# Continuous Glucose Monitoring and Insulin Delivery for Managing Diabetes (for Pennsylvania Only)

**Policy Number**: CS024PA.AC
**Effective Date**: June 1, 2024

➲ Instructions for Use

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**Related Policy**

- Durable Medical Equipment, Orthotics, Medical Supplies, and Repairs/Replacements (for Pennsylvania Only)

## Application

This Medical Policy only applies to Medicaid and CHIP in the state of Pennsylvania. Any requests for services that do not meet criteria set in the PARP will be evaluated on a case-by-case basis. Refer to Pennsylvania Exceptions, Pennsylvania Code, Title 55, Chapter 1101.

## Coverage Rationale

➲ See Benefit Considerations

### Insulin Delivery

For coverage guidelines for tubeless insulin delivery devices including OmniPod, CeQur, and V-Go, refer to the Pennsylvania Medical Assistance Handbook Prior Authorization of Pharmaceutical Services.

**Other external insulin pumps that deliver insulin by continuous subcutaneous infusion are proven and medically necessary for managing individuals with type 1 or insulin-requiring type 2 diabetes**. For medical necessity clinical coverage criteria, refer to the InterQual® Client Defined, CP: Durable Medical Equipment, Insulin Pump, Ambulatory (Custom) - UHG.

Click here to view the InterQual® criteria.

**Due to insufficient evidence of efficacy, the following devices are unproven and not medically necessary for managing individuals with diabetes**:

- Implantable insulin pumps
- Insulin infuser ports
- Nonprogrammable transdermal insulin delivery systems other than those listed above

### Continuous Glucose Monitoring (CGM)

For coverage guidelines for continuous glucose monitoring products, refer to the Pennsylvania Medical Assistance Handbook Prior Authorization of Pharmaceutical Services.

# Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by federal, state, or contractual requirements and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

| CPT Code | Description |
|---|---|
| 0446T | Creation of subcutaneous pocket with insertion of implantable interstitial glucose sensor, including system activation and patient training |
| 0447T | Removal of implantable interstitial glucose sensor from subcutaneous pocket via incision |
| 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 |
| 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; physician or other qualified health care professional (office) provided equipment, 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; analysis, interpretation and report |



**Coding Clarification**: HCPCS code E1399 is often misused when reporting the i-Port device; however, the i-Port device is not durable medical equipment (DME).

| HCPCS Code | Description |
|---|---|
| A4211 | Supplies for self-administered injections |
| A4226 | Supplies for maintenance of insulin infusion pump with dosage rate adjustment using therapeutic continuous glucose sensing, per week |
| A4238 | Supply allowance for adjunctive, nonimplanted continuous glucose monitor (CGM), includes all supplies and accessories, 1 month supply = 1 unit of service |
| A4239 | Supply allowance for non-adjunctive, nonimplanted continuous glucose monitor (CGM), includes all supplies and accessories, 1 month supply = 1 unit of service |
| A9274 | External ambulatory insulin delivery system, disposable, each, includes all supplies and accessories |
| A9276 | Sensor; invasive (e.g., subcutaneous), disposable, for use with nondurable medical equipment interstitial continuous glucose monitoring system (CGM), 1 unit = 1-day supply |
| A9277 | Transmitter; external, for use with nondurable medical equipment interstitial continuous glucose monitoring system (CGM) |
| A9278 | Receiver (monitor); external, for use with nondurable medical equipment interstitial continuous glucose monitoring system (CGM) |
| E0784 | External ambulatory infusion pump, insulin |
| E0787 | External ambulatory infusion pump, insulin, dosage rate adjustment using therapeutic continuous glucose sensing |
| E1399 | Durable medical equipment, miscellaneous (Note: The i-Port device is not durable medical equipment (DME), nor does it have a listed code.) |
| E2102 | Adjunctive, nonimplanted continuous glucose monitor (CGM) or receiver |
| E2103 | Non-adjunctive, nonimplanted continuous glucose monitor (CGM) or receiver |
| S1030 | Continuous noninvasive glucose monitoring device, purchase (For physician interpretation of data, use CPT code) |

