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| BSC2.11 | Diabetes Prevention Program | | |
| Original Policy Date: | March 1, 2016 | Effective Date: | June 1, 2023 |
| Section: | 8.0 Therapy | Page: | Page 1 of 10 |

Policy Statement

- I. Participation in the Diabetes Prevention Program (DPP) may be considered **medically necessary** in individuals when **all** of the following are met:
 - A. Member is at least 18 years old
 - B. Member is overweight (Body Mass Index [BMI] greater than or equal to 24; greater than or equal to 22 if Asian)
 - C. Member has completed the Centers for Disease Control and Prevention "Prediabetes Screening Test" **or** has had a blood test result in the prediabetes range within the past year as evidenced by **any** of the following:
 1. Hemoglobin A1C: 5.7 to 6.4%
 2. Fasting plasma glucose: 100 to 125 milligrams per deciliter (mg/dL)
 3. Two-hour plasma glucose (after a 75 gram [gm] glucose load): 140 to 199 mg/dL
 4. Member was previously diagnosed with gestational diabetes
 - D. Female member is not pregnant

NOTE: Refer to [Appendix A](#) to see the policy statement changes (if any) from the previous version.

Policy Guidelines

The Diabetes Prevention Program (DPP) is limited to once per year and prospective participants should be motivated to complete the program and make the necessary lifestyle changes. Due to the comprehensive lifestyle changes required, insufficiently motivated individuals are not recommended as candidates for the DPP. Individuals must be screened for prediabetes prior to acceptance into the program, ensuring that the individual is sufficiently motivated and meets the eligible criteria. Acceptance into the program for a particular individual is at the sole discretion of the applicable DPP provider.

The official "CDC Prediabetes Screening Test" is available through the following link:
<https://www.cdc.gov/prediabetes/takethetest/>.

The official DPP curriculum and participant handouts are available on the Centers for Disease Control and Prevention (CDC) website:
<https://www.cdc.gov/diabetes/prevention/resources/curriculum.html>

For reimbursement under the Blue Shield of California benefit, the participating program must be recognized by the CDC in its registry of approved programs (Diabetes Prevention Recognition Program, or DPRP).

Coding

Typically, DPP services utilize one of the following CPT codes:

- **0403T:** Preventive behavior change, intensive program of prevention of diabetes using a standardized diabetes prevention program curriculum, provided to individuals in a group setting, minimum 60 minutes, per day
- **99412:** Preventive medicine counseling and/or risk factor reduction intervention(s) provided to individuals in a group setting (separate procedure); approximately 60 minutes

The following CPT codes may be used for DPP services when delivered online:

- **0488T**: Preventive behavior change, online/electronic structured intensive program for prevention of diabetes using a standardized diabetes prevention program curriculum, provided to an individual, per 30 days
- **99421**: Online digital evaluation and management service, for an established patient, for up to 7 days, cumulative time during the 7 days; 5-10 minutes
- **99422**: Online digital evaluation and management service, for an established patient, for up to 7 days, cumulative time during the 7 days; 11-20 minutes
- **99423**: Online digital evaluation and management service, for an established patient, for up to 7 days, cumulative time during the 7 days; 21 or more minutes
- **98970**: Qualified nonphysician health care professional online digital evaluation and management service, for an established patient, for up to 7 days, cumulative time during the 7 days; 5-10 minutes
- **98971**: Qualified nonphysician health care professional online digital evaluation and management service, for an established patient, for up to 7 days, cumulative time during the 7 days; 11-20 minutes
- **98972**: Qualified nonphysician health care professional online digital evaluation and management service, for an established patient, for up to 7 days, cumulative time during the 7 days; 21 or more minutes

CPT codes 99401-99404, 99411, and 99429 (Counseling Services: Risk Factor and Behavioral Change Modification) may be acceptable.

