HIGHMARK Delaware
HEALTH OPTIONS

CLINICAL MEDICAL POLICY	
Policy Name:	Long-Term Use Continuous Glucose Monitoring of Interstitial Fluid
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Responsible Department(s):	Medical Management
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Products:	Highmark Health Options Medicaid
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Page Number(s):	1 of 21

DISCLAIMER

Highmark Health Options medical policy is intended to serve only as a general reference resource regarding coverage for the services described. This policy does not constitute medical advice and is not intended to govern or otherwise influence medical decisions.

POLICY STATEMENT

Highmark Health Options may provide coverage under the durable medical equipment (DME) benefits of the Company's Medicaid products for medically necessary long-term use of continuous glucose monitors.

This policy is designed to address medical necessity guidelines that are appropriate for the majority of individuals with a particular disease, illness or condition. Each person's unique clinical circumstances warrant individual consideration, based upon review of applicable medical records.

The qualifications of the policy will meet the standards of the National Committee for Quality Assurance (NCQA) and the Delaware Department of Health and Social Services (DHSS) and all applicable state and federal regulations.

DEFINITIONS

Hypoglycemic Unawareness – A complication in which a diabetic patient is unaware of a precipitous drop in blood sugar (due to failure to trigger the secretion of epinephrine that would normally generate characteristic symptoms of hypoglycemia that serve to warn the patient of decreasing blood glucose levels). Hypoglycemia unawareness may result in prolonged exposure to hypoglycemia, resulting in a seizure, loss of consciousness, or brain damage. The development of hypoglycemia unawareness may also make intensified blood glucose control more difficult and put the patient at risk for severe hypoglycemia-related complications.

Continuous Glucose Monitoring Devices (CGM) – Devices that measure interstitial glucose at regular intervals throughout the day, producing data that shows the trends in glucose measurements.

Hypoglycemia – A condition characterized by abnormally low blood glucose levels, usually less than 70 mg/dL. Symptoms may include shakiness, nervousness, sweating, chills and clamminess, confusion including delirium, hunger, nausea, and tachycardia.

Severe Hypoglycemia – A condition that is the result of a blood sugar level that drops below 35-40 mg/dL. Assistance is required by another individual to treat this condition. If left untreated, permanent neurological damage and death can occur. Symptoms may include seizures or convulsions, loss of consciousness, coma, and hypothermia.

Therapeutic Continuous Glucose Monitors – Per CMS, this is a continuous glucose monitoring system that replaces blood glucose monitors for diabetes treatment decisions as opposed to using CGM as an adjunct to regular blood glucose monitors.

Artificial Pancreas Device System – This system consists of a series of devices (e.g., continuous glucose monitor, blood glucose device and an insulin pump, and a computer algorithm that communicates with all of these devices. Artificial pancreas systems are also known as closed-loop system or autonomous systems for glucose control.

PROCEDURES

This medical policy addresses the long-term use of the continuous glucose monitor (CGM) as part of the durable medical equipment (DME) benefit. The provider use of short-term CGM (3 to 7 days) is a covered service and is not addressed in this policy.

1. **Continuous Glucose Monitors**
   For long-term use of continuous glucose monitors, the following medical necessity criteria must be met:
   A. The patient must be diagnosed with Type 1 diabetes and must be receiving insulin therapy; AND
   B. The CGM device must be FDA-approved and ordered by a professional provider; AND
   C. The patient has been using a home blood glucose monitor (BGM) and performing frequent (four or more times a day) BGM testing; AND
   D. The patient is insulin treated with multiple (three or more) daily injections of insulin or a continuous insulin infusion pump; AND

E. The provider must assess and document in the medical record that the patient is motivated to control his or her diabetes and has the ability to operate and use the device; AND
F. Prior to the ordering of the CGM device, the patient must have had a face-to-face diabetic evaluation performed by the treating physician within the previous six months; AND
G. The patient must have a face-to-face assessment with the treating physician every six months that documents the patient's compliance with the CGM (use of the device for at least 70% [e.g., 5 out of 7 days] of the time based on log data), that use of the CGM is effective in attaining positive health outcomes, and the patient is adhering to the diabetic treatment plan; AND
H. The patient has completed a comprehensive diabetic education program; AND
I. The patient's medical record must have documentation by an endocrinologist of recurrent unexplained, severe hypoglycemia (blood glucose levels ≤ 50 mg/dL) in a 30-day period with hypoglycemic unawareness despite appropriate modifications in insulin regimen and compliance with frequent self-monitoring (at least 4 finger sticks per day). Acceptable forms of severe hypoglycemia would include:
    1) Recurrent unexplained severe hypoglycemic unawareness demonstrated by reports of short-term (72-hour) CGM and/or an individual comprehensive patient's log of self-monitored blood sugars; AND
    2) A completed Hypoglycemia Awareness Questionnaire (*see Attachment D*); AND
J. The patient has been unable to achieve an A1c level of 8% or less for two consecutive readings within the last 12 months with evidence of cardiovascular, oncologic, neurologic, or metabolic comorbidities; OR
K. Macrovascular or microvascular diabetic complications, e.g., retinopathy, neuropathy, or nephropathy; OR
L. Patients with Type 1 diabetes who are pregnant (pre-gestational), and their diabetes is poorly controlled. Symptoms of poorly controlled Type 1 diabetes would include unexplained hypoglycemic episodes, hypoglycemic unawareness, suspected postprandial hyperglycemia, and diabetic ketoacidosis.

NOTE: Coverage for continuous glucose monitoring is intended to complement, not replace, the information obtained from finger-stick values.

2. **Covered CGM Devices**
    A. Standard/Nontherapeutic Continuous Glucose Monitors (A9276, A9277, A9278)
    This type of CGM must be approved by the FDA for use as adjunctive devices which complement, not replace, data from blood glucose monitors. Examples: Medtronic MiniMed.

