events associated with pacemaker implantation include:

- Peri-operative complications related to venous access and lead displacement, which include pneumothorax, haemothorax, haematoma, and infections.
- Later complications: In the medium term the generator may develop an intrinsic malfunction or might be affected by an extrinsic source of electromagnetic radiation e.g., magnetic resonance imaging (MRI) scanning. In these instances replacement of the generator may become necessary. Lead fracture or insulation breakdown can occur. Lead displacement and cardiac perforation may occur after some delay.
- Pacemaker syndrome: Pacemaker syndrome is a symptom complex related to the presence of a ventricular pacemaker. It has been attributed to the superimposition of atrial and ventricular contractions. Pacemaker syndrome is predominantly associated with single chamber ventricular pacing. However, it has been reported in dual chamber pacing, despite the potential to program atrioventricular (AV) delay in dual chamber devices. Symptoms of pacemaker syndrome broadly suggest low cardiac output and may resemble congestive heart failure e.g., dizziness, weakness and fatigue, shortness of breath on exertion or when lying flat, and ankle swelling.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

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

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

Implementation and Audit

- Clinicians who care for people who have symptomatic bradycardia associated with sick sinus syndrome and/or atrioventricular block should review their current practice and policies to take account of the guidance set out in Section 1 of the original guideline document (and in the "Major Recommendations" section above).
- Local guidelines, protocols, or care pathways that refer to the care of people with symptomatic bradycardia associated with sick sinus syndrome and/or atrioventricular block should incorporate the guidance.
- To measure compliance locally with the guidance, the following criteria could be used. Further details on suggestions for audit are presented in Appendix C of the original guideline document.
    - Dual-chamber pacing is used for the management of symptomatic bradycardia due to sick sinus syndrome, atrioventricular block, or a combination of sick sinus syndrome and atrioventricular block, except in the following circumstances:
        - In the management of sick sinus syndrome in a patient for whom, after full evaluation, there is no evidence of impaired atrioventricular conduction; in this situation, single-chamber atrial pacing is used.
        - In the management of atrioventricular block in a patient with continuous atrial fibrillation; in this situation, single-chamber ventricular pacing is used.
        - In the management of atrioventricular block (atrioventricular block alone or in combination with sick sinus syndrome), when patient-specific factors influence the balance of risks and benefits in favour of single-chamber ventricular pacing.
- The Central Cardiac Audit Database, which is part of the National Clinical Audit Support Programme, includes the collection of data on the use of cardiac pacemakers.

IMPLEMENTATION TOOLS

Audit Criteria/Indicators
Foreign Language Translations
Patient Resources
Quick Reference Guides/Physician Guides

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

Living with Illness

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

National Institute for Clinical Excellence (NICE). Dual-chamber pacemakers for symptomatic bradycardia due to sick sinus syndrome and/or atrioventricular block. London (UK): National Institute for Clinical Excellence (NICE); 2005 Feb. 36 p. (Technology appraisal; no. 88).

ADAPTATION

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

DATE RELEASED

2005 Feb

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

Appraisal Committee Members: Dr Jane Adam, Radiologist, St George's Hospital, London; Professor Ron Akehurst, Dean of School of Health and Related Research, University of Sheffield; Dr Sunil Angris, General Practitioner, Waterhouses Medical Practice, Staffordshire; Professor David Barnett (*Chair*) Professor of Clinical Pharmacology, University of Leicester; Professor John Cairns, Professor of Health Economics, Public Health and Policy, London School of Hygiene and Tropical Medicine; Mrs Fiona Duncan, Clinical Nurse Specialist, Anaesthetic Department, Blackpool Victoria Hospital, Blackpool; Dr Paul Ewings, Statistician, Taunton and Somerset NHS Trust, Taunton; Dr Trevor Gibbs, Global Clinical Safety and Pharmacovigilance, GlaxoSmithKline; Mr Sanjay Gupta, Stroke Services Manager, Basildon and Thurrock University Hospitals NHS Trust; Professor Philip Home (*Vice-Chair*) Professor of Diabetes Medicine, Department of Medicine, University of Newcastle upon Tyne; Dr Peter Jackson, Clinical Pharmacologist, Molecular and Clinical Pharmacology, University of Sheffield; Dr Mike Laker, Medical Director, Newcastle Hospitals NHS Trust, Royal Victoria Infirmary, Newcastle-Upon-Tyne; Dr George Levvy, Chief Executive, Motor Neurone Disease Association; Mr Terence Lewis, Mental Health Consultant, National Institute for Mental Health in England, Solihull; Professor Richard Lilford, Professor of Clinical Epidemiology, Department

of Public Health and Epidemiology, University of Birmingham; Professor John Lumley, Honorary Consultant, The Ernest Cooke Clinic Microvascular Unit, Great Ormond Street, Bart's and the Royal London NHS Trust, Barbican, London; Dr Simon Mitchell, Consultant Neonatal Paediatrician, St Mary's Hospital, Manchester; Dr Stephen Saltissi, Consultant Cardiologist, Royal Liverpool University Hospital; Dr Lindsay Smith, General Practitioner, Westlake Surgery, Somerset; Mr Mike Spencer, General Manager, Clinical Support Services, Cardiff and Vale NHS Trust; Professor Mary Watkins, Professor of Nursing, University of Plymouth; Dr Norman Waugh, Department of Public Health, University of Aberdeen; Mrs Miranda Wheatley-Price, Director of Service Development, Colon Cancer Concern

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:

- Dual-chamber pacemakers for symptomatic bradycardia due to sick sinus syndrome and/or atrioventricular block. Quick reference guide. London (UK): National Institute for Health and Clinical Excellence (NICE); 2005 Feb. 2 p. (Technology appraisal 88). Available in Portable Document Format (PDF) from the National Institute for Health and Clinical Excellence (NICE) Web site.
- The effectiveness and cost effectiveness of dual chamber pacemakers compared to single chamber pacemakers for bradycardia due to atrioventricular block or sick sinus syndrome: systematic review and economic evaluation. Assessment report for appraisal. Exeter (UK): Peninsula Technology Assessments Group; 2004 May 27. 268 p. (Technology appraisal 88). Available in Portable Document Format (PDF) from the NICE Web site.

Print copies: Available from the Department of Health Publications Order Line 0870 1555 455. ref: N0802. 11 Strand, London, WC2N 5HR.

Additionally, Audit Criteria can be found in Appendix C of the original guideline document.

PATIENT RESOURCES

The following is available:

- Dual-chamber pacemakers for the treatment of symptomatic bradycardia. Understanding NICE guidance - information for people with symptomatic bradycardia, their families and carers, and the public. London (UK): National Institute for Health and Clinical Excellence (NICE); 2005 Feb. 10 p.

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

Print copies: Available from the Department of Health Publications Order Line 0870 1555 455. ref: N0803. 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 summary was completed by ECRI on November 29, 2005.

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