Complete Summary

GUIDELINE TITLE

Capecitabine and oxaliplatin in the adjuvant treatment of stage III (Dukes´ C) colon cancer.

BIBLIOGRAPHIC SOURCE(S)

National Institute for Health and Clinical Excellence (NICE). Capecitabine and oxaliplatin in the adjuvant treatment of stage III (Dukes' C) colon cancer. London (UK): National Institute for Health and Clinical Excellence (NICE); 2006 Apr. 34 p. (Technology appraisal guidance; no. 100).

GUIDELINE STATUS

This is the current release of the guideline.

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SCOPE

DISEASE/CONDITION(S)

Stage III (Dukes' C) colon cancer

GUIDELINE CATEGORY

Assessment of Therapeutic Effectiveness
Treatment

CLINICAL SPECIALTY

Oncology

INTENDED USERS

Advanced Practice Nurses
Physician Assistants
Physicians

GUIDELINE OBJECTIVE(S)

To examine the clinical and cost effectiveness of oxaliplatin (Eloxatin®, sanofi-aventis) in combination with 5-fluorouracil/leucovorin (5-FU/LV), and capecitabine (Xeloda®, Roche) monotherapy as adjuvant therapies in the treatment of completely resected stage III (Dukes' C) colon cancer

TARGET POPULATION

Patients with completely resected stage III (Dukes' C) colon cancer

INTERVENTIONS AND PRACTICES CONSIDERED

1. Oxaliplatin (Eloxatin®, sanofi-aventis) in combination with 5-fluorouracil/leucovorin (5-FU/LV)
2. Capecitabine (Xeloda®, Roche) monotherapy

MAJOR OUTCOMES CONSIDERED

- Clinical effectiveness
    - Overall survival
    - Disease-free or relapse-free survival
    - Time to treatment failure
    - Adverse effects of treatment/toxicity
    - Health-related quality of life (QoL)
- 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Searches of Unpublished Data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 University of Sheffield,

School of Health and Related Research [ScHARR]. (See the "Companion Documents" field.)

Clinical Effectiveness

Identification of Studies

The aim of the search was to provide as comprehensive a retrieval as possible of randomised controlled trials (RCTs) of oxaliplatin or capecitabine as adjuvant therapies in the treatment of colon cancer.

Sources Searched

Nine electronic databases were searched providing coverage of the biomedical and grey literature and current research. The publications lists and current research registers of thirty plus health services research related organisations were consulted via the World Wide Web (WWW). Keyword searching of the WWW was undertaken using the Google search engine. The submissions of evidence to NICE by sponsors were hand-searched as well as references of retrieved papers. A list of the sources searched is provided in Appendix 3 of the Assessment Report (see "Availability of Companion Documents" field).

Keyword Strategies

Sensitive keyword strategies using free-text and, where available, thesaurus terms were developed to search the electronic databases. Synonyms relating to the intervention (oxaliplatin, capecitabine) were combined with synonyms relating to the condition (colon cancer). Keyword strategies for all electronic databases are provided in Appendix 3 of the Assessment Report (see "Availability of Companion Documents" field).

Search Restrictions

A methodological filter aimed at restricting search results to RCTs was used in the searches of Medline, Embase, and Web of Science (WoS). The search of PubMed was restricted to the last 180 days to capture recent and unindexed Medline references. Date limits were not used on any other database. Language restrictions were not used on any database. All searches were undertaken in January 2005.

Inclusion and Exclusion Criteria

Two reviewers independently screened all titles and abstracts. Full paper manuscripts of any titles/abstracts that were considered relevant by either reviewer were obtained where possible. The relevance of each study was assessed according to the criteria set out below. Studies that did not meet all the criteria were excluded and their bibliographic details listed with reasons for exclusion in Appendix 4 of the Assessment Report (see "Availability of Companion Documents" field). Any disagreements were resolved by discussion.

Population

Patients (either gender at any age) with stage III (Dukes' stage C) colon cancer after complete surgical resection of the primary tumour were included.

Interventions

This review covered the effectiveness of the following two alternative chemotherapeutic agents, used within their respective licensed indications:

- Oxaliplatin (Eloxatin®, sanofi-aventis) used in combination with 5-fluorouracil/leucovorin (5-FU/LV)
- Capecitabine (Xeloda®, Roche)

Comparators

The comparator treatment included chemotherapy as adjuvant therapy with an established fluorouracil-containing regimen.