    Component Replacement
    - Code A9276 is reimbursable per unit; one unit equals a one-day supply. Sensor replacement is based on manufacturer recommendation. Typically sensor replacement is between 3 and 7 days.
    - Code A9277 (transmitter device) is limited to the device manufacturer's recommended replacement guidelines, not to exceed 4 in 12 months
    - Code A9278 (receiver device) is limited to 1 device in a 12-month period

NOTE: Transmitter devices (A9277) with non-replaceable batteries (e.g., silver oxide) may require more frequent replacement (e.g., every 6 months).

B. Therapeutic Continuous Glucose Monitors (K0553, K0554)
This type of device must be approved by the FDA are used to replace other blood glucose monitoring systems and to make diabetic treatment decisions. Examples: Dexcom G5 or G-6 and the Freestyle Libre Flash System.

Please reference the Clinical Pharmacy policy CP-206.156-MD-PA, Freestyle Libre CGM system.

The supply allowance for supplies used with a therapeutic CGM system encompasses all items necessary for the use of the device and includes but is not limited to: CGM sensor, CGM transmitter, home BGM and related BGM supplies (test strips, lancets, lancing device, and calibration solutions) and batteries. Supplies or accessories billed separately will be denied as unbundling.

Therapeutic CGM systems are to be billed using K0553 and K0554 (e.g., Dexcom G5, Dexcom G-6, and FreeStyle Libre Flash System). These CGM devices are replacements for the standard blood glucose monitor and associated supplies. In order to be reimbursed for these CGM systems, claims are to be submitted using the appropriate codes, K0553 & K0554. Do not submit codes A9276, A9277, or A9278.

K0553 describes a supply allowance used with therapeutic CGM devices. This allowance includes all items necessary for the use of the device and includes but is not limited to: CGM sensor, CGM transmitter, home blood glucose monitor along with related monitor supplies (test strips, lancing device, and calibration solutions) and batteries. K0553 is not to be used for supplies used with the CGM coded as A9278. K0554 describes a continuous glucose monitor that is to be therapeutic (Dexcom G5, Dexcom G6 and the FreeStyle Libre Flash system).

There is no coverage for supplies and accessories used with equipment that is not classified as DME. Coverage of a CGM system supply allowance (K0553) is available for those therapeutic CGM systems where the patient uses a receiver classified as DME to display glucose data. In addition, coverage is available for a CGM system supply allowance if a non-DME device (watch, smartphone, tablet, laptop computer, etc.) is used in conjunction with the durable CGM receiver (K0554). The following are examples of this provision:

- Coverage of a CGM supply allowance is available where a patient uses a durable CGM receiver to display their glucose data and also transmits that data to a caregiver through a smart phone or other non-DME receiver.
- Coverage of a CGM system supply allowance is available where a patient uses a durable CGM receiver on some days to review their glucose data but may also use a non-DME device on other days.
- If a patient never uses a DME receiver for a therapeutic CGM, the supply allowance is not covered.

Smart devices are non-covered because they do not meet the definition of DME (i.e., not primarily medical in nature and are useful in the absence of illness). Claims for smart devices must be billed using code A9270 (noncovered item or service).

3. Contraindications
   No contraindications were identified. There are warnings related to the use of several medications, such as acetaminophen, causing incorrect findings.

4. **Noncovered Implantable CGM**
   Eversense®, an implantable CGM system, is considered investigational and therefore not medically necessary. The safety of the device has not been established in published scientific literature.

5. When personal continuous glucose monitors are not covered
   Continuous glucose monitors are not covered for conditions other than those listed above because the scientific evidence has not been established. Conditions not covered include Type 2 diabetes, pregnancy with Type 2 diabetes or gestational diabetes, nondiabetic patients following gastric bypass surgery, or patients with nesidioblastosis (primary islet cell hypertrophy). Requests for CGM in these types of situations will be denied as not medically necessary.

   Remote glucose monitoring is unproven and considered not medically necessary for managing patients with diabetes. There is insufficient evidence in the clinical literature to conclude that remote glucose monitoring demonstrates improvement in clinical outcomes. Remote glucose monitoring and remote, mobile communication devices that use a wireless connection to transmit glucose levels are not considered medically necessary.

   Replacement of CGM systems are not covered while the device is still covered under the manufacturer's warranty; nor is the replacement of a properly functioning CGM system when additional/special features are not medically necessary or expected to contribute towards improving the patient's glycemic control and/or reducing the incidence of hyper- or hypoglycemia.

6. Durable Medical Equipment (DME)
   CGM devices are available by prescription only and are considered DME. Insertion of the sensors into the subcutaneous tissue can be performed by the patient or caregiver after training by a professional health care provider.

7. Post-payment Audit Statement
   The medical record must include documentation that reflects the medical necessity criteria and is subject to audit by Highmark Health Options at any time pursuant to the terms of your provider agreement.

8. Place of Service
   The place of service is outpatient under the DME benefit.

GOVERNING BODIES APPROVAL

There are several continuous glucose monitoring devices approved by the FDA.

CMS
CMS considers CGM precautionary and therefore not covered under the DME benefit.
On January 12, 2017, CMS established benefit coverage for the therapeutic CGM. CMS Ruling 1682R classified CGM systems into therapeutic and non-therapeutic. This system is a replacement for finger stick blood glucose testing and requires at least 2 daily finger stick tests for calibration purposes, but additional

fingersticks are not necessary because treatment decisions can be made based on device readings. CMS provides coverage of therapeutic CGMs because the information obtained can be used to make treatment decisions. Because the information obtained from the device can necessitate patient action, the device meets the CMS definition of DME. All other CGMs approved by the FDA for use as adjunctive devices to complement, not replace, information obtained from a blood glucose monitor are referred to as 'non-therapeutic' CGMs.

