

DIABETES BASKET OF CARE SUBCOMMITTEE

Report to:

Minnesota Department of Health

June 22, 2009

BASKET TOPIC DETERMINED BY BASKETS OF CARE STEERING COMMITTEE:

Diabetes

BASKET NAME AS DETERMINED BY BASKET OF CARE SUBCOMMITTEE:

Medically Uncomplicated Type 2 Diabetes

SCOPE STATEMENT:¹

Assessment, monitoring, and outpatient management of adults (ages 18 to 65 years of age) with medically uncomplicated Type 2 diabetes excluding those individuals with advanced or end stage diabetes-related complications (refer to Attachment A); and/or other severe conditions as specifically defined (refer to Attachment B); or pregnancy.

Rationale for Scope Selection:

The subcommittee engaged in extensive conversation regarding initial scope selection, wanting to be innovative as well as to create opportunities to impact current care, such as with prediabetes. The subcommittee elected to focus initially on the care of the medically uncomplicated patient with type 2 diabetes, as there exists strong evidence, guidelines, and standards supporting this care. Acknowledging the wide range of variation in patients with type 2 patients, the subcommittee established a framework, based upon levels of complications, to be used to determine whether or not the patient meets criteria for inclusion in the basket. The subcommittee provided detailed information at the "medical" and "public" level to enhance utilization of this framework. Furthermore, the subcommittee considered the following items related to an age range selection of 18-65 years of age: Medicare age of 65 years of age (the health reform law does not apply to services paid for by Medicare); ICSI guideline entry of 18 years of age; potential care variations associated with treating adolescents versus adults, i.e., use of statins and aspirin; and acknowledgement of less clearly established guidelines for diabetes care in those under 18 years of age. The subcommittee recognized and agreed that multiple baskets could be developed to cover the spectrum of care required for patients with

diabetes. Additionally, the subcommittee recognized that once components are in place for a provider to deliver care following a basket concept, that this care may benefit other patients while not specifically included in the basket.

BASKET OF CARE COMPONENTS:

Basket components were identified based on current literature, existing guidelines, current standards of practice and in some cases evidence informed consensus.

Description	Timeframe
Assessment ²	
<ul style="list-style-type: none"> ● Primary Provider Evaluation, including: <ul style="list-style-type: none"> ▪ Diabetes-related history and physical ³ ▪ Vital signs ⁴ ▪ Counseling ▪ Test coordination ▪ Comprehensive cardiovascular and cerebrovascular risk assessment (including tobacco assessment) ▪ Foot examination and risk assessment ▪ Assessment of self-management skills ▪ Psychosocial assessment ▪ Hypoglycemia assessment ▪ Review of medications ▪ Allergy and immunization review ▪ Nutrition assessment ▪ Physical activity assessment ● Eye examination: retinal photography screening or comprehensive evaluation by ophthalmologist or optometrist 	<ul style="list-style-type: none"> ● Minimum of 2 yearly encounters ⁵ ● Minimum of 1 yearly, unless prior eye examination within 2 years was normal; and then every 2 years thereafter

Lab Monitoring	
<ul style="list-style-type: none"> • Nephropathy assessment (micro albumin and/or 24 hour urine protein) • Creatinine (serum) and/or estimated glomerular filtration rate • A1c ⁶ • Lipid profile • Liver function tests (AST or ALT) ⁷ 	<ul style="list-style-type: none"> • Minimum yearly • Minimum yearly • Minimum of 1 in last 6 months; 2 – 4 per year • Minimum yearly • Minimum yearly
Management	
<ul style="list-style-type: none"> • Education/coaching/counseling/support for nutrition therapy, physical activity, glucose monitoring, weight management, medication management and all other aspects of self-management. Diabetes self-management training (DSMT) and medical nutrition therapy (MNT) are well-established programs for delivering these elements. DMST and MNT incorporate the personal needs and patient’s willingness and ability to change. Refer to Attachment C for additional information. • Flu shot 	<ul style="list-style-type: none"> • Minimum of yearly assessment with an individual plan developed, implemented, and monitored until patient achieves goals ⁸ • Yearly

