General

Guideline Title
Evidence-based clinical practice guideline: eye care of the patient with diabetes mellitus.

Bibliographic Source(s)

Guideline Status
This is the current release of the guideline.

This guideline updates a previous version: American Optometric Association. Care of the patient with diabetes mellitus. St. Louis (MO): American Optometric Association; 2009. 74 p. [127 references]

Recommendations

Major Recommendations
Definitions for the strength of evidence (A–D) and strength of recommendations (A–D) are presented at the end of the "Major Recommendations" field.

Note: Grades are displayed with the evidence strength listed first, followed by the strength of the clinical recommendation. A statement with a strength of evidence of "B" and a clinical recommendation of "A" is shown as B/A.

Diagnosis of Ocular Complications of Diabetes Mellitus

Individuals with Undiagnosed Diabetes Mellitus

Ocular Examination

The ocular examination of an individual suspected of having undiagnosed diabetes should include all aspects of a comprehensive eye examination* with supplemental testing, as noted in the original guideline document.

*Refer to the Optometric Clinical Practice Guideline for Comprehensive Adult Eye and Vision Examination

Persons without a diagnosis of diabetes who present with signs suggestive of diabetes during the initial examination should be referred to their primary care physician for evaluation, or an A1C test or fasting blood glucose analysis may be ordered.

Individuals with Diagnosed Diabetes Mellitus
The ocular examination of a person with diabetes should include all aspects of a comprehensive eye examination,* with supplemental testing, as indicated, to detect and thoroughly evaluate ocular complications.

*Refer to the Optometric Clinical Practice Guideline for Comprehensive Adult Eye and Vision Examination.

Patients should be questioned about the awareness of their personal diabetes ABCs (A1C, blood pressure, and cholesterol levels and their history of smoking).

**Ocular Examination**

The initial ocular examination should include, but is not limited to, the following evaluations:

- Review of patient medical history
- Best-corrected visual acuity
- Pupillary reflexes
- Ocular motility
- Refractive status
- Confrontation visual field testing or visual field evaluation
- Slit lamp biomicroscopy
- Tonometry
- Dilated retinal examination

**Dilated Retinal Examination**

Retinal examinations for diabetic retinopathy should be performed through a dilated pupil.

When vitreous hemorrhage prevents adequate visualization of the retina, prompt referral to an ophthalmologist experienced in the management of diabetic retinal disease should be made for further evaluation.

The individual's primary care physician should be informed of eye examination results following each examination, even when retinopathy is minimal or not present.

**Ocular Examination Schedule**

**Persons with Diabetes Mellitus**

As diabetes may go undiagnosed for many years, any individual with type 2 diabetes should have a comprehensive dilated eye examination soon after the diagnosis of diabetes (American Diabetes Association, 2013).

Individuals with diabetes should receive at least annual dilated eye examinations. More frequent examination may be needed depending on changes in vision and the severity and progression of diabetic retinopathy.

Women with pre-existing diabetes who are planning pregnancy or who become pregnant should have a comprehensive eye examination prior to a planned pregnancy or during the first trimester, with follow-up during each trimester of pregnancy.

**Persons with Non-retinal Ocular Complications of Diabetes Mellitus**

Examination of persons with non-retinal ocular complications of diabetes should be consistent with current recommendations of care for each condition.

**Persons with Retinal Complications of Diabetes Mellitus**

Prompt referral to a vitreo-retinal surgeon is indicated when a vitreous hemorrhage, a retinal detachment or other evidence of proliferative diabetic retinopathy is present.

**Treatment and Management**

**Management of Ocular Complications of Diabetes Mellitus**

**Basis for Treatment**

**Persons with Non-retinal Ocular Complications**
Treatment protocols for persons with non-retinal ocular and visual complications should follow current recommendations for care, and include education on the subject and recommendations for follow-up visits.

As part of the proper management of diabetes, the optometrist should make referrals for concurrent care when indicated.

