Harvard Pilgrim Health Care

Medical Review Criteria Continuous Glucose Monitoring Systems

STRIDEsm (HMO) MEDICARE ADVANTAGE

Effective Date: January 1, 2017

Subject: Continuous Glucose Monitoring Systems (CGMS)

Policy:
Harvard Pilgrim Stride[SM] (HMO) Medicare Advantage covers Continuous Glucose Monitoring Systems (CGMS) that are medically necessary to supplement to self-monitoring of blood glucose, optimize glycemic control, and reduce incidences of hyperglycemia and hypoglycemia in insulin-requiring type 1 diabetics (including pregnant women with poorly controlled type 1 diabetes).

Covered devices must be:

- Reasonable and medically necessary based on the member's condition, complexity of requested service(s), and accepted standards of clinical practice;
- An essential part of active treatment of the member's medical condition, and ordered under a plan of care established and reviewed regularly by the attending physician caring for the member; and
- Furnished by providers with appropriate state licensure, and/or accreditation or certification from an appropriate accrediting organization.[1]

Harvard Pilgrim Stride[SM] (HMO) Medicare Advantage does not cover CGMS for individuals with type 2 diabetes, or for pregnant women with gestational diabetes as there is limited evidence that the use of such monitoring leads to improved glycemic control.

Authorization:
Prior authorization from Harvard Pilgrim Stride[SM] (HMO) Medicare Advantage is required for all Personal CGMS (i.e., CGMS purchased for the individual patient)[2], and for replacement of personal CGMS and/or components (e.g., transmitters, receivers).

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[1] Appropriate accrediting organizations include the Joint Commission for the Accreditation of Healthcare Organizations (JCAHO), or another Centers for Medicare and Medicaid Services (CMS) approved Accrediting Organization.

[2] Professional CGM (provider owned equipment) is covered as an adjunct to standard care when monitoring is medically necessary to establish optimal insulin regimens for patients with insulin-requiring diabetes and inadequate glycemic control despite compliance with frequent self-monitoring. Prior authorization is not required for professional CGM (CPT codes 95250 & 95251); physicians who bill these codes are reimbursed up to 4 times per year for professional services.

Harvard Pilgrim Stride[SM] (HMO) policies are based on medical science and relevant information including current Medicare coverage (including National and Local Coverage Determinations), Harvard Pilgrim medical policies, and Harvard Pilgrim Stride[SM] (HMO) Medicare Advantage Plan materials. These policies are intended to provide benefit coverage information and guidelines specific to the Harvard Pilgrim Stride[SM] (HMO) Medicare Advantage Plan. Providers are responsible for reviewing the CMS Medicare Coverage Center guidance; in the event that there is a conflict between this document and the CMS Medicare Coverage Center guidance, the CMS Medicare Coverage Center guidance will control.

Criteria:
Personal CGMS are authorized for adults and children/adolescents with Type 1 diabetes when relevant criteria (below) are met.

	Criteria
Adults	Personal CGMS and related supplies are covered when medical record documentation confirms ALL the following are met: 1. CGMS is ordered by the attending endocrinologist for a member with Type 1 diabetes who requires insulin injections (at least 3 times per day), or use of an insulin pump, for maintenance of blood sugar control; 2. Requested device is FDA-approved and appropriate for the individual member; 3. Member has experienced ANY of the following: • Inability to achieve optimal glycemic control as defined by the current version of the American Diabetes Association *Standards of Medical Care in Diabetes* [3]; • Episodes of hypoglycemia unawareness[4]; • Recurring episodes of severe hypoglycemia (<50 mg/dl). 4. Member has demonstrated compliance with a physician ordered diabetic treatment plan (including regular self-monitoring and multiple alterations in insulin administration regimens), and is capable of using a long-term CGMS.

[3] A reasonable A1C goal for many nonpregnant adults is <7%. Lowering A1C to below or around 7% has been shown to reduce microvascular and neuropathic complications of diabetes and, if implemented soon after the diagnosis of diabetes, is associated with long-term reduction in macrovascular disease.

[4] Hypoglycemia unawareness is 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.

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	Criteria
Children and Adolescents	Purchase of Personal CGMS may be authorized when medical record documentation confirms ALL criteria below are met: 1. CGMS is ordered by the attending endocrinologist, and requested device is FDA-approved and appropriate for the individual member[5]; 2. The member has type 1 diabetes mellitus; 1. The member or his/her caregiver is capable of using a long-term CGM system; 2. Member meets ONE of the following: • Has achieved HbA1c levels below 7.0%, and the CGM device is medically necessary to limit the risk of hypoglycemia; OR • Has HbA1c levels greater than 7.5%, and is willing and able to use the CGM device on a daily basis.