Notes:

1. Scope

The subcommittee considered the following items related to an age range selection of 18-65 years of age: Medicare age of 65 years of age (the health reform law does not apply to services paid for by Medicare); ICSI guideline entry of 18 years of age; potential care variations associated with treating adolescents versus adults, i.e., use of statins and aspirin; and acknowledgement of less clearly established guidelines for diabetes care in those under 18 years of age. Given these considerations, the subcommittee chose the age range in the scope to be 18 to 65 years of age. The subcommittee recognizes and agrees that multiple baskets could be developed to cover the spectrum of care required for patients with diabetes. Additionally, the subcommittee recognizes that once components are in place for a provider to deliver care following a basket concept, that this care may benefit other patients while not specifically “in the basket”.

2. Assessment

It is recommended that the delivery of Assessment components be coordinated with the Management components. The subcommittee did not designate a specific provider level for this Assessment component leaving room for innovation in care delivery.

3. Diabetes-Related History and Physical

The diabetes-related history and physical is not intended to replace a preventive services history and physical when applicable.

4. Vital Signs

Vital signs include those customary items captured at routine visits and could include such things as BMI.

5. Encounters

Encounters are interactions between providers of health services and patients. These would not be required to be face-to-face visits.

6. A1c

It is recommended that the A1c monitoring be coordinated with the Assessment and Management components.

7. Liver Function Tests

The subcommittee recognized that most providers currently monitor liver function using ALT. The subcommittee reviewed indications appropriate for yearly liver function testing, including glycemic and cholesterol medications, and consensus was this represented preferred practice.

8. Management

It is recommended that this Management component be coordinated with the Assessment component. Furthermore, it is strongly recommended that this involve referral to/or utilization of resources that meet national standards. Refer to Attachment C for description of DSMT and MNT programs. No distinction was made in this proposed basket between patients in the first year of diagnosis and those with a diagnosis for several years.

Components considered but not included:

- A comprehensive matrix was prepared and reviewed which identified most services a patient with type 2 diabetes could require. As further work was done to refine the complications framework (narrowing the basket to those with early complications), several items were excluded, as they were not applicable to the type 2 diabetes medically uncomplicated patient population.
- Pharmaceuticals – considering the inherent variation with medication use for this population of patients, these was not included

- Durable medical equipment – again, considering the inherent variation with things such as specific glucose monitoring devices, this as not included. The subcommittee acknowledged the existence of state law payer mandates that directly address access to such equipment.
- Components were limited to ambulatory care does not include any hospital care.

Components in initial basket that were deleted or modified for final draft:

- History & Physical- this was clarified to indicate “diabetes-related” history and physical. Additionally, information was added to clarify that this is not intended to replace a preventive services history and physical when applicable.
- Assessment timeframe- this was modified to reflect a minimum of two encounters yearly versus one. It was further clarified that these interactions between providers of health services and patients would not be required to be face-to-face visits. Additionally, the subcommittee did not designate a specific provider level for this component allowing for innovation in care delivery. Lastly, the subcommittee recommended that the delivery of the Assessment component be coordinated with the Management component.
- Eye examination timeframe- revised to include ongoing care requirements, “and then every 2 years thereafter.”
- Liver function test- specified this to include AST and/or ALT as subcommittee recognized most providers use these liver function tests currently.
- Management component- specified medication management as an area for education/coaching/counseling/support along with other aspects previously included.
- Management timeframe- language revised to include ongoing monitoring until patient achieves goals.
- Attachment A- several modifications made from original draft to ensure accuracy and integrity across the levels of complications.
- Attachment B- list modified to include only: cancer; Human Immunodeficiency Virus Infection; significant mental health disorders that interfere with assessment and management of diabetes; and significant cognitive barriers, including dementia, that interfere with assessment and management of diabetes.

