Continuous Glucose Monitoring System

Policy Number:
MM.02.003
Line(s) of Business:
HMO; PPO; QUEST Integration
Section:
DME
Place(s) of Service:
Home; Office; Outpatient

Original Effective Date:
03/13/2001
Current Effective Date:
08/29/2018

I. Description

A continuous glucose monitoring system (CGMS) continuously monitors and records interstitial fluid glucose levels. Some CGMSs are designed for short-term diagnostic or professional use, referred to as intermittent monitoring. These devices store glucose measurements for review at a later time. Other CGMSs are designed for long-term patient use and display information in real-time, allowing the patient to take action based on the data.

Intermittent monitoring with a CGMS can be beneficial in patients with diabetes to detect nocturnal hypoglycemia, the dawn phenomenon, and postprandial hyperglycemia and to assist in the management of hypoglycemic unawareness when significant changes are made to their diabetes regimen (such as instituting new insulin or pump therapy).

Glucose measurements provided during continuous monitoring are intended to be an adjunct to, rather than replacement for, standard self-monitoring of blood glucose with fingerstick blood samples, as they enable patients to monitor their glucose trends over time. For this reason, CGMS is most effective when used consistently every day or nearly every day.

Some insulin pump systems include a CGMS. This policy addresses CGMS devices, not the insulin pump component of these systems. For criteria/guidelines regarding insulin pumps, see HMSA's Insulin Pumps – External medical policy.

II. Criteria/Guidelines

A. CGMS (receiver, transmitters and sensors) is covered (subject to Limitations and Administrative Guidelines) for patients with type 1 diabetes for the first six months of therapy when the following criteria are met:
   1. CGMS is ordered and follow-up care will be provided by an endocrinologist, or in the absence of an endocrinologist, by a physician or licensed healthcare practitioner with experience and expertise in the use of CGMS;
   2. The patient has been utilizing best practices for at least 3 months, including all of the following:

   a. Completion of a comprehensive diabetes self-management program, including carbohydrate counting;
   b. Compliance and competence with an intensive insulin therapy, including use of an insulin pump or multiple daily injections, i.e., at least 3 injections per day;
   c. Glucose self-testing an average of at least three times per day; and
   d. Frequent self-adjustment of insulin dose based on glucose measurement and carbohydrate count and/or content of meal.
3. It is anticipated that the patient will use CGMS consistently on a nearly daily basis.

B. CGMS (receiver, transmitters and sensors) is covered (subject to Limitations and Administrative Guidelines) for patients with type 2 diabetes when criteria II.A.1 to 3 are met and diabetes is suboptimally controlled. Suboptimally controlled diabetes includes (but is not necessarily limited to) the following:
   a. Glycosylated hemoglobin level (HbA1c) greater than 7 percent;
   b. Repeated and unpredictable hypoglycemia;
   c. Wide fluctuations in preprandial blood glucose;
   d. Dawn phenomenon with fasting blood sugars frequently exceeding 200 mg/dl;
   e. Severe glycemic excursions; or
   f. Hypoglycemic unawareness.

C. CGMS may be covered concurrently with initiation of an insulin pump when the criteria listed in A.1 to 4 above and when criteria for insulin pumps are met. For criteria/guidelines regarding insulin pumps, see HMSA's Insulin Pumps - External medical policy.

D. CGMS transmitters and sensors are covered beyond the first six months of therapy when documentation supports that the patient continues to be on an intensive insulin regimen, is compliant with CGMS use and is benefiting from its use.

E. Replacement of CGMS receiver is covered when the following criteria are met:
   1. Documentation from the patient's medical record supports that the CGMS receiver is malfunctioning and out of warranty; or
   2. Documentation from the patient's medical record supports that CGMS with newer technology or special features is medically necessary.
   3. The request for replacement is initiated by the treating physician.
   4. The patient continues to be on an intensive insulin regimen (multiple daily does or insulin pump), is compliant with CGMS use and is benefiting from its use.
   5. Documentation from the patient's medical record supports that the patient is using a receiver rather than a smart device (e.g., smartphone) application.

F. Intermittent monitoring, i.e., up to 72 hours, of glucose levels in interstitial fluid is covered (subject to Limitations and Administrative Guidelines) for patients with type 1 and type 2 diabetes when the following criteria are met:
   1. Monitoring is performed by an endocrinologist or in the absence of an endocrinologist, by a physician or licensed healthcare provider with experience and expertise in the use of intermittent monitoring of glucose in interstitial fluid; and
   2. Diabetes is suboptimally controlled despite current use of best practices (see criteria II.A.2. a-d above). Suboptimally controlled diabetes includes (but is not necessarily limited to) the following:
      a. Glycosylated hemoglobin level (HbA1c) greater than 7 percent;

   b. Repeated and unpredictable hypoglycemia;
   c. Wide fluctuations in preprandial blood glucose;
   d. Dawn phenomenon with fasting blood sugars frequently exceeding 200 mg/dl;
   e. Severe glycemic excursions
   f. Hypoglycemic unawareness.
3. It is performed prior to insulin pump initiation to determine basal insulin levels.

