STRIDE[SM] (HMO) MEDICARE ADVANTAGE

Subject: Diabetes Management Devices

Background: Diabetes mellitus is a set of conditions in which the body is unable to regulate glucose. While typically controlled through dietary and activity adjustment and, at times, the administration of insulin, practicing a successful regimen can in some cases be difficult. A continuous glucose monitoring system is a minimally invasive device comprised of a small catheter sensor, typically replaced every one to three weeks depending on manufacturer, that measures interstitial fluid glucose concentration, a monitor that displays and records the readings of the sensor, and a transmission system, typically replaced once to four times a year, connecting the two. While not able to replace self-monitoring of blood glucose (SMBG), these systems can provide detailed data to aid in planning glucose control strategies and warn a user of the need to perform SMBG.

Continuous glucose monitoring systems come in two varieties: short-term "professional" systems store data for retrospective analysis by a physician to help develop more successful management regimens and long-term "personal" systems that display readings in real time to help users build more beneficial habits. External insulin infusion pumps consist of computer-controlled pumps that deliver insulin, both at a set basal rate and at user-initiated and determined elevated "bolus doses" in response to food intake, via cannulas inserted just under the skin. Artificial pancreas device systems, also called "sensor-enhanced insulin pumps" and "sensor-augmented insulin pump therapy," are systems in which the operation of an insulin pump is modified by the readings of a continuous glucose monitor. Systems can take the form of integrated devices or separate devices connected by third-party data transfer (ether wires or wireless) and software.

Authorization: Prior authorization from Harvard Pilgrim Stride[SM] (HMO) Medicare Advantage is required for all diabetes management devices.

Policy and Coverage Criteria:

Intermittent/Professional Continuous Glucose Monitors

Harvard Pilgrim Stride[SM] (HMO) Medicare Advantage considers continuous glucose monitoring systems designed and used for professional monitoring as medically necessary when documentation confirms ALL of the following:

- Use of the monitor will be over a set period of three, six, seven, or fourteen consecutive days; AND
- When not used more than once in the preceding twelve-month period; AND
- A physician is supervising monitoring and interpretation, and ANY the following indications are present:
  - Insulin-Dependent or type 2 diabetes mellitus when ALL the following are met:
    - Glycemic control is inadequate, as indicated by EITHER of the following:
      - Glycosylated hemoglobin (HbA1c) proportion in excess of seven percent on multiple consecutive readings that include a test taken in the past three months, OR
      - Recurrent severe hypoglycemia (less than 50mg/dl);
    - Glycemic control inadequacy has persisted despite a frequently modified insulin administration and self-monitoring regimen; AND

        - Use of an insulin pump or injection of insulin at least thrice daily has been necessary; AND
        - Member is in compliance with self-monitoring, generally indicated by self-monitoring being performed at a frequency of at least four self-tests per day;
    - Suspected primary islet cell hypertrophy (nesidioblastosis) or persistent hyperinsulinemic hypoglycemia of infancy (PHHI, congenital hypoglycemia) supported by consistent symptoms; AND
    - Need for established basal insulin levels with which to calibrate an imminent insulin pump initiation; AND
    - Pregnancy or imminent pregnancy and EITHER of the following:
        - Type I diabetes requiring insulin therapy, OR
        - Gestational diabetes requiring insulin therapy.

Long term/personal Glucose Monitors

Harvard Pilgrim Stride℠ (HMO) Medicare Advantage considers long-term personal use of therapeutic continuous glucose monitoring systems as reasonable and medically necessary when BOTH of the following indications and all-age specific criteria are met:

- Diabetes when BOTH the following are confirmed with an in-person visit to the treating practitioner to evaluate diabetes control:
    - Persistence of inadequate glucose control despite BOTH of the following:
        - frequently modified insulin administration and self-monitoring regimen; AND
        - member compliance, generally shown by frequent (at least four times daily) self-monitoring; AND
    - Use of an insulin pump or injection of insulin at least thrice daily has been necessary; AND
- the treating practitioner has an in-person visit every six months following initial prescription to assess adherence to their CGM regimen and diabetes treatment plan.

Insulin Pumps

Harvard Pilgrim Stride℠ (HMO) Medicare Advantage considers external insulin infusion pumps as reasonable and medically necessary for the management of diabetes mellitus when ANY of the following criteria are met:

- Poorly controlled diabetes, displaying ALL the following criteria:
    - Diabetes is EITHER:
        - Type I, or
        - Type II and C-peptide testing showing BOTH of the following:
            - Results showing EITHER of the following:
                - Fasting C-peptide level no greater than double the lower limit of normal in the laboratory's measurement method when member with renal insufficiency and a creatine clearance no greater than 50ml/minute, OR
                - C-peptide level no greater than 110% of the lower limit of normal of the laboratory's measurement method
            - Fasting blood sugar obtained concurrently to the C-peptide level is no greater than 225mg/dl;
    - Prior attempts to bring diabetes under control including ALL the following:
        - Insulin injections have been required at a frequency of at least three administrations per day; AND
        - Blood glucose measurements have been required at a frequency of at least four per day; AND
        - Completion of a comprehensive diabetes and self-management education program in recent years; AND
        - Multiple adjustments to insulin administration and self-monitoring regimens; AND
        - Frequent self-adjustment of insulin dose;
    - Persistence of ANY of the following:
        - Glycosylated hemoglobin (HbA1c) proportion in excess of seven percent on multiple consecutive readings that include a test taken in the past three months, OR
        - Recurrent hypoglycemia or ketoacidosis resulting in hospitalization, OR