Description

This policy implements the evidence-based Centers for Disease Control and Prevention (CDC) National Diabetes Prevention Program (DPP) for Blue Shield of California (BSC). Utilizing a format approved by the CDC, over 625 organizations nationally offer this year-long DPP service, which emphasizes realistic lifestyle change in a manner that has been shown to reduce the risk of development of Type 2 diabetes among its participants by 58%. Utilizing either in-person or online contact, participants receive mentorship by a trained coach, and work with other participants in small groups on eating healthier foods, incorporating physical activity into their daily routines, and augmenting their coping and problem solving skills.

Related Policies

- Lifestyle Modification Program for Reversing Heart Disease

Benefit Application

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

Some state or federal mandates (e.g., Federal Employee Program [FEP]) prohibits plans from denying Food and Drug Administration (FDA)-approved technologies as investigational. In these instances, plans may have to consider the coverage eligibility of FDA-approved technologies on the basis of medical necessity alone.

Regulatory Status

- N/A

Rationale

Background

Prediabetes is one of the most prevalent premorbid conditions, with an estimated 86 million American adults (about 33% of patients in an average primary care practice) having this early disease process. Progression to overt type 2 (adult-onset) diabetes can be as rapid as five years from the initial rise of blood glucose above normal levels; the connection between diagnosed diabetes and blindness, renal failure, heart disease, stroke, and extremity vascular compromise is well-established in the literature.¹⁻⁴

To reduce the public health impact of type 2 diabetes, Congress authorized the CDC to establish the National Diabetes Prevention Program, a public and privately-sponsored initiative to introduce evidence-based and cost-effective interventions to prevent type 2 diabetes. The study on which the DPP was based was a major multicenter randomized control trial that was designed to determine whether or not modest weight loss through diet and changes in physical activity, or through treatments with metformin, could delay or prevent the onset of type II diabetes in 3,234 study participants who were overweight and whose blood sugar levels were somewhat above normal. Although treatment with metformin did cause a mild decrease in blood sugar levels, a very striking decrease in blood sugar and a 58% reduction in the development of overt diabetes occurred in the lifestyle intervention group that had received intensive training in diet, physical activity, and behavior modification. Of interest also was that the risk of developing overt diabetes in study participants age 60 and over reduced by 71%. In the metformin-only group, the risk for developing diabetes only dropped by 31%. The initial DPP study was reported in the *New England Journal of Medicine* on February 7, 2002.⁵

The formal diabetes prevention program that developed out of this initial research is a year-long program that empowers patients with diabetes to take control of their well-being and overall health. The program is conducted either virtually or in small live groups, and features a trained lifestyle coach who meets with the participants for 16 sessions over six months, and then in six or more follow-up sessions over the next six months. A highly structured curriculum teaches patients ways to incorporate healthier eating and moderate physical activity, as well as problem-solving, stress reduction, and coping skills into their daily lives.

As a part of the DPP, the CDC also established the Diabetes Prevention Recognition Program (DPRP) to recognize and register organizations that have shown they can effectively deliver the diabetes prevention lifestyle intervention approved by the CDC. The DPRP also supervises the quality of diabetes prevention programs, offers technical assistance to programs, and provides public information about their performance.

The DPP program has been studied extensively over time. The Diabetes Prevention Program Research Group followed program participants for 10 years after their successful completion of the program, and found that those who had participated in the lifestyle change program had an overall 34% lower incidence of type II diabetes compared to program non-participants. The potential cost efficacy of the program can be inferred from the statistic that people who carry a diagnosis of diabetes incur on the average 2.3 times the medical expenses of people without diabetes; most of these expenditures are for treatment of complications.

Literature Review

Diabetes Prevention Program Research Group

The landmark study demonstrating the value of intensive behavioral counseling intervention was a National Institutes of Health-funded (NIH) multicenter randomized controlled trial of 3,234 overweight adults at risk for the development of type II diabetes, which compared lifestyle intervention against treatment with a biguanide anti-hyperglycemic agent, metformin.⁵

The study, conducted by the Diabetes Prevention Program Research Group, was entitled "*Reduction in the Incidence of Type II Diabetes with Lifestyle Intervention or Metformin*" and was designed to determine whether or not either of these two interventions would prevent or delay the onset of diabetes. The study also compared the effectiveness of the two interventions and assessed this effectiveness across many factors, including age, sex, race, and ethnic group. Participants in the study were required to be 25 years of age and have a body mass index of 24 or higher; the study also required a baseline blood glucose concentration of 95 to 125 mg per deciliter. Other requirements excluded participants who were taking medication known to alter glucose tolerance, who had illnesses that would reduce life expectancy, or who had physical inability to participate in the trial.

