Clinical Policy Title: Outpatient diabetes self-management training (DSMT)

Coverage policy

Keystone First considers the use of outpatient diabetes self-management and training (DSMT) to be clinically proven and, therefore, medically necessary when ordered by a qualified health care professional and when the following criteria are met:

<table>
<thead>
<tr>
<th>Patient eligibility criteria (must meet at least one of criterion A, B, C, or D)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>A.</strong> The individual is newly diagnosed with diabetes mellitus by means of one of the following:</td>
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<td>• A fasting blood sugar greater than or equal to 126 mg/dL on two different occasions.</td>
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<td>• A two-hour post-glucose challenge ≥ 200 mg/dL.</td>
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<td>• A random glucose test &gt; 200 mg/dL for an individual with symptoms of uncontrolled diabetes.</td>
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<td>• An HbA1C level ≥ 6.5 percent.</td>
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<tr>
<td><strong>B.</strong> The individual diagnosed with diabetes exhibits poor glycemic control evidenced by a glycosylated</td>
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</tbody>
</table>
**Patient eligibility criteria (must meet at least one of criterion A, B, C, or D)**

- Hemoglobin (HbA1C) ≥ 9.5 percent in the 90 days before attending the DSMT.

C. The treating professional health care provider detects that the individual diagnosed with diabetes requires a change in the treatment regimen where re-education or refresher training is necessary (e.g., from no diabetes medication to any diabetes medication, or from oral diabetes medication to insulin).

D. The treating professional health care provider detects that the individual with diagnosed diabetes is deemed to be at high risk based on either:
  - Evidence of poor glycemic control, with documentation of acute episodes of severe hypoglycemia, or acute severe hyperglycemia within the past year that required third-party assistance for either emergency room visits or hospitalization.
  - Documented complications including, but not limited to, one of the following:
    - An absence of feeling in the foot or other foot complications (e.g., foot ulcer, amputation).
    - Pre-proliferative or proliferative retinopathy, or prior laser treatment of the eye.
    - Renal complications related to diabetes (e.g., macroalbuminuria, elevated creatinine).

and

**DSMT program criteria**

*(criteria A, B, C, D, and E must be met)*

A. Assessment of the diabetic individual’s specific education needs, including all of the following:
  - Family involvement, social support, and community resources.
  - Nutrition and meal planning, skin care, exercise, and physical activity needs.
  - Use of medications, safety and effectiveness, and an insulin treatment plan developed specifically for the individual, where applicable.
  - Prevention, detection, and treatment of acute and chronic complications.

B. Identification of the individual’s specific diabetes self-management goals.

C. Behavioral intervention and education to help the individual achieve his or her identified diabetes self-management goal, including:
  - Instruction in blood glucose self-monitoring.
  - Motivation for the individual to use the skills acquired with DSMT.

D. Ongoing evaluation of the individual’s actualization of his or her identified diabetic self-management goals.

E. The DSMT includes a comprehensive plan of care that describes the content, number, frequency, and duration of the DSMT as applied to either of the following:
  - Services furnished in a group setting of two to 20 individuals.
  - The need for individual DSMT sessions is justified by one of the following:
    - Group sessions are unavailable within two months of the date the training is ordered.
    - The physician or professional health care provider orders additional insulin education.
    - The individual is unable to participate in a group setting due to, but not limited to, one of the following:
      - Severe vision, hearing, or language limitations.
      - Special conditions identified by the treating physician or professional health care provider.

**Limitations:**
• All other uses of DSMT are not medically necessary.
• An initial 10 hours of DSMT within a continuous 12-month period is medically necessary for a member diagnosed with diabetes.
• A maximum of two hours of DSMT each year is medically necessary for a member with diabetes, beginning with the calendar year in which the recipient received their initial training.
• The need for DSMT and program plan must be maintained and documented in the member’s medical record. Included are statements regarding the number of hours, topics covered, and the member’s need for individual or group training.
• DSMT is not medically necessary for a member who is a patient in a hospital, skilled nursing facility, hospice, or nursing home.
• DSMT in the home setting is an integral part of a home visit; as such it is not eligible for separate reimbursement.
• The health care provider maintains a certificate of recognition from the American Diabetes Association (ADA), American Association of Diabetes Educators (AADE), or other Centers for Medicare & Medicaid Services (CMS)-acknowledged certification entity that affirms recognized provider status for the diabetes educator and education program.

Alternative covered services:

• Diabetes self-management education as part of an inpatient occurrence.
• Diabetes self-management education as an integral part of a home visit.

