



D I A B E T E S M E L L I T U S

Diabetes

clinical practice guidelines 2009

Mellitus



MEDICAL MUTUAL OF OHIO®
AND ITS FAMILY OF COMPANIES



DIABETES MELLITUS

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INTRODUCTION

Diabetes mellitus is a major health concern for our member population. Nearly 13 percent of Americans ages 20 and older have diabetes, but 40 percent of those remain undiagnosed. An additional 57 million people have pre-diabetes.¹

The Diabetes Mellitus Clinical Practice Guidelines 2009 provide an overview of evidence-based recommendations for diabetes mellitus evaluation and management that stress: early detection, complication prevention, patient education and regular physician monitoring. These guidelines are intended to improve quality of care and health outcomes by decreasing inappropriate variation, while accelerating implementation of evidence-based treatments in everyday practice.

The Diabetes Mellitus Clinical Practice Guidelines 2009 are largely based on the American Diabetes Association (ADA) *Clinical Practice Recommendations 2009*² and suggestions from our practicing physician consultants. Our Company reviews and updates practice guidelines every two years, or earlier when significant scientific evidence or new national standards are published.

These recommendations are not intended to be, and should not serve as, an exclusive course of treatment or a substitute for medical treatment or advice. Decisions regarding care are subject to individual consideration and should be made by the patient in concert with treating medical personnel. The recommended services may not be covered. Coverage and eligibility depend upon the specific terms and conditions of the applicable benefit plan.

DIAGNOSIS AND CLASSIFICATION

Diagnosis

Three diagnostic tests are available to establish a diagnosis of diabetes mellitus. Unless unequivocal symptoms of hyperglycemia are also present, a diagnosis of diabetes mellitus can only be established if a positive result is confirmed on a subsequent day by repeat testing using any of the three methods.

Diagnosis of Diabetes Mellitus		
Testing	Result	Comments
Random Plasma Glucose	≥ 200 mg/dl AND symptoms of diabetes mellitus	Symptoms: <ul style="list-style-type: none">• Polyuria• Polydipsia• Unexplained weight loss
Fasting Plasma Glucose (FPG)	≥ 126 mg/dl	FPG is the preferred test when establishing a diagnosis in children and non-pregnant adults.
Oral Glucose Tolerance Test (OGTT): Two-Hour Plasma Glucose	≥ 200 mg/dl	The OGTT should utilize the World Health Organization criteria, using a glucose load containing the equivalent of 75-g anhydrous glucose in water.

Classification

Pre-diabetes is defined as:

- Impaired Fasting Glucose (IFG) = FPG 100-125 mg/dl
- Impaired Glucose Tolerance (IGT) = two-hour plasma glucose 140-199 mg/dl

1. **Type 1 Diabetes Mellitus:** Results from β -cell destruction and insulin deficiency
2. **Type 2 Diabetes Mellitus:** Results from insulin secretory defect and progressive insulin resistance

Screening

Approximately six million adults in the United States have undiagnosed diabetes mellitus. Uncontrolled diabetes mellitus and chronic hyperglycemia are associated with nephropathy, neuropathy and retinopathy. Individuals with uncontrolled type 2 diabetes mellitus are also at significantly higher risk for coronary heart disease, stroke and peripheral vascular disease.

Current Screening Recommendations		
Population	Screening Method	Frequency
All patients age 45 and older	FPG or two-hour OGTT	If normal, retest every three years.
Adults of any age with BMI* \geq 25 AND one or more risk factors	FPG or two-hour OGTT	If normal, retest within three years.
Overweight children** WITH any two risk factors (see below)	FPG preferred in children	Initiate screening at age 10 or at onset of puberty, whichever comes first. If normal, retest every three years.

