Complete Summary

GUIDELINE TITLE

Varenicline for smoking cessation.

BIBLIOGRAPHIC SOURCE(S)

National Institute for Health and Clinical Excellence (NICE). Varenicline for smoking cessation. London (UK): National Institute for Health and Clinical Excellence (NICE); 2007 Jul. 13 p. (Technology appraisal guidance; no. 123).

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 1, 2008, Chantix (varenicline): New information has been added to the WARNINGS and PRECAUTIONS sections in Chantix's prescribing information about serious neuropsychiatric symptoms experienced in patients taking this medication.

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SCOPE

DISEASE/CONDITION(S)

Tobacco dependence

GUIDELINE CATEGORY

Assessment of Therapeutic Effectiveness
Prevention
Treatment

CLINICAL SPECIALTY

Family Practice
Internal Medicine

INTENDED USERS

Advanced Practice Nurses
Nurses
Physician Assistants
Physicians

GUIDELINE OBJECTIVE(S)

To evaluate the clinical effectiveness and cost-effectiveness of varenicline for smoking cessation in adults

TARGET POPULATION

Adult smokers

INTERVENTIONS AND PRACTICES CONSIDERED

Varenicline as part of a programme of behavioural support

MAJOR OUTCOMES CONSIDERED

- Clinical effectiveness
    - Continuous quit rate
    - Continuous abstinence rates at 52 weeks
- 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

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 Evidence Review Group (ERG) report. The ERG report for this technology appraisal was prepared by the School of Health and Related research (ScHAAR), University of Sheffield. (See the "Availability of Companion Documents" field).

Description of Manufacturer's Search Strategy and Comment on Whether the Search Strategy Was Appropriate

The manufacturers searched ten publicly accessible databases (to December 1, 2006): MEDLINE, EMBASE, Cochrane, AMED, CINAHL, TOXNET, Development and Reproductive Toxicology, Hazardous Substances Databank, Psych-info and Web of Science. They also searched the bibliographies of published systematic reviews and Pfizer's own clinical trials database. Searches were not limited by language, sex or age. A substantial proportion of the clinical effectiveness section of the manufacturer's submission, is based on a separate piece of work, undertaken by researchers at McMaster University, funded by Pfizer, and previously published in a peer-reviewed journal (*BMC Public Health*).

Manufacturer's Submission: Clinical Evidence Search Strategy

The search utilises a combination of free-text and Medical Subject Headings (MeSH) terms. However it is not clear from the reporting of the search strategy which terms are free-text and which are MeSH. Regarding the MeSH terms, it is not reported whether these were exploded or focused. Similarly it is not reported which fields were searched for the free-text terms (e.g. all fields, title and abstract, title only, etc). Boolean operators are not reported so it is not possible to identify the relationship between the search terms. No methodological search filters have been used and the search utilised terms for the intervention only – no terms for population, outcome or comparator(s) were included in the search. In general, the search methodology is not sufficiently "transparent" to replicate exactly.

Manufacturer's Submission: Cost-Effectiveness Search Strategy

The terms used for the cost-effectiveness search appear to be exactly same as the clinical evidence search; therefore, all the issues surrounding the clinical effectiveness searches also apply to the cost-effectiveness searches. Four databases were searched to identify studies relating to the cost-effectiveness of varenicline. Two of these databases were the same as the clinical evidence search, so presumably the same results were retrieved. Two additional databases that had not been searched for clinical evidence were also searched for cost-effectiveness evidence. One of these was the National Health Service (NHS) Economic Evaluation Database (EED); this was the only database where a

different search strategy was applied. The search strategy reported for EED is very basic (searching for the term 'smoking') which at the time of writing would retrieve 355 references. If a more sensitive search strategy was used, including cost-effectiveness terms, fewer references would be retrieved and these would be more specific to the topic.

The McMaster Review

The search strategy for the McMaster review is identical to that of the manufacturer's submission, but it does not specify search terms (presumably it included terms to identify nicotine replacement therapy (NRT) and bupropion trials, as well as trials for varenicline) and there is no sample search strategy as in the manufacturer's submission.