        - Recurrent hypoglycemia or severe glycemic excursion, OR
        - Widely fluctuating blood glucose concentrations leading up to mealtimes, OR
        - Frequent early morning blood glucose increases ("dawn phenomena") in excess of 200mg/dl;
    - Passage of an assessment of amenability to proper device use, including training, self-care processes and follow-up;
- Successful use of an insulin infusion pump obtained prior to enrollment and a documented glucose self-testing frequency of at least 4 times per day during the month leading up to enrollment, OR
- Gestational diabetes endangering fetal health.

Sensor-Augmented Pump Therapy
Harvard Pilgrim Stride℠ (HMO) Medicare Advantage considers sensor-augmented pump therapy, commonly called "artificial pancreases", such as the MiniMed 530G, 630G, and 670G, as reasonable and medically necessary when ALL the following indications criteria are met:

- Member qualifies for both an insulin pump and a long-term continuous glucose monitor; AND
- Member is in need of a new device due to ANY of the following:
    - Scheduled replacement of device previously approved by HPHC, OR
    - New qualification, OR
    - Persistent insufficient glycemic control, defined as EITHER of the following:
        - Glycated hemoglobin (HbA1c) concentrations between seven and ten percent on multiple consecutive readings that include a test taken in the past three months, OR
        - Recurrent severe hypoglycemia (less than 50mg/dl)
- Member is willing and able to self-monitor his/her long-tern diabetes stability through ALL the following:
    - Taking four blood glucose concentration observations (either through device CGM capability or fingerstick) per day; AND
    - Maintaining contact with his/her primary healthcare provider; AND
    - Notice warnings, signals, alerts, and alarms from the device (please see section on enhancements and accommodations for visual and auditory impairments);
- System requires interaction for post-meal bolusing and retains the functionality of both a standalone glucose monitor and insulin pump.

Enhancements and Accommodations for the Visually and/or Auditorily Impaired
Harvard Pilgrim Stride℠ (HMO) Medicare Advantage considers accessories to, software for, and specialized models of continuous glucose monitoring systems designed to accommodate visual or auditory impairments as reasonable and medically necessary when ALL the following criteria are met:

- Member has a visual or auditory impairment that precludes the successful use of a standard model without assistance beyond initial setup and instruction; AND
- The standard model does not come with accommodations sufficient to allow successful independent use; AND
- The accommodation feature being requested is appropriate for the needs of the member.

Replacement
Harvard Pilgrim Stride℠ (HMO) Medicare Advantage considers the replacement of a continuous glucose monitoring system, insulin pump, or combined system as reasonable and medically necessary when documentation confirms that ALL the following indications are met:

- Documentation is in the form of clinical notes or letters generated by a clinician overseeing the member's diabetic condition; AND
- The present monitor has been rendered ineffective or inoperable due to EITHER:
    - A change in member condition that the current monitor is unable to accommodate, OR
    - Being damaged by events outside the control of the user; AND
- Device has been used according to treatment plan; AND
- Continued use of the device is supported; AND

- Device replacement cannot be obtained from the manufacturer or supplier due the expiration of device warranty; AND
- Loss/damage is not attributable to abuse, sabotage, or neglect on the part of the user; AND
- The cost of replacement rather than repair is justified by the nature of damage and useful lifetime of the device; AND
- The replacement is not an additional/backup monitor; AND
- The replacement monitor is synonymous to the monitor being replaced unless replacement has been necessitated by a change in member condition the old device is unable to accommodate.

Note: in cases where neither the make and model of the device being replaces nor directly competitive devices from other brands are available, selection of a new device must be based on meeting the requirements associated with member condition.

Exclusions: Harvard Pilgrim Stride[SM] considers short-term continuous glucose monitoring systems as experimental/investigational for all other indications. In addition, HPHC does not cover:

- CGMS for gastric bypass surgery without diabetes
- CGMS for nesidioblastosis
- Noninvasive continuous glucose monitors (i.e. Glucowatch)
- Remote continuous glucose monitors (i.e. mySentry),
- Biostator sensor-augmented pump therapy,
- Closed-loop sensor-augmented pump therapy,
- Implantable infusion pumps for the delivery of insulin,
- Disposable external insulin pumps without wireless communication capability (e.g., V-Go),
- Accessories, such as shower covers, belt clips, and additional software or hardware for data transfer unless necessitated by a documented disability,
- Lasette laser blood glucose monitoring devices,
- Eversense Continuous Glucose Monitoring System,
- Insulin infuser ports (applicable to the insulin pumps of artificial pancreas systems)

Harvard Pilgrim Health Care (HPHC) considers the supply of disposable supplies and parts for diabetes management devices (e.g. sensors for CGM systems) as not medically necessary outside of FDA labelling on use and replacement frequency.