Outcomes

Data on the following outcomes were included:

- Overall survival
- Disease-free or relapse-free survival
- Time to treatment failure
- Adverse effects of treatment/toxicity
- Health-related quality of life (QoL)

Overall survival was defined as the interval from randomisation to death from any cause. Disease-free survival was defined as the time from trial entry or randomisation until recurrence of colorectal cancer or death from any cause. Relapse-free survival was defined in the same way as disease-free survival but excluding deaths unrelated to disease progression or treatment. Time to treatment failure was defined as the interval from randomisation to discontinuation of treatment for any reason (including treatment toxicity and death). Adverse effects of treatment, toxicities, and health-related QoL were abstracted as reported, however defined.

Study Design

Randomised controlled trials that compared oxaliplatin in combination with 5-FU/LV or oral capecitabine, to an adjuvant chemotherapy with an established fluorouracil-containing regimen were included in the assessment of clinical effectiveness.

Cost Effectiveness

Identification of Studies

The aim of the search was to provide as comprehensive a retrieval as possible of economic evaluations of oxaliplatin or capecitabine as adjuvant therapies in the treatment of colon cancer.

Sources Searched

Seven electronic databases were searched providing coverage of the biomedical and health technology assessment literature. The publications lists and current research registers of thirty plus health services research related organisations were consulted via the WWW. Keyword searching of the WWW was undertaken using the Google search engine. The economic assessments submitted by sponsors were identified as studies for inclusion in the review. In addition, the sponsor submissions were hand-searched for further references to studies. A list of the sources searched is provided in Appendix 9 of the Assessment Report (see "Availability of Companion Documents" field).

Keyword Strategies

The keyword strategies developed in the review of clinical effectiveness were used, with the RCT methodological filter being replaced by a filter aimed at restricting search results to economic and cost related studies. Keyword strategies for all electronic databases are provided in Appendix 9 of the Assessment Report (see "Availability of Companion Documents" field).

Search Restrictions

The same limits and restrictions used in the review of clinical effectiveness were applied with the exception of the methodological filter as described above. All searches were undertaken in January 2005.

Inclusion /Exclusion Criteria

Studies were selected for inclusion according to pre-determined inclusion and exclusion criteria. Studies were included if they reported the cost-effectiveness of oxaliplatin or capecitabine in the adjuvant treatment of colorectal cancer. Studies which were considered to be methodologically unsound, that were not reported in sufficient detail or that did not report an estimate of costs-effectiveness (e.g., costing studies) were excluded. Two reviewers independently screened all titles and abstracts. Disagreement was settled through discussion. Full paper manuscripts were obtained for any titles/abstracts that were considered relevant or where the title/abstract information was not sufficient to make a decision.

NUMBER OF SOURCE DOCUMENTS

Clinical Effectiveness

Three phase III randomised controlled trials of varying methodological quality were included in the review.

Cost Effectiveness

Three studies were identified as meeting the review criteria. Together with the two sponsor submissions a total of five studies were identified for inclusion in the review.

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

Clinical Effectiveness

Data Abstraction Strategy

Data relating to both study design and quality were extracted by one reviewer into a standardised data extraction form and independently checked for accuracy by a second. Any discrepancies were resolved by consensus. Where multiple publications of the same study were identified, data were extracted and reported as a single study.

Critical Appraisal Strategy

The quality of the individual studies was assessed by one reviewer and independently checked for agreement by a second. Disagreements were resolved by consensus. The quality of the clinical effectiveness studies was assessed according to criteria based on those proposed by the National Health Service (NHS) Centre for Reviews and Dissemination. Full details of the critical appraisal strategy are reported in Appendix 5 of the Assessment Report (see "Availability of Companion Documents" field).

Methods of Data Synthesis

The extracted data and quality assessment variables were presented for each study, both in structured tables and as a narrative description. Where sufficient data were available, treatment effects were presented in the form of hazard ratios. Where sufficient data were available, the absolute risk reduction and number needed to treat were calculated using a previously published method.

In addition, results of eligible studies were statistically synthesised (meta-analysed) where: (a) there was more than one trial with similar populations, interventions, and outcomes; and, (b) there were adequate data. All analyses were by intention-to-treat. For time-to-event analyses (disease-, relapse-, or overall-survival), combined hazard ratios and 95% confidence intervals (CI) were calculated using the Cochrane Collaboration Review Manager 4.2.3 software. This uses the log hazard ratio and its variance from the relevant outcome of each trial.

These, in turn, were calculated using a Microsoft Excel spreadsheet authored by Matt Sydes of the Medical Research Council Clinical Trials Unit, which incorporates Parmar's methods for extracting summary statistics to perform meta-analyses of the published literature for survival endpoints.

The log hazard ratio and its variance were estimated indirectly from the hazard ratio and its 95% confidence intervals using method three of Parmar's hierarchy of methods, (depending on the availability of summary statistics). Note that the forest plots generated by the meta-view software present hazard ratios, although they are labelled 'OR' (odds ratio).