Background

Diabetes mellitus is a chronic endocrine disease that involves a detrimental change in the secretion of insulin from the pancreas marked by high levels of blood glucose resulting from defects in insulin production, insulin action, or both. Diabetes mellitus is classified as type 1 (destruction of insulin-producing pancreatic beta-cells) and type 2 (gradual loss of the ability to produce insulin). The risk of diagnosed diabetes is highest among those of Asian, Hispanic, and non-Hispanic black descent (Centers for Disease Control and Prevention [CDC] 2014).

Prediabetes is a condition in which the blood glucose levels are higher than normal, but are not yet high enough to be diagnosed as type 2 diabetes (T2DM). Interventions such as diet and exercise can correct prediabetes and prevent or delay T2DM. Diabetes and prediabetes may affect anyone at any time during his or her life span (CDC 2014).

DSMT:

Diabetes requires long-term medical management to limit the extent of complications associated with the disease. DSMT is an ongoing, collaborative process in which diabetes educators help diabetic individuals gain the knowledge, coping, problem-solving, decision making, and self-behavior skills needed to
successfully manage the disease and its associated comorbidities (Minet 2010). DSMT integrates functional, medical, cultural, psychosocial, and spiritual goals of care. The degree to which individuals are able to learn, process, and understand health information is a factor of their health literacy. Successful diabetes self-management entails active participation in a large amount of tasks of varying complexity that integrate learned behaviors into the context of daily life (Wallace 2010).

**Searches**

Keystone First searched PubMed and the databases of:
- UK National Health Services Centre for Reviews and Dissemination.
- Agency for Healthcare Research and Quality's (AHRQ's) National Guideline Clearinghouse and other evidence-based practice centers.
- CMS.

We conducted searches on January 18, 2017. Search terms were: "diabetes self-management," "diabetes mellitus/education" (MeSH), "diabetes mellitus/organization and administration" (MeSH), and "diabetes mellitus/prevention and control" (MeSH).

We included:
- **Systematic reviews**, which pool results from multiple studies to achieve larger sample sizes and greater precision of effect estimation than in smaller primary studies. Systematic reviews use predetermined transparent methods to minimize bias, effectively treating the review as a scientific endeavor, and are thus rated highest in evidence-grading hierarchies.
- **Guidelines based on systematic reviews**.
- **Economic analyses**, such as cost-effectiveness, and benefit or utility studies (but not simple cost studies), reporting both costs and outcomes — sometimes referred to as efficiency studies — which also rank near the top of evidence hierarchies.

**Findings**

Evidence from systematic reviews shows that DSMT can significantly improve glycemic control, diabetes knowledge, self-management skills, and self-efficacy and empowerment (Steinsbekk 2012; Duke 2009; Couch 2008; Deakin 2005). DSMT and education are considered integral parts of diabetic care, and medical treatment without these components is considered inadequate (American Diabetes Association [ADA] 2014; Haas 2014). The ADA and the American Association of Diabetes Educators place the diabetic individual’s condition, desires, abilities, and tolerances at the center of the decision-making process (Haas 2014).

Typically, a certified diabetes educator performs a one-hour assessment to develop an appropriate education program tailored to the individual’s specific needs. Group sessions are usually two hours in length, while individual diabetes education may use one hour sessions to address individual requirements. Evidence based standards guide instructions for nutrition (diet) and exercise, self-monitoring of blood
glucose, and the inclusion of an insulin treatment plan (for each individual who is insulin-dependent) or oral medication (for those on oral therapy).

Presently, higher-intensity face-to-face interventions (group or one-to-one) set the current standard for DSMT. Computer-based, cellular phone, and web-based interventions are readily available tools that could improve health outcomes in diabetes care by facilitating intense patient self-management. For these interventions to improve outcomes, they must help patients improve their knowledge and understanding of diabetes and change their patterns of eating, physical activity, and adherence to treatment regimens. Their value has been demonstrated in other areas of chronic disease self-management.

Policy updates:

Two systematic reviews examined the role of information communication technology in facilitating diabetes self-management and improving patient outcomes (Pal, 2013; Hayes, 2014). The evidence from these systematic reviews is based on multiple randomized controlled trials (RCTs) of low to moderate quality with variable intervention protocols and reporting of study details that make the risk of bias difficult to determine in most cases. These systematic reviews found:

- Sufficient evidence to show that computer-based, cellular phone, and web-based interventions are safe interventions with minimal to no adverse effects reported.
- Insufficient evidence to support the routine use of computer-based, cellular phone, and web-based interventions in DSMT. There is low- to moderate-quality evidence of effectiveness showing that mobile phones and two-way communication with frequent feedback improve HbA1C and adherence to self-management regimens in adults in the short term, but evidence in children and adolescents is limited with inconsistent results.
- Insufficient evidence to support either the clinical relevance of these intermediate outcomes on health outcomes or the cost-effectiveness of these interventions compared to the current standards of care.