CODING REQUIREMENTS

Procedure Codes

HCPCS Codes	Description
A9276	Sensor; invasive (e.g., subcutaneous), disposable, for use with interstitial continuous glucose monitoring system, one unit = 1 day supply
A9277	Transmitter; external, for use with interstitial continuous glucose monitoring system
A9278	Receiver (monitor); external, for use with interstitial continuous glucose monitoring system
K0553	Supply allowance for therapeutic continuous glucose monitor (CGM), includes all supplies and accessories, 1 month supply = 1 unit of service
K0554	Receiver (monitor), dedicated, for use with therapeutic continuous glucose monitor system

Sensors used with a continuous glucose monitoring device, or a combination infusion and monitoring device, are limited to a 90-day supply purchase every 90 days.

- Code A9276 is reimbursable per unit; one unit equals one day supply
- Code A9277 (transmitter device) is limited to the device manufacturer's recommended replacement guidelines, not to exceed 4 in 12 months. Note: Transmitter devices with non-replaceable batteries (e.g., silver oxide) may require more frequent replacement (e.g., every 6 months).
- Code A9278 (receiver device) is limited to one device in a 12-month period
- Therapeutic CGM devices replace a standard home blood glucose monitor (HCPCS codes E0607, E2100, E2101) and related supplies (HCPCS codes A4233-A4236, A4244-A4247, A4250, A4253, A4255-A4259). Claims for standard home glucose monitors and all related supplies, billed in addition to a CGM system and associated supply allowance, will be denied as unbundling.

In the following table, a Column II code is included in the allowance for the corresponding Column I code when provided at the same time.

Column I	Column II
E0607	A4233, A4234, A4235, A4236
E2100	A4233, A4234, A4235, A4236
E2101	A4233, A4234, A4235, A4236
K0553	E0607, E2100, E2101, A4233-A4236, A4244-A4247, A4250, A4253, A4255-A4259

Diagnosis Codes

ICD-10 Codes	Description
E08.39	Diabetes mellitus due to underlying condition with other diabetic ophthalmic complication
E08.40	Diabetes mellitus due to underlying condition with diabetic neuropathy unspecified
E08.41	Diabetes mellitus due to underlying condition with diabetic mononeuropathy
E08.42	Diabetes mellitus due to underlying condition with diabetic polyneuropathy
E08.43	Diabetes mellitus due to underlying condition with diabetic autonomic (poly) neuropathy
E08.44	Diabetes mellitus due to underlying condition with diabetic amyotrophy
E08.49	Diabetes mellitus due to underlying condition with other diabetic neurological complication
E08.51	Diabetes mellitus due to underlying condition with diabetic peripheral angiopathy without gangrene
E08.610	Diabetes mellitus due to underlying condition with diabetic neuropathic arthropathy
E08.618	Diabetes mellitus due to underlying condition with other diabetic arthropathy
E08.620	Diabetes mellitus due to underlying condition with foot ulcer
E08.622	Diabetes mellitus due to underlying condition with other skin ulcer
E08.628	Diabetes mellitus due to underlying condition with other skin complications
E08.630	Diabetes mellitus due to underlying condition with periodontal disease
E08.638	Diabetes mellitus due to underlying condition with other oral complications
E08.641	Diabetes mellitus due to underlying condition with hypoglycemia with coma
E08.65	Diabetes mellitus due to underlying condition with hyperglycemia
E08.69	Diabetes mellitus due to underlying condition with other specified complication
E08.8	Diabetes mellitus due to underlying condition with unspecified complications
E08.9	Diabetes mellitus due to underlying condition without complications
E09.01	Drug or chemical induced diabetes mellitus with hyperosmolarity with coma
E09.10	Drug or chemical induced diabetes mellitus with ketoacidosis without coma
E09.11	Drug or chemical induced diabetes mellitus with ketoacidosis with coma
E09.21	Drug or chemical induced diabetes mellitus with diabetic nephropathy
E09.311	Drug or chemical induced diabetes mellitus with unspecified diabetic retinopathy with macular edema
E09.319	Drug or chemical induced diabetes mellitus with unspecified diabetic with retinopathy without macular edema
E09.39	Drug or chemical induced diabetes mellitus with other diabetic ophthalmic complication
E09.40	Drug or chemical induced diabetes mellitus with neurological complications with diabetic neuropathy, unspecified
E09.41	Drug or chemical induced diabetes mellitus with neurological complications with diabetic mononeuropathy
E09.42	Drug or chemical induced diabetes mellitus with neurological complications with diabetic polyneuropathy
E09.43	Drug or chemical induced diabetes mellitus with neurological complications with diabetic autonomic (poly) neuropathy
E09.44	Drug or chemical induced diabetes mellitus with neurological complications with diabetic amyotrophy