Treatment of Retinal Complications

Laser Photocoagulation

Non-proliferative Diabetic Retinopathy (NPDR)

Panretinal photocoagulation (PRP) may be considered in patients with severe or very severe NPDR, or early proliferative diabetic retinopathy (PDR) with a high risk of progression (e.g., pregnancy, poor glycemic control, inability to follow-up, initiation of intensive glycemic control, impending ocular surgery, renal impairment and rapid progression of retinopathy) (Mohamed, Ross, & Chu, 2011). (A/A)

Proliferative Diabetic Retinopathy

Patients with high-risk PDR should receive referral to an ophthalmologist experienced in the management of diabetic retinal disease for prompt scatter PRP (Early Treatment Diabetic Retinopathy Study Research Group [ETDRS], 1991; Chew et al., 2003). (A/A; B/B)

Eyes in which PDR has not advanced to the high-risk stage should also be referred for consultation with an ophthalmologist experienced in the management of diabetic retinal disease (ETDRS, 1991; Chew et al., 2003). (A/A; B/B)

Following successful treatment with PRP, patients should be re-examined every 2 to 4 months. The follow-up interval may be extended based on disease severity and stability.

Diabetic Macular Edema (DME)

Following focal photocoagulation for DME, re-examination should be scheduled in 3 to 4 months.

Patients with center-involved DME should be referred to an ophthalmologist experienced in the management of diabetic retinal disease for possible treatment.

Individuals with DME, but without clinically significant macular edema (CSME), should be re-examined at 4- to 6-month intervals. Once CSME develops, treatment with focal laser photocoagulation or intravitreal anti-vascular endothelial growth factor (VEGF) injection is indicated (Mohamed, Ross, & Chu, 2011). (A/A)

Vitrectomy

Eyes with vitreous hemorrhage (VH), traction retinal detachment (TRD), macular traction or an epiretinal membrane should be referred to an ophthalmologist experienced in the management of diabetic retinal disease for evaluation for possible vitrectomy.

Vascular Endothelial Growth Factor Inhibitors

The current standard of care for treatment of center-involved DME in persons with best corrected visual acuity of 20/32 or worse, is anti-VEGF injections (Diabetic Retinopathy Clinical Research Network, 2008; Diabetic Retinopathy Clinical Research Network et al., 2010). (A/A)

Patient Education

Persons should be educated about the ocular signs and symptoms of diabetic retinopathy and other non-retinal complications of diabetes, and encouraged to comply with recommendations for follow-up eye examinations and care.

Individuals should be advised of the risks of smoking related to diabetes and encouraged to quit smoking and/or seek smoking cessation assistance.

Individuals should be educated about the long-term benefits of glucose control in saving sight, based on their individual medically appropriate A1C target.

Management of Systemic Complications and Co-morbidities of Diabetes Mellitus

Glycemic Control

The glycemic goal for persons with diabetes should be individualized, taking into consideration their risk of hypoglycemia, anticipated life
expectancy, duration of disease and co-morbid conditions (American Diabetes Association, 2013).

Optometrists should have a rapid-acting carbohydrate (e.g., glucose gel or tablets, sugar-sweetened beverage or fruit juice) in their office for use with diabetes patients who experience acute hypoglycemia during an eye examination.

**Lipid-Lowering Treatment**

The majority of persons with diabetes are at risk of coronary heart disease and can benefit from reducing low-density lipoprotein (LDL) cholesterol levels to the currently recommended targets (Knopp et al., 2006). (B/B)

**Weight Management**

When indicated, overweight individuals should be referred to a qualified health care provider for assistance with weight loss.

**Treatment Modalities**

Individuals with diabetes should receive nutrition and dietary recommendations preferably provided by a registered dietician who is knowledgeable about diabetes management.

**Management of Persons with Visual Impairment**

Individuals who experience vision loss from diabetes should be provided, or referred for, a comprehensive examination of their visual impairment by a practitioner trained or experienced in vision rehabilitation.

Persons with diabetes who experience visual difficulties should be counseled on the availability and scope of vision rehabilitation care and encouraged to utilize these services.

Referral for counseling is indicated for any individual experiencing difficulty dealing with vision and/or health issues associated with diabetes or diabetic retinopathy. Educational literature and a list of support agencies and other resources should be made available to these individuals.