The participants were randomized double-blinded to one of three interventions: standard lifestyle recommendations plus metformin twice daily, standard lifestyle recommendations plus placebo twice daily, or intensive program of lifestyle modification alone. A fourth intervention, use of an agent called troglitazone, was discontinued early because of hepatic toxicity of that agent. In the metformin arm, the dosage of that medication was titrated as appropriate. Adherence to the treatment regimen was assessed by interview and pill counting. For the lifestyle intervention group, written information about diet and personal interventions were provided in written format, and the members attended an annual individual introductory session. All materials encouraged the participants to follow the food guide pyramid and the equivalent of a National Cholesterol Education Program Step 1 diet, with the goal of achieving and maintaining a weight reduction of at least 7% of initial body weight and to engage in physical activity of moderate intensity for at least 150 minutes per week. In addition, a 16 lesson culturally-sensitive curriculum discussing diet, exercise, and behavior modification was taught by case managers individually to participants during the first six months, with follow-up sessions for the following six months designed to reinforce the cultural changes.

The primary outcome of the study was the development of overt diabetes; generally, diabetes was diagnosed if the participant's plasma glucose exceeded 126 mg/dL or exceeded 200 mg/dL during a glucose tolerance test. Activity was assessed using the Modifiable Activity Questionnaire which considered the metabolic equivalent of all activities, the frequency of physical activity in hours per week, and the type of activity. Composition of usual daily caloric intake was assessed by use of the Block food frequency questionnaire.

Adherence to the assigned interventions in the study was closely monitored. At the close of the study, 92.5% of the participants had attended a scheduled visit within the previous five months, connoting excellent participation.

The blinded treatment phase ended a year earlier than was planned, as evidence of efficacy had reached 65% of the planned person-years of observation and showed with statistical significance that the incidence of diabetes had been reduced by 58% with lifestyle intervention alone and by 31% with metformin, as compared with placebo. The cumulative incidence of diabetes at three years was 28% in the placebo group, 21.7% in the metformin group and 14.4% in the lifestyle intervention group; the number needed to treat for three years to prevent one case of diabetes was 6.9 for the lifestyle intervention group and 13.9 for the metformin group. These results were similar across genders and in all racial and ethnic groups. Specifically, for the lifestyle intervention group, 50% of the participants had achieved a weight loss goal of 7% or greater by the end of the first six month's curriculum, and 38% had sustained this weight loss by the end of the study. Activity goals in the lifestyle intervention

group were met by 74% of participants at the close of the first six months, and 58% sustained this level of activity at the close of the study.

The study demonstrated that participation in a structured lifestyle intervention program for the prevention of diabetes was a safe and effective intervention, with considerable benefit over the use of the medication best thought at the time to prevent diabetes, metformin. The study also noted that, at the time, about 10 million persons in the United States resembled the participants in the DPP, considering age, BMI, and blood glucose concentrations; the study authors thus postulated that a diabetes lifestyle intervention program could have great public health benefit across the United States in delaying or preventing the irreversible, highly morbid and costly development of diabetes and its complications.

The principal investigators of the Diabetes Prevention Program Research Group also conducted a 10 year follow-up of diabetes incidence and weight loss in the original DPP study participants, and found that the overall incidence of diabetes in the 10 intervening years was reduced by 34% in the lifestyle intervention group compared to placebo. Interestingly, those participants who were 45 years of age or older at the time of the original study were better able to sustain their weight loss over the 10 intervening years. For those in the original lifestyle intervention group, if diabetes occurred, the delay to onset of overt diabetes was four years compared to placebo.⁷

