



# **Complete Summary**

#### **GUIDELINE TITLE**

American Association of Clinical Endocrinologists medical guidelines for clinical practice for the management of diabetes mellitus. Microvascular complications.

## **BIBLIOGRAPHIC SOURCE(S)**

AACE Diabetes Mellitus Clinical Practice Guidelines Task Force. AACE diabetes mellitus guidelines. Microvascular complications. Endocr Pract 2007 May-Jun;13(Suppl 1):50-5. [72 references]

#### **GUIDELINE STATUS**

This is the current release of the guideline.

This guideline updates a previously published version: American Association of Clinical Endocrinologists, American College of Endocrinology. Medical guidelines for the management of diabetes mellitus: the AACE system of intensive diabetes self-management--2002 update. Endocr Pract 2002 Jan-Feb;8(Suppl 1):40-82.

#### **\*\* 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.

- <u>December 12, 2007, Carbamazepine</u>: The U.S. Food and Drug Administration (FDA) has provided recommendations for screening that should be performed on specific patient populations before starting treatment with carbamazepine.
- <u>May 2, 2007, Antidepressant drugs</u>: Update to the existing black box warning on the prescribing information on all antidepressant medications to include warnings about the increased risks of suicidal thinking and behavior in young adults ages 18 to 24 years old during the first one to two months of treatment.

## **COMPLETE SUMMARY CONTENT**

\*\* REGULATORY ALERT \*\* SCOPE METHODOLOGY - including Rating Scheme and Cost Analysis RECOMMENDATIONS EVIDENCE SUPPORTING THE RECOMMENDATIONS BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS QUALIFYING STATEMENTS IMPLEMENTATION OF THE GUIDELINE INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES IDENTIFYING INFORMATION AND AVAILABILITY DISCLAIMER

# SCOPE

## DISEASE/CONDITION(S)

- Diabetes mellitus, including:
  - Type 1 diabetes
  - Type 2 diabetes
  - Gestational diabetes
- Nephropathy
- Retinopathy
- Neuropathy

## **GUIDELINE CATEGORY**

Diagnosis Management Risk Assessment Screening Treatment

# **CLINICAL SPECIALTY**

Cardiology Endocrinology Family Practice Internal Medicine Nursing Nutrition Obstetrics and Gynecology Preventive Medicine

# **INTENDED USERS**

Advanced Practice Nurses Dietitians Nurses Physician Assistants Physicians

# **GUIDELINE OBJECTIVE(S)**

To provide clinicians with clear and accessible guidelines to care for patients with diabetes mellitus

# TARGET POPULATION

Children, adolescents, and adults with or at risk of developing diabetes mellitus

# INTERVENTIONS AND PRACTICES CONSIDERED

- 1. Glycemic management strategies
  - Glucose control
  - Control of risk factors (hypertension, dyslipidemias, smoking)
  - Lifestyle modification (weight control/reduction, exercise)
  - Prevention of diabetes related complications
- 2. Nephropathy
  - Screening for chronic kidney disease: albumin-to-creatinine ratio, estimated glomerular filtration rate
  - Diagnostic criteria for chronic kidney disease: estimated glomerular filtration rate, microalbuminuria, macroalbuminuria
  - Antihypertensive regimens: angiotensin-converting enzyme inhibitor, angiotensin receptor blocker, calcium channel blocker, beta-adrenergic blocker, diuretic
  - Reduction of protein intake
  - Referral for renal replacement therapy
  - Monitoring (electrolytes, intact parathyroid hormone, anemia parameters)
  - Paricalcitol where indicated
  - Glycemic control at time of renal transplantation
- 3. Retinopathy
  - Referral to ophthalmologist and/or retinal specialist
- 4. Neuropathy
  - Assessment for neuropathy at time of diagnosis and frequency thereafter: signs of autonomic dysfunction, heart rate variability
  - Inspection of feet
  - Comprehensive foot examination
  - Referral to podiatrist, orthopedist, or neurologist
  - Duloxetine or pregabalin
  - Treatment of cardiac autonomic neuropathy
  - Use of tricyclic antidepressants, topic capsaicin, antiepileptic drugs for symptomatic relief
  - Referral for podiatric and peripheral vascular studies and care

## MAJOR OUTCOMES CONSIDERED

- Plasma glucose concentration
- Side effects of therapy

## 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

References were obtained by performing a computerized search of the literature using PubMed and other search engines; scanning incoming journals in the medical library; and reviewing references in publications relevant to diabetes including review articles, leading textbooks, and syllabi from national and international meetings.