E09.49	Drug or chemical induced diabetes mellitus with neurological complications with other diabetic neurological complication
E09.51	Drug or chemical induced diabetes mellitus with diabetic peripheral angiopathy without gangrene
E09.610	Drug or chemical induced diabetes mellitus with diabetic neuropathic arthropathy
E09.618	Drug or chemical induced diabetes mellitus with other diabetic arthropathy
E09.620	Drug or chemical induced diabetes mellitus with diabetic dermatitis
E09.622	Drug or chemical induced diabetes mellitus with other skin ulcer
E09.628	Drug or chemical induced diabetes mellitus with other skin complications
E09.630	Drug or chemical induced diabetes mellitus with periodontal disease
E09.638	Drug or chemical induced diabetes mellitus with other oral complications
E09.641	Drug or chemical induced diabetes mellitus with hypoglycemia with coma
E09.649	Drug or chemical induced diabetes mellitus with hypoglycemia without coma
E09.65	Drug or chemical induced diabetes mellitus with hyperglycemia
E09.69	Drug or chemical induced diabetes mellitus with other specified complication
E09.8	Drug or chemical induced diabetes mellitus with unspecified complications
E09.9	Drug or chemical induced diabetes mellitus without complication
E10.10	Type 1 diabetes mellitus with ketoacidosis without coma
E10.11	Type 1 diabetes mellitus with ketoacidosis with coma
E10.21	Type 1 diabetes mellitus with other diabetic kidney complication
E10.22	Type 1 diabetes mellitus with diabetic chronic kidney disease
E10.29	Type 1 diabetes mellitus with other diabetic kidney complication
E10.311	Type 1 diabetes mellitus with unspecified diabetic retinopathy with macular edema
E10.319	Type 1 diabetes mellitus with unspecified diabetic retinopathy without macular edema
E10.3211	Type 1 diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, right eye
E10.3212	Type 1 diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, left eye
E10.3213	Type 1 diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, bilateral
E10.3291	Type 1 diabetes mellitus with mild nonproliferative diabetic retinopathy without macular edema, right eye
E10.3292	Type 1 diabetes mellitus with mild nonproliferative diabetic retinopathy without macular edema, left eye
E10.3293	Type 1 diabetes mellitus with mild nonproliferative diabetic retinopathy without macular edema, bilateral
E10.3311	Type 1 diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, right eye
E10.3312	Type 1 diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, left eye
E10.3313	Type 1 diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, bilateral
E10.3391	Type 1 diabetes mellitus with moderate nonproliferative diabetic retinopathy without macular edema, right eye
E10.3392	Type 1 diabetes mellitus with mild nonproliferative diabetic retinopathy without macular edema, left eye

E10.3393	Type 1 diabetes mellitus with mild nonproliferative diabetic retinopathy without macular edema, bilateral
E10.3411	Type 1 diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, right eye
E10.3412	Type 1 diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, left eye
E10.3413	Type 1 diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, bilateral
E10.3491	Type 1 diabetes mellitus with severe nonproliferative diabetic retinopathy without macular edema, right eye
E10.3492	Type 1 diabetes mellitus with severe nonproliferative diabetic retinopathy without macular edema, left eye
E10.3493	Type 1 diabetes mellitus with severe nonproliferative diabetic retinopathy without macular edema, bilateral
E10.3511	Type 1 diabetes mellitus with proliferative diabetic retinopathy with macular edema, right eye
E10.3512	Type 1 diabetes mellitus with proliferative diabetic retinopathy with macular edema, left eye
E10.3513	Type 1 diabetes mellitus with proliferative diabetic retinopathy with macular edema, bilateral
E10.3521	Type 1 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment involving the macula, right eye
E10.3522	Type 1 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment involving the macula, left eye
E10.3523	Type 1 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment involving the macula, bilateral
E10.3531	Type 1 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment not involving the macula, right eye
E10.3532	Type 1 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment not involving the macula, left eye
E10.3533	Type 1 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment not involving the macula, bilateral
E10.3541	Type 1 diabetes mellitus with proliferative diabetic retinopathy with combined traction retinal detachment and rhegmatogenous retinal detachment, right eye
E10.3542	Type 1 diabetes mellitus with proliferative diabetic retinopathy with combined traction retinal detachment and rhegmatogenous retinal detachment,
E10.3543	Type 1 diabetes mellitus with proliferative diabetic retinopathy with combined traction retinal detachment and rhegmatogenous retinal detachment,
E10.3551	Type 1 diabetes mellitus with stable proliferative diabetic retinopathy, right eye
E10.3552	Type 1 diabetes mellitus with stable proliferative diabetic retinopathy, left eye
E10.3553	Type 1 diabetes mellitus with stable proliferative diabetic retinopathy, bilateral
E10.3591	Type 1 diabetes mellitus with proliferative diabetic retinopathy without macular edema, right eye
E10.3592	Type 1 diabetes mellitus with proliferative diabetic retinopathy without macular edema, left eye
E10.3593	Type 1 diabetes mellitus with proliferative diabetic retinopathy without macular edema, bilateral

E10.36	Type 1 diabetes mellitus with diabetic cataract
E10.37X1	Type 1 diabetes mellitus with diabetic macular edema, resolved following treatment, right eye
E10.37X2	Type 1 diabetes mellitus with diabetic macular edema, resolved following treatment, left eye
E10.37X3	Type 1 diabetes mellitus with diabetic macular edema, resolved following treatment, bilateral
E10.39	Type 1 diabetes mellitus with other diabetic ophthalmic complication
E10.40	Type 1 diabetes mellitus with diabetic neuropathy, unspecified
E10.41	Type 1 diabetes mellitus with diabetic mononeuropathy
E10.42	Type 1 diabetes mellitus with diabetic polyneuropathy
E10.43	Type 1 diabetes mellitus with diabetic autonomic (poly) neuropathy
E10.44	Type 1 diabetes mellitus with diabetic amyotrophy
E10.49	Type 1 diabetes mellitus with other diabetic neurologic complication
E10.51	Type 1 diabetes mellitus with diabetic angiopathy without gangrene
E10.52	Type 1 diabetes mellitus with diabetic peripheral angiopathy with gangrene
E10.59	Type 1 diabetes mellitus with other circulatory complications
E10.610	Type 1 diabetes mellitus with diabetic neuropathic arthropathy
E10.618	Type 1 diabetes mellitus with other diabetic arthropathy
E10.618	Type 1 diabetes mellitus with other diabetic arthropathy
E10.620	Type 1 diabetes mellitus with diabetic dermatitis
E10.621	Type 1 diabetes mellitus with foot ulcer
E10.622	Type 1 diabetes mellitus with other skin ulcer
E10.628	Type 1 diabetes mellitus with other skin complications
E10.630	Type 1 diabetes mellitus with periodontal disease
E10.638	Type 1 diabetes mellitus with other oral complications
E10.641	Type 1 diabetes mellitus with hypoglycemia with coma
E10.649	Type 1 diabetes mellitus with hypoglycemia without coma
E10.65	Type 1 diabetes mellitus with hyperglycemia
E10.69	Type 1 diabetes mellitus with other specified complications
E10.8	Type 1 diabetes mellitus with unspecified complications
E10.9	Type 1 diabetes mellitus with without complications
024.0	Pre-existing diabetes mellitus, Type 1, in pregnancy, childbirth and puerperium
024.01	Pre-existing diabetes mellitus, Type 1, in pregnancy
024.011	Pre-existing diabetes mellitus, Type 1, in pregnancy, first trimester
024.012	Pre-existing diabetes mellitus, Type 1, in pregnancy, second trimester
024.013	Pre-existing diabetes mellitus, Type 1, in pregnancy, third trimester
024.019	Pre-existing diabetes mellitus, Type 1, in pregnancy, unspecified trimester
024.02	Pre-existing diabetes mellitus, Type 1, in childbirth
O24.03	Pre-existing diabetes mellitus, Type 1, in the puerperium
Z79.4	Long term (current) use of insulin