**Definitions:**

**Strength of Evidence**

<table>
<thead>
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<td>A</td>
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<td>B</td>
<td>RCTs or diagnostic studies with minor limitations; overwhelmingly consistent evidence from observational studies. Weaker RCTs (weak design but multiple studies confirm). Cohort study (this may include retrospective and prospective studies).</td>
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<td>Studies of strong design, but with substantial uncertainty about conclusions, or serious doubts about generalization, bias, research design, or sample size; or retrospective or prospective studies with small sample size.</td>
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**Strength of Recommendations**

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Clinical Algorithm(s)

The following clinical algorithms are provided in the appendices in the original guideline document:

- Optometric management of the patient with undiagnosed diabetes mellitus: a flowchart
- Optometric management of the patient with diagnosed diabetes mellitus: a flowchart

Scope

Disease/Condition(s)

Ocular and visual complications of diabetes mellitus:

- Non-proliferative diabetic retinopathy
- Proliferative diabetic retinopathy
- Diabetic macular edema
- Non-retinal ocular and visual complications of diabetes

Guideline Category

Diagnosis
Evaluation
Management
Prevention
Treatment

Clinical Specialty

Endocrinology
Family Practice
Internal Medicine
Ophthalmology
Optometry

Intended Users

Advanced Practice Nurses
Health Care Providers
Health Plans
Managed Care Organizations
Nurses
Optometrists
Patients
Physician Assistants
Physicians
Public Health Departments
Students

Guideline Objective(s)

- To provide doctors of optometry with examination and management recommendations designed to preserve vision and reduce the risk of vision loss in persons with diabetes, through timely diagnosis, appropriate management and referral
- To assist optometrists in achieving the following objectives:
  - Identification of individuals at risk for diabetes
  - Identification of individuals with undiagnosed diabetes mellitus
  - Identification of individuals at risk of vision loss from diabetes
  - Preservation of vision by reducing the risk of vision loss in persons with diabetes through timely diagnosis, intervention, determination of need for future evaluation, and appropriate referral
  - Improvement in the quality of care rendered to persons with diabetes
  - Education of individuals and health care practitioners regarding the ocular complications of diabetes
  - Dissemination of information and education of individuals on the benefits of vision rehabilitation
  - Provision of vision rehabilitation services or referral for care of persons with vision loss from diabetes

Target Population

Patients of any age with diabetes mellitus

Interventions and Practices Considered

Diagnosis

1. Individuals with undiagnosed diabetes mellitus
   - Patient history
   - Diabetes risk assessment
   - Ocular examination with supplemental testing as needed
2. Individuals with diagnosed diabetes mellitus
   - Patient history
   - Ocular examination with supplemental testing as needed
3. Referral as needed
4. Ocular examination schedule (frequency of evaluation)

Treatment/Management

1. Management of ocular complications of diabetes mellitus
   - Basis for treatment
   - Treatment of retinal complications (laser photocoagulation, vitrectomy, intraocular steroids, vascular endothelial growth factor inhibitors)
   - Patient education
2. Management of systemic complications and comorbidities of diabetes mellitus
   - Glycemic control
   - Lipid-lowering treatment
   - Weight management
   - Treatment modalities

3. Management of persons with visual impairment

Major Outcomes Considered

- Effectiveness of management interventions to reduce ocular complications of diabetes
- Quality of care
- Health-related quality of life
- Progression rate

Methodology

Methods Used to Collect/Select the Evidence

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

Clinical questions to be addressed in the Guideline were identified and refined during an initial meeting of the Guideline Development Group and served as the basis for a search of the clinical and research literature.