*BMI: Body Mass Index is the measure of body fat based on height and weight in kg/m²

**BMI >85th percentile for age and sex, weight for height >85th percentile or weight >120% of ideal weight for height

Risk Factors for Type 2 Diabetes in Adults

- First-degree relative with diabetes mellitus
- Habitual physical inactivity
- High-risk ethnic population (African American, Latino, Native American, Asian American, Pacific Islander)
- Hypertension (blood pressure \geq 140/90 mm/Hg) or on therapy for hypertension
- HDL cholesterol level <35 mg/dl and/or a triglyceride level >250 mg/dl
- History of gestational diabetes mellitus or delivery of infant over 9 lbs
- Polycystic ovary syndrome (PCOS)
- Signs of insulin resistance or clinical conditions associated with insulin resistance (acanthosis nigricans and severe obesity)
- History of cardiovascular disease
- History of IFG or IGT on previous testing

Risk Factors for Type 2 Diabetes in Children

- First- or second-degree relative with diabetes mellitus
- High-risk ethnic population (African American, Latino, Native American, Asian American, Pacific Islander)
- Signs of insulin resistance or clinical conditions associated with insulin resistance (e.g., acanthosis nigricans, hypertension, dyslipidemia, PCOS or small-for-gestational-age birthweight)
- Maternal history of pre-existing diabetes or gestational diabetes mellitus

Body Mass Index (BMI)

	Normal						Overweight					Obese							
BMI	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33	34	35		
Height (inches)	Body Weight (pounds)																		
58	91	96	100	105	110	115	119	124	129	134	138	143	148	153	158	162	167		
59	94	99	104	109	114	119	124	128	133	138	143	148	153	158	163	168	173		
60	97	102	107	112	118	123	128	133	138	143	148	153	158	163	168	174	179		
61	100	106	111	116	122	127	132	137	143	148	153	158	164	169	174	180	185		
62	104	109	115	120	126	131	136	142	147	153	158	164	169	175	180	186	191		
63	107	113	118	124	130	135	141	146	152	158	163	169	175	180	186	191	197		
64	110	116	122	128	134	140	145	151	157	163	169	174	180	186	192	197	204		
65	114	120	126	132	138	144	150	156	162	168	174	180	186	192	198	204	210		
66	118	124	130	136	142	148	155	161	167	173	179	186	192	198	204	210	216		
67	121	127	134	140	146	153	159	166	172	178	185	191	198	204	211	217	223		
68	125	131	138	144	151	158	164	171	177	184	190	197	203	210	216	223	230		
69	128	135	142	149	155	162	169	176	182	189	196	203	209	216	223	230	236		
70	132	139	146	153	160	167	174	181	188	195	202	209	216	222	229	236	243		
71	136	143	150	157	165	172	179	186	193	200	208	215	222	229	236	243	250		
72	140	147	154	162	169	177	184	191	199	206	213	221	228	235	242	250	258		
73	144	151	159	166	174	182	189	197	204	212	219	227	235	242	250	257	265		
74	148	155	163	171	179	186	194	202	210	218	225	233	241	249	256	264	272		
75	152	160	168	176	184	192	200	208	216	224	232	240	248	256	264	272	279		
76	156	164	172	180	189	197	205	213	221	230	238	246	254	263	271	279	287		
	Obese				Extremely Obese														
BMI	36	37	38	39	40	41	42	43	44	45	46	47	48	49	50	51	52	53	54
Height (inches)	Body Weight (pounds)																		
58	172	177	181	186	191	196	201	205	210	215	220	224	229	234	239	244	248	253	258
59	178	183	188	193	198	203	208	212	217	222	227	232	237	242	247	252	257	262	267
60	184	189	194	199	204	209	215	220	225	230	235	240	245	250	255	261	266	271	276
61	190	195	201	206	211	217	222	227	232	238	243	248	254	259	264	269	275	280	285
62	196	202	207	213	218	224	229	235	240	246	251	256	262	267	273	278	284	289	295
63	203	208	214	220	225	231	237	242	248	254	259	265	270	278	282	287	293	299	304
64	209	215	221	227	232	238	244	250	256	262	267	273	279	285	291	296	302	308	314
65	216	222	228	234	240	246	252	258	264	270	276	282	288	294	300	306	312	318	324
66	223	229	235	241	247	253	260	266	272	278	284	291	297	303	309	315	322	328	334
67	230	236	242	249	255	261	268	274	280	287	293	299	306	312	319	325	331	338	344
68	236	243	249	256	262	269	276	282	289	295	302	308	315	322	328	335	341	348	354
69	243	250	257	263	270	277	284	291	297	304	311	318	324	331	338	345	351	358	365
70	250	257	264	271	278	285	292	299	306	313	320	327	334	341	348	355	362	369	376
71	257	265	272	279	286	293	301	308	315	322	329	338	343	351	358	365	372	379	386
72	265	272	279	287	294	302	309	316	324	331	338	346	353	361	368	375	383	390	397
73	272	280	288	295	302	310	318	325	333	340	348	355	363	371	378	386	393	401	408
74	280	287	295	303	311	319	326	334	342	350	358	365	373	381	389	396	404	412	420
75	287	295	303	311	319	327	335	343	351	359	367	375	383	391	399	407	415	423	431
76	295	304	312	320	328	336	344	353	361	369	377	385	394	402	410	418	426	435	443