Non-covered Diagnosis Codes
Requests for the following procedures require review by a Medical Director

ICD-10 Codes	Description
E16.9	Disorder of pancreatic internal secretion, unspecified [nesidioblastosis]
O24.111	Pre-existing diabetes mellitus, Type 2, in pregnancy, first trimester
O24.112	Pre-existing diabetes mellitus, Type 2, in pregnancy, second trimester
O24.113	Pre-existing diabetes mellitus, Type 2, in pregnancy, third trimester
O24.119	Pre-existing diabetes mellitus, Type 2, in pregnancy, unspecified trimester
O24.12	Pre-existing diabetes mellitus, Type 2, in childbirth
O24.13	Pre-existing diabetes mellitus, Type 2, in puerperium
O24.410	Gestational diabetes mellitus in pregnancy, diet controlled
O24.414	Gestational diabetes mellitus in pregnancy, insulin controlled
O24.419	Gestational diabetes mellitus in pregnancy, unspecified control
O24.420	Gestational diabetes mellitus in childbirth, diet controlled
O24.424	Gestational diabetes mellitus in childbirth, insulin controlled
O24.429	Gestational diabetes mellitus in childbirth, unspecified control
O24.430	Gestational diabetes mellitus in the puerperium, diet controlled
O24.434	Gestational diabetes mellitus in puerperium, insulin controlled
O24.439	Gestational diabetes mellitus in puerperium, unspecified control

REIMBURSEMENT

Participating facilities will be reimbursed per their Highmark Health Options contract.

SUMMARY OF LITERATURE

Diabetes mellitus is a well-known chronic disabling disease that affects an estimated 26 million people in the United States (ADA, 2011.) The Diabetes Control and Complications Trial highlighted the importance of tightly controlling glycemia in order to prevent long-term complications (Fleisher et al., 1993).

Several devices have been developed that measure the glucose in the interstitial fluid that automatically measures glucose values twenty-four hours a day. The data produced show trends in glucose measurement in contrast to isolated glucose readings of traditional blood glucose monitoring.

Liles (2013) identified advantages and drawbacks of CGM.
Advantages include:

- Display of blood sugar level every few minutes
- The device can be set to alarm at specific glucose levels
- It can be of benefit for patients with hypoglycemic unawareness

Disadvantages include:

- CGM sensors are not as accurate or have inconsistent results compared to traditional blood glucose meters
- The device can alarm based on incorrect glucose readings
- Finger stick blood glucose level monitoring is still required

- The costs associated with CGM are much greater than traditional blood glucose monitors.

The Endocrine Society (Klonoff et al., 2011) recommends that long-term personal use of CGM be used for the following:

- Adult patients with Type 1 diabetes who have HbA1c levels of at least 7.0% and who have demonstrated that they can use these devices on a nearly daily basis
- Adult patients with Type 1 diabetes who have HbA1c levels less than 7.0% and who have demonstrated that they can use these devices on a nearly daily basis
- Children and adolescents with Type 1 diabetes who have achieved glycosated hemoglobin levels below 7% to maintain target levels
- Children and adolescents with Type 1 diabetes who have glycosated hemoglobin levels that are greater than 7% who are able to use the device on a nearly daily basis
- There is no recommendation for or against the use of CGM in children with Type 1 diabetes who are less than 8 years of age.

The guidelines also suggest the intermittent use of CGM systems designed for short-term retrospective analysis in adult patients with Type 1 diabetes when there is a concern about the following:

- Nocturnal hypoglycemia, dawn phenomenon, and postprandial hyperglycemia
- Hypoglycemic unawareness
- Changes to a patient's diabetes regimen (e.g., instituting new insulin or switching from multiple daily injections (MDI) to pump therapy)

The authors noted that there is evidence that intermittent use of CGM systems designed for short-term retrospective analysis can provide additional insights in adults with Type 2 diabetes mellitus regarding glucose levels and the time in target range.

AACE/ACE clinical practice guidelines state that CGM may be considered for patients with Type 1 diabetes and Type 2 diabetes on basal-bolus therapy to improve A1C levels and reduce hypoglycemia. Although data from small-scale randomized trials and retrospective or prospective observational studies suggest CGM may provide benefits in insulin-using patients with Type 2 diabetes, additional research is needed before recommendations can be made regarding use in this patient population (Handelsman et al., 2015).