OPPORTUNITIES FOR INNOVATION INCLUDE:

- The subcommittee discussed current reimbursement situations and acknowledged the limitations and impact this has on care of patients with type 2 diabetes. The

subcommittee believes there is great opportunity for innovation in this basket including such things as new partnerships within the community, alternatives to face-to-face service, greater coordination of care by the diverse health care disciplines involved in diabetes care, etc. The subcommittee believed being less prescriptive in the basket in designating who provides the components, as well as how components are delivered, allows for such innovative opportunities.

- Prediabetes – the subcommittee felt the greatest opportunity for innovation was in this area. The subcommittee invested additional time, over that originally established for the subcommittee work, to develop a second basket addressing prediabetes. Refer to the separate basket developed for prediabetes.

ADDITIONAL CONSIDERATIONS:

- The subcommittee questioned whether consideration should be given to the use of a patient multiplier based on level of severity of disease
- The subcommittee identified examples of situations that could involve care beyond the scope of this basket once in place i.e. increased complications, increased glucose management concerns, etc. which could require the potential establishment of “exit criteria” from the basket
- The subcommittee discussed potential malpractice concerns that could arise related to the basket and standard of care
- Ongoing consideration may need to be given to the availability of resources for rural providers

JUNE 4, 2009 STEERING COMMITTEE REVIEW AND COMMENT:

- Is there an opportunity for a pharmaceutical consortium to address medications in association with such a basket to address the risk concern?

ATTACHMENT A

COMPLICATION LEVELS BY BODY SYSTEM WITH MEDICAL AND PUBLIC DESCRIPTIONS

The information below is intended to provide a framework to assist in determining whether an individual meets criteria to receive care within the Basket of Care. Additionally, the public information is provided to assist with patient understanding of who may be eligible for this Basket of Care.

***Note: Patients that have any of the clinical attributes defined in either Level 3 or Level 4 should be considered ineligible for this Basket of Care, that is, most patients with any of these attributes will require greater levels of service than those described in this basket.** Those patients not meeting criteria for care within the basket would continue to receive health care services through their normal health insurance coverage.

	Levels 1 and 2 Included in Basket of Care		Levels 3 & 4 *Excluded from Basket of Care	
Body System	Level 1	Level 2	Level 3	Level 4
	Normal	Early Complications	*Advanced Complications	*End Stage Complications
Eye – medical	<ul style="list-style-type: none"> • Normal 	<ul style="list-style-type: none"> • Retinopathy 	<ul style="list-style-type: none"> • Laser treatment or vitrectomy 	<ul style="list-style-type: none"> • Blind or partial visual loss due to diabetes
Eye – public	<ul style="list-style-type: none"> • Normal 	<ul style="list-style-type: none"> • Changes in the back of the eye due to diabetes (leaking blood vessels or fluid leaking into eye) but have not required laser treatment or surgery 	<ul style="list-style-type: none"> • Laser surgery to seal off leaking blood vessels or surgery to remove blood from the eye • 	<ul style="list-style-type: none"> • Blind due to effects of diabetes or enough loss of vision to be classified as “legally blind”
Kidney – medical	Stage 1-2 (Normal) <ul style="list-style-type: none"> • **eGFR > 60 (Serum Cr normal) • No micro-albuminuria 	Stage 3 <ul style="list-style-type: none"> • eGFR 30-60 (Serum Cr <2) and/or • positive micro-albuminuria (30-300) 	Stage 4 <ul style="list-style-type: none"> • eGFR 15-29 (Serum Cr >2) and/or • macroalbuminuria (>300) 	Stage 5 (End stage) <ul style="list-style-type: none"> • eGFR <15 • kidney transplant or dialysis
Kidney – public	<ul style="list-style-type: none"> • Normal kidney not leaking any protein (albumin) 	<ul style="list-style-type: none"> • Slight decrease in kidney function (blood test your provider does) • Have a small amount of protein in the urine 	<ul style="list-style-type: none"> • Moderate decrease in kidney function (blood test your provider does) • Have a large amount of protein in the urine 	<ul style="list-style-type: none"> • Little or no kidney function left or on dialysis or have had a kidney transplant