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

The Manufacturer's Submission

The manufacturer's evidence review eligibility criteria were any randomised controlled trials (RCT) of at least one year's duration which evaluated NRT (however delivered), bupropion or varenicline using chemical confirmation of smoking cessation, defined as either sustained abstinence or point-prevalence of abstinence. The manufacturer claims to have excluded dose ranging studies, non-RCTs, post-hoc analyses, maintenance therapy, and studies that reported outcomes as self-report were excluded.

The McMaster Review

The McMaster review states the same inclusion criteria as the manufacturer's submission.

What Studies Were Included in the Submission and What Were Excluded

The Manufacturer's Submission

Although the manufacturer's submission states that eligible studies were those evaluating NRT, bupropion or varenicline, they only report, tabulate and discuss studies which evaluate varenicline (regardless of comparator). The Evidence Review Group (ERG) has re-run what they believe might approximate the manufacturer's search strategy and confirms that the table of identified varenicline studies in the manufacturer's submission is complete.

Refer to Section 4.1 of the ERG Report for detailed description of included and excluded studies.

NUMBER OF SOURCE DOCUMENTS

Clinical Effectiveness

The Evidence Review Group identified 8 varenicline studies.

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
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 Evidence Review Group (ERG) report. The ERG report for this technology appraisal was prepared by the School of Health and Related research (ScHAAR), University of Sheffield. (See the "Availability of Companion Documents" field).

Clinical Effectiveness

Critique of Submitted Evidence Syntheses

- The manufacturer's submission is largely based on a systematic review of the randomised controlled trials (RCTs) evaluating varenicline, bupropion and nicotine replacement therapy (NRT), which they have commissioned: the McMaster review. While that review is largely well designed and conducted, certain studies may be inappropriately included or excluded with unknown effects on the Incremental Cost-Effectiveness Ratio (ICER).
- The McMaster review also provides indirect treatment comparisons, which the manufacturer has used in its submission, despite a direct comparison being available.
- The selection of studies used in the McMaster group's meta-analyses which, in turn, inform their indirect comparisons (the bases for the manufacturer's economic model), provides an optimistic basis for the assessment of varenicline's treatment effect because:
    - It allows the inclusion of phase II varenicline studies excluded by the manufacturer's submission and which improve the varenicline effect size
    - It allows the inclusion of studies where bupropion or placebo are given with other active therapies (diluting the treatment effect)

Refer to Sections 4.1 and 4. 2 in the Evidence Review Group (ERG) report for more information.

Cost-Effectiveness

Overview of Manufacturer's Economic Evaluation

Scope of the Economic Evaluation of Varenicline

The health economic evaluation presented within the sponsor submission to NICE presents estimates of the incremental cost-effectiveness of varenicline as compared to other smoking cessation interventions which are routinely available on the National Health Service (NHS) in the UK. Two health economic models are presented within the submission.

- The first model estimates the incremental cost-effectiveness of the standard regimen of varenicline as compared to bupropion, NRT, and placebo at the initial quit attempt (Group 1).
- The second model estimates the incremental cost-effectiveness of varenicline as compared to placebo for a population who have remained abstinent at the end of a 12-week course of varenicline (Group 2).

Counselling was also specified as a comparator for the analysis by NICE; however this has not been included in the sponsor submission. Both models are capable of estimating costs and health outcomes for individuals attempting unaided cessation without intervention, although results for this smoking cessation strategy are not presented in the submission. Both models employ similar structural and parametric assumptions; the key difference between the two models concerns the efficacy rates assumed for varenicline and the comparator therapies. The primary health economic outcome for the evaluation is the incremental cost per quality adjusted life year (QALY) gained; the model also estimates the incremental cost per life year gained (LYG) and the incremental/net cost per quitter. The economic evaluation was undertaken from the perspective of the NHS only, as the sponsor states that the quantification of Personal Social Services (PSS) resources relevant to smoking was not possible. In the base case analysis, cost-effectiveness is evaluated over a lifetime horizon using an annual cycle length.

Refer to Sections 5.1 and 5.2 of the ERG Report for more information.

Additional Work Undertaken by the ERG

Meta-Analyses

The first meta-analysis was of all placebo-controlled trials evaluating smoking cessation at 12 months (point prevalence or complete abstinence), with chemical validation, using any delivery method of NRT with intensive support (as in the NHS).