Nørgaard et al. (2013) reported on the largest and longest multicenter prospective observational study of continuous glucose monitoring with insulin infusion pumps, so called sensor-augmented pump therapy. The investigators reported on a 12-month observational study in patients with Type 1 diabetes treated with continuous subcutaneous insulin infusion (CSII), upon the introduction of continuous glucose monitoring (CGM). The study was conducted in 15 countries to document the real-life use of sensor-augmented pump therapy and assess which variables are associated with improvement in Type 1 diabetes management. Data from 263 patients (38% male; mean age, 28.0 ± 15.7 years [range, 1-69 years]; body mass index, 23.3 ± 4.9 kg/m2; diabetes duration, 13.9 ± 10.7 years; CSII duration, 2.6 ± 3 years) were collected. Baseline mean glycated hemoglobin A1C (HbA1c) was 8.1 ± 1.4%; 82% had suboptimal HbA1c (≥ 7%). The investigators found that the average sensor use for 12 months was only 30% (range, 0-94%), and that sensor use decreased with time (first 3 months, 37%; last 3 months, 27%). The investigators found that there were significantly more patients with an HbA1c value of < 7.5% after 3 months of sensor-augmented pump therapy than at baseline (baseline, 29%; 3 months, 37%) However, the percentage of patients with an HbA1c value of < 7.5% decreased over the 12-month observation period, such that the percentage of patients with an HbA1c value of < 7.5% after 12 months was not statistically significantly higher than at baseline.

The 2016 *Standards of Medical Care in Diabetes* make the following recommendations:

- When used properly, CGM in conjunction with intensive insulin regimen is a useful tool to lower A1C in selected adults (aged ≥ 25 years) with Type 1 diabetes.
- Although the evidence for A1C lowering is less strong in children, teens and younger adults, CGM may be helpful in these groups. Success correlates with adherence to ongoing use of the device.
- CGM may be a supplemental tool to self-monitoring of blood glucose (SMBG) in individuals with hypoglycemia unawareness and/or frequent hypoglycemic episodes.
- Given variable adherence to CGM, assess individual readiness for continuing CGM use prior to prescribing.
- When prescribing CGM, robust diabetes education, training and support are required for optimal CGM implementation and ongoing use.

Updated guidelines were issued by The National Institute for Health and Care Excellence (NICE) in 2015 regarding the use of continuous glucose monitoring in the management of pregnant women with diabetes. The guidelines include:

- Do not offer CGM routinely in pregnant women;
- Consider CGM for pregnant women on insulin therapy:
  - When the pregnant woman is having severe problematic hypoglycemia (with or without impaired awareness of hypoglycemia); OR
  - When the pregnant woman has unstable blood glucose levels in order to minimize variability; OR
  - When there is a need to gain insight about the variability of blood glucose levels.
- Support must be available for pregnant women who are using CGM from a member of the joint diabetes and antenatal care team with expertise in its use.

Golden et al. (2012) reported on a recent published meta-analysis comparing real-time CGM with SMBG in Type 1 diabetes that showed a benefit of real-time CGM in improving glycemic control with no difference in hypoglycemia frequency; however, other non-glycemic outcomes were not reported. Prior studies suggest that those who benefit most are adults and individuals compliant with regular sensor use, but this needs to be confirmed. Clinicians can combine real-time CGM with CSII therapy in the form of a sensor-augmented pump. However, there has not been a systematic review comparing sensor-augmented pump therapy (CSII and real-time CGM) with intensive insulin therapy (CSII or MDI) and SMBG.

Mauras et al. (2012) assessed the benefit of continuous glucose monitoring (CGM) in young children aged 4 to 9 years with Type 1 diabetes. A total of 146 children with Type 1 diabetes (mean age 7.5 ± 1.7 years) were randomly assigned to CGM or to usual care. The primary outcome was reduction in HbA1c at 26 weeks by ≥ 0.5% without the occurrence of severe hypoglycemia. The primary outcome was achieved by 19% in the CGM group and 28% in the control group. Mean change in HbA1c was -0.1% in each group. Severe hypoglycemia rates were similarly low in both groups. CGM wear decreased over time, with only 41% averaging at least 6 days/week at 26 weeks. There was no correlation between CGM use and change in HbA1c. The authors concluded that CGM in 4- to 9-year-olds did not improve glycemic control despite a high degree of parental satisfaction with CGM. This finding may be related in part to limited use of the CGM glucose data in day-to-day management and to an unremitting fear of hypoglycemia.

Matsuda and Brennan (2014) conducted a review of clinical trials to evaluate the efficacy of CGM for adolescents (aged 12 to 18 years) with Type 1 diabetes who used CGM versus SBMG alone. The searches spanned the time frame 2002 to 2012 and identified random controlled trials (RCTs) or quasi-RCTs that examined the number of hypoglycemic episodes (blood glucose < 70 mg/dL) and HbA1c levels. Only 2

RCTs (n = 85) met the study inclusion criteria. The overall combined mean difference in HbA1c from baseline to 26 weeks between patients in both studies using CGM and those using SMBG alone was − 0.11 (95% CI, − 0.61 to 0.39; P = 0.674). Therefore, CGM was not significantly more efficacious than SMBG in these patients for controlling HbA1c. Both RCTs lacked age-specific data on hypoglycemia. However, 1 study found only 4 occurrences of severe hypoglycemia in the SMBG group, whereas the other RCT observed 14 events, 11 of which occurred in the CGM group. This analysis is limited by the fact that only 2 studies were eligible for inclusion to target the adolescent age group, and then only 1 outcome could be quantified. The review concluded that more evaluation is needed of the efficacy of CGM in the adolescent population, and in particular, studies that examine barriers to effectiveness in this age group.

