

Insulin Delivery Devices and Continuous Glucose Monitoring Systems

Last Review Date: April 7, 2017

Number: MG.MM.ME.16m

Medical Guideline Disclaimer

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Definitions

Continuous glucose monitoring (CGM) — CGM systems are minimally invasive or noninvasive devices that measure glucose levels in interstitial fluid at frequent intervals over a period of several days. CGM systems are designed to obtain information regarding diurnal patterns in glucose levels that, when evaluated in real time or reviewed retrospectively by a physician, can guide adjustments to therapy.

Combination CGM devices — comprised of a monitoring and insulin delivery (pump) component. A transmitter connected to a sensor sends data wirelessly to the pump and display unit, which can automatically adjust insulin levels.

The glucose measurements provided during CGM are not intended to replace standard self-monitoring of blood glucose (SMBG) obtained using fingerstick blood sample.

Guideline

Members are eligible for a single external insulin infusion delivery system, an interstitial CGM, or a combined CGM and insulin-delivery device for either short-term (72-hour) blood glucose level evaluation or long-term insulin-dosing management (on-going) (as appropriate) when criteria 1, 2 or 3 are met.

Note: The device must be prescribed by an endocrinologist or maternal fetal medicine specialist for adults < 25 and children. Long-term criteria is restricted to either severe recurrent hypoglycemia [< 50] or evidence of hypoglycemia unawareness)

1. 72-hour (**preauthorization not required**) — considered appropriate for Types 1 or 2 diabetes for either:
 - a. Repeated hypoglycemia (< 50 mg/dl) or hyperglycemia (> 150 mg/dl)
 - b. Episodic hypoglycemic unawareness or nocturnal hypoglycemia
2. Long-term — combined CGM/Insulin-delivery device — Type 1 diabetes or pregnant members who are on insulin and all of the following:
 - a. ≥ 4 finger sticks required per day
 - b. Insulin injections required ≥ 3 times per day or member utilizes an insulin pump
 - c. Despite aggressive therapy and compliance documented in physician progress notes and member daily logs; **i or ii** must be met:

Hemoglobin A1C — 2 measurements > 7.0 separated by 3 months or more over a 6-month period; *and*, inadequate glycemic control despite consistent SMBG — ≥ 4 times daily over a 3-month period, which can include fasting hyperglycemia (> 150 mg/dl) or episodic recurrence of severe hypoglycemia (< 50 mg/dl) or fluctuations of > 200 mg/dl per day

OR

- i. Episodic hypoglycemic unawareness or nocturnal hypoglycemia (if demonstrated > 1 time during the 3 months of data), as presented in a and b above.

3. Long-term — single external insulin delivery infusion pump

- a. The member has completed a comprehensive diabetes education program; has been on a program of multiple daily injections of insulin (i.e., ≥ 3 injections per day) with frequent self-adjustments of insulin dose for ≥ 6 months prior to initiation of the insulin pump; has documented frequency of glucose self-testing an average of ≥ 4 times per day during the 2 months prior to initiation of the insulin pump and meets ≥ 1 of the following criteria while on the multiple injection regimen:
 - i. Glycosylated hemoglobin level (HbA1C) > 7 %
 - ii. History of recurring hypoglycemia
 - iii. Wide fluctuations in blood glucose before mealtime
 - iv. Dawn phenomenon with fasting blood sugars frequently exceeding 200 mg/dL
 - v. History of severe glycemic excursions

OR

- b. The member has been on an external insulin infusion pump prior to enrollment with the plan and has documented frequency of glucose self-testing an average of ≥ 4 times per day during the month prior to enrollment

Limitations/Exclusions

1. Only FDA-approved devices will be covered.
2. Members must meet eligibility criteria for a combined monitoring insulin delivery device in order to qualify for systems with a low glucose auto-suspend feature such as the MiniMed® 530G and 630 systems.
3. Requests for upgrades to the MiniMed 670G hybrid closed looped system (a closer approximation to an artificial pancreas device system [APDS] due to the additional features of automated basal delivery and predictive suspend technologies]) will be reviewed on a case by case basis.
4. Effective 1/12/2017, Medicare members are covered for the Dexcom G5® Mobile System when the following criteria (a–d) are met:
 - a. The beneficiary has diabetes mellitus; and,
 - b. The beneficiary has been using a home blood glucose monitor (BGM) and performing frequent (four or more times a day) BGM testing; and,
 - c. The beneficiary is insulin-treated with multiple daily injections (MDI) of insulin or a continuous subcutaneous insulin infusion (CSII) pump; and,
 - d. The beneficiary's insulin treatment regimen requires frequent adjustment by the beneficiary on the basis of therapeutic CGM testing results.