Other Studies

Numerous other studies were inspired by the work of the Diabetes Prevention Program Research Group, and confirmed the landmark study's design and conclusions, and showed the adaptability of the lifestyle intervention design in numerous settings:

- Johnson et al conducted a systematic review of 17 translational studies confirming that group-based lifestyle interventions resulted not only in significant weight loss with the expected reduction in the incidence of type II diabetes, but also that this weight loss was sustained over time. This study also confirmed the effectiveness of the individual behavioral modules of the lifestyle intervention program used by the DPP study.⁸
- Hamman et al studied the original participants in the DPP Research Group study and found that the primary predictor of reduced diabetes developing in the group was weight loss.⁹
- Ackermann et al reported on the work of the Diabetes Education and Prevention with a Lifestyle Intervention Offered at the YMCA (DEPLOY) study, which was designed to utilize low-cost YMCA staff to provide brief behavioral counseling similar to the DPP study. The study showed that a scaled-down, low cost form of the DPP study was as effective in achieving weight loss.¹⁰
- Ma et al conducted a randomized controlled trial in a primary care clinic which demonstrated that group intervention led by coaching and self-directed DVD interventions achieve weight loss similar to the DPP study.¹¹
- Sepah et al utilized a completely online-based program using social networking, online health coaching, and wireless scales and pedometers to achieve results similar to the Diabetes Prevention Recognition Program model.¹²
- Ratner et al studied the impact of the lifestyle intervention model used in the original DPP study on hypertension and hyperlipidemia and found that high-density lipoprotein cholesterol increased, triglycerides decreased, and hypertension control improved significantly in the lifestyle intervention group. This group was also able to reduce medication use for elevated lipids and hypertension by 25%.¹³
- Herman et al applied a simulation model based on data from the original DPP study demonstrating cost efficacy across all age groups for the lifestyle intervention model. Lifestyle interventions cost approximately \$1100 per quality adjusted life year (QALY) according to the simulation, demonstrating very high value of the intervention compared to its cost.¹⁴

- Trevor et al performed a secondary analysis of the data from the DPP study and found that both lifestyle intervention and metformin reduced the development of metabolic syndrome among the 45% of participants who did not have metabolic syndrome when the study started. The investigators concluded that the DPP lifestyle intervention program may also have significant impact on the development of cardiovascular disease.¹⁵

Summary of Evidence

The prevention of the development of diabetes in those people with significant risk factors can have significant impact on their overall quality of life, productivity, and their overall cost of healthcare. The Diabetes Prevention Program, as developed by the Diabetes Prevention Program Research Group, has demonstrated remarkable efficacy in the avoidance of this disease, excellent compliance among program participants, and significant cost efficiency. Both live and online-based formats for this program are equally effective.

References

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14. Herman WH, Hoerger TJ, Brandle M, et al. The cost-effectiveness of lifestyle modification or metformin in preventing type 2 diabetes in adults with impaired glucose tolerance. *Ann Intern Med*. 2005;142(5):323-332.

15. Trevor J. Orchard, MD; Marinella Temprosa, MS; Ronald Goldberg, MD; Steven Haffner, MD; Robert Ratner, MD; Santica Marcovina, PhD, DSc; Sarah Fowler, PhD, Diabetes Prevention Program Research Group. The Effect of Metformin and Intensive Lifestyle Intervention on the Metabolic Syndrome: The Diabetes Prevention Program Randomized Trial. *Ann Intern Med.* 2005;142(8):611-619.

Documentation for Clinical Review

Please provide the following documentation:

- History and physical and/or consultation notes including:
 - Documentation of age, weight, and Body Mass Index
 - Pregnancy status (if applicable)
 - Documentation of history of gestational diabetes (if applicable)
 - Documentation of any prior history of diabetes
 - Family history of diabetes if applicable
- Completed Centers for Disease Control "Prediabetes Screening Test" form **or** laboratory study results within the past year with results of any of the following:
 - Hemoglobin A1C
 - Fasting plasma glucose
 - Two-hour oral glucose challenge

Coding

This Policy relates only to the services or supplies described herein. Benefits may vary according to product design; therefore, contract language should be reviewed before applying the terms of the Policy.