Supporting Information:

The use of continuous glucose monitoring (CGM) systems for type I diabetes when a successful management program cannot be successfully developed is well established, with large trials and meta-studies supporting its use. The 2017 standards of care from the American Diabetes Foundation (ADF) states that continuous glucose monitoring with intensive insulin regimens "is a useful tool to lower A1C" with its highest grade of confidence in evidence and that CGM "has an important role in assessing the effectiveness and safety of treatment in subgroups of patients with type I diabetes and in selected patients with type 2." Similarly, the American Association of Clinical Endocrinologists and the American College of Endocrinology Consensus Conference (AACE/ACE CC) on CGM strongly supports the coverage of CGM for type I diabetic patients who have been unable to achieve satisfactory control without it, while their consensus statement on insulin pumps recommends the technology for type one and intensively-managed, c-peptide-positive type two diabetics with very labile diabetes, frequent severe hypoglycemia or glycemia unawareness, or significant "dawn phenomenon" who have been screened to ensure a likelihood of proper use. The 2016 Endocrine Society Clinical Guidelines, developed in conjunction with the American Association for Clinical Chemistry, the American Association of Diabetes Educators, and the European Society of Endocrinology and focusing on adults, recommend long-term/real-time continuous glucose monitors for patients with type one diabetes who have A1C levels above target and are willing and able to use the devices properly as well as adults with well-managed type one diabetes who can be trusted to use the

devices properly, short-term CGM's with type two diabetes and A1C levels of at least seven percent, and insulin pump therapy for type one diabetics who have failed to meet A1C benchmarks, experience severe hypoglycemia or high glucose variability, or require greater insulin delivery flexibility and type two diabetics with poor glycemic control resistant to intensive insulin therapy, oral agents, other injectable therapy, and lifestyle modification, provided the patient pass a structured assessment of his mental and psychological status, prior adherence with diabetes self-care measures, desire to try the continuous insulin infusion, and availability to attend the requisite follow-up regimen.

Research in the use of CGM and insulin pump systems by those with type 2 diabetes is more limited, but there is sufficient evidence for the use of short-term/professional use CGM systems that both the ADF and AACE/ACE CC support its use for the personalization of diabetes treatment plans and most professional organizations support the use of insulin pumps for type-2 diabetes that cannot be otherwise controlled. Likewise, the addition of CGM to existing treatments for a person with type 1 diabetes upon pregnancy has been understudied, but professional/short-term CGM to establish what modifications to diabetes management pregnancy has necessitated when diabetes control has become poor have sufficient support to be widely recommended. Artificial Pancreas Device Systems are a relatively new technology in which an insulin pump uses the readings of a continuous glucose monitor to adjust infusion levels. Low-glucose-suspend systems function by cutting off or drastically lowering insulin delivery to prevent hypoglycemia when glucose drops below a preset level. While small in in number, large and long-term randomized control trials have found low-glucose-suspend devices to show good performance compared to stand-alone insulin pumps or continuous glucose monitoring, particularly overnight. Recently, the FDA granted approval to a hybrid closed-loop system, which increases and decreases insulin delivery to keep glucose levels within a pre-set range. While extant studies have demonstrated safety and promising performance, published comparisons against threshold-suspend artificial pancreas systems have been short in term, so that evidence of long-term advantages is currently unavailable.

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. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible.

CPT® Code	Description
95249	Patient-provided equipment, sensor placement, hook-up, calibration of monitor, patient training and printout of recording
95250	Ambulatory continuous glucose monitoring of interstitial tissue fluid via a subcutaneous sensor for up to 72 hours;

HCPCS Code	Description
A4253	Blood glucose test or reagent strips for home blood glucose monitor, per 50 strips
A4255	Platforms for home blood glucose monitor, 50 per box
A4256	Normal, low and high calibrator solution/chips
A9274	External ambulatory insulin delivery system, disposable, each, includes all supplies and accessories
A9276	Sensor; invasive (e.g. subcutaneous) disposable, for use with interstitial 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.
E0784	External ambulatory infusion pump, insulin

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

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Summary of Changes:

Date	Change
3/20	Exclusion of OmniPod device removed
9/19	Management of professional CGM's and documentation requirements adjusted
6/17	Update: references and supporting information updated, criteria rewritten with replacement policy, insulin pumps and artificial pancreases added
12/16	Delete code A4253 (not relevant to purchase of CGMS),

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

Approved by Medical Policy Committee: 3/10/20
Approved by Clinical Policy Operational Committee: 8/15, 1/16, 8/16, 12/16, 11/19; 4/20
Policy Effective Date: 4/21/2020
Initiated: 8/15