# NUMBER OF SOURCE DOCUMENTS

Not stated

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

Weighting According to a Rating Scheme (Scheme Given)

# RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

# Levels of Substantiation in Evidence-Based Medicine<sup>a</sup>

Level-of- Evidence Category <sup>b</sup>	Study Design or Information Type	Comments
1	Randomized controlled trials	Well-conducted, well-controlled trials at 1 or more medical centers
	Multicenter trials Large meta-analyses with quality ratings	Data derived from a substantial number of trials with adequate power; substantial number of subjects and outcome data Consistent pattern of findings in the population for which the recommendation is made – generalizable results
		Compelling nonexperimental, clinically obvious evidence (e.g., use of insulin in diabetic ketoacidosis); "all or none" evidence
2	Randomized controlled trials	Limited number of trials, small number of subjects
	Prospective cohort studies	Well-conducted studies Inconsistent findings or results not
	Meta-analyses of cohort studies	representative for the target population
	Case-control studies	

Level-of- Evidence Category <sup>b</sup>	Study Design or Information Type	Comments
3	Methodologically flawed randomized controlled trials	Trials with 1 or more major or 3 or more minor methodologic flaws
	Nonrandomized	Uncontrolled or poorly controlled trials
	controlled trials	Retrospective or observational data
	Observational studies	Conflicting data with weight of evidence unable to support a final recommendation
	Case series or case reports	
4		Inadequate data for inclusion in level-of- evidence categories 1, 2, or 3; data necessitates an expert panel's synthesis of the
	experience	literature and a consensus
	Theory-driven conclusions	
	Unproven claims	
	Experience-based information	

<sup>a</sup>Adapted from the American Association of Clinical Endocrinologists Protocol for the Standardized Production of Clinical Practice Guidelines.

<sup>b</sup>Level-of-evidence categories 1 through 3 indicate scientific substantiation or proof; level-of-evidence category 4 indicates unproven claims.

#### METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review

## DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

The American Association of Clinical Endocrinologists (AACE) Task force members reviewed selected reports and studies and rated the clinical evidence from these sources.

## METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

# DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

When possible, clinical recommendations put forth in the clinical practice guideline have been assigned a letter grade (A-D) based on the level of scientific

substantiation (see "Rating Scheme for the Strength of the Recommendations"). However, when task force members determined that clinical judgment regarding a recommendation outweighed study findings or a recommendation lacked supporting studies, they assigned the final grade based on their extensive clinical experience and expertise in diabetes management. An A grade is the strongest recommendation, and a D grade is the weakest recommendation. These recommendations include subjective components such as: (a) judgment regarding whether results from a particular study are conclusive; (b) the relative weighing of positive and negative conclusive study results; (c) assignment of evidence rating when certain study methodologies are controversial; (d) the impact of riskbenefit analysis; (e) the impact of cost-effectiveness; (f) assessment of geographical differences in practice standards and availability of certain technologies; (g) assessment of ethnic, racial, and genetic differences in pathophysiology; (h) incorporation of patient preferences; and (i) incorporation of physician preferences.