The following codes are included below for informational purposes. Inclusion or exclusion of a code(s) does not constitute or imply member coverage or provider reimbursement policy. Policy Statements are intended to provide member coverage information and may include the use of some codes for clarity. The Policy Guidelines section may also provide additional information for how to interpret the Policy Statements and to provide coding guidance in some cases.

| Type | Code | Description |
|------|-------|--|
| CPT® | 0403T | Preventive behavior change, intensive program of prevention of diabetes using a standardized diabetes prevention program curriculum, provided to individuals in a group setting, minimum 60 minutes, per day |
| | 0488T | Preventive behavior change, online/electronic structured intensive program for prevention of diabetes using a standardized diabetes prevention program curriculum, provided to an individual, per 30 days |
| | 82947 | Glucose; quantitative, blood (except reagent strip) |
| | 82950 | Glucose; post glucose dose (includes glucose) |
| | 82951 | Glucose; tolerance test (GTT), 3 specimens (includes glucose) |
| | 83036 | Hemoglobin; glycosylated (A1C) |
| | 98970 | Qualified nonphysician health care professional online digital assessment and management, for an established patient, for up to 7 days, cumulative time during the 7 days; 5-10 minutes |
| | 98971 | Qualified nonphysician health care professional online digital assessment and management, for an established patient, for up to 7 days, cumulative time during the 7 days; 11-20 minutes |

| Type | Code | Description |
|-------|-------|---|
| | 98972 | Qualified nonphysician health care professional online digital assessment and management, for an established patient, for up to 7 days, cumulative time during the 7 days; 21 or more minutes |
| | 99401 | Preventive medicine counseling and/or risk factor reduction intervention(s) provided to an individual (separate procedure); approximately 15 minutes |
| | 99402 | Preventive medicine counseling and/or risk factor reduction intervention(s) provided to an individual (separate procedure); approximately 30 minutes |
| | 99403 | Preventive medicine counseling and/or risk factor reduction intervention(s) provided to an individual (separate procedure); approximately 45 minutes |
| | 99404 | Preventive medicine counseling and/or risk factor reduction intervention(s) provided to an individual (separate procedure); approximately 60 minutes |
| | 99411 | Preventive medicine counseling and/or risk factor reduction intervention(s) provided to individuals in a group setting (separate procedure); approximately 30 minutes |
| | 99412 | Preventive medicine counseling and/or risk factor reduction intervention(s) provided to individuals in a group setting (separate procedure); approximately 60 minutes |
| | 99421 | Online digital evaluation and management service, for an established patient, for up to 7 days, cumulative time during the 7 days; 5-10 minutes |
| | 99422 | Online digital evaluation and management service, for an established patient, for up to 7 days, cumulative time during the 7 days; 11-20 minutes |
| | 99423 | Online digital evaluation and management service, for an established patient, for up to 7 days, cumulative time during the 7 days; 21 or more minutes |
| | 99429 | Unlisted preventive medicine service |
| HCPCS | None | |

Policy History

This section provides a chronological history of the activities, updates and changes that have occurred with this Medical Policy.

| Effective Date | Action |
|----------------|---|
| 03/01/2016 | Custom policy |
| 08/01/2017 | Policy revision without position change |
| 01/01/2018 | Coding update |
| 07/01/2018 | Policy revision without position change |
| 06/01/2019 | Policy revision without position change |
| 03/01/2020 | Coding update |
| 06/01/2020 | Annual review. No change to policy statement. |
| 06/01/2021 | Annual review. No change to policy statement. |
| 07/01/2022 | Annual review. No change to policy statement. |
| 06/01/2023 | Annual review. Policy statement updated. |

Definitions of Decision Determinations

Medically Necessary: Services that are Medically Necessary include only those which have been established as safe and effective, are furnished under generally accepted professional standards to treat illness, injury or medical condition, and which, as determined by Blue Shield, are: (a) consistent with Blue Shield medical policy; (b) consistent with the symptoms or diagnosis; (c) not furnished primarily for the convenience of the patient, the attending Physician or other provider; (d) furnished at the most appropriate level which can be provided safely and effectively to the patient; and (e) not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of the Member's illness, injury, or disease.