MANAGEMENT FOR DIABETES MELLITUS

Initial Evaluation

Patients with type 1 or type 2 diabetes mellitus should undergo an initial comprehensive medical history, physical examination and laboratory evaluation.

Medical History

- Weight changes (calculate BMI)
- Prior A1C records
- Current Diabetes Treatment Plan: medications, meal plan, results of glucose monitoring and patient's use of data
- Physical activity history
- Diabetic Ketoacidosis (DKA) frequency, severity and cause
- Hypoglycemic episodes: frequency, severity and cause
- Diabetes-related complications
 - Macrovascular: cardiac, cardiovascular and peripheral artery disease
 - Microvascular: eye, kidney, nerve
 - Other: sexual dysfunction, gastroparesis
- Social

Physical Examination

- Height, weight, BMI and blood pressure
- Cardiovascular, including heart rate and peripheral pulses
- Fundoscopic examination (see Diabetic Retinopathy)
- Skin examination (insulin injection sites and acanthosis nigricans)
- Thyroid palpation
- Foot examination (see page 12)

Laboratory Evaluation

- A1C
- Serum creatinine and calculated glomerular filtration rate (GFR)
- Fasting Lipid Profile (total cholesterol, LDL and HDL cholesterol and triglycerides)
- Test for microalbuminuria
- Thyroid-stimulating hormone in type 1 diabetes, dyslipidemia or women over age 50
- Liver function
- Screen for celiac disease in all type 1 diabetics and as indicated in type 2 diabetics

MANAGEMENT FOR DIABETES MELLITUS *(CONTINUED)*

Initial Comprehensive Management Plan

The treating physician should complete an individualized management plan containing the following essential components within the first four visits:

- Short- and long-term treatment goals
- Identification of necessary lifestyle changes
- Education to enable effective self-management and self-monitoring
- Education regarding medications
- Medical Nutrition Therapy (MNT): individualized nutrition recommendations and instructions, preferably by a registered dietician experienced in diabetes mellitus
- Pneumococcal vaccine
- Influenza vaccine annually
- Smoking cessation intervention
- Referral for retinal eye exam
- Diabetes educator if not provided by physician or office staff

Cardiovascular Risk Management

Numerous studies have shown the efficacy of controlling cardiovascular risk factors in preventing or slowing cardiovascular disease in people with diabetes.

- For diabetics \geq ages 40 without overt cardiovascular disease (CVD) and who have one or more CVD risk factors, statin therapy to achieve LDL cholesterol reduction of 30-40% is recommended regardless of baseline LDL cholesterol.
- For diabetics <ages 40 without overt CVD who are at increased risk (other cardiovascular risk factors or long duration of diabetes), pharmacologic therapy is appropriate when unable to meet lipid goals through lifestyle modification. The primary LDL cholesterol goal is <100mg/dl.
- Diabetics with overt CVD are at very high risk for future events and should be treated with a statin. Lowering the LDL cholesterol goal to <70mg/dl may improve outcomes.
- The goal for serum triglycerides is <150 mg/dl.
- The goals for HDL cholesterol are >40mg/dl for men and >50mg/dl for women.