# **RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS**

Grade	Description
A	Homogeneous evidence from multiple well-designed randomized controlled trials with sufficient statistical power
	Homogeneous evidence from multiple well-designed cohort controlled trials with sufficient statistical power
	$\geq$ 1 conclusive level of evidence category 1 publications demonstrating benefit >> outweighs risk
В	Evidence from at least one large well-designed clinical trial, cohort or case- controlled analytic study, or meta-analysis
	No conclusive level of evidence category 1 publication; $\geq 1$ conclusive level of evidence category 2 publications demonstrating benefit $>>$ risk
С	Evidence based on clinical experience, descriptive studies, or expert consensus opinion
	No conclusive level 1 or 2 publication; $\geq$ 1 conclusive level of evidence category 3 publications demonstrating benefit >> risk
	No conclusive risk at all and no conclusive benefit demonstrated by evidence
D	Not rated
	No conclusive level of evidence category 1, 2, or 3 publication demonstrating benefit >> risk
	Conclusive level of evidence category 1, 2, or 3 publication demonstrating risk >> benefit

## **Recommendation Grades in Evidence-Based Medicine**<sup>a</sup>

<sup>a</sup>Adapted from the American Association of Clinical Endocrinologists Protocol for the Standardized Production of Clinical Practice Guidelines.

## COST ANALYSIS

Published cost analyses were not reviewed.

## METHOD OF GUIDELINE VALIDATION

Peer Review

## DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

A separate panel composed of American Association of Clinical Endocrinologists (AACE) members with expertise in diabetes reviewed the compiled report. Final recommendations included in this clinical practice guideline represent a consensus among the task force members and have been approved by reviewers, the AACE Publications and Executive Committees, and the AACE Board of Directors.

# RECOMMENDATIONS

## MAJOR RECOMMENDATIONS

The levels of evidence (1-4) and the recommendation grades (A-D) are defined at the end of the "Major Recommendations" field.

## Microvascular Complications

## **All Patients With Diabetes Mellitus**

- Encourage all patients to strive to achieve glycemic goals (*grade A*).
- Use results from postprandial glucose monitoring and the calculated standard deviation of downloaded meter results of self-monitoring of blood glucose when considering glycemic management strategies (*grade B*); evidence demonstrates that glycemic variability is an independent risk factor for microvascular disease (*grade B*).
- Consider preprandial and postprandial self-monitoring of blood glucose readings separately; adjust therapy if 25% of measurements exceed glycemic targets (*grade C*).
- Control other risk factors including (grade A):
  - Hypertension—treat blood pressure to the target of less than 130/80 mm Hg
  - Dyslipidemia—strive to achieve all lipid level goals
  - Smoking—refer patients to smoking cessation program as needed
  - Lifestyle—initiate weight reduction/control and individualized exercise regimen
- Select drug therapy with attention to cardiovascular risk (grade A).

## Nephropathy

• Screen all patients with diabetes mellitus for chronic kidney disease annually; screening should begin 5 years after diagnosis in patients with T1DM and at

the time of diagnosis in patients with type 2 diabetes mellitus (T2DM) (*grade* **A**). Testing includes:

