# Medical Policy:

## Insulin Delivery Devices and Continuous Glucose Monitoring Systems

| POLICY NUMBER | LAST REVIEW |
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| MG.MM.ME.16v | March 8, 2024 |



The treating physician or primary care provider must submit to EmblemHealth, or ConnectiCare, as applicable (hereinafter jointly referred to as "EmblemHealth"), the clinical evidence that the member meets the criteria for the treatment or surgical procedure. Without this documentation and information, EmblemHealth will not be able to properly review the request preauthorization or post-payment review. The clinical review criteria expressed below reflects how EmblemHealth determines whether certain services or supplies are medically necessary. This clinical policy is not intended to pre-empt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. Health care providers are expected to exercise their medical judgment in rendering appropriate care.

EmblemHealth established the clinical review criteria based upon a review of currently available clinical information (including clinical outcome studies in the peer reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). EmblemHealth expressly reserves the right to revise these conclusions as clinical information changes and welcomes further relevant information. Each benefit program defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered and/or paid for by EmblemHealth, as some programs exclude coverage for services or supplies that EmblemHealth considers medically necessary.

If there is a discrepancy between this guideline and a member's benefits program, the benefits program will govern. Identification of selected brand names of devices, tests and procedures in a medical coverage policy is for reference only and is not an endorsement of any one device, test or procedure over another. In addition, coverage may be mandated by applicable legal requirements of a state, the Federal Government or the Centers for Medicare & Medicaid Services (CMS) for Medicare and Medicaid members. All coding and web site links are accurate at time of publication.

EmblemHealth may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice. EmblemHealth Services Company, LLC, has adopted this policy in providing management, administrative and other services to EmblemHealth Plan, Inc., EmblemHealth Insurance Company, EmblemHealth Services Company, LLC, and Health Insurance Plan of Greater New York (HIP) related to health benefit plans offered by these entities. ConnectiCare, an EmblemHealth company, has also adopted this policy. All of the aforementioned entities are affiliated companies under common control of EmblemHealth Inc.

## Definitions

| Pumps | |
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| **External insulin infusion** | Programmable, battery-powered mechanical syringe/reservoir devices controlled by a micro-computer to provide continuous subcutaneous insulin infusion (CSII). |
| **Sensor-augmented** | Suspend insulin when glucose is low or predicted to go low within the next 30 minutes. |
| **Continuous Glucose Monitoring (CGM)** | |
| **Real-time CGM (rtCGM)** | CGM systems that measure and display glucose levels continuously. |
| **Intermittently scanned CGM (isCGM) with and without alarms** | CGM systems that measure glucose levels continuously but require scanning for visualization and storage of glucose values. |
| **Professional CGM** | CGM devices that are placed on the patient in the provider's office (or with remote instruction) and worn for a discrete period of time (generally 7–14 days). Data may be blinded or visible to the person wearing the device. The data are used to assess glycemic patterns and trends. Unlike rtCGM and isCGM devices, these devices are clinic-based and not owned by the person with diabetes. |

| Implantable interstitial glucose sensors (also referred to as Implantable Continuous Glucose Monitor [ICG-M]) | |
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| **Implantable Continuous Glucose Monitor (ICG-M)** | Device that provides real-time glucose monitoring every five minutes for up to 90 days at a time. The system consists of an implantable fluorescence-based sensor, a smart transmitter, and a mobile application for displaying glucose values, trends and alerts on the patient's compatible mobile device. It is designed to replace fingerstick blood glucose testing. |
| **Automated Insulin Delivery Systems (combined functionality)** | |
| **Automated Insulin Delivery System** | Increase and decrease insulin delivery based on sensor derived glucose level to begin to approximate physiologic insulin delivery. These systems consist of three components:<br>▪ Insulin pump<br>▪ Continuous glucose sensor<br>▪ Algorithm that determines insulin delivery<br>With these systems, insulin delivery can not only be suspended but also increased or decreased based on sensor glucose values. |

## Guidelines

- **A. External insulin infusion pumps**
- **B. Personal CGM devices**
- **C. Automated Insulin Delivery Systems**
- **D. Implantable Interstitial Glucose Sensors (Commercial and Medicare)**

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### A. External insulin infusion pumps

External insulin infusion pumps (including but not limited to tubeless disposable pumps such as the OmniPod®) are considered medically necessary for Type 1, Type 2 or gestational diabetes when the member or caregiver is able to hear, view and appropriately respond to device alerts.