The Medicare DME Benefit excludes coverage for non-medical items, even when the items may be used to serve a medical purpose. As a result, smart devices (smart phones, tablets, personal computers, etc.) are non-covered by Medicare under this exclusion. In addition to the DME receiver included in the Dexcom G5® Mobile CGM System, an alternative option for displaying the received data is with a smart device using the Dexcom G5® app and a beneficiary-owned smart device such as a smart phone or tablet. Medicare does not cover a beneficiary-owned smart device. (See also [Noridian Coding and Coverage — Therapeutic Continuous Glucose Monitors \[CGM\]](#)).

5. Use of a programmable disposable external insulin pump with wireless communication capability to a hand-held control unit (e.g., OmniPod®) is an acceptable alternative to a standard pump when the medical necessity criteria above are met. **(OmniPod is covered for Commercial and Medicare members only)**
6. Use of an attachment (e.g., MiniMed Connect) to allow wireless transmission from a continuous glucose monitor to a smart phone or computer is not considered medically necessary, as it is regarded as a convenience feature.
7. No additional reimbursement will be provided for a wireless transmission feature that is integrated into a continuous glucose monitor (e.g., Dexcom SHARE), as it is regarded as a convenience feature.”
8. The following devices are not considered medically necessary, and are therefore not covered, due to insufficient evidence of therapeutic value:
 - a. Implantable insulin pumps
 - b. Nonprogrammable disposable insulin delivery systems without wireless communication capability (e.g., V-Go® Disposable Insulin Delivery Device)
 - c. Remote wireless glucose monitoring devices for real-time monitoring, as a technique of diabetic monitoring (e.g., Dexcom C5®)

Revision History

4/7/2017 — added coverage of the Dexcom G5 for Medicare members only (exclusions apply; listed above).

3/10/2017 — communicated that upgrade requests for the MiniMed 670 System will be reviewed on a case by case basis.

8/24/2016 — clarified that remote wireless and smartphone capabilities are not considered medically necessary.

8/5/2016 — added OmniPod clarification to differentiate from V-Go.

Applicable Procedure Codes

95250	Ambulatory continuous glucose monitoring of interstitial tissue fluid via a subcutaneous sensor for a minimum of 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 a minimum of 72 hours; interpretation and report.
0446T	Creation of subcutaneous pocket with insertion of implantable interstitial glucose sensor, including system activation and patient training (New Code: 01/01/2017)
0447T	Removal of implantable interstitial glucose sensor from subcutaneous pocket via incision (New Code: 01/01/2017)
0448T	Removal of implantable interstitial glucose sensor with creation of subcutaneous pocket at different anatomic site and insertion of new implantable sensor, including system activation (New Code: 01/01/2017)
A4224	Supplies for maintenance of insulin infusion catheter, per week (New Code: 01/01/2017)
A4225	Supplies for external insulin infusion pump, syringe type cartridge, sterile, each (New Code: 01/01/2017)
A4230	Infusion set for external insulin pump, non-needle cannula type
A4231	Infusion set for external insulin pump, needle type
A4232	Syringe with needle for external insulin pump, sterile, 3 cc
A9274	External ambulatory insulin delivery system, disposable, each, includes all supplies and accessories (Not covered when used to report nonprogrammable external insulin delivery systems (e.g., V-Go®)
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
A9999	Miscellaneous DME supply or accessory, not otherwise specified

E0607	Home blood glucose monitor
E0784	External ambulatory infusion pump, insulin (Coverage is limited to Commercial and Medicare members when code is reported specific to the OmniPod)
E1399	Durable medical equipment, miscellaneous
E2100	Blood glucose monitor with integrated voice synthesizer
E2101	Blood glucose monitor with integrated lancing/blood sample