- Measurement of albumin-to-creatinine ratio in a spot urine specimen and measurement of the estimated glomerular filtration rate derived from serum creatinine
- The following are diagnostic criteria for chronic kidney disease:
  - Estimated glomerular filtration rate <60 mL/min/1.73 m<sup>2</sup> or albumin-to-creatinine ratio  $\geq$ 30 mg albumin/g creatinine
  - Microalbuminuria ≥30 mg albumin/g creatinine
  - Macroalbuminuria ≥300 mg albumin/g creatinine
- Prescribe an angiotensin-converting enzyme inhibitor or an angiotensin receptor blocker in the antihypertensive regimen in the absence of contraindications (*grade A*).
- Consider prescribing non-dihydropyridine calcium channel blockers, betaadrenergic blockers, or diuretics to manage blood pressure in the setting of albuminuria or nephropathy in patients unable to tolerate angiotensinconverting enzyme inhibitors and/or angiotensin receptor blockers; taking non-dihydropyridine calcium channel blockers may reduce albuminuria in patients with diabetes mellitus, including those patients who are pregnant (grade C).
- Reduce protein intake to 0.8 to 1.0 g/kg per day in patients who are in the earlier stages of chronic kidney disease and to 0.8 g/kg per day in patients who are in the later stages of chronic kidney disease (**grade B**).
- The diagnosis of anemia is established if the hemoglobin level is less than 13.5 g/dL in adult men and less than 12 g/dL in adult women (**grade B**).
- When the estimated glomerular filtration rate is less than 30 mL/min/1.73 m<sup>2</sup>, refer patients for consultation and evaluation for renal replacement therapy by a nephrologist (*grade B*); kidney transplantation, in-center hemodialysis, home hemodialysis, and peritoneal dialysis should be considered (*grade B*).
- Monitor diuretic and angiotensin-converting enzyme inhibitor/angiotensin receptor blocker therapy with periodic electrolyte measurement and estimation of glomerular filtration rate (*grade C*).
- Monitor intact parathyroid hormone levels for secondary hyperparathyroidism if the glomerular filtration rate is less than 60 mL/min/1.73 m<sup>2</sup> (*grade D*); consider treatment with paricalcitol (*grade D*).
- Monitor for anemia associated with chronic kidney disease (grade B).
- Use perioperative intravenous insulin infusion for glycemic control at the time of renal transplantation (*grade B*).
- American College of Endocrinology/American Association of Clinical Endocrinologists (ACE/AACE) does not recommend pancreas-only transplantation for the isolated indications of retinopathy or neuropathy in patients without life-threatening or disabling metabolic complications of diabetes mellitus who do not require renal replacement therapy (*grade C*).

# Retinopathy

Refer the patient to a trained examiner (ophthalmologist and/or retinal specialist) for annual dilated retinal examination at the time type 2 diabetes mellitus (T2DM) is diagnosed, or 5 years after type 1 diabetes mellitus (T1DM) is diagnosed; annual examinations should be performed thereafter (*grade A*).

- Alternatively, the results from 7-field stereo color fundus photography or digital retinal imaging may be read by a qualified reading center, as long as the center operates under the direction of a medical director who is a retinal specialist (*grade B*).
- Promptly refer the patient to a retinal specialist if there is evidence that early retinopathy is progressing or if advanced retinopathy exists (*grade A*).

# Neuropathy

- All patients with T2DM should be assessed for neuropathy at the time of diagnosis, and all patients with T1DM should be assessed 5 years after diagnosis (*grade A*); annual examinations should be performed thereafter in all patients. Screening may include:
  - History and examination eliciting signs of autonomic dysfunction
  - Testing for heart rate variability, if indicated, which may include expiration-to-inspiration ratio and response to the Valsalva maneuver and standing.
- Inspect the patient's feet at every visit; evaluate skin, nails, pulses, temperature, evidence of pressure, and hygiene (*grade B*).
- Perform an annual comprehensive foot examination (*grade B*); assess sensory function by pinprick, temperature and vibration sensation using a tuning fork, or pressure using a monofilament.
- Refer the patient to a qualified podiatrist, orthopedist, or neurologist if there is a lack sensation or mechanical foot changes (*grade C*).
- Consider treatment with duloxetine or pregabalin, both of which are indicated to treat diabetic neuropathy (*grade C*).
- When treating patients with cardiac autonomic neuropathy, choose strategies appropriate for protection against cardiovascular disease (*grade A*).
- Tricyclic antidepressants; topical capsaicin; and antiepileptic drugs such as carbamazepine, gabapentin, pregabalin, topiramate, and lamotrigine may provide symptomatic relief, but must be prescribed with knowledge of potential toxicities (*grade C*).
- Further study is required before botanical preparations and dietary supplements can be advocated to treat neuropathic symptoms (*grade C*).
- Maintain a referral network for podiatric and peripheral vascular studies and care (*grade C*).