A fixed effects model was used for the analyses. Heterogeneity between trial results was tested where appropriate using the chi^2test and I^2 measure. The chi^2 test measures the amount of variation in a set of trials. Small p-values suggest that there is more heterogeneity present than would be expected by chance. Chi^2 is not a particularly sensitive test: a cut-off of $p<0.10$ is often used to indicate significance, but lack of statistical significance does not mean there is no heterogeneity. The I^2 measure is the proportion of variation that is due to heterogeneity rather than chance. Large values of I^2 suggest heterogeneity. I^2 values of 25%, 50%, and 75% could be interpreted as representing low, moderate, and high heterogeneity.

Handling of the Company Submission

Company submissions were screened for data additional to that identified in published studies retrieved from the literature search.

Cost Effectiveness

Quality Assessment

The Drummond checklist was used to assess the quality of each economic evaluation considered, enabling a thorough, detailed and structured evaluation of the strengths and weaknesses of each study and industry submission to be made (see Appendix 10 of the Assessment Report [see "Availability of Companion Documents" field). The use of the checklist ensures a consistent approach to assessing the quality of each economic evaluation.

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 Assessment Group reviewed three published economic evaluations, two of which were submitted by manufacturers. It also presented its own three-state Markov model to estimate the cost effectiveness of oxaliplatin plus 5-fluorouracil/folinic acid (5-FU/FA) versus 5-FU/FA alone, and of capecitabine versus 5-FU/FA alone.

In the Assessment Group model, hypothetical individuals were assumed to move between three states: alive without relapse, alive with relapse, and dead. Transition probabilities in the Assessment Group model and one of the manufacturer models were estimated from the disease-free survival curve and the partitioned overall survival curves for patients with and without relapse. This joint modelling of disease-free and overall survival differs from the approach adopted in the model submitted by the manufacturer of capecitabine, where there was independent modelling of relapse-free survival and overall survival with inconsistent results.

Key assumptions used in the Assessment Group model were as follows:

- Overall survival of people who relapse is assumed to be independent of the time of relapse.
- Overall survival of people who relapse is equivalent to that of patients who are initially diagnosed with advanced (stage IV – Dukes' D) colorectal cancer.
- All relapses occur within the 5 years following resection of the primary tumour.
- Overall survival of people alive and disease free at 5 years is similar to the survival in the general population, adjusting for age and sex.
- People who relapse are assumed to receive first-line 5-FU/FA followed upon progression by single-agent irinotecan.
- People receiving 5-FU/FA via the de Gramont regimen are assumed to receive their treatment on an outpatient basis.

All of these assumptions, except for the last two, are also used in the model submitted by the manufacturer of oxaliplatin. Instead of using the cost of a specific chemotherapy regimen to estimate cost of relapse, the manufacturer's model uses an average cost of relapse that is calculated from a distribution using costs of treatment for four different types of relapse.

Evidence for estimating preference-based utilities for the different health states is scarce. The submissions from the manufacturers of both drugs based their utility estimates on a study of 173 patients with colorectal cancer (40 of whom had stage III disease). In this study, generic and cancer-specific quality of life (QoL) tools were administered at regular intervals following diagnosis, starting at 13 months post diagnosis. Although the study did not differentiate between patients who relapsed and those who did not, both submissions used a disutility of approximately 0.2 for people who experienced relapse. In the manufacturer submission for oxaliplatin, utilities while on treatment were also corrected for adverse events.

The Assessment Group noted that because the study used in the manufacturers' submissions started long after diagnosis, and a relatively small proportion of patients had stage III disease, they could only use data from this study to estimate the utility for people in remission (0.92).

From a second study that elicited utilities from 81 patients with colorectal cancer with all stages of the disease (including those with stage III undergoing resection and chemotherapy), utilities were taken for those people undergoing treatment without adverse events (0.7) and with adverse events (0.63), as well as for those who relapse (0.24).

See Section 4.2 of the original guideline document for a detailed discussion of the cost-effectiveness analysis.

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

- The following are recommended as options for the adjuvant treatment of patients with stage III (Dukes' C) colon cancer following surgery for the condition:
    - Capecitabine as monotherapy
    - Oxaliplatin in combination with 5-fluorouracil and folinic acid
- The choice of adjuvant treatment should be made jointly by the individual and the clinicians responsible for treatment. The decision should be made after an informed discussion between the clinicians and the patient; this discussion should take into account contraindications and the side-effect profile of the agent(s) and the method of administration as well as the clinical condition and preferences of the individual.