NOTE: Coverage for a personal CGM device (sensor/transmitter) with wireless communication to a compatible external insulin pump (e.g., Paradigm® REAL-Time System) is authorized only when:

1. **Criteria (above) are met; AND**
2. **Documentation confirms the attending physician has determined that an external insulin infusion pump is medically necessary for the individual member.**

Replacement Devices:

Replacement (with a comparable device/component) of a malfunctioning personal CGM device or component (i.e., transmitter, receiver) is authorized when documentation confirms ALL the following:

1. The attending endocrinologist has evaluated the member within the last 6 months, and recommends continued use of CGMS for an insulin-requiring member with type 1 diabetes;
2. The member has successfully utilized and benefitted from long-term use of authorized CGMS[6];
3. Replacement is needed due to an irreparable malfunction resulting from ordinary wear and tear.

Replacement devices with additional or special features (e.g., talking device) are authorized only when documentation confirms ALL the following:

[5] CGM devices currently approved by the FDA for use in children and adolescents include the Dexcom G4 Platinum Pediatric system (approved for use in children aged 2 to 17 years of age), and the Medtronic MiniMed 530G with Enlite (approved for ages 16 and older).

[6] Documentation must confirm the member has utilized long-term CGM as a supplement to self-monitoring of blood glucose, and achieved optimal or improved glycemic control, and/or experienced reduced incidences of hyper- and/or hypoglycemia.

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1. Requested features are reasonable and medically necessary due to a change in the member's medical condition;
2. Added features are expected to directly contribute toward improving the member's glycemic control, and/or reducing the incidence(s) of hyper- or hypoglycemia.

NOTE: Replacement is not authorized for devices/components that can be repaired or are still covered under a manufacturer's warranty, or items lost or damaged through neglect or misuse.

Exclusions:
Harvard Pilgrim Stride[SM] (HMO) Medicare Advantage does not cover CGMS when criteria above are not met.

In addition, Harvard Pilgrim Stride[SM] (HMO) Medicare Advantage does not cover:

- Personal CGMS for ANY of the following:
  - Individuals with type 2 diabetes
  - Pregnant women with gestational diabetes who are not type 1 diabetics
  - Nondiabetic persons following gastric bypass surgery;
  - Members with nesidioblastosis (primary islet cell hypertrophy)
- GlucoWatch® Automatic Glucose Biographer
- Artificial pancreas systems, including (but not limited to) closed-loop monitoring devices with low glucose suspend (LGS) features
- Personal CGM systems that are considered investigational and unproven, including single closed-loop systems (combined external insulin pumps and continuous blood glucose monitors) that do not require direct patient interaction
- Repair or replacement of CGM systems or components that are lost or damaged secondary to abuse or neglect
- Replacement of CGM systems that are still covered under manufacturer's warranty
- Replacement of a properly functioning CGM system when additional/special features are not medically necessary or expected to contribute towards improving the member's glycemic control and/or reducing the incidence(s) of hyper- or hypoglycemia

Coding: Codes are listed below for informational purposes only, and do not guarantee member coverage or provider reimbursement. The list may not be all-inclusive.

HCPCS Codes	Description
A4256	Normal, low and high calibrator solution/chips
A9276	Sensor; invasive (e.g. subcutaneous) disposable, for use with interstitial

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HCPCS Codes	Description
	continuous glucose monitoring system, 1 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.

Summary of Changes

Date	Change
12/12/16	Delete code A4253 (not relevant to purchase of CGMS),
9/28/16	Coding update: Delete CPT 95250, 95251 (not relevant to purchase of CGMS), HCPCS S1030 (non-covered code).
8/24/16	Annual review/update. Minor language/formatting changes. Updated references.
1/4/16	Delete additional code (S1031). Not reimbursed per Vendor Contracting.
12/3/15	Delete unrelated codes (82962, 83037).

Approved by UMCPC: 12/14/16 (effective 1/1/17)

- **Revised: 1/4/16, 8/24/16**
- **Initial Approval: 8/12/15 (effective 1/1/16)**

References:

1. Medicare Benefit Policy Manual; Chapter 15 Covered Medical and Other Services (Rev. 13, 05-13-04)
2. ADA Standards of Medical Care in Diabetes 2016 available at: http://care.diabetesjournals.org/content/suppl/2015/12/21/39.Supplement_1.DC2/2016-Standards-of-Care.pdf (accessed 8/4/16)
3. Continuous glucose monitoring: an Endocrine Society clinical practice guideline. Klonoff DC, Buckingham B, Christiansen JS, Montori VM, Tamborlane WV, Vigersky RA, Wolpert H, Endocrine Society. Continuous glucose monitoring: an Endocrine Society clinical practice guideline. J Clin Endocrinol Metab. 2011 Oct;96(10):2968-79. http://www.guideline.gov/content.aspx?id=35254#Section427 (accessed 8/4/16)

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