For any patient, the frequency of testing should depend upon the treatment regimen employed and the judgment of the clinician.

Aspirin Therapy

Aspirin is recommended for primary and secondary prevention of cardiovascular events in high-risk diabetic individuals.

- Use aspirin therapy (75-162 mg/day) as a primary prevention strategy in those with type 1 or type 2 diabetes at increased cardiovascular risk, including those who are >40 years of age or have additional risk factors (family history of CVD, hypertension, smoking, dyslipidemia or albuminuria).
- Use aspirin therapy as a secondary prevention strategy in type 1 and type 2 diabetics with a history of myocardial infarction, vascular bypass procedure, stroke or transient ischemic attack, peripheral vascular disease and/or angina.
- Diabetics with aspirin allergy, bleeding tendencies, recent gastrointestinal bleeding, clinically active hepatic disease or on anticoagulant therapy are not suitable candidates for aspirin therapy. Other anti-platelet agents may be a reasonable alternative for patients at high risk.
- Aspirin therapy should not be recommended for patients under the age of 21 because of the associated risk of Reye's syndrome. People under the age of 30 have not been studied.

Nephropathy

Annual testing for the presence of microalbuminuria is recommended:

- Type 1 – Begin at age 10 and after five years disease duration.
- Type 2 – Begin at the time of diagnosis.

Screening for microalbuminuria can be performed by three methods:

- Random, spot urine albumin/creatinine ratio (recommended method).
- 24 hour urine collection with creatinine clearance.
- Timed urine collection (e.g., four hours or overnight).

Because of variability in urinary albumin excretion, **two of three specimens within a three- to six-month period** should be abnormal before establishing a diagnosis of microalbuminuria or clinical albuminuria.

Comparison of Values in Urinary Albumin Excretion Testing Methods

Testing Method	Spot Collection ($\mu\text{g alb/mg creat}$)	24-Hour Collection ($\text{mg}/24\text{h}$)	Timed Collection ($\mu\text{g}/\text{min}$)
Normal Results	<30	<30	<20
Microalbuminuria	30-299	30-299	20-199
Clinical Albuminuria	≥ 300	≥ 300	≥ 200

The use of angiotensin converting enzyme (ACE) inhibitors and angiotensin receptor blockers (ARB) for the management of diabetic nephropathy:

- In the treatment of both micro and macroalbuminuria, either an ACE inhibitor or an ARB should be used (except during pregnancy).
- In type 1 diabetics with hypertension and any degree of albuminuria, ACE inhibitors have been shown to delay the progression of nephropathy.
- In type 2 diabetics with hypertension and microalbuminuria, ACE inhibitors and ARBs have been shown to delay the progression to macroalbuminuria.
- In type 2 diabetics with hypertension, macroalbuminuria and renal insufficiency (serum creatinine $>1.5 \text{ mg/dL}$), the use of an ARB has been shown to delay the progression of nephropathy.
- If an ACE inhibitor is not tolerated, therapy with an ARB (and vice-versa) should be attempted. Consider referral to a physician experienced in the care of diabetic renal disease when GFR is $<60 \text{ ml/min per } 1.73 \text{ m}^2$ or if difficulties occur in the management of hypertension or hyperkalemia.

Retinopathy

Recommended Ophthalmologic Examination Schedule		
Patient Group	First Examination*	Routine Minimum Follow-Up
Type 1 (Child)	Once patient is age 10 or within five years after onset of diabetes	Yearly**
Type 1 (Adult)	Within five years after diagnosis is established	Yearly**
Type 2 (All)	As soon as possible after diagnosis is established	Yearly**
Pregnancy with pre-existing diabetes	During 1 st trimester	Close follow-up throughout pregnancy and for one year postpartum

*Eye exams should be dilated, comprehensive and performed by an eye doctor.