III. Limitations

A. Intermittent monitoring is generally conducted in 72-hour periods. It may be repeated at a subsequent time depending on the patient's level of diabetes control.
B. CGMS is covered for patients who have been utilizing best practices for at least 3 months; however, coverage will be considered on a case by case basis for patients who have been utilizing best practices for less than 3 months.
C. Replacement of CGMS for the sole purpose of receiving an upgrade in technology is not covered.
D. A replacement receiver is not covered when a patient is using a smart device application in place of a receiver.

IV. Administrative Guidelines

A. Precertification is required for initial use of CGMS (receiver, transmitter, sensors), continuation of use of transmitters and sensors and at 6 months, no further precertification is necessary. To precertify, complete HMSA's Precertification Request and mail or fax the form or use iExchange.
B. If HMSA's Precertification Request form is used, medical record documentation supporting the following must be submitted:
   1. For initial 6 months use of CGMS for a patient with type 1 diabetes:
      a. The patient has type 1 diabetes.
      b. The patient is utilizing best practices, if an insulin pump has not been previously approved by HMSA.
   2. For initial 6 months use of CGMS for a patient with type 2 diabetes:
      a. The patient is utilizing best practices, if an insulin pump has not previously been approved by HMSA.
      b. The patient has suboptimally controlled diabetes and/or justification as to why CGMS is medically necessary.
   3. For continuation of transmitters and sensors beyond six months:
      a. The patient is compliant with care (i.e., summary of CGMS use over the last month downloaded from the device, etc.).
      b. The patient is benefiting from use of CGMS.
   4. For replacement of receiver:
      a. CGMS receiver is malfunctioning and out of warranty or CGMS newer technology or special features is medically necessary.
      b. The patient continues to be on an intensive insulin regimen.

   c. The patient is compliant with care (i.e., summary of CGMS use over the last month downloaded from the device, or documentation supporting compliance with use, if a summary cannot be downloaded from the device).
   d. The patient is benefiting from use.
   e. The patient is using a receiver rather than a smart device application.

C. If iExchange is used and even if Auto Approved, documentation supporting medical necessity must be kept in the patient's medical records and be made available to HMSA upon request. HMSA reserves the right to perform retrospective review using the above criteria to validate if services rendered met payment determination criteria.
D. Precertification is not required for office-based intermittent monitoring. Documentation supporting medical necessity must be kept in the patient's medical records and be made available to HMSA upon request. HMSA reserves the right to perform retrospective review using the above criteria to validate if services rendered met payment determination criteria.

CPT Codes	**Description**
95250	Ambulatory continuous glucose monitoring of interstitial tissue fluid via a subcutaneous sensor for up to 72 hours; sensor placement, hook-up, calibration of monitor, patient training, removal of sensor, and printout of recording.
95251	Ambulatory continuous glucose monitoring of interstitial tissue fluid via a subcutaneous sensor for up to 72 hours; physician interpretation and report

Codes requiring precertification	
HCPCS Codes	**Description**
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 glucose continuous monitor system
S1036	Transmitter; external, for use with artificial pancreas device system
S1037	Receiver (monitor); external, for use with artificial pancreas device system

ICD-10-CM Codes	**Description**
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 diabetic nephropathy
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
E10.321	Type 1 diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema
E10.329	Type 1 diabetes mellitus with mild nonproliferative diabetic retinopathy without macular edema
E10.331	Type 1 diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema
E10.339	Type 1 diabetes mellitus with moderate nonproliferative diabetic retinopathy without macular edema
E10.341	Type 1 diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema
E10.349	Type 1 diabetes mellitus with severe nonproliferative diabetic retinopathy without macular edema
E10.351	Type 1 diabetes mellitus with proliferative diabetic retinopathy with macular edema
E10.359	Type 1 diabetes mellitus with proliferative diabetic retinopathy without macular edema
E10.36	Type 1 diabetes mellitus with diabetic cataract
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 neurological complication
E10.51	Type 1 diabetes mellitus with diabetic peripheral 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
E10.620	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 complication
E10.8	Type 1 diabetes mellitus with unspecified complications
E10.9	Type 1 diabetes mellitus without complications
E11.00	Type 2 diabetes mellitus with hyperosmolarity without nonketotic hyperglycemic-hyperosmolar coma (NKHHC)
E11.01	Type 2 diabetes mellitus with hyperosmolarity with coma
E11.21	Type 2 diabetes mellitus with diabetic nephropathy
E11.22	Type 2 diabetes mellitus with diabetic chronic kidney disease
E11.29	Type 2 diabetes mellitus with other diabetic kidney complication
E11.311	Type 2 diabetes mellitus with unspecified diabetic retinopathy with macular edema
E11.319	Type 2 diabetes mellitus with unspecified diabetic retinopathy without macular edema
E11.321	Type 2 diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema
E11.329	Type 2 diabetes mellitus with mild nonproliferative diabetic retinopathy without macular edema
E11.331	Type 2 diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema
E11.339	Type 2 diabetes mellitus with moderate nonproliferative diabetic retinopathy without macular edema