# **Definitions**:

Study Design or	Comments
, .	
Randomized controlled trials	Well-conducted, well-controlled trials at 1 or more medical centers
Multicenter trials	Data derived from a substantial number of trials with adequate power; substantial
Large meta-analyses with quality ratings	number of subjects and outcome data
	Consistent pattern of findings in the
	trials Multicenter trials Large meta-analyses

## Levels of Substantiation in Evidence-Based Medicine<sup>a</sup>

Level-of- Evidence Category <sup>b</sup>	Study Design or Information Type	Comments
		population for which the recommendation is made – generalizable results
		Compelling nonexperimental, clinically obvious evidence (e.g., use of insulin in diabetic ketoacidosis); "all or none" evidence
2	Randomized controlled trials	Limited number of trials, small number of subjects
	Prospective cohort studies	Well-conducted studies
		Inconsistent findings or results not representative for the target population
	Case-control studies	
3	Methodologically flawed randomized controlled trials	Trials with 1 or more major or 3 or more minor methodologic flaws
		Uncontrolled or poorly controlled trials
	Nonrandomized	. ,
	controlled trials	Retrospective or observational data
	Observational studies	Conflicting data with weight of evidence unable to support a final recommendation
	Case series or case reports	
4	Expert consensus	Inadequate data for inclusion in level-of- evidence categories 1, 2, or 3; data
	Expert opinion based on experience	necessitates an expert panel's synthesis of the literature and a consensus
	Theory-driven conclusions	
	Unproven claims	
	Experience-based information	

<sup>a</sup>Adapted from the American Association of Clinical Endocrinologists Protocol for the Standardized Production of Clinical Practice Guidelines.

<sup>b</sup>Level-of-evidence categories 1 through 3 indicate scientific substantiation or proof; level-of-evidence category 4 indicates unproven claims.

# **Recommendation Grades in Evidence-Based Medicine**<sup>a</sup>

Grade

Description

Grade	Description
A	Homogeneous evidence from multiple well-designed randomized controlled trials with sufficient statistical power
	Homogeneous evidence from multiple well-designed cohort controlled trials with sufficient statistical power
	$\geq$ 1 conclusive level of evidence category 1 publications demonstrating benefit >> outweighs risk
В	Evidence from at least one large well-designed clinical trial, cohort or case- controlled analytic study, or meta-analysis
	No conclusive level of evidence category 1 publication; $\geq$ 1 conclusive level of evidence category 2 publications demonstrating benefit >> risk
С	Evidence based on clinical experience, descriptive studies, or expert consensus opinion
	No conclusive level 1 or 2 publication; $\geq$ 1 conclusive level of evidence category 3 publications demonstrating benefit >> risk
	No conclusive risk at all and no conclusive benefit demonstrated by evidence
D	Not rated
	No conclusive level of evidence category 1, 2, or 3 publication demonstrating benefit >> risk
	Conclusive level of evidence category 1, 2, or 3 publication demonstrating risk >> benefit

<sup>a</sup>Adapted from the American Association of Clinical Endocrinologists Protocol for the Standardized Production of Clinical Practice Guidelines.

# CLINICAL ALGORITHM(S)

None provided

# **EVIDENCE SUPPORTING THE RECOMMENDATIONS**

## TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for each recommendation (see "Major Recommendations").

**BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS** 

#### **POTENTIAL BENEFITS**

Intensive treatment of diabetes mellitus and conditions known to be risk factors can significantly decrease the development and/or progression of chronic complications.

#### **POTENTIAL HARMS**

Side effects of therapy

## **QUALIFYING STATEMENTS**

#### QUALIFYING STATEMENTS

- Criticism that purely evidence-based clinical practice guidelines do not reflect real life because subjective input is stifled or precluded is addressed to some extent by the American Association of Clinical Endocrinologists (AACE) methodology for developing the guidelines. When the task force members judged that subjective factors influenced the grade of a recommendation to an extent that outweighed the available best evidence, this logic was explicitly described in the detailed discussion that follows each topic section's executive summary. Thus, the process of developing evidence-based recommendations and the incorporation of subjective components are transparent to the reader.
- These methods, nevertheless, have the following shortcomings: (a) reliance on some subjective measures, which compromises reproducibility; (b) dependence on the best available evidence, even if only one study is used to formulate a recommendation grade; and (c) dependence on task force primary authors to perform a comprehensive literature search. Multiple levels of review by both AACE-credentialed and non-AACE-credentialed experts from academia and clinical practice backgrounds serve to address these predicted shortcomings.