| HCPCS Code | Description |
|---|---|
| S1031 | Continuous noninvasive glucose monitoring device, rental, including sensor, sensor replacement, and download to monitor (For physician interpretation of data, use CPT code) |
| S1034 | Artificial pancreas device system (e.g., low glucose suspend [LGS] feature) including continuous glucose monitor, blood glucose device, insulin pump and computer algorithm that communicates with all of the devices |
| S1035 | Sensor; invasive (e.g., subcutaneous), disposable, for use with artificial pancreas device system |
| S1036 | Transmitter; external, for use with artificial pancreas device system |
| S1037 | Receiver (monitor); external, for use with artificial pancreas device system |

| Diagnosis Code | Description |
|---|---|
| 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 |
| 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 |
| E11.3211 | Type 2 diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, right eye |
| E11.3212 | Type 2 diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, left eye |
| E11.3213 | Type 2 diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, bilateral |
| E11.3219 | Type 2 diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, unspecified eye |
| E11.3291 | Type 2 diabetes mellitus with mild nonproliferative diabetic retinopathy without macular edema, right eye |
| E11.3292 | Type 2 diabetes mellitus with mild nonproliferative diabetic retinopathy without macular edema, left eye |
| E11.3293 | Type 2 diabetes mellitus with mild nonproliferative diabetic retinopathy without macular edema, bilateral |
| E11.3299 | Type 2 diabetes mellitus with mild nonproliferative diabetic retinopathy without macular edema, unspecified eye |
| E11.3311 | Type 2 diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, right eye |
| E11.3312 | Type 2 diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, left eye |
| E11.3313 | Type 2 diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, bilateral |
| E11.3319 | Type 2 diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, unspecified eye |
| E11.3391 | Type 2 diabetes mellitus with moderate nonproliferative diabetic retinopathy without macular edema, right eye |
| E11.3392 | Type 2 diabetes mellitus with moderate nonproliferative diabetic retinopathy without macular edema, left eye |
| E11.3393 | Type 2 diabetes mellitus with moderate nonproliferative diabetic retinopathy without macular edema, bilateral |

| Diagnosis Code | Description |
|---|---|
| E11.3399 | Type 2 diabetes mellitus with moderate nonproliferative diabetic retinopathy without macular edema, unspecified eye |
| E11.3411 | Type 2 diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, right eye |
| E11.3412 | Type 2 diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, left eye |
| E11.3413 | Type 2 diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, bilateral |
| E11.3419 | Type 2 diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, unspecified eye |
| E11.3491 | Type 2 diabetes mellitus with severe nonproliferative diabetic retinopathy without macular edema, right eye |
| E11.3492 | Type 2 diabetes mellitus with severe nonproliferative diabetic retinopathy without macular edema, left eye |
| E11.3493 | Type 2 diabetes mellitus with severe nonproliferative diabetic retinopathy without macular edema, bilateral |
| E11.3499 | Type 2 diabetes mellitus with severe nonproliferative diabetic retinopathy without macular edema, unspecified eye |
| E11.3511 | Type 2 diabetes mellitus with proliferative diabetic retinopathy with macular edema, right eye |
| E11.3512 | Type 2 diabetes mellitus with proliferative diabetic retinopathy with macular edema, left eye |
| E11.3513 | Type 2 diabetes mellitus with proliferative diabetic retinopathy with macular edema, bilateral |
| E11.3519 | Type 2 diabetes mellitus with proliferative diabetic retinopathy with macular edema, unspecified eye |
| E11.3521 | Type 2 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment involving the macula, right eye |
| E11.3522 | Type 2 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment involving the macula, left eye |
| E11.3523 | Type 2 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment involving the macula, bilateral |
| E11.3529 | Type 2 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment involving the macula, unspecified eye |
| E11.3531 | Type 2 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment not involving the macula, right eye |
| E11.3532 | Type 2 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment not involving the macula, left eye |
| E11.3533 | Type 2 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment not involving the macula, bilateral |
| E11.3539 | Type 2 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment not involving the macula, unspecified eye |
| E11.3541 | Type 2 diabetes mellitus with proliferative diabetic retinopathy with combined traction retinal detachment and rhegmatogenous retinal detachment, right eye |
| E11.3542 | Type 2 diabetes mellitus with proliferative diabetic retinopathy with combined traction retinal detachment and rhegmatogenous retinal detachment, left eye |
| E11.3543 | Type 2 diabetes mellitus with proliferative diabetic retinopathy with combined traction retinal detachment and rhegmatogenous retinal detachment, bilateral |
| E11.3549 | Type 2 diabetes mellitus with proliferative diabetic retinopathy with combined traction retinal detachment and rhegmatogenous retinal detachment, unspecified eye |
| E11.3551 | Type 2 diabetes mellitus with stable proliferative diabetic retinopathy, right eye |
| E11.3552 | Type 2 diabetes mellitus with stable proliferative diabetic retinopathy, left eye |
| E11.3553 | Type 2 diabetes mellitus with stable proliferative diabetic retinopathy, bilateral |
| E11.3559 | Type 2 diabetes mellitus with stable proliferative diabetic retinopathy, unspecified eye |