Applicable ICD-10 Codes

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 (Incomplete Code 10/01/2016)
E10.3211	Type 1 diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, right eye (Eff. 10/01/2016)
E10.3212	Type 1 diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, left eye (Eff. 10/01/2016)
E10.3213	Type 1 diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, bilateral (Eff. 10/01/2016)
E10.3219	Type 1 diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, unspecified eye (Eff. 10/01/2016)
E10.329	Type 1 diabetes mellitus with mild nonproliferative diabetic retinopathy without macular edema (Incomplete Code 10/01/2016)
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E10.3299	Type 1 diabetes mellitus with mild nonproliferative diabetic retinopathy without macular edema, unspecified eye (Eff. 10/01/2016)
E10.331	Type 1 diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema (Incomplete Code 10/01/2016)
E10.3311	Type 1 diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, right eye (Eff. 10/01/2016)
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E10.3319	Type 1 diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, unspecified eye (Eff. 10/01/2016)
E10.339	Type 1 diabetes mellitus with moderate nonproliferative diabetic retinopathy without macular edema (Incomplete Code 10/01/2016)
E10.3391	Type 1 diabetes mellitus with moderate nonproliferative diabetic retinopathy without macular edema, right eye (Eff. 10/01/2016)
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E10.3393	Type 1 diabetes mellitus with moderate nonproliferative diabetic retinopathy without macular edema, bilateral (Eff. 10/01/2016)
E10.3399	Type 1 diabetes mellitus with moderate nonproliferative diabetic retinopathy without macular edema, unspecified eye (Eff. 10/01/2016)
E10.341	Type 1 diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema (Incomplete Code 10/01/2016)
E10.3411	Type 1 diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, right eye (Eff. 10/01/2016)
E10.3412	Type 1 diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, left eye (Eff. 10/01/2016)
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E10.3419	Type 1 diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, unspecified eye (Eff. 10/01/2016)
E10.349	Type 1 diabetes mellitus with severe nonproliferative diabetic retinopathy without macular edema (Incomplete Code 10/01/2016)
E10.3491	Type 1 diabetes mellitus with severe nonproliferative diabetic retinopathy without macular edema, right eye (Eff. 10/01/2016)
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E10.3493	Type 1 diabetes mellitus with severe nonproliferative diabetic retinopathy without macular edema, bilateral (Eff. 10/01/2016)
E10.3499	Type 1 diabetes mellitus with severe nonproliferative diabetic retinopathy without macular edema, unspecified eye (Eff. 10/01/2016)
E10.351	Type 1 diabetes mellitus with proliferative diabetic retinopathy with macular edema (Incomplete Code 10/01/2016)
E10.3511	Type 1 diabetes mellitus with proliferative diabetic retinopathy with macular edema, right eye (Eff. 10/01/2016)
E10.3512	Type 1 diabetes mellitus with proliferative diabetic retinopathy with macular edema, left eye (Eff. 10/01/2016)
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E10.3519	Type 1 diabetes mellitus with proliferative diabetic retinopathy with macular edema, unspecified eye (Eff. 10/01/2016)
E10.3521	Type 1 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment involving the macula, right eye (Eff. 10/01/2016)
E10.3522	Type 1 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment involving the macula, left eye (Eff. 10/01/2016)
E10.3523	Type 1 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment involving the macula, bilateral (Eff. 10/01/2016)
E10.3529	Type 1 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment involving the macula, unspecified eye (Eff. 10/01/2016)
E10.3531	Type 1 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment not involving the macula, right eye (Eff. 10/01/2016)
E10.3532	Type 1 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment not involving the macula, left eye (Eff. 10/01/2016)
E10.3533	Type 1 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment not involving the macula, bilateral (Eff. 10/01/2016)
E10.3539	Type 1 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment not involving the macula, unspecified eye (Eff. 10/01/2016)
E10.3541	Type 1 diabetes mellitus with proliferative diabetic retinopathy with combined traction retinal detachment and rhegmatogenous retinal detachment, right eye (Eff. 10/01/2016)
E10.3542	Type 1 diabetes mellitus with proliferative diabetic retinopathy with combined traction retinal detachment and rhegmatogenous retinal detachment, left eye (Eff. 10/01/2016)
E10.3543	Type 1 diabetes mellitus with proliferative diabetic retinopathy with combined traction retinal detachment and rhegmatogenous retinal detachment, bilateral (Eff. 10/01/2016)
E10.3549	Type 1 diabetes mellitus with proliferative diabetic retinopathy with combined traction retinal detachment and rhegmatogenous retinal detachment, unspecified eye (Eff. 10/01/2016)
E10.3551	Type 1 diabetes mellitus with stable proliferative diabetic retinopathy, right eye (Eff. 10/01/2016)