#### IMPLEMENTATION OF THE GUIDELINE

#### **DESCRIPTION OF IMPLEMENTATION STRATEGY**

An implementation strategy was not provided.

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

#### IOM CARE NEED

Living with Illness Staying Healthy

#### **IOM DOMAIN**

Effectiveness Patient-centeredness

#### **IDENTIFYING INFORMATION AND AVAILABILITY**

#### **BIBLIOGRAPHIC SOURCE(S)**

AACE Diabetes Mellitus Clinical Practice Guidelines Task Force. AACE diabetes mellitus guidelines. Microvascular complications. Endocr Pract 2007 May-Jun;13(Suppl 1):50-5. [72 references]

## ADAPTATION

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

## DATE RELEASED

2000 Jan (revised 2007)

## **GUIDELINE DEVELOPER(S)**

American Association of Clinical Endocrinologists - Medical Specialty Society American College of Endocrinology - Medical Specialty Society

## SOURCE(S) OF FUNDING

American Association of Clinical Endocrinologists (AACE)

#### **GUIDELINE COMMITTEE**

American Association of Clinical Endocrinologists (AACE) Diabetes Mellitus Clinical Practice Guidelines Task Force

## COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Task Force Members: Helena W. Rodbard, MD, FACP, MACE (Chairperson) Medical Director, Endocrine and Metabolic Consultants Past President, American Association of Clinical Endocrinologists Past President, American College of Endocrinology, Rockville, Maryland; Lawrence Blonde, MD, FACP, FACE, Director, Ochsner Diabetes Clinical Research Unit; Section on Endocrinology, Diabetes, and Metabolic Diseases Associate Residency Program Director, Department of Internal Medicine, New Orleans, Louisiana; Susan S. Braithwaite, MD, FACP, FACE, Clinical Professor of Medicine, University of North Carolina, Division of Endocrinology, Chapel Hill, NC; Elise M. Brett, MD, FACE, Assistant Clinical Professor of Medicine; Division of Endocrinology, Diabetes, and Bone Disease; Mount Sinai School of Medicine, New York, New York; Rhoda H. Cobin, MD, MACE, Clinical Professor of Medicine; Division of Endocrinology, Diabetes, and Bone Disease; Mount Sinai School of Medicine, Immediate Past President, American College of Endocrinology, Past President, American Association of Clinical Endocrinologists, New York, New York; Yehuda Handelsman, MD, FACP, FACE, Medical Director, Metabolic Institute of America, Senior Scientific Consultant, Metabolic Endocrine Education Foundation, Tarzana, California; Richard Hellman, MD, FACP, FACE, Clinical Professor of Medicine, University of Missouri-Kansas City School of Medicine, President, American Association of Clinical Endocrinologists, North Kansas City, Missouri; Paul S. Jellinger, MD, MACE, Professor of Medicine and Voluntary Faculty, University of Miami School of Medicine, Past President, American College of Endocrinology Past President, American Association of Clinical Endocrinologists, Hollywood, Florida; Lois G. Jovanovic, MD, FACE, CEO & Chief Scientific Officer,

Sansum Diabetes Research Institute, Adjunct Professor Biomolecular Science and Engineering, University of California-Santa Barbara, Clinical Professor of Medicine, University of Southern California, Keck School of Medicine, Santa Barbara, CA; Philip Levy, MD, FACE, Clinical Professor of Medicine, University of Arizona College of Medicine, Past President, American College of Endocrinology, Phoenix, Arizona; Jeffrey I. Mechanick, MD, FACP, FACE, FACN, Associate Clinical Professor of Medicine and Director of Metabolic Support; Division of Endocrinology, Diabetes, and Bone Disease; Mount Sinai School of Medicine, New York, New York; Farhad Zangeneh, MD, FACP, FACE, Assistant Clinical Professor of Medicine, George Washington University School of Medicine, Washington, DC, Endocrine, Diabetes and Osteoporosis Clinic (EDOC), Sterling, Virginia