	Levels 1 and 2 Included in Basket of Care		Levels 3 & 4 *Excluded from Basket of Care	
Body System	Level 1	Level 2	Level 3	Level 4
Nerves – medical	<ul style="list-style-type: none"> • Normal 	<ul style="list-style-type: none"> • Mild peripheral neuropathy (abn. 128 Hz tuning fork but normal 10g monofilament) • No neuropathy meds • No hypoglycemia unawareness • Mild to moderate hypoglycemia, but not severe hypoglycemia requiring assistance of another person 	<ul style="list-style-type: none"> • Peripheral neuropathy requiring medications (often abn. 10 gram monofilament test), or • Documented autonomic neuropathy, or • Severe hypoglycemia or hypoglycemia unawareness 	<ul style="list-style-type: none"> • Severe peripheral neuropathy or advanced (autonomic neuropathy (orthostatic, bladder, gastrointestinal)
Nerves – Public	<ul style="list-style-type: none"> • No pain or numbness due to diabetes 	<ul style="list-style-type: none"> • Mild numbness or pain in the feet (not requiring nerve medications) • No stomach, bowel, or bladder abnormalities due to diabetes • May have mild to moderate hypoglycemia (where one has signs of low blood sugar they can treat themselves), but not severe hypoglycemia requiring assistance from another person 	<ul style="list-style-type: none"> • Moderate pain or numbness in the feet requiring nerve pain medicine • Do not feel low blood sugars or have had more than one episode of severe hypoglycemia that you required help from someone to recover 	<ul style="list-style-type: none"> • Severe pain or complete loss of feeling in feet/legs • Unsteadiness • Trouble with stomach, bowels or emptying bladder due to diabetes

	Levels 1 and 2 Included in Basket of Care		Levels 3 & 4 *Excluded from Basket of Care	
Body System	Level 1	Level 2	Level 3	Level 4
Heart – medical	<ul style="list-style-type: none"> • Normal 	<ul style="list-style-type: none"> • No history of myocardial infarction or congestive heart failure (if available LVEF > 50%) • Angina – intermittent and responding to medications • Stent – no angina post procedure 	<ul style="list-style-type: none"> • Myocardial infarction, or • Coronary artery bypass graft surgery, or • Acute coronary syndrome, or • Frequent angina but some response to medications, or • Mild/Moderate congestive heart failure 	<ul style="list-style-type: none"> • Heart transplant, or • End stage heart failure, or • Unstable angina
Heart – public	<ul style="list-style-type: none"> • No known heart disease 	<ul style="list-style-type: none"> • No history or heart attack or congestive heart failure (fluid build-up in the lungs with shortness of breath) • Mild and occasional chest pain due to narrowed blood vessels to the heart (angina) – responds to chest pain medicine (like nitroglycerin) • Have had a stent placed to open a blood vessel around the heart – no chest pain afterwards 	<ul style="list-style-type: none"> • History of heart attack or heart bypass surgery to open up blood flow around the heart • Frequent chest pain (angina) despite medications • Congestive heart failure but still able to be somewhat active (shortness of breath due to fluid in lungs from weak heart) 	<ul style="list-style-type: none"> • Heart transplant • Unstable angina • Congestive heart failure (shortness of breath that keeps you from being active)

	Levels 1 and 2 Included in Basket of Care		Levels 3 & 4 *Excluded from Basket of Care	
Body System	Level 1	Level 2	Level 3	Level 4
Vascular – medical	<ul style="list-style-type: none"> • No history of stroke or transient ischemic attack • Normal peripheral blood flow; either normal ankle brachial index (> 0.9 if available) or no claudication with ambulation 	<ul style="list-style-type: none"> • Narrow carotid artery <70% by carotid ultrasound (if available) • Reduced ankle brachial index (ABI > 0.5 but < 0.9 if available) may have intermittent claudication but able to ambulate with minimal difficulty • May have blisters and minor pressure ulcer (not requiring surgical debridement) but not recurrent ulcers 	<ul style="list-style-type: none"> • Preventive carotid artery surgery, or • Transient ischemic attack, or • Stroke with no residual deficits, or • Recurrent ulcers feet/extremities (requiring surgical debridement), or • Consistent claudication reducing ability to ambulate or ABI, or • Peripheral artery graft, stent or angioplasty 	<ul style="list-style-type: none"> • Stroke with residual deficits • Amputation