An English language literature search for the years 2009–2013 was conducted. The search was initiated in October 2011 and continued through April 2013. If the search did not produce results, the search parameters were extended to 5 years earlier and subsequently, 10 years earlier. In addition, a review of selected earlier research publications was conducted based on previous versions of this Guideline. The literature search was conducted using the following electronic databases:

- Agency for Healthcare Research and Quality (AHRQ)
- American Academy of Ophthalmology
- American Diabetes Association professional for the site Diabetes Pro Standards of Medical Care in Diabetes 2011
- American Optometric Association
- Cochrane Collection
- Diabetes Prevention Program
- Diabetic Retinopathy Clinical Research Network
- Diabetologia (International)
- Elsevier
- European Association for the Study of Diabetes (EASD) Eye Complications Study Group
- European Association for the Study of Diabetes (EASD, Europe's ADA)
- Eye (Journal)
- Guidelines International Network
- Institute of Medicine Clinical Guideline Welcome Trust
- Mayo Clinic
- Medical Expenditure Panel Survey (MEPS)
- National Guideline Clearinghouse of the Agency for Healthcare Research and Quality (AHRQ)
- National Institute for Health and Care Excellence (British)
- National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) National Diabetes Information Clearinghouse
- National Library of Medicine Loansome Doc
- NEI National Eye Institute
- Ophthalmologica (International Journal of Ophthalmology)
All terms related to the disease of diabetes and ocular and systemic manifestations of the disease were included in the literature search. All references meeting the criteria were reviewed to determine their relevance to the clinical questions addressed in the guideline. A total of 576 papers were identified and filtered for relevance as meeting the key question parameters. Of this number, 298 were categorized as background information and provided to the medical writer.

Number of Source Documents

Of the 278 papers read and graded by the Guideline Development Group (GDG), 94 were found to have high-quality of evidence value and/or high grading for clinical recommendations and were included in the guideline references.

Methods Used to Assess the Quality and Strength of the Evidence

Expert Consensus (Committee)

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

Strength of Evidence

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Methods Used to Analyze the Evidence

Review of Published Meta-Analyses

Systematic Review

Description of the Methods Used to Analyze the Evidence

Two clinicians independently read each assigned paper and graded the strength of evidence (see the "Rating Scheme for the Strength of the Evidence" field). The results were recorded on an Evidence and Recommendation Grading Sheet and recorded by the American Optometric Association (AOA) staff for transparency documentation.

During two face-to-face articulation meetings which followed the reading and grading process, all papers that met the inclusion criteria were reviewed. These papers were given a final strength of evidence grade, agreed and voted on by the Guideline Development Reading Group, based on the following criteria:
If both readers of a paper were in agreement with the strength of evidence grade – each grading the paper above or below the A-B/C-D line – the lowest grade of the two (above or below the line) would be recorded.

If there were three readers for a paper, the strength of evidence grade defaults to the majority (above or below the A-B/C-D line) and the lowest grade of the two, above or below the line, is recorded.

Methods Used to Formulate the Recommendations

Expert Consensus

Description of Methods Used to Formulate the Recommendations

During two articulation meetings of the Evidence-Based Optometry Guideline Development Group (GDG), all evidence was reviewed and clinical recommendations were developed. Grading for the recommendations were based on the quality of the research and the benefits and risks of the procedure or therapy recommended. Where direct scientific evidence to support a recommendation was weak or lacking, a consensus of the Evidence-Based Optometry Subcommittee members was required to approve a recommendation.

Two clinicians independently read each assigned paper and recorded the clinical recommendation(s) gleaned from the paper. These statements were then graded on the strength of the recommendation as stated in the "Rating Scheme for the Strength of the Recommendations" field. The results were recorded on an Evidence and Recommendation Grading Sheet and returned to American Optometric Association (AOA) staff for transparency documentation.

Two articulation meetings were held to formulate wording and vote on the clinical recommendations submitted by the readers. The recommendations were articulated, given a final strength of recommendation grade, and voted on by the Guideline Development Reading Group, based on the following criteria:

- If both readers of a paper were in agreement with the strength of recommendation grade – each grading the paper above or below the A-B/C-D line – the lowest grade of the two (above or below the line) would be recorded.
- If there were three readers for a paper, the strength of recommendation grade defaults to the majority (above or below the A-B/C-D line) and the lowest grade of the two, above or below the line, is recorded.
- Only papers receiving an A or B grade for strength of clinical recommendation were included in the guideline.

