

BSC2.11	Diabetes Prevention Program		
Original Policy Date:	March 1, 2016	Effective Date:	June 1, 2025
Section:	8.0 Therapy	Section:	8.0 Therapy

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: <u>https://www.cdc.gov/prediabetes/risktest/index.html</u>.

The official DPP curriculum and participant handouts are available on the Centers for Disease Control and Prevention (CDC) website: <u>https://www.cdc.gov/diabetes-prevention/php/lifestyle-change-resources/t2-</u> <u>curriculum.html?CDC_AAref_Val=</u>

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

See the <u>Codes table</u> for details.

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 member health services contract language. To the extent there are any conflicts between this Medical Policy and the member health services 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 law prohibit health plans from denying FDA-approved Healthcare Services as investigational or experimental. In these instances, Blue Shield of California may be obligated to determine if these FDA-approved Healthcare Services are Medically Necessary.

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

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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

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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

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- 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.

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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)
 - o 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

The list of codes in this Medical Policy is intended as a general reference and may not cover all codes. Inclusion or exclusion of a code(s) does not constitute or imply member coverage or provider reimbursement policy. Page 7 of 10

Type	Code	Description		
		Preventive behavior change intensive program of prevention of		
	0403T	diabetes using a standardized diabetes prevention program curriculum		
		provided to individuals in a group setting, minimum 60 minutes, per day		
		Preventive behavior change, online/electronic structured intensive		
	0488T	program for prevention of diabetes using a standardized diabetes		
	04001	prevention program curriculum, provided to an individual, per 30 days		
	82947	Glucose: guantitative blood (except reagent strip)		
	82950	Glucose: post glucose dose (includes glucose)		
	82951	Glucose: tolerance test (GTT). 3 specimens (includes alucose)		
	83036	Hemoglobin: glycosylated (A1C)		
	05050	Nonphysician audified health care professional online diaital		
	98970	assessment and management for an established nations for up to 7		
		days, cumulative time during the 7 days; 5-10 minutes (Code revision		
		1/1/2025)		
		Nonphysician qualified health care professional online digital		
	98971	assessment and management, for an established patient, for up to 7		
	505/1	days, cumulative time during the 7 days; 11-20 minutes <i>(Code revision</i>		
		1/1/2025)		
		Nonphysician qualified health care professional online digital		
	98972	assessment and management, for an established patient, for up to 7		
	50572	days, cumulative time during the 7 days; 21 or more minutes <i>(Code</i>		
		revision 1/1/2025)		
		Preventive medicine counseling and/or risk factor reduction		
	99401	intervention(s) provided to an individual (separate procedure);		
CPT		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 50 minutes		
	00/10	preventive medicine counseling and/or risk factor reduction		
	99412	intervention(s) provided to individuals in a group setting (separate		
		Online divital evaluation and management convice for an established		
	99421	online digital evaluation and management service, for an established		
	00/22	Online digital evaluation and management corvice, for an established		
		patient for up to 7 days, sumulative time during the 7 days; 11-20		
	99422	minutos		
	99423	Online digital evaluation and management convice for an established		
		online digital evaluation and management service, for an established		
		minutes		
	00/.20	minutes		
	33423 C0001	Coordinated care fee, initial rate		
HCPCS	03001	Coordinated care ree, initial rate		
	69002	Coordinated care ree		
	G9003	Coordinated care fee, risk adjusted high, initial		

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Туре	Code	Description
	G9004	Coordinated care fee, risk adjusted low, initial
	G9005	Coordinated care fee risk adjusted maintenance
	G9006	Coordinated care fee, home monitoring

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.
06/01/2024	Annual review. No change to policy statement.
02/01/2025	Coding update
06/01/2025	Annual review. No change to policy statement.

Definitions of Decision Determinations

Healthcare Services: For the purpose of this Medical Policy, Healthcare Services means procedures, treatments, supplies, devices, and equipment.

Medically Necessary: Healthcare 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 of California, are: (a) consistent with Blue Shield of California 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 member; 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 or Experimental: Healthcare Services which do not meet ALL of the following five (5) elements are considered investigational or experimental:

- A. The technology must have final approval from the appropriate government regulatory bodies.
 - This criterion applies to drugs, biological products, devices and any other product or procedure that must have final approval to market from the U.S. Food and Drug Administration ("FDA") or any other federal governmental body with authority to regulate the use of the technology.
 - Any approval that is granted as an interim step in the FDA's or any other federal governmental body's regulatory process is not sufficient.
 - The indications for which the technology is approved need not be the same as those which Blue Shield of California is evaluating.

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- B. The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes.
 - The evidence should consist of well-designed and well-conducted investigations published in peer-reviewed journals. The quality of the body of studies and the consistency of the results are considered in evaluating the evidence.
 - The evidence should demonstrate that the technology can measure or alter the physiological changes related to a disease, injury, illness, or condition. In addition, there should be evidence, or a convincing argument based on established medical facts that such measurement or alteration affects health outcomes.
- C. The technology must improve the net health outcome.
 - The technology's beneficial effects on health outcomes should outweigh any harmful effects on health outcomes.
- D. The technology must be as beneficial as any established alternatives.
 - The technology should improve the net health outcome as much as, or more than, established alternatives.
- E. The improvement must be attainable outside the investigational setting.
 - When used under the usual conditions of medical practice, the technology should be reasonably expected to satisfy Criteria C and D.

Feedback

Blue Shield of California is 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. Our medical policies are available to view or download at www.blueshieldca.com/provider.

For medical policy feedback, please send comments to: <u>MedPolicy@blueshieldca.com</u>

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 <u>www.blueshieldca.com/provider</u>.

Disclaimer: 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 member health services contract language, including definitions and specific contract provisions/exclusions, take precedence over medical policy and must be considered first in determining covered services. Member health services contracts may differ in their benefits. Blue Shield reserves the right to review and update policies as appropriate.

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Appendix A

POLICY STATEMENT				
(No change)				
BEFORE	AFTER			
Diabetes Prevention Program BSC2.11	Diabetes Prevention Program BSC2.11			
 Policy Statement: Participation in the Diabetes Prevention Program (DPP) may be considered medically necessary in individuals when all of the following are met: Member is at least 18 years old Member is overweight (Body Mass Index [BMI] greater than or equal to 24; greater than or equal to 22 if Asian) 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: Hemoglobin AIC: 5.7 to 6.4% Fasting plasma glucose: 100 to 125 milligrams per deciliter (mg/dL) Two-hour plasma glucose (after a 75 gram [gm] glucose load): 140 to 199 mg/dL 	 Policy Statement: Participation in the Diabetes Prevention Program (DPP) may be considered medically necessary in individuals when all of the following are met: Member is at least 18 years old Member is overweight (Body Mass Index [BMI] greater than or equal to 24; greater than or equal to 22 if Asian) 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: Hemoglobin A1C: 5.7 to 6.4% Fasting plasma glucose: 100 to 125 milligrams per deciliter (mg/dL) Two-hour plasma glucose (after a 75 gram [gm] glucose load): 140 to 199 mg/dL 			
D. Female member is not pregnant	D. Female member is not pregnant			