Larson and Pinsker (2013) reported on the role of CGM in children with Type 1 diabetes. The study noted that there are many theoretical and demonstrated virtues of CGM in children with Type 1 diabetes, however, many providers/clinics that care for these children do not have the time nor clinical or financial support to facilitate the use of CGM in all patients. Issues such as clinicians who do not practice in large diabetic centers are not exposed to CGM and may feel intimidated, there is lack of sufficient time to coordinate with online systems, and possible difficulty in interpreting computer reports.
In addition, the major issue with CGM is encouraging consistent use of the device since children show waning adherence over time. Benefits of the CGM require that the device be utilized more than 70% of the time which is equivalent to ≥ 5 days per week. Patients and families do not always understand that the use of the CGM is often more time consuming because the device forces the patient and family to constantly focus on diabetes care.

Some common problems seen with the use of CGM in children and adolescents include painful sensor insertions, sensors do not adhere to the skin or cause irritation, and there may be too many 'nuisance alarms' that do not agree with the traditional blood glucose monitors. Therefore, it is imperative that providers select appropriate pediatric patients for CGM use.

A pilot study conducted by Ahmet et al. (2011) was performed to determine the prevalence of nocturnal hypoglycemia (NH) in pediatric Type 1 diabetes, to compare the prevalence of NH detected by continuous glucose monitoring (CGM) and self-monitored blood glucose (SMBG), and to compare the prevalence of NH using different thresholds. A total of 25 patients wore a continuous glucose monitor for 3 nights and also conducted SMBG. NH was defined with three thresholds: (1) < 3.9 mmol/L; (2) < 3.3 mmol/L; and (3) < 2.9 mmol/L. The prevalence of NH with CGM was 68%, 52%, and 48% with the different thresholds. Of the 35 episodes of NH detected by CGM, 25 were not symptomatic and therefore not detected by SMBG. The mean difference in blood glucose between CGM and SMBG was - 0.18 mmol/L (P = .35). The authors concluded that this study suggests that the prevalence of NH in pediatric patients with Type 1 diabetes with conventional treatment may be as high as 68%, although this varied according to the method of detection and threshold used. Patients may benefit from CGM to detect asymptomatic NH. This study is limited by small sample size and a lack of randomization and control.

2017 Update
The American Diabetes Association (ADA) published the first Standards of Care in Diabetes in 2009 in which supplemental continuous glucose monitoring was recommended to lower A1C in select adults (age ≥ 25 years) with Type 1 diabetes. In 2010, the ADA reported that CGM did not provide significant results in lowering HbA1c and that further research was necessary on the benefits of CGM in the pediatric population. In 2013, the ADA recommendations for CGM was not revised in relation to CGM as a useful tool for adults (aged > 25 years). For children, teens, and younger adults, the ADA assigned a C rating. In 2017, the ADA reaffirmed the same positon.

In addition, the ADA noted that CGM can be helpful in lowering A1C in children, teens, and younger adults. It was noted that several studies indicate that success is based on compliance with the device.

Recent advancements in technology have led to the development of implantable continuous glucose monitors. These systems include an implanted sensor that is placed in the upper arm during an office visit. A rechargeable transmitter device is worn on top of the skin, directly over the sensor. This powers the implant and transmits current glucose values and trends to a smartphone. The transmitter is removable but must be on, so that glucose readings are available. At the time of the policy development, there are no FDA-approved implantable systems.

Professional Societies	Comments
American Diabetes Assoc. (ADA)	Recommends CGM in conjunction with intensive insulin regimens in select Type 1 adults (at least 25 years old); while poor evidence of lower A1C, CGM can be useful in children, teens, and younger adults with adherence to the device; use as supplemental tool to self-monitor blood glucose in patients with hypoglycemic unawareness and/or frequent hypoglycemic episodes.(2017) Recommends a sensor-augmented, low glucose threshold suspend pump for patients with frequent nocturnal hypoglycemia and/or hypoglycemic unawareness. (2018)
CMS	Adjunctive CGM is not covered because it is considered precautionary equipment. Since Medicare does not cover the CGM, supplies for the CGM are not covered. There is no NCD or LCD addressing artificial pancreas systems. The CMS NCD 40.3, Closed-Loop Blood Glucose Control Device (CBGCD) provides direction that this system is only covered when provided as a short-term treatment for critically ill patients that are inpatient. Effective January 12, 2017 CMS provides coverage for therapeutic CGM devices (Dexcom & Libre)
Hayes	Review of 24 RCTs found the technology is reasonably safe, but there is conflicting evidence concerning efficacy that is difficult to interpret. See Hayes Rating Summary below. In October 2016, Hayes reported on the MiniMed 670G and indicated that there was insufficient evidence to support coverage.
American Association of Clinical Endocrinologists and American College of Endocrinology	Recommend CGM in all Type 1 patients, especially those with severe hypoglycemia. For pediatrics, all Type 1 pediatric patients, especially those with severe hypoglycemia and hypoglycemic unawareness. Recommends a sensor-augmented, low glucose threshold suspend pump for patients with frequent nocturnal hypoglycemia and/or hypoglycemic unawareness. (2015)

Hayes Ratings Summary:

B – For the use of continuous glucose monitoring (CGM) in adults with Type 1 diabetes who have not achieved adequate glycemic control despite frequent self-monitoring of blood glucose (SMBG). This Rating reflects highly consistent findings that CGM is beneficial in studies in which data for pediatric and adult patients with Type 1 diabetes are combined, as well as some positive findings concerning the benefits of CGM in studies of only adult patients with Type 1 diabetes.

C – For the use of CGM in adults with Type 2 diabetes. This Rating reflects some positive but inconsistent findings concerning the benefits of CGM in this diabetic population.