E11.341	Type 2 diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema
E11.349	Type 2 diabetes mellitus with severe nonproliferative diabetic retinopathy without macular edema
E11.351	Type 2 diabetes mellitus with proliferative diabetic retinopathy with macular edema
E11.359	Type 2 diabetes mellitus with proliferative diabetic retinopathy without macular edema
E11.36	Type 2 diabetes mellitus with diabetic cataract
E11.39	Type 2 diabetes mellitus with other diabetic ophthalmic complication
E11.40	Type 2 diabetes mellitus with diabetic neuropathy, unspecified
E11.41	Type 2 diabetes mellitus with diabetic mononeuropathy
E11.42	Type 2 diabetes mellitus with diabetic polyneuropathy
E11.43	Type 2 diabetes mellitus with diabetic autonomic (poly)neuropathy
E11.44	Type 2 diabetes mellitus with diabetic amyotrophy
E11.49	Type 2 diabetes mellitus with other diabetic neurological complication
E11.51	Type 2 diabetes mellitus with diabetic peripheral angiopathy without gangrene
E11.52	Type 2 diabetes mellitus with diabetic peripheral angiopathy with gangrene
E11.59	Type 2 diabetes mellitus with other circulatory complications
E11.610	Type 2 diabetes mellitus with diabetic neuropathic arthropathy
E11.618	Type 2 diabetes mellitus with other diabetic arthropathy
E11.620	Type 2 diabetes mellitus with diabetic dermatitis
E11.621	Type 2 diabetes mellitus with foot ulcer
E11.622	Type 2 diabetes mellitus with other skin ulcer
E11.628	Type 2 diabetes mellitus with other skin complications
E11.630	Type 2 diabetes mellitus with periodontal disease
E11.638	Type 2 diabetes mellitus with other oral complications
E11.641	Type 2 diabetes mellitus with hypoglycemia with coma
E11.649	Type 2 diabetes mellitus with hypoglycemia without coma
E11.65	Type 2 diabetes mellitus with hyperglycemia
E11.69	Type 2 diabetes mellitus with other specified complication

E11.8	Type 2 diabetes mellitus with unspecified complications
E11.9	Type 2 diabetes mellitus without complications

V. Important Reminder

The purpose of this Medical Policy is to provide a guide to coverage. This Medical Policy is not intended to dictate to providers how to practice medicine. Nothing in this Medical Policy is intended to discourage or prohibit providing other medical advice or treatment deemed appropriate by the treating physician.

Benefit determinations are subject to applicable member contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control.

This Medical Policy has been developed through consideration of the medical necessity criteria under Hawaii's Patients' Bill of Rights and Responsibilities Act (Hawaii Revised Statutes §432E-1.4), generally accepted standards of medical practice and review of medical literature and government approval status. HMSA has determined that services not covered under this Medical Policy will not be medically necessary under Hawaii law in most cases. If a treating physician disagrees with HMSA's determination as to medical necessity in a given case, the physician may request that HMSA reconsider the application of the medical necessity criteria to the case at issue in light of any supporting documentation.

VI. References

1. Battelino T, Phillip M, Bratina N, et al. Effect of Continuous Glucose Monitoring on Hypoglycemia in Type 1 Diabetes. Diabetes Care 2011 April; 34(4): 795–800.
2. Blue Cross Blue Shield Association. Continuous or Intermittent Monitoring of Glucose in Interstitial Fluid. Medical Policy Reference Manual. Policy 1.01.20. Last reviewed July 2017.
3. American Diabetes Association. Standards of Medical Care in Diabetes—2017. Diabetes Care 2017; 40 (Suppl. 1).
4. Garg SK, Voelmle MK, Beatson CH, et.al. Use of Continuous Glucose Monitoring in Subjects With Type 1 Diabetes on Multiple Daily Injections Versus Continuous Subcutaneous Insulin Infusion Therapy. Diabetes Care 2011 March; 34(3); 574-579.
5. Handelsman Y, Bloomgarden ZT, Grunberger G, et al. American Association of Clinical Endocrinologists and American College of Endocrinology – Clinical Practice Guidelines for developing a diabetes mellitus comprehensive care plan. Endocrine Practice. 2015;21 (Suppl. 1):1-8