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### B. Personal CGM devices

Personal CGM devices (including but not limited to Medtronic Guardian Connect, Dexcom G7, FreeStyle Libre 3, etc.) are considered medically necessary for diabetes when criteria under Section **A** is met.

Note regarding EmblemHealth: Members on a commercial plan do not require the criteria under Section A to be met for personal CGM coverage.

### C. Automated Insulin Delivery Systems

Automated Insulin Delivery Systems (including but not limited to MiniMed 670G, 770G, and 780G [Medtronic], OmniPod 5, T:slimX [Tandem], etc.) are considered medically necessary for diabetes when criteria under Section **A** is met.

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### D. Implantable interstitial glucose sensors

Implantable Continuous Glucose Monitors (Eversense®) are considered medically necessary for Commercial and Medicare members ≥ 18 years of age with diabetes when criteria under Section **A** is met.

## Limitations and Exclusions

1. Only FDA-approved devices are covered (including, but not limited to alternate controller enabled [ACE] devices such as the t:Slim X2).
2. Replacement of a pump or a continuous glucose monitor is considered medically necessary when the device is malfunctioning, cannot be refurbished, and is out of warranty.
3. Combination devices that include a home blood glucose monitor combined with a blood pressure monitor, cholesterol screening analyzer, or other devices (e.g., cellular telephone), not specifically indicated for the management of diabetes mellitus, are regarded as not medically necessary convenience items.
4. The following devices are not considered medically necessary due to insufficient evidence of therapeutic value:
    - Implantable insulin pumps
    - Nonprogrammable disposable insulin delivery systems without wireless communication capability (e.g., V-Go® Disposable Insulin Delivery Device)
    - Remote wireless glucose monitoring devices (e.g., mySentry)
5. For Medicare information regarding the use of smart devices (watch, smartphone, tablet, laptop computer, etc.) in conjunction with a therapeutic continuous glucose monitor (CGM) see Noridian Glucose Monitor Policy Article .

## Procedure Codes

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| 0446T | Creation of subcutaneous pocket with insertion of implantable interstitial glucose sensor, including system activation and patient training (cover for Medicare and Commercial only) |
| 0447T | Removal of implantable interstitial glucose sensor from subcutaneous pocket via incision (cover for Medicare and Commercial only) |
| 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 (cover for Medicare and Commercial only) |
| 95249 | Ambulatory continuous glucose monitoring of interstitial tissue fluid via a subcutaneous sensor for a minimum of 72 hours; 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 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. |
| A4224 | Supplies for maintenance of insulin infusion catheter, per week |
| A4225 | Supplies for external insulin infusion pump, syringe type cartridge, sterile, each |
| A4230 | Infusion set for external insulin pump, non-needle cannula type |
| A4232 | Syringe with needle for external insulin pump, sterile, 3 cc |
| A4239 | Supply allowance for non-adjunctive, non-implanted continuous glucose monitor (cgm), includes all supplies and accessories, 1 month supply = 1 unit of service |

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| A4271 | Integrated lancing and blood sample testing cartridges for home blood glucose monitor, per month (eff. 04/01/2024) |
| 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 |
| A9999 | Miscellaneous DME supply or accessory, not otherwise specified |
| E0607 | Home blood glucose monitor |
| E0784 | External ambulatory infusion pump, insulin |
| E1399 | Durable medical equipment, miscellaneous |
| E2100 | Blood glucose monitor with integrated voice synthesizer |
| E2101 | Blood glucose monitor with integrated lancing/blood sample |
| E2102 | Adjunctive continuous glucose monitor or receiver |
| E2103 | Nonadjunctive, nonimplanted continuous glucose monitor (CGM) or receiver |
| G0308 | Creation of subcutaneous pocket with insertion of 180 day implantable interstitial glucose sensor, including system activation and patient training (Medicare Only) |
| G0309 | Removal of implantable interstitial glucose sensor with creation of subcutaneous pocket at different anatomic site and insertion of new 180 day implantable sensor, including system activation (Medicare Only) |
| 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 |

## ICD-10 Diagnoses

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| 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 |
| E10.3211 | 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 |
| E10.3219 | Type 1 diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, unspecified eye |
| E10.3291 | Type 1 diabetes mellitus with mild nonproliferative diabetic retinopathy without macular edema, right eye |