The ERG's meta-analysis suggests that odds of smoking cessation at 12 months using NRT are 82% greater than using placebo. Note that this estimate is 11% higher than the estimate derived by the McMaster team for NRT versus any control. It is also 4% higher than the estimate derived by the McMaster team for NRT versus placebo.

The second meta-analysis was of all placebo-controlled trials evaluating smoking cessation at 12 months (point prevalence or complete abstinence), with chemical validation, using bupropion with intensive support (as in the NHS).

The ERG's meta-analysis suggests that odds of smoking cessation at 12 months using bupropion are 82% greater than using placebo. Note that this estimate is 26% higher than the estimate derived by the McMaster team for bupropion versus any control as reported in the published paper). It is also 18% higher than the estimate derived by the McMaster team for bupropion versus placebo as reported in the published paper).

Indirect Comparisons

Because the composition of the McMaster meta-analyses creates an optimistic basis for the indirect comparison of varenicline with NRT the ERG has attempted to rerun the McMaster's indirect comparison using what they consider to be more balanced assumptions. Using the method used by Bucher, they indirectly compared the NRT treatment effect derived through their own meta-analysis.

The ERG found that varenicline was still superior to NRT when compared to a placebo control at one year. The ERG estimate is 12% lower than the estimate derived from the McMaster indirect comparison.

Further Sensitivity Analyses

Owing to computational errors in the model, no further sensitivity analyses were undertaken.

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 presented a cost-effectiveness analysis based on a Markov model. It assumes an individual makes a single quit attempt at the beginning of the model. The individual is followed from this initial quit attempt to various health states and potential comorbidities including lung cancer, asthma exacerbations, chronic obstructive pulmonary disease, stroke and cardiovascular disease. The probabilities of relapsing and developing comorbidities are assumed to decrease over time from smoking cessation. The efficacy rates for the treatments are calculated from the odds ratios derived from the results of the pooled direct clinical trials and the indirect comparison. The probabilities associated with relapse are derived from relative risks reported in US-based long-

term longitudinal and cohort studies into smoking and abstinence. The costs and utilities are derived from several published sources. Some health-related utility estimates are based on US data, including baseline health-related utilities.

The Committee considered the evidence on the cost effectiveness of varenicline submitted by the manufacturer. The Committee noted the comments of the Evidence Review Group (ERG) that the submission was not transparent and possessed limited external validity. The model included an extrapolation of 1-year clinical data to a lifetime horizon and included an assumption of a single quit attempt. The Committee also noted the computational errors identified by the ERG, and noted that the ERG had expressed concerns about a number of other assumptions in the model, in particular the use of US data for baseline risk and the use of all-cause morbidity instead of other-cause morbidity. Nevertheless, the Committee considered that these concerns were not sufficient to undermine the inference that the use of varenicline in smoking cessation was likely to be a cost-effective use of National Health Service (NHS) resources.

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

Varenicline is recommended within its licensed indications as an option for smokers who have expressed a desire to quit smoking.

Varenicline should normally be prescribed only as part of a programme of behavioural support.

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 varenicline for the cessation of smoking in adults

POTENTIAL HARMS

Varenicline may be associated with nausea and other gastrointestinal disorders such as vomiting.

For full details of side effects and contraindications, see the summary of product characteristics (SPC).

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 appropriate decisions in the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.
- Summary of uncertainties and issues

  The base case analysis of the BENESCO (Benefits of Smoking Cessation on Outcomes) model presented in the submission suggests that varenicline dominates bupropion, nicotine replacement therapy (NRT) and placebo at the initial quit attempt. For individuals who have remained abstinent following a 12-week course of varenicline, varenicline is also reported to dominate placebo. However, several key issues should be borne in mind when considering the reliability of these results. The external validity of the model is questionable, as the analysis assumes only a single quit attempt using a single smoking cessation intervention; in reality smokers may attempt to quit more than once using several smoking cessation technologies. Within the model, the probability of short-term relapse to smoking is modelled using 1-year pooled quit rates and an indirect comparison. Beyond this point annual relapse probabilities are assumed to be independent of smoking cessation intervention, hence short-term benefits are assumed to be sustained in the long-term. Shorter time horizons may be subject to less uncertainty, but may underestimate the benefits of varenicline. Longer time horizons provide more

favourable cost-effectiveness estimates for varenicline, yet are subject to a considerable degree of uncertainty.