A meta-analysis summarized the results of 62 studies, representing 67 RCTs, of the effect of consumer health information technologies on outcomes in DSMT (Or 2014). The use of these technologies was associated with significant reductions in HbA1C, blood pressure, total cholesterol, and triglycerides levels when compared with the usual care. However, only a small proportion of the trials reported positive effects on patient outcomes. The effectiveness of the technologies in improving patient outcomes still awaits confirmation in future studies.

A comprehensive systematic review of 120 RCTs comprising more than 22,000 total participants and 118 unique interventions found robust data demonstrating that engagement in DSMT results in a statistically significant decrease in HbA1C levels (Chrval 2016). Combination DSMT resulted in the largest decreases in HbA1C (0.88) compared with only group, individual, and remote interventions. The magnitude of reductions in HbA1C in participants exposed to DSMT exceeded that of usual care by more than 0.5 percent for all modes of delivery other than primarily remote. However, only 12 studies offered remote interventions, and the results should be interpreted cautiously. More than 10 contact hours were
associated with a greater proportion of interventions with significant reduction in HbA1C (70.3 percent). In patients with persistently elevated glycemic values (HbA1C > 9), a greater proportion of studies reported statistically significant reduction in HbA1C (83.9 percent). The data suggest mode of delivery, hours of engagement, and baseline HbA1C can affect the likelihood of achieving statistically significant and clinically meaningful improvement in HbA1C.

People with severe mental illness are at higher risk of developing T2DM. It is not clear if existing treatment guidelines for T2DM are generalizable to those with severe mental illness. One new Cochrane review found insufficient evidence from one low-quality RCT to determine if a tailored approach to diabetes education was more effective than usual diabetes care plus information in this population (McBain, 2016). These results do not change previous conclusions. Therefore no policy changes are warranted.

Summary of clinical evidence:

<table>
<thead>
<tr>
<th>Citation</th>
<th>Content, Methods, Recommendations</th>
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<tbody>
<tr>
<td>Chrvala (2016)</td>
<td>Key points:</td>
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</table>
| DSMT and support methods, providers, duration, and contact time on glycemic control in adults with T2DM | - Systematic review of 120 RCTs (11,854 participants in intervention group, 11,093 participants in control group) and 118 unique interventions.  
- Overall quality: low with high risk of bias.  
- Overall mean reduction in HbA1C was 0.74 and 0.17 for intervention and control groups, respectively; an average absolute reduction in HbA1C of 0.57.  
- Combination DSMT resulted in the largest decreases in HbA1C (0.88) compared with group, individual, and remote interventions.  
- Contact hours > 10 were associated with a greater proportion of interventions with significant reduction in HbA1C (70.3%).  
- In patients with persistently elevated glycemic values (HbA1C > 9), a greater proportion of studies reported statistically significant reduction in HbA1C (83.9%).  
- No differences in the mean change in HbA1C between single or team DSMT providers.  
- DSME > 10 hours was associated with a slightly higher overall mean reduction in HbA1C. |
| McBain (2016) | Key points: |
| Cochrane review DSMT tailored for people with T2DM and severe mental illness | - Systematic review of one RCT (three publications; 64 total participants with schizophrenia or schizoaffective disorder) comparing a 24-week Diabetes Awareness and Rehabilitation Training program to usual care plus information.  
- Overall quality: unclear risk of bias.  
- No significant improvement in total energy expenditure, HbA1C at six or 12 months of follow-up, or blood pressure. Anecdotal small improvements in body mass index, weight, diabetes knowledge, and self-efficacy immediately post-intervention, and knowledge also at six months. |
| Hayes (2014) | Key points: |
| Information communication technology (ICT, cellular phones with short message service) | - Systematic review of 18 RCTs (sample sizes: 30 to 463 patients).  
- Overall quality: low to moderate.  
- ICT improves HbA1C and adherence to self-management regimens in adults, but evidence in children and adolescents is limited with inconsistent results.  
- ICT with two-way communication with frequent feedback is most effective. |
The use of ICT is safe with no reported side effects.