| Diagnosis Code | Description |
|---|---|
| E11.3591 | Type 2 diabetes mellitus with proliferative diabetic retinopathy without macular edema, right eye |
| E11.3592 | Type 2 diabetes mellitus with proliferative diabetic retinopathy without macular edema, left eye |
| E11.3593 | Type 2 diabetes mellitus with proliferative diabetic retinopathy without macular edema, bilateral |
| E11.3599 | Type 2 diabetes mellitus with proliferative diabetic retinopathy without macular edema, unspecified eye |
| E11.36 | Type 2 diabetes mellitus with diabetic cataract |
| E11.37X1 | Type 2 diabetes mellitus with diabetic macular edema, resolved following treatment, right eye |
| E11.37X2 | Type 2 diabetes mellitus with diabetic macular edema, resolved following treatment, left eye |
| E11.37X3 | Type 2 diabetes mellitus with diabetic macular edema, resolved following treatment, bilateral |
| E11.37X9 | Type 2 diabetes mellitus with diabetic macular edema, resolved following treatment, unspecified eye |
| 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 |
| 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 |
| O24.415 | Gestational diabetes mellitus in pregnancy, controlled by oral hypoglycemic drugs |
| O24.419 | Gestational diabetes mellitus in pregnancy, unspecified control |
| O24.430 | Gestational diabetes mellitus in the puerperium, diet controlled |
| O24.435 | Gestational diabetes mellitus in the puerperium, controlled by oral hypoglycemic drugs |

| Diagnosis Code | Description |
|---|---|
| O24.439 | Gestational diabetes mellitus in the puerperium, unspecified control |

# Description of Services

Diabetes mellitus can be classified into the following general categories (American Diabetes Association, 2023):

- Type 1 diabetes [due to autoimmune beta-cell destruction, usually leading to absolute insulin deficiency, including latent autoimmune diabetes of adulthood (LADA)]. LADA can be classified as a more slowly progressing variation of type 1 diabetes, yet it is often misdiagnosed as type 2.
- Type 2 diabetes (due to a non-autoimmune progressive loss of adequate beta-cell insulin secretion frequently on the background of insulin resistance and metabolic syndrome).
- Gestational diabetes mellitus (GDM) (diabetes diagnosed in the second or third trimester of pregnancy that was not clearly overt diabetes prior to gestation). GDM resembles type 2 diabetes and usually disappears after childbirth.
- Specific types of diabetes due to other causes, e.g., monogenic diabetes syndromes (such as neonatal diabetes and maturity-onset diabetes of the young), diseases of the exocrine pancreas (such as cystic fibrosis and pancreatitis), and drug- or chemical-induced diabetes (such as with glucocorticoid use, in the treatment of HIV/AIDS, or after organ transplantation).

If poorly controlled, diabetes can lead to complications such as heart disease, stroke, peripheral vascular disease, retinal damage, kidney disease, nerve damage and impotence. In GDM, fetal and maternal health can be compromised.

Improved glycemic control has been shown to slow the onset or progression of major complications. Management of diabetes involves efforts to maintain blood glucose levels near the normal range. Blood glucose monitoring (BGM) and laboratory testing of hemoglobin A1c (HbA1c) to measure longer term glycemic control are standard methods for glucose testing (ADA, 2023).

## Insulin Delivery

Standard external insulin pumps connect to flexible plastic tubing that ends with a needle inserted through the skin into the fatty tissue. Another type of insulin pump (OmniPod®) combines an insulin reservoir placed on the skin with a wireless device to manage dosing and perform BGM. Both types of devices can be programmed to release small doses of insulin continuously (basal), or a bolus dose close to mealtime to control the rise in blood glucose after a meal. Newer patch devices (e.g., V-Go®) deliver preset basal and on-demand bolus dosages of insulin transdermally and lack programmability.

Implantable insulin pumps are placed inside the body to deliver insulin in response to remote-control commands from the user (ADA Common Terms website).