C – For the use of CGM in children and adolescents with Type 1 diabetes who have not achieved adequate glycemic control despite frequent SMBG. This Rating reflects highly consistent findings that CGM is beneficial in studies in which data on pediatric and adult patients with Type 1 diabetes are combined, as well as somewhat consistent findings that CGM is not beneficial in studies of only pediatric patients with Type 1 diabetes.

D2 – For the use of CGM in children and adolescents with Type 2 diabetes. This Rating reflects the paucity of evidence concerning use of CGM in this diabetic population.

D2 – For the use of CGM in pregnant women with pre-gestational Type 1 or Type 2 diabetes, or with gestational diabetes. This Rating reflects the small number of available studies that evaluate CGM in pregnant women.

Key for Hayes Ratings:

A	**Established benefit.** Published evidence shows conclusively that safety and impact on health outcomes are comparable to or better than standard treatment/testing. Long-term safety and impact on health outcomes have been established, and other important questions concerning application of the technology have been answered. Drugs, biologics, and devices with an A rating have FDA approval, but not necessarily for the specific clinical application(s) under consideration.
B	**Some proven benefit.** Published evidence indicates that safety and impact on health outcomes are at least comparable to standard treatment/testing. However, there are outstanding questions regarding long-term safety and impact on health outcomes, clinical indications, contraindications, optimal treatment/testing parameters, and/or effects in different patient subpopulations. Drugs, biologics, and devices with a B rating have FDA approval, but not necessarily for the specific clinical application(s) under consideration.
C	**Potential but unproven benefit.** Some published evidence suggests that safety and impact on health outcomes are at least comparable to standard treatment/testing. However, substantial uncertainty remains about safety and/or impact on health outcomes because of poor-quality studies, sparse data, conflicting study results, and/or other concerns.
D1	**No proven benefit and/or not safe.** Published evidence shows that the technology does not improve health outcomes or patient management for the reviewed application(s) or is unsafe.
2	**Insufficient evidence.** There is insufficient published evidence to assess the safety and/or impact on health outcomes or patient management.

Hypoglycemia Questionnaire

Question	**Never**	**Rarely**	**Occasionally**	**Usually**
I get tired or exhausted				
I forget things easily				
I feel sleepy during the day				
I get down or depressed				
I get down over nothing				
I have trouble concentrating				
I get nervous or shaky				
I easily get angry				
I eat or crave sweets, or once used to				
I awaken during the night				
Total				

Scoring

Total the number of checks in each column for RARELY, OCCASIONALLY, AND USUALLY and then calculate as follows:

Rarely (Total) x 1=	
Occasionally (Total) x 2 =	
Usually (Total) x 3 =	
Total Score	

If your **TOTAL SCORE** is:
Less than 8: Hypoglycemic disease is unlikely.
Between 8 to 15: Hypoglycemic disease is possible.
Above 15: Hypoglycemic disease is present.

POLICY SOURCE(S)

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Policy History

Date	Activity
11/28/2016	Initial policy developed
03/14/2017	QI/UM Committee Approval
05/01/2017	Provider effective date
06/21/2017	Revised policy: Added procedure code S1034 as noncovered code under the Procedure Code section
08/09/2017	Revision: Added procedure code S1034 to policy under the Procedure Code section as a non-covered service; Added Disclaimer Statement in opening of medical policy. EHS Revisions: Added Issue Date to opening policy box; added covered to Procedure code table in Attachment B and in the diagnosis table in Attachment C; Added 'Noncovered' to 2nd diagnosis table in Attachment C; Added 'Informational' to Attachment D; Updated Operational Guidelines.
09/27/2017	QI/UM Committee Review
11/01/2017	Provider Effective Date
12/20/2017	Revisions: Under Procedure section, added updated criteria for medical necessity; removed 30-day requirement in Letter I; deleted table of FDA-approved CGM devices; revised CMS coverage position; Removed the age restriction in Procedure section 1.B.; updated Professional Society table; updated Summary of Literature and Reference Sources sections; added new CGM HCPCS codes K0553 and K0554. Additional ICD-10 codes which include: E10.22-29, E10.3211-13, E10.3291-93, E10.3311-13, E10.3391-93, E10.3411-13, E10.3491-93, E10.3511-13, E10.3521-23, E10.3531-33, E10.354-43, E10.3551-53, E10.3591-93, E10.37X1-X3, E10.41-49, E10.52, E10.59, E10610, and E10.618 & Z79.4.
03/13/2018	QI/UM Committee Review Approval
05/15/2018	Provider effective date
03/12/2019	EHS Review: Removed the word 'Covered' from the procedure and diagnosis code tables in Attachment B & C; Deleted ineligible diagnosis codes O24.0 and O24.01. Updated Operational Guidelines. Added therapeutic continuous glucose monitors to Definition section on page 2. Removed diagnosis code Z79.4 from ineligible diagnosis table correcting an error.
03/12/2019	Annual Review: updated definitions; in the Procedure section 1 added section on artificial pancreas device systems with qualifying criteria for low-glucose suspend devices; Section 3 revised information regarding use of HCPCS codes K0553 & K0554; added requirements for replacement and noncoverage criteria for the artificial devices; updated the Governing Bodies section; updated Summary of Literature and Professional Societies table; revised covered procedure codes to include S1034 to S1037; updated Reference section and deleted hyperlinks from all references. Added reference to Clinical Pharmacy policy for Libre CGM.
03/12/2019	QI/UM Committee review
05/06/2019	Provider effective date

03/25/2019	Urgent Revision: Formatting changes; addition of 0446T, 0447T, 0448T for the Eversense device; updated the Governing Bodies Approval section; Removed all reference to artificial pancreas due to new policy.
07/17/2019	QI/UM Committee Review
09/16/2019	Provider effective date