Key points:

- Systematic review of 16 RCTs (3,578 total patients).
- Overall quality: unclear risk of bias. No blinding, heterogeneous interventions, incomplete reporting of critical study design details.
- Age of participants was 46 – 67 years, mean time since diagnosis was six – 13 years. The duration of the interventions one to 12 months. Three reported deaths.
- Computer-based DSMT has limited effectiveness: small benefits on glycemic control (pooled effect on HbA1C: -2.3 mmol/mol or -0.2% [95% confidence interval [CI] -0.4 to -0.1; P = 0.009; 2,637 participants; 11 trials). The effect size on HbA1C was larger in the mobile phone subgroup (mean difference in HbA1C -5.5 mmol/mol or -0.5% [95% CI -0.7 to -0.3]; P < 0.00001; 280 participants; three RCTs).
- Current interventions do not show adequate evidence for improving depression, HRQOL, weight, or other outcomes. No documented adverse effects.
- Two studies provided limited cost-effectiveness data — one study found costs per patient of less than $140 (in 1997) and another showed no change in health behavior and resource utilization.

References

Professional society guidelines/other:


Peer-reviewed references:


**CMS National Coverage Determinations (NCDs):**


Local Coverage Determinations (LCDs):

No LCDs identified as of the writing of this policy.

Commonly submitted codes

Below are the most commonly submitted codes for the service(s)/item(s) subject to this policy. This is not an exhaustive list of codes. Providers are expected to consult the appropriate coding manuals and bill in accordance with those manuals.

<table>
<thead>
<tr>
<th>CPT Code</th>
<th>Description</th>
<th>Comment</th>
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<tbody>
<tr>
<td>97802</td>
<td>Medical nutrition therapy; initial assessment and intervention, individual, face-to-face with the patient, each 15 minutes</td>
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<tr>
<td>97803</td>
<td>Medical nutrition therapy; re-assessment and intervention, individual, face-to-face with the patient, each 15 minutes</td>
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<tr>
<td>97804</td>
<td>Medical nutrition therapy, group (2 or more individual(s)), each 30 minutes.</td>
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<tr>
<td>98960</td>
<td>Education and training for patient self-management by a qualified, non-physician health care professional using a standardized curriculum, face-to-face with the patient (could include caregiver/family) each 30 minutes; individual patient</td>
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<tr>
<td>98961</td>
<td>Education and training for patient self-management by a qualified, non-physician health care professional using a standardized curriculum, face-to-face with the patient (could include caregiver/family) each 30 minutes; 2-4 patients</td>
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<tr>
<td>98962</td>
<td>Education and training for patient self-management by a qualified, non-physician health care professional using a standardized curriculum, face-to-face with the patient (could include caregiver/family) each 30 minutes; 5-8 patients</td>
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<tr>
<td>99078</td>
<td>Physician or other qualified health care professional qualified by education, training, licensure/regulation (when applicable) educational services rendered to patients in a group setting (eg prenatal, obesity, or diabetic instructions)</td>
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<thead>
<tr>
<th>ICD-10 Code</th>
<th>Description</th>
<th>Comment</th>
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<tbody>
<tr>
<td>E08.xx</td>
<td>Diabetes mellitus due to underlying condition</td>
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<tr>
<td>E09.xx</td>
<td>Drug or chemical induced diabetes mellitus</td>
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<tr>
<td>E10.xx</td>
<td>Type 1 diabetes mellitus</td>
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<tr>
<td>E11.xx</td>
<td>Type 2 diabetes mellitus</td>
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<tr>
<td>E13.xx</td>
<td>Other specified diabetes mellitus</td>
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<tr>
<td>HCPCS Level II Code</td>
<td>Description</td>
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<tr>
<td>G0108</td>
<td>Diabetes outpatient self-management training services (DSMT); individual session, face-to-face with the pt, each 30 minutes of training</td>
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<tr>
<td>G0109</td>
<td>Diabetes outpatient self-management training services (DSMT), group session (2 or more), face-to-face with the pts, each 30 minutes of training per 30 minutes</td>
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<tr>
<td>S9140</td>
<td>Diabetic management program, follow-up visit to non-MD provider</td>
<td>Not covered by</td>
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<tr>
<td>S9141</td>
<td>Diabetic management program, follow-up visit to MD provider</td>
<td>Not covered by</td>
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<tr>
<td>S9455</td>
<td>Diabetic management program, group session</td>
<td>Not covered by</td>
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<tr>
<td>S9460</td>
<td>Diabetic management program, nurse visit</td>
<td>Not covered by</td>
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<tr>
<td>S9465</td>
<td>Diabetic management program, dietitian visit</td>
<td>Not covered by</td>
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