An insulin infuser port is a device used to reduce the number of needle injections for individuals with insulin-dependent diabetes. An insertion needle guides a soft cannula into the subcutaneous tissue. Once applied, the insertion needle is removed, leaving the soft cannula under the skin to act as a direct channel into the subcutaneous tissue. Insulin is then injected through the cannula using a standard needle and syringe or insulin pen. Devices remain in place for up to 72 hours to accommodate multiple drug injections without additional needle sticks.

# Benefit Considerations

For details regarding repair and replacement coverage, refer to the Medical Policy titled Durable Medical Equipment, Orthotics, Medical Supplies, and Repairs/Replacements (for Pennsylvania Only).

# Clinical Evidence

## Insulin Delivery

### *Nonprogrammable Transdermal Insulin Delivery*

There is insufficient evidence in the clinical literature demonstrating the safety and efficacy of transdermal insulin delivery in the management of individuals with diabetes.

### *Implantable Insulin Pumps*

Implantable insulin pumps are a promising new technology for the treatment of insulin-dependent diabetes but at this time are only available in a clinical trial setting.

### *Insulin Infuser Ports*

There is insufficient evidence in the clinical literature demonstrating that the use of insulin infuser ports results in improved glycemic control beyond what can be achieved by using standard insulin delivery methods. Further well-designed, large-scale randomized controlled trials are needed to establish the safety and efficacy of these devices.

Khan et al. (2019) conducted a prospective study evaluating the i-Port system in 55 insulin-treated patients. Of the 55 patients, 93% had type 1 diabetes and used an insulin pen. Patients were divided into two groups: regular users of the i-Port (n = 27), who used it for ≥ 3 months, and irregular users (n = 28), who used it for < 3 months. Irregular users had a longer duration of diabetes at baseline compared to regular users, were less likely to report noncompliance with insulin usage, were more likely to self-inject insulin and had a lower HbA1c. Although there were fewer hospitalizations and hypoglycemic episodes, and compliance improved with i-Port usage, there were no statistical differences between groups in treatment satisfaction or mean glycemic control scores.

Blevins et al. (2008) conducted a prospective, randomized controlled cross-over trial comparing the outcomes of insulin-dependent diabetics (n = 74) who used the i-Port compared to standard multi-injection insulin therapy. Type 1 (n = 56) and type 2 (n = 18) diabetics were randomly assigned to one of four cohort groups. Cohort 1 (n = 18) compared standard injections (SI) to single i-Port, cohort 2 (n = 20) compared single i-Port to SI, cohort 3 (n = 18) compared dual i-Ports to single i-Port and cohort 4 (n = 18) compared single i-Port to dual i-Ports. At the end of the first three weeks, each group switched to the alternative method for an additional three weeks. Ten participants were lost to follow-up, six of which were due to device related issues (adhesive failure, discomfort, hyperglycemia, cannula bends and adverse events). Participant's glycosylated albumin was not significantly different between SI, single i-Port and dual i-Port treatment regiments. HbA1c levels were similar among all cohorts at the initiation and completion of the study. Adverse events included erythema, suppuration, skin irritation, itching, and bruising at the i-Port insertion site. Three events of severe hyperglycemia were also reported.

## U.S. Food and Drug Administration (FDA)

This section is to be used for informational purposes only. FDA approval alone is not a basis for coverage.

### Insulin Delivery

For information on external insulin pumps, refer to the following website (use product code LZG): http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. (Accessed February 14, 2023)

For information on hybrid closed-loop insulin pumps, refer to the following website (use product code OZP): https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm. (Accessed February 14, 2023)

No implantable insulin pumps have received FDA approval at this time.
The i-Port® Injection Port was approved by the FDA on September 9, 2005 (K052389). The injection port is indicated for use by people requiring multiple daily subcutaneous injections of physician prescribed medications, including insulin. The device is designed for use on adults and children for up to 72 hours. Additional information available at: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID=K052389. (Accessed February 14, 2023)

The i-Port Advance® Injection Port was approved by the FDA on February 16, 2012 (K120337). This model has the same indications as the original device but includes an automatic insertion component. Additional information available at: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K120337. (Accessed February 14, 2023)

Insulin Pump Models with or without a CGM component (this is not an exhaustive list):

- Insulet Omnipod 5
- Insulet Omnipod DASH
- Medtronic MiniMed 630G
- Medtronic MiniMed 770G
- Sooil Dana Diabecare
- Tandem t: slim X2 with Basal – IQ
- Tandem t: slim X2 with Control - IQ