	Levels 1 and 2 Included in Basket of Care		Levels 3 & 4 *Excluded from Basket of Care	
Body System	Level 1	Level 2	Level 3	Level 4
Vascular - public	<ul style="list-style-type: none"> No history of stroke or transient ischemic attack (temporary stroke that resolves) 	<ul style="list-style-type: none"> No history of stroke or transient ischemic attack (temporary stroke that resolves) Told you may have reduced circulation to legs and may get cramps in calves occasionally when walking that goes away when you rest (intermittent claudication) Told you may have narrowing in a blood vessel in neck supplying blood to brain (carotid artery) – may have had surgery to prevent a problem Occasional blister or sore on foot due to rubbing in shoes or breakdown of a callus (but did not require surgery to clean up the sore or ulcer) 	<ul style="list-style-type: none"> Had a temporary or transient stroke Had a mild stroke that resolved with no after effects on speech or weakness of limbs Get cramps when walking that limits your ability to get around as you wish (claudication) Have sores or ulcers on your feet that do not heal or that keep coming back (and have required surgery to clean up the sore or ulcer) Need surgery on blood vessels in legs to increase blood flow 	<ul style="list-style-type: none"> Had a stroke and have problems with speech or weakness in an arm or leg that remains Had an amputation of toes or part of foot or leg due to poor circulation or infections (ulcers)

	Levels 1 and 2 Included in Basket of Care		Levels 3 & 4 *Excluded from Basket of Care	
Body System	Level 1	Level 2	Level 3	Level 4
Depression - medical and public	<ul style="list-style-type: none"> • Depression controlled not requiring medical intervention 	<ul style="list-style-type: none"> • Depression controlled but requiring medical intervention: <ul style="list-style-type: none"> • CBT, • Behavioral Rx, medication 	<ul style="list-style-type: none"> • Persistent Depression despite medical management 	<ul style="list-style-type: none"> • Depression requiring hospitalization or ECT within last 1-2 yrs.

*Denotes complication levels to be excluded from Diabetes Basket

** eGFR = Estimated Glomerular Filtration Rate

ATTACHMENT B

POTENTIAL INDIVIDUAL PATIENT EXCLUSIONARY CONDITIONS

- Cancer
- Human Immunodeficiency Virus Infection
- Significant mental health disorders that interfere with assessment and management of diabetes
- Significant cognitive barriers, including dementia, that interfere with assessment and management of diabetes

ATTACHMENT C

DIABETES SELF MANAGEMENT TRAINING (DSMT)

DSMT provides assessment of self-management skills, self-management education, planning and support for the following 7 content areas:

1. Healthy eating
2. Being active
3. Taking medication
4. Monitoring
5. Problem-solving
6. Healthy coping
7. Reducing risks

MEDICAL NUTRITION THERAPY (MNT)

MNT provides nutrition assessment, planning and support for the following while reinforcing the DSMT content areas:

1. Individualized modification of food plan/physical activity/medication for improved post prandial control and hypoglycemia prevention
2. Individualized modification of carbohydrate, protein, fat and sodium intake and guidance to achieve lipids and blood pressure goals
3. Individualized weight loss planning and coaching
4. Education and support on additional topics to promote flexibility in meal planning, food purchasing/preparation, recipe modification, eating away from home

SUPPORTING REFERENCES:

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Note: These references were submitted by subcommittee members through the course of their efforts in defining the Diabetes Basket of Care. These references provide recommendation, support and discussion, as well as strong evidence in some cases, for the particular care components included in the Diabetes Basket of Care.