Investigational/Experimental: A treatment, procedure, or drug is investigational when it has not been recognized as safe and effective for use in treating the particular condition in accordance with generally accepted professional medical standards. This includes services where approval by the federal or state governmental is required prior to use, but has not yet been granted.

Split Evaluation: Blue Shield of California/Blue Shield of California Life & Health Insurance Company (Blue Shield) policy review can result in a split evaluation, where a treatment, procedure, or drug will be considered to be investigational for certain indications or conditions, but will be deemed safe and effective for other indications or conditions, and therefore potentially medically necessary in those instances.

Prior Authorization Requirements and Feedback (as applicable to your plan)

Within five days before the actual date of service, the provider must confirm with Blue Shield that the member's health plan coverage is still in effect. Blue Shield reserves the right to revoke an authorization prior to services being rendered based on cancellation of the member's eligibility. Final determination of benefits will be made after review of the claim for limitations or exclusions.

Questions regarding the applicability of this policy should be directed to the Prior Authorization Department at (800) 541-6652, or the Transplant Case Management Department at (800) 637-2066 ext. 3507708 or visit the provider portal at www.blueshieldca.com/provider.

We are interested in receiving feedback relative to developing, adopting, and reviewing criteria for medical policy. Any licensed practitioner who is contracted with Blue Shield of California or Blue Shield of California Promise Health Plan is welcome to provide comments, suggestions, or concerns. Our internal policy committees will receive and take your comments into consideration.

For utilization and medical policy feedback, please send comments to: MedPolicy@blueshieldca.com

Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. Blue Shield of California may consider published peer-reviewed scientific literature, national guidelines, and local standards of practice in developing its medical policy. Federal and state law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over medical policy and must be considered first in determining covered services. Member contracts may differ in their benefits. Blue Shield reserves the right to review and update policies as appropriate.

Appendix A

| POLICY STATEMENT | |
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| BEFORE Red font: Verbiage removed | AFTER Blue font: Verbiage Changes/Additions |
| <p>Diabetes Prevention Program BSC2.11</p> <p>Policy Statement:</p> <ol style="list-style-type: none"> I. Participation in the Diabetes Prevention Program (DPP) may be considered medically necessary in patients when all of the following are met: <ol style="list-style-type: none"> A. Member is at least 18 years old B. Member is overweight (Body Mass Index [BMI] greater than or equal to 24; greater than or equal to 22 if Asian) C. Member has completed the Centers for Disease Control and Prevention "Prediabetes Screening Test" or has had a blood test result in the prediabetes range within the past year as evidenced by any of the following: <ol style="list-style-type: none"> 1. Hemoglobin A1C: 5.7 to 6.4% 2. Fasting plasma glucose: 100 to 125 milligrams per deciliter (mg/dL) 3. Two-hour plasma glucose (after a 75 gram [gm] glucose load): 140 to 199 mg/dL 4. Member was previously diagnosed with gestational diabetes D. Female member is not pregnant | <p>Diabetes Prevention Program BSC2.11</p> <p>Policy Statement:</p> <ol style="list-style-type: none"> I. Participation in the Diabetes Prevention Program (DPP) may be considered medically necessary in individuals when all of the following are met: <ol style="list-style-type: none"> A. Member is at least 18 years old B. Member is overweight (Body Mass Index [BMI] greater than or equal to 24; greater than or equal to 22 if Asian) C. Member has completed the Centers for Disease Control and Prevention "Prediabetes Screening Test" or has had a blood test result in the prediabetes range within the past year as evidenced by any of the following: <ol style="list-style-type: none"> 1. Hemoglobin A1C: 5.7 to 6.4% 2. Fasting plasma glucose: 100 to 125 milligrams per deciliter (mg/dL) 3. Two-hour plasma glucose (after a 75 gram [gm] glucose load): 140 to 199 mg/dL 4. Member was previously diagnosed with gestational diabetes D. Female member is not pregnant |