## Continuous Glucose Monitors (CGM)

For information on CGMs, refer to the following website (use product code MDS): https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm. (Accessed February 14, 2023)
CGM Models (this is not an exhaustive list):

- Abbott FreeStyle Libre 2 and Libre 14
- Dexcom G6
- Dexcom G7
- Medtronic Guardian Connect
- Ascensia Eversense E3

The Eversense CGM system received FDA premarket approval (P160048) on June 21, 2018. The original device was indicated for continually measuring glucose levels in adults (18 years or older) with diabetes for up to 90 days and did not replace information obtained from standard home blood glucose monitoring devices. On June 6, 2019, the device was approved for non-adjunctive use (P160048/S006). On February 10, 2022, the Eversense E3 device received FDA premarket approval (P160048/S016) expanding the indicated use up to 180 days in adults (18 years or older). Eversense is classified under product codes QCD and QHJ. Additional information is available at: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P160048. (Accessed February 14, 2023)

# References


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Pennsylvania Continuous Glucose Monitoring Medical Assistance Handbook Prior Authorization of Pharmaceutical Services. Refer to: https://www.dhs.pa.gov/providers/Pharmacy-Services/Documents/Clinical%20Guidelines%20SW%20PDL/Continuous%20Glucose%20Monitoring%20Products%20240108.pdf. Accessed January 16, 2024.

Pennsylvania Tubeless Insulin Delivery Devices Medical Assistance Handbook Prior Authorization of Pharmaceutical Services. Refer to: https://www.dhs.pa.gov/providers/Pharmacy-Services/Documents/Clinical%20Guidelines%20SW%20PDL/Tubeless%20Insulin%20Delivery%20Devices%2020240108.pdf. Accessed January 16, 2024.


# Policy History/Revision Information

| Date | Summary of Changes |
|---|---|
| 06/01/2024 | **Coverage Rationale**<br>***Insulin Delivery***<br>• Added instruction to refer to the *Pennsylvania Medical Assistance Bulletin: Prior Authorization of Tubeless Insulin Delivery Devices – Pharmacy Services* for coverage guidelines for tubeless insulin delivery devices including OmniPod, CeQur, and V-G<br>• Replaced language indicating "external insulin pumps that deliver insulin by continuous subcutaneous infusion are proven and medically necessary for managing individuals with type 1 or insulin-requiring type 2 diabetes" with "*other* external insulin pumps *[not listed in the policy]* that deliver insulin by continuous subcutaneous infusion are proven and medically necessary for managing individuals with type 1 or insulin-requiring type 2 diabetes" |

| Date | Summary of Changes |
|---|---|
| | • Removed language indicating programmable disposable external insulin pumps (e.g., OmniPod) are considered clinically equivalent to standard insulin pumps; for OmniPod 5, refer to the federal, state, or contractual requirement<br>• Revised list of unproven and not medically necessary devices for managing individuals with diabetes; replaced "nonprogrammable transdermal insulin delivery systems *(e.g., V-Go)*" with "nonprogrammable transdermal insulin delivery systems *other than those listed [as proven and medically necessary in the policy]*"<br>***Continuous Glucose Monitoring (CGM)***<br>• Replaced coverage guidelines with instruction to refer to the *Pennsylvania Medical Assistance Bulletin: Prior Authorization of Continuous Glucose Monitoring Products – Pharmacy Services* for coverage guidelines for continuous glucose monitoring products<br>**Supporting Information**<br>• Updated *Description of Services*, *Clinical Evidence*, and *References* sections to reflect the most current information<br>• Removed *Definitions* section<br>• Archived previous policy version CS024PA.AB |

# Instructions for Use

This Medical Policy provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the federal, state or contractual requirements for benefit plan coverage must be referenced as the terms of the federal, state or contractual requirements for benefit plan coverage may differ from the standard benefit plan. In the event of a conflict, the federal, state or contractual requirements for benefit plan coverage govern. Before using this policy, please check the federal, state or contractual requirements for benefit plan coverage. UnitedHealthcare reserves the right to modify its Policies and Guidelines as necessary. This Medical Policy is provided for informational purposes. It does not constitute medical advice.

UnitedHealthcare may also use tools developed by third parties, such as the InterQual® criteria, to assist us in administering health benefits. The UnitedHealthcare Medical Policies 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.