**Less frequent eye exams (every two years) may be considered following one or more normal eye exams.

Diabetic retinopathy is reported to be the most frequent cause of new onset blindness among adults ages 20 to 74.³ The Diabetes Control and Complications Trial (DCCT) demonstrated a definitive relationship in type 1 diabetics between hyperglycemia and diabetic microvascular complications, as manifested by retinopathy, nephropathy and neuropathy.

Referral to an eye care specialist experienced in the management of diabetic retinopathy is important for diabetics with any level of macular edema, severe nonproliferative diabetic retinopathy or proliferative diabetic retinopathy.

Neuropathy – Foot Evaluation

A comprehensive diabetic foot exam should be performed and documented at least annually.

A Comprehensive Foot Exam Includes:		
Inspection	Palpation	Testing for Loss of Protective Sensation
<ul style="list-style-type: none">• Skin color• Distribution of hair• Bony deformities• Joint swelling• Breaks in the skin• Evidence of infection• Callus formation	<ul style="list-style-type: none">• Skin temperature• Presence/absence of pulses (dorsalis pedis/posterior tibial)	<ul style="list-style-type: none">• 10-g Monofilament Test (Semmes-Weinstein) plus one of the following:<ul style="list-style-type: none">– Pinprick sensation– Ankle reflexes– Vibration using 128-Hz tuning fork

All patients should be carefully instructed about the importance of foot hygiene, proper footwear, avoidance of foot trauma and the need for smoking cessation. Techniques to prevent foot ulcers range from the simple, but often neglected, foot inspection, to complicated vascular surgery. **If an abnormality is discovered during a routine foot evaluation, a comprehensive foot exam should be performed at every subsequent routine diabetes mellitus visit.**

Diabetic Patient Education

All diabetic patients should receive individualized verbal and/or written instructions addressing nutrition, activity and the importance of glucose control in preventing disease complications. Providing the patient with current evidence-based educational materials made available through recognized authoritative sources is strongly encouraged.

Nutrition

Medical Nutrition Therapy (MNT) is an essential component of successful diabetes mellitus management. It is recommended that a registered dietician assume the responsibility for providing nutritional education to the patient and all appropriate family members. Dietary Guidelines for Americans and MyPyramid, developed by the U.S. Department of Agriculture (USDA), summarize nutrient needs and nutritional guidelines for all healthy Americans, and provide important information that should be made available to all diabetic patients. This information is available at the following Web site: mypyramid.gov. An adaptation of MyPyramid for diabetics is available from the ADA at diabetes.org/nutrition-and-recipes/nutrition/foodpyramid.jsp.

MNT should include the following general recommendations:

- Monitoring total grams of carbohydrate, whether by use of exchanges or carbohydrate counting, remains a key strategy in achieving glycemic control.
- The recommended dietary allowance for digestible carbohydrate is 130g/day.
- To reduce the risk of nephropathy, protein intake should be limited to the recommended dietary allowance (RDA) of 0.8 –1.0g/kg in those with earlier stages of chronic kidney disease (CKD) and 0.8 g/kg in the later stages of CKD.
- Saturated fat intake should be <7% of total calories.
- Intake of trans fat should be minimized.
- Weight loss using therapeutic lifestyle changes, decreased caloric intake and increased physical activity is recommended for all overweight individuals.

Physical Activity

- Regular physical activity has been shown to improve glucose control, decrease cardiovascular risk, assist with weight loss and improve general well being. Following a detailed medical evaluation, a regular physical activity program is recommended for all diabetics capable of participating. The presence of diabetic complications and co-morbid conditions should be carefully considered in the formulation of such a program.
- Diabetics should be encouraged to engage in 150 minutes/week of moderate intensive aerobic activity.
- In the absence of contraindications, people with type 2 diabetes are encouraged to perform resistance training three times per week.