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 capecitabine and oxaliplatin in the adjuvant treatment of stage III (Dukes' C) colon cancer

POTENTIAL HARMS

Capecitabine

Dose-limiting toxicities include diarrhoea, abdominal pain, nausea, stomatitis, and hand–foot syndrome (erythema and desquamation of the palms and the soles of the feet). Most adverse events are reversible and do not require permanent discontinuation of therapy, although doses may need to be withheld or reduced.

Oxaliplatin

Neurotoxic side effects can be dose limiting. Acute paraesthesias or dysaesthesias of the extremities, triggered or exacerbated by cold temperatures, occur in 85 to 95% of people within hours of oxaliplatin infusion. These symptoms are normally mild and resolve within hours or days. However, with increasing cumulative dose, peripheral sensory symptoms increase in duration and intensity. Symptoms may progress to functional impairment. Cumulative neurotoxicity is reversible in most, but not all, cases, with regression of symptoms occurring in 4 to 6 months in about 80% of patients. Other side effects include gastrointestinal disturbances and myelosuppression.

For full details of side effects and contraindications, see the Summary of Product Characteristics for each drug, available at http://emc.medicines.org.uk/

CONTRAINDICATIONS

CONTRAINDICATIONS

Capecitabine

Capecitabine is contraindicated in patients with severe leucopenia, neutropenia, or thrombocytopenia, and in patients with severe hepatic impairment or severe renal impairment.

Oxaliplatin

Oxaliplatin is contraindicated in patients who have myelosuppression before starting the first course, as evidenced by a baseline neutrophil count of less than 2×10^9 per litre and/or a platelet count of less than 100×10^9 per litre. It is also contraindicated in patients who have a peripheral neuropathy with functional impairment before the first course.

For full details of side effects and contraindications, see the Summary of Product Characteristics for each drug, 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 evidence available. 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.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

Implementation and Audit

- Clinicians with responsibility for treating people with stage III (Dukes' C) colon cancer should review their current practice and policies to take account of the guidance (see the "Major Recommendations" field).
- Local guidelines, protocols, or care pathways that refer to the care of people with stage III (Dukes' C) colon cancer 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.
    - A person with stage III (Dukes' C) colon cancer is offered the following as options for the adjuvant treatment following surgery for the condition:
        - Capecitabine as monotherapy
        - Oxaliplatin in combination with 5-fluoroouracil/folinic acid (5-FU/FA)
    - The individual and the clinicians responsible for treatment decide jointly on the choice of adjuvant treatment after an informed discussion.
- Local clinical audits on the management of colon cancer could also include measurement of compliance with accepted clinical guidelines or protocols or with the measures for the treatment of colorectal cancer that are suggested in *Guidance on cancer service*: "Improving outcomes in colorectal cancers" (see section 8.3 of the original guideline document).

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

Living with Illness

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

National Institute for Health and Clinical Excellence (NICE). Capecitabine and oxaliplatin in the adjuvant treatment of stage III (Dukes' C) colon cancer. London (UK): National Institute for Health and Clinical Excellence (NICE); 2006 Apr. 34 p. (Technology appraisal guidance; no. 100).

ADAPTATION

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

DATE RELEASED

2006 Apr

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

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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:

- Capecitabine and oxaliplatin in the adjuvant treatment of stage III (Dukes' C) colon cancer. Quick reference guide. London (UK): National Institute for Health and Clinical Excellence (NICE); 2006 Apr. 2 p. (Technology appraisal 100). Available in Portable Document Format (PDF) from the National Institute for Health and Clinical Excellence (NICE) Web site.
- Costing template and costing report. Capecitabine and oxaliplatin in the adjuvant treatment of stage III (Dukes' C) colon cancer. London (UK): National Institute for Health and Clinical Excellence (NICE); 2006 Apr. Various p. (Technology appraisal 100). Available in Portable Document Format (PDF) from the NICE Web site.
- The use of oxaliplatin and capecitabine for the adjuvant treatment of colon cancer. Assessment report. The School of Health and Related Research (ScHARR), University of Sheffield. 2005 Aug 8. Electronic copies: Available from the NICE Web site.

Print copies: Available from the National Health Service (NHS) Response Line 0870 1555 455. ref: N1026. 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:

- Capecitabine and oxaliplatin in the adjuvant treatment of stage III (Dukes' C) colon cancer. Understanding NICE guidance. Information for people with stage III colon cancer, their families and carers, and the public. London (UK): National Institute for Health and Clinical Excellence (NICE); 2006 Apr. 10 p. (Technology appraisal 100).

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: N1027. 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

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Date Modified: 9/22/2008