The discussions and votes were recorded for transparency documentation, and the final document was forwarded to the clinical practice guideline writer.

Rating Scheme for the Strength of the Recommendations

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<td>Clinicians should be aware of this recommendation. The outcome is an invalid surrogate for a clinically important population, or the applicability of the study is irrelevant. There is both a lack of pertinent evidence and an unclear balance between benefit and harm.</td>
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Cost Analysis
A formal cost analysis was not performed and published cost analyses were not reviewed.

Method of Guideline Validation

External Peer Review

Internal Peer Review

Description of Method of Guideline Validation

At the Draft Reading Meeting of the Evidence-Based Optometry Guideline Development Group (GDG), the Guideline document was reviewed and edited and the final draft was approved by the GDG via conference call. The final draft of the Guideline was then made available for peer and public review for 30 days in order for numerous stakeholders (individuals and organizations) to make comments. All suggested revisions were reviewed and, if accepted by the GDG, incorporated into the Guideline.

Evidence Supporting the Recommendations

References Supporting the Recommendations


Type of Evidence Supporting the Recommendations

The type of supporting evidence is identified and graded for selected recommendations (see the "Major Recommendations" field).

Benefits/Harms of Implementing the Guideline Recommendations
Potential Benefits

Until modalities are in place to prevent or cure diabetic retinopathy and other complications of diabetes mellitus, emphasis must be placed on identification, careful follow-up, and timely treatment, including laser photocoagulation, for patients with diabetic retinopathy and diabetic eye disease. Proper care will result in reduction of personal suffering for those involved and a substantial cost savings for the involved individuals, their families, and the country as a whole.

Potential Harms

- Complications and side effects of panretinal photocoagulation (PRP) include visual field constriction, night blindness, color vision changes, decreased accommodation, scotoma, anisocoria, glaucoma and traction retinal detachment. PRP may worsen retinal thickening in some patients with center-involved macular edema. Since the relative risk of vision loss in patients without high-risk characteristics is low, treatment of clinically significant macular edema (CSME) or center-involved diabetic macular edema (DME) should be considered before panretinal laser photocoagulation is used.
- Potential complications of vitrectomy include neovascular glaucoma, retinal detachment, vitreous hemorrhage, retinal tear formation, cataract and endophthalmitis. Glaucoma is more likely to occur in people with associated preoperative retinal detachment.
- The use of intravitreal triamcinolone acetonide (IVTA) has been associated with the risk of elevated intraocular pressure and the rates of visually significant cataracts were substantially higher compared to eyes receiving focal/grid laser treatment.
- Long-term systemic vascular endothelial growth factor (VEGF) inhibition can result in increased risk of ischemic and thromboembolic events.
- Ocular adverse events resulting from the intravitreal injection itself include endophthalmitis, ocular inflammation, retinal detachment, vitreous hemorrhage and traumatic cataract.
- Bevacizumab (Avastin®) is approved for treatment of cancer and its systemic use is known to be associated with an increased risk of stroke. It is unknown if a substantially smaller dose, when used intravitreally, has any significant systemic toxicity. It is used off-label for the treatment of DME.
- Clinicians should use caution in administering topically applied drugs for pupillary dilation in pregnant women. Topically applied drugs for pupillary dilation, such as tropicamide, hydroxyamphetamine and phenylephrine are Pregnancy Category C drugs.

Qualifying Statements

Qualifying Statements

- The components of patient care described in this Guideline are not intended to be all-inclusive. Professional judgment and individual patient symptoms and findings may have a substantial impact on the nature, extent and course of the services provided and/or recommended.
- Recommendations made in this guideline do not represent a standard of care. Instead, the recommendations are intended to assist the clinician in the decision-making process. Patient care and treatment should always be based on a clinician's independent professional judgment, given the individual's circumstances, state laws and regulations.
- The information in this guideline is current as of the date of publication.

Implementation of the Guideline

Description of Implementation Strategy

The American Optometric Association (AOA) has formed a team to develop strategies for translation of the guideline to patient care. This team is comprised of members of the AOA Health Promotion Committee, experts in diabetes care, patient(s) and patient advocates.