It is also noteworthy that many of the model parameters, specifically those describing the medium- to long-term probability of relapse to smoking, are based on US studies which may not reflect the smoking/abstinence behaviour of the smoking population of England and Wales. Methods for identifying and selecting costs and health utilities associated with morbidities are not reported or justified within the sponsor submission. It should also be noted that several computational errors were identified: the number of patients in the model is not constant over time, the risk of relapse between years 2 and 5 is incorrect, and all cause mortality appears to have been used for individuals who specifically do not experience smoking-related morbidities. The sensitivity analysis presented within the submission is very narrow and underestimates the true uncertainty surrounding the incremental cost-effectiveness of varenicline.

Finally, the external validity of the model has not been considered through comparison with other models or cohort studies.

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, "Availability of Companion Documents" field).
    - Local costing template incorporating a costing report 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

Staying Healthy

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

National Institute for Health and Clinical Excellence (NICE). Varenicline for smoking cessation. London (UK): National Institute for Health and Clinical Excellence (NICE); 2007 Jul. 13 p. (Technology appraisal guidance; no. 123).

ADAPTATION

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

DATE RELEASED

2007 Jul

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, Derbyshire County PCT; Mr Brian Buckley, Chairman, Incontact; Dr Carol Campbell, Senior Lecturer, University of Teesside; Professor Mike Campbell, Professor of Medical Statistics, University of Sheffield; Ms Jude Cohen, Manager of Resources and Administration, Council for Psychotherapy (UKCP); 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; Dr Rachel A Elliott, Clinical Senior Lecturer, University of Manchester; Mrs. Eleanor Grey, Lay member; Dr Catherine Jackson, Clinical Lecturer in Primary Care Medicine, Alyth Health Centre; Dr Peter Jackson, Clinical Pharmacologist, University of Sheffield; Ms Rachel Lewis, Practice Development Facilitator, Manchester PCT; Professor Jonathan Michaels, Professor of Vascular Surgery, University of Sheffield; Dr Eugene Milne, Deputy Medical Director, North East Strategic Health Authority; Dr Richard Alexander Nakielny, Consultant Radiologist, Royal Hallamshire Hospital, Sheffield; Dr Katherine Payne, Health Economics Research Fellow, University of Manchester; Professor Andrew Stevens (Chair), Professor of Public Health, University of Birmingham; Dr Cathryn Thomas, Senior Lecturer, 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:

- Smoking cessation – varenicline. Quick reference guide. London (UK): National Institute for Health and Clinical Excellence (NICE); 2007 Jul. 2 p. (Technology appraisal 123). Available in Portable Document Format (PDF) from the National Institute for Health and Clinical Excellence (NICE) Web site.
- Smoking cessation – varenicline. Costing template and report. London (UK): National Institute for Health and Clinical Excellence (NICE); 2007 Jul. 1 p. (Technology appraisal 123). Available in Portable Document Format (PDF) from the NICE Web site.
- Smoking cessation – varenicline. Audit criteria. London (UK): National Institute for Health and Clinical Excellence (NICE); 2007 Aug 3. 8 p.

(Technology appraisal 123). Available in Portable Document Format (PDF) from the NICE Web site.

- Varenicline for smoking cessation: a single technology appraisal. Evidence Review Group report. School of Health and Related Research (ScHARR). University of Sheffield, Sheffield, UK; 2006 Oct 17. 89 p. (Technology appraisal 123). 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: TA123, 11 Strand, London, WC2N 5HR.

PATIENT RESOURCES

The following is available:

- Varenicline for smoking cessation. Understanding NICE guidance - Information for people who use NHS services. London (UK): National Institute for Health and Clinical Excellence (NICE); 2007 Jul. 4 p. (Technology appraisal 123).

Available in Portable Document Format (PDF) from the NICE Web site.

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 October 15, 2007. This summary was updated by ECRI Institute on February 5, 2008, following the U.S. Food and Drug Administration advisory on Chantix (varenicline).

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