Medical Writer: Christopher G. Parkin, MS

*Reviewers*: Lewis E. Braverman, MD; Samuel Dagogo-Jack, MD, FACE; Vivian A. Fonseca, MD, FACE; Martin M. Grajower, MD, FACP, FACE; Virginia A. LiVolsi, MD; Fernando Ovalle, MD, FACE; Herbert I. Rettinger, MD, FACE; Talla P. Shankar, MD, FACE; Joseph J. Torre, MD, FACP, FACE; Dace L. Trence, MD, FACE

# FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Dr. Lawrence Blonde reports that he has received grant/research support from Amylin Pharmaceuticals, Inc.; AstraZeneca LP; Bristol-Myers Squibb Company; Eli Lilly and Company; MannKind Corporation; Merck & Co., Inc.; Novo Nordisk Inc.; Novartis Corporation; Pfizer Inc.; and sanofi-aventis U.S. He has received speaker and consultant honoraria from Abbott Laboratories; Amylin Pharmaceuticals, Inc.; Eli Lilly and Company; GlaxoSmithKline; LifeScan, Inc.; Merck & Co., Inc.; Novartis, Novo Nordisk Inc.; Pfizer Inc.; and sanofi-aventis U.S. He has received consultant honoraria from Kos Pharmaceuticals, Inc. and U.S. Surgical. Dr. Blonde has also disclosed that his spouse is a stock shareholder of Amylin Pharmaceuticals, Inc. and Pfizer Inc., in an account that is not part of their community property.

Dr. Susan S. Braithwaite reports that she does not have any financial relationships with any commercial interests.

Dr. Elise M. Brett reports that her spouse is an employee of Novo Nordisk Inc.

Dr. Rhoda H. Cobin reports that she has received speaker honoraria from GlaxoSmithKline; Pfizer Inc.; sanofi-aventis U.S.; and Novartis and consultant honoraria from Abbott Laboratories.

Dr. Yehuda Handelsman reports that he has received speaker honoraria from Abbott Laboratories; Amylin Pharmaceuticals, Inc.; AstraZeneca LP; Bristol-Myers Squibb Company; GlaxoSmithKline; Merck & Co., Inc.; Novartis; and sanofiaventis U.S. and consultant honoraria from Abbott Laboratories; Daiichi Sankyo, Inc.; Novartis; and sanofi-aventis U.S.

Dr. Richard Hellman reports that he has received speaker honoraria from Daiichi Sankyo, Inc. and Pfizer Inc. and research grants for his role as an independent contractor from Abbott Laboratories; Pfizer Inc.; and Medtronic, Inc.

Dr. Paul S. Jellinger reports that he has received speaker honoraria from Eli Lilly and Company; Merck & Co., Inc.; Novartis; Novo Nordisk Inc.; and Takeda Pharmaceuticals North America, Inc.

Dr. Lois G. Jovanovic reports that she has received research grants for her role as investigator from Eli Lilly and Company; DexCom Inc.; LifeScan, Inc.; Novo Nordisk Inc.; Pfizer Inc.; Roche Pharmaceuticals; sanofi-aventis U.S.; and Sensys Medical, Inc.

Dr. Philip Levy reports that he has received speaker honoraria from Abbott Laboratories; Amylin Pharmaceuticals, Inc.; GlaxoSmithKline; Eli Lilly and Company; Merck & Co., Inc.; Novo Nordisk Inc.; Novartis; Pfizer Inc.; and sanofiaventis U.S. and research grants from Amylin Pharmaceuticals, Inc.; MannKind Corporation; Novo Nordisk Inc.; Pfizer Inc.; and sanofi-aventis U.S.