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| 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 |
| E10.3299 | Type 1 diabetes mellitus with mild nonproliferative diabetic retinopathy without macular edema, unspecified eye |
| E10.3311 | Type 1 diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, right eye |
| E10.3312 | Type 1 diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, left eye |
| E10.3313 | Type 1 diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, bilateral |
| E10.3319 | Type 1 diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, unspecified eye |
| E10.3391 | Type 1 diabetes mellitus with moderate nonproliferative diabetic retinopathy without macular edema, right eye |
| E10.3392 | Type 1 diabetes mellitus with moderate nonproliferative diabetic retinopathy without macular edema, left eye |
| E10.3393 | Type 1 diabetes mellitus with moderate nonproliferative diabetic retinopathy without macular edema, bilateral |
| E10.3399 | Type 1 diabetes mellitus with moderate nonproliferative diabetic retinopathy without macular edema, unspecified eye |
| E10.3411 | Type 1 diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, right eye |
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| E10.3413 | Type 1 diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, bilateral |
| E10.3419 | Type 1 diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, unspecified eye |
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| E10.3493 | Type 1 diabetes mellitus with severe nonproliferative diabetic retinopathy without macular edema, bilateral |
| E10.3499 | Type 1 diabetes mellitus with severe nonproliferative diabetic retinopathy without macular edema, unspecified eye |
| 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 |
| E10.3519 | Type 1 diabetes mellitus with proliferative diabetic retinopathy with macular edema, unspecified eye |
| 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 |
| E10.3529 | Type 1 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment involving the macula, unspecified eye |
| 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 |
| E10.3539 | Type 1 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment not involving the |

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| | macula, unspecified eye |
| 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, left eye |
| E10.3543 | Type 1 diabetes mellitus with proliferative diabetic retinopathy with combined traction retinal detachment and rhegmatogenous retinal detachment, bilateral |
| E10.3549 | Type 1 diabetes mellitus with proliferative diabetic retinopathy with combined traction retinal detachment and rhegmatogenous retinal detachment, unspecified eye |
| 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 |
| E10.3559 | Type 1 diabetes mellitus with stable proliferative diabetic retinopathy, unspecified eye |
| 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 |
| E10.3599 | Type 1 diabetes mellitus with proliferative diabetic retinopathy without macular edema, unspecified eye |
| 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 |
| E10.37X9 | Type 1 diabetes mellitus with diabetic macular edema, resolved following treatment, unspecified eye |
| 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 |

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| 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 |
| E11.10 | Type 2 diabetes mellitus with ketoacidosis without coma |
| E11.11 | Type 2 diabetes mellitus with ketoacidosis with coma |
| E11.21 | Type 2 diabetes mellitus with diabetic nephropathy |
| E11.22 | Type 2 diabetes mellitus with diabetic chronic kidney disease |
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| 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 |
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| 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 |

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| 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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Specialty-matched clinical peer review.

## Revision History

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| 3/8/2024 | Updated definitions and device versions. |
| 10/1/2023 | Removed insulin frequency adjustments as a prerequisite. |
| 6/11/1021 | Removed glucose testing prerequisite<br>Added note to CGM section communicating that Commercial members are not required to meet criterion A.<br>Removed prerequisite pertaining to new pump requests (for newly enrolled members whose pumps were supplied from another insurance plan), which required glucose testing frequency information to be submitted. |
| 1/8/2021 | Updated definitions and device versions.<br>Added Commercial and Medicare coverage for Eversense® ICG-M. |
| 5/12/2020 | Removed prerequisite for devices to be prescribed by endocrinologists or maternal fetal medicine specialists only. |
| 5/8/2020 | Removed hypoglycemic unawareness prerequisite for long-term combined monitoring/insulin delivery devices. |
| 5/10/2019 | Added Type 2 diabetes to long-term combined CGM/insulin-delivery devices section to coincide with FDA approvals.<br>Added implantable glucose sensors (e.g., Eversense®) as investigational.<br>Added pump/CGM replacement criteria. |
| 4/12/2019 | Added coverage of the t:slim X2. |
| 3/9/2019 | Added t:slim X2 Insulin Pump to Limitations/Exclusions as investigational. |
| 6/8/2018 | Added hypoglycemic unawareness to long-term criteria. |
| 5/3/2018 | For long term usage; combined the section for single external insulin delivery infusion pumps with the section for combined CGM/Insulin-delivery devices (with the addition of real-time monitoring devices) to create a single section with simplified criteria.<br>Added that combination devices that include a home blood glucose monitor combined with a blood pressure monitor, cholesterol screening analyzer, or other devices (e.g., cellular telephone) not specifically indicated for the management of diabetes mellitus, are regarded as not medically necessary convenience items. |
| 2/9/2018 | Added coverage of the Freestyle Libre Flash Glucose Monitoring System. |
| 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® 670G 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®. |