Continuing Management

Continuing care visits should occur at least semi-annually and include:

Medical History

- Effectiveness and results of self-monitoring of blood glucose (SMBG)
- Current medications
- Smoking history
- Exercise history

Physical Examination

- Height, weight and BMI
- Blood pressure (< 130/80 mmHg is recommended)
- Foot inspection (see page 12 for details)

Laboratory Evaluation

- A1C at least two times a year when meeting treatment goals with stable glycemic control, and quarterly when therapy has changed or when glycemic goals are not met
- A1C goal for non-pregnant adults is <7% in general*
- Serum creatinine and calculated glomerular filtration rate in adults annually
- Test for urine albumin excretion with spot urine/albumin ratio annually
- Fasting lipid profile in adults annually.
- Target goals:
 - HDL >50mg/dl for women and >40mg/dl for men
 - LDL <100mg/dl
 - Triglycerides <150mg/dl

*An A1C goal >7% may be suitable for patients with a history of severe hypoglycemia, advanced complications, extensive comorbid conditions or patients who have been unable to meet the general goal with optimum medical and self management.

REFERENCES

1. *NIH News*, Jan 26, 2009, National Institute of Health, U.S. Department of Health and Human Services.
2. *Diabetes Care*, Vol. 32, Supplement 1, American Diabetes Association: Clinical Practice Recommendations 2009, Standards of Medical Care in Diabetes.
3. *Diabetes Care*, Vol. 32, Supplement 1, American Diabetes Association: Clinical Practice Recommendations 2009, Standards of Medical Care in Diabetes, Pages S35.

DISEASE AND MATERNITY MANAGEMENT PROGRAM

We are committed to serving the healthcare needs of our members. To assist individuals diagnosed with chronic diseases or who are pregnant, we offer the *SuperWell® Disease and Maternity Management Program*. The program helps members who have chronic conditions or who are pregnant better manage their care by providing specially trained health coaches who offer structured education and support to increase a member's knowledge of their disease or pregnancy. In addition, health coaches work with the member to teach them how to avoid potential complications and the importance of complying with their prescribed treatment plan. Members benefit from routine monitoring of their condition by their health coach with program emphasis on improving a member's overall well-being.

We currently offer the *SuperWell Disease and Maternity Management Program* for eligible members who are pregnant or diagnosed with one or more of the following conditions:

- Congestive heart failure
- Chronic obstructive pulmonary disease
- Diabetes
- Coronary artery disease
- Asthma
- Chronic pain conditions
- Depression

For more information or to enroll a member, please call 800/861-4826, or visit one of our Web sites, MedMutual.com, ConsumersLife.com or CarolinaCarePlan.com.

DIABETES MELLITUS MANAGEMENT SUMMARY

A1C Testing:

- Treatment goal is <7%.
- Two times a year for patients who meet treatment goals
- Quarterly for patients whose therapy has changed or who are not meeting treatment goals
- An A1C goal > 7% may be suitable for patients with a history of severe hypoglycemia, advanced complications, extensive comorbid conditions for patients who have been unable to meet the general goal with optimum medical and self management

Lipid Profile:

- Annually or more often if needed to achieve goals

Target Goals	
HDL	>40 mg/dL (males) >50 mg/dL (females)
LDL	<100 mg/dL
Triglycerides	<150 mg/dL

Blood Pressure:

- Treatment goal is <130/80 mmHg.
- Measure and record at every office visit

Nephropathy Screening:

- Annual random spot urine for microalbuminuria with analysis of albumin-to-creatinine ratio
- Annual screening of serum creatinine to estimate glomerular filtration rate (GFR), regardless of degree of urine albumin excretion

Eye Exam

- Annual, comprehensive, dilated eye exam by an eye care professional

Foot Exam

- Annual, comprehensive foot exam including inspection, pulse palpation, and testing for loss of protective sensation using vibratory (tuning fork) and monofilament (Semmes-Weinstein)
- Annual education on foot self-care

These recommendations are for your information only. They are not intended to be, and should not serve as, an exclusive course of treatment or a substitute for professional medical advice, diagnosis or treatment. Decisions regarding care are subject to individual consideration and should be made by the patient in concert with the treating medical professionals. The information does not establish or imply coverage for any particular treatment or service. The recommended services may not be covered. Eligibility and coverage depend upon the specific terms and conditions of your applicable benefit plan.

CLINICAL PRACTICE GUIDELINES 2009
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