Dr. Jeffrey I. Mechanick reports that he does not have any financial relationships with any commercial interests.

Dr. Helena W. Rodbard reports that she has received consultant honoraria from Ortho-McNeil, Inc.; Pfizer Inc.; sanofi-aventis U.S.; and Takeda Pharmaceuticals North America, Inc.; speaker honoraria from Abbott; GlaxoSmithKline; Merck & Co., Inc.; Novo Nordisk; Pfizer Inc.; and sanofi-aventis U.S. and research support from Biodel, Inc. and sanofi-aventis U.S.

Dr. Farhad Zangeneh reports that he has received speaker honoraria from Eli Lilly and Company; GlaxoSmithKline; Novartis; Novo Nordisk Inc.; Pfizer Inc.; Roche Pharmaceuticals; sanofi-aventis U.S.; and Takeda Pharmaceuticals North America, Inc.

## **GUIDELINE STATUS**

This is the current release of the guideline.

This guideline updates a previously published version: American Association of Clinical Endocrinologists, American College of Endocrinology. Medical guidelines for the management of diabetes mellitus: the AACE system of intensive diabetes self-management--2002 update. Endocr Pract 2002 Jan-Feb;8(Suppl 1):40-82.

# **GUIDELINE AVAILABILITY**

Electronic copies: Available in Portable Document Format (PDF) from the American Association of Clinical Endocrinologists (AACE) Web site.

Print copies: Available from the American Association of Clinical Endocrinologists (AACE), 1000 Riverside Avenue, Suite 205, Jacksonville, FL 32204.

# **AVAILABILITY OF COMPANION DOCUMENTS**

The following is available:

 American Association of Clinical Endocrinologists protocol for standardized production of clinical practice guidelines. Endocrine Pract 2004 Jul-Aug; 10(4):353-61.

Electronic copies: Available in Portable Document Format (PDF) from the <u>American Association of Clinical Endocrinologists (AACE) Web site</u>.

Print copies: Available from the American Association of Clinical Endocrinologists (AACE), 1000 Riverside Avenue, Suite 205, Jacksonville, FL 32204.

## **PATIENT RESOURCES**

None available

## NGC STATUS

This NGC summary was completed by ECRI on March 1, 2000. The summary was verified by the guideline developer as of March 8, 2000. This summary was updated on April 16, 2002. The information was verified by the guideline developer on November 11, 2002. This summary was updated by ECRI Institute on September 27, 2007. The updated information was verified by the guideline developer on November 12, 2007. This summary was updated by ECRI Institute on January 10, 2008, following the U.S. Food and Drug Administration advisory on Carbamazepine.

## **COPYRIGHT STATEMENT**

All rights reserved. No part of these materials may be reproduced or retransmitted in any manner without the prior written permission of American Association of Clinical Endocrinologists (AACE)/American College of Endocrinology (ACE).

## DISCLAIMER

## NGC DISCLAIMER

The National Guideline Clearinghouse<sup>™</sup> (NGC) does not develop, produce, approve, or endorse the guidelines represented on this site.

All guidelines summarized by NGC and hosted on our site are produced under the auspices of medical specialty societies, relevant professional associations, public or private organizations, other government agencies, health care organizations or plans, and similar entities.

Guidelines represented on the NGC Web site are submitted by guideline developers, and are screened solely to determine that they meet the NGC Inclusion Criteria which may be found at http://www.guideline.gov/about/inclusion.aspx .

NGC, AHRQ, and its contractor ECRI Institute make no warranties concerning the content or clinical efficacy or effectiveness of the clinical practice guidelines and related materials represented on this site. Moreover, the views and opinions of developers or authors of guidelines represented on this site do not necessarily state or reflect those of NGC, AHRQ, or its contractor ECRI Institute, and inclusion or hosting of guidelines in NGC may not be used for advertising or commercial endorsement purposes.

Readers with questions regarding guideline content are directed to contact the guideline developer.

© 1998-2008 National Guideline Clearinghouse

Date Modified: 9/22/2008