E10.3552	Type 1 diabetes mellitus with stable proliferative diabetic retinopathy, left eye (Eff. 10/01/2016)
E10.3553	Type 1 diabetes mellitus with stable proliferative diabetic retinopathy, bilateral (Eff. 10/01/2016)
E10.3559	Type 1 diabetes mellitus with stable proliferative diabetic retinopathy, unspecified eye (Eff. 10/01/2016)
E10.359	Type 1 diabetes mellitus with proliferative diabetic retinopathy without macular edema (Incomplete Code 10/01/2016)
E10.3591	Type 1 diabetes mellitus with proliferative diabetic retinopathy without macular edema, right eye (Eff. 10/01/2016)
E10.3592	Type 1 diabetes mellitus with proliferative diabetic retinopathy without macular edema, left eye (Eff. 10/01/2016)
E10.3593	Type 1 diabetes mellitus with proliferative diabetic retinopathy without macular edema, bilateral (Eff. 10/01/2016)
E10.3599	Type 1 diabetes mellitus with proliferative diabetic retinopathy without macular edema, unspecified eye (Eff. 10/01/2016)
E10.36	Type 1 diabetes mellitus with diabetic cataract
E10.37X1	Type 1 diabetes mellitus with diabetic macular edema, resolved following treatment, right eye (Eff. 10/01/2016)
E10.37X2	Type 1 diabetes mellitus with diabetic macular edema, resolved following treatment, left eye (Eff. 10/01/2016)
E10.37X3	Type 1 diabetes mellitus with diabetic macular edema, resolved following treatment, bilateral (Eff. 10/01/2016)
E10.37X9	Type 1 diabetes mellitus with diabetic macular edema, resolved following treatment, unspecified eye (Eff. 10/01/2016)
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
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E11.3551	Type 2 diabetes mellitus with stable proliferative diabetic retinopathy, right eye (Eff. 10/01/2016)
E11.3552	Type 2 diabetes mellitus with stable proliferative diabetic retinopathy, left eye (Eff. 10/01/2016)
E11.3553	Type 2 diabetes mellitus with stable proliferative diabetic retinopathy, bilateral (Eff. 10/01/2016)
E11.3559	Type 2 diabetes mellitus with stable proliferative diabetic retinopathy, unspecified eye (Eff. 10/01/2016)
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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
O24.011	Pre-existing type 1 diabetes mellitus, in pregnancy, first trimester
O24.012	Pre-existing type 1 diabetes mellitus, in pregnancy, second trimester
O24.013	Pre-existing type 1 diabetes mellitus, in pregnancy, third trimester
O24.019	Pre-existing type 1 diabetes mellitus, in pregnancy, unspecified trimester
O24.02	Pre-existing type 1 diabetes mellitus, in childbirth
O24.03	Pre-existing type 1 diabetes mellitus, in the puerperium

O24.111	Pre-existing type 2 diabetes mellitus, in pregnancy, first trimester
O24.112	Pre-existing type 2 diabetes mellitus, in pregnancy, second trimester
O24.113	Pre-existing type 2 diabetes mellitus, in pregnancy, third trimester
O24.119	Pre-existing type 2 diabetes mellitus, in pregnancy, unspecified trimester
O24.12	Pre-existing type 2 diabetes mellitus, in childbirth
O24.13	Pre-existing type 2 diabetes mellitus, in the 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 the puerperium, insulin controlled
O24.439	Gestational diabetes mellitus in the puerperium, unspecified control

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