Implementation Tools

Chart Documentation/Checklists/Forms
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)


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

Date Released
1993 (revised 2014)

Guideline Developer(s)
American Optometric Association - Professional Association

Source(s) of Funding
This Clinical Practice Guideline was funded by the American Optometric Association (AOA) without financial support from any commercial sources.

Guideline Committee
Composition of Group That Authored the Guideline

Evidence-Based Optometry Committee Members: Diane T. Adamczyk, O.D. (Chair), State University of New York, College of Optometry, New York, New York; John F. Amos, O.D., M.S., University of Alabama at Birmingham School of Optometry, Birmingham, Alabama, Retired Dean; Felix M. Barker, II, O.D., M.S., W. G. (Bill) Hefner VAMC, Salisbury, North Carolina; A. Paul Chous, M.A., O.D., Chous EyeCare Associates, Tacoma, Washington; Linda M. Chous, O.D., United HealthCare Services, Inc., Minneapolis, Minnesota; Lynn D. Greenspan, O.D., Salus University, Pennsylvania College of Optometry, Elkins Park, Pennsylvania; Lori L. Grover, O.D., Ph.D., Center for Translational Health Science, Arizona State University, Phoenix, Arizona; Tina R. MacDonald, O.D., Certified Diabetes Educator, The Center for the Partially Sighted, Culver City, California; David K. Mashdas, O.D., Utah Eye Associates - The Diabetic Eye Center, Salt Lake City, Utah; Bennett McAllister, O.D., Western University of Health Sciences, College of Optometry, Pomona, California; Carl J. Urbanski, O.D., Family Vision Care of Kingston, Kingston, Pennsylvania

Non-Voting Members: Stephen C. Miller, O.D., Chief Editor, Innovative Writing Works, St. Louis, Missouri; Beth A. Kneib, O.D., Director of Clinical Resources, American Optometric Association, St. Louis, Missouri; Danette Miller, AOA Manager of Quality Improvement, American Optometric Association, St. Louis, Missouri; Alisa Krewet, AOA Quality Improvement Coordinator, American Optometric Association, St. Louis, Missouri

Multidisciplinary and Patient Stakeholders: Jerry Cavallerano, O.D., Ph.D., Beetham Eye Institute, Joslin Diabetes Center, Harvard Medical School, Boston, Massachusetts; William Hsu, M.D., Joslin Diabetes Center, Harvard Medical School, Boston, Massachusetts; Katherine K. Killilea, M.Ed., Patient Advocate, Wilmington, Massachusetts; Paolo Antonio S. Silva, M.D., Beetham Eye Institute, Joslin Diabetes Center, Harvard Medical School, Boston, Massachusetts; Evelyn Smith DeMille, M.S., M.P.H., Patient, Arlington, Massachusetts

Financial Disclosures/Conflicts of Interest

All Committee, Guideline Development Group, and other guideline participants provided full written disclosure of conflicts of interest prior to each meeting and prior to voting on the strength of evidence or clinical recommendations contained within.

No financial relationships or conflicts of interest relative to this guideline were present.

Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: American Optometric Association. Care of the patient with diabetes mellitus. St. Louis (MO): American Optometric Association; 2009. 74 p. [127 references]

Guideline Availability

Electronic copies: Available from the American Optometric Association Web site.

Availability of Companion Documents

The following is available:


In addition, Comparison of ETDRS and International Clinical Diabetic Retinopathy and Macular Edema Severity Scale (Appendix Table 1) and Effects of Systemic Medications on the Onset and Progression of Diabetic Retinopathy (Appendix Table 2) are available in the original guideline document.
Patient Resources

The following are available:


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 December 2, 1999. The information was verified by the guideline developer on January 27, 2000. This summary was updated by ECRI on April 16, 2004. The information was verified by the guideline developer on May 10, 2004. This summary was updated by ECRI Institute on October 11, 2011. The updated information was verified by the guideline developer on November 9, 2011. This summary was updated by ECRI Institute on July 10, 2014. The updated information was verified by the guideline developer on August 1, 2014.

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