

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

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[Instructions for Use](#)

Table of Contents	Page
<a href="#">Application</a> .....	1
<a href="#">Coverage Rationale</a> .....	1
<a href="#">Applicable Codes</a> .....	2
<a href="#">Description of Services</a> .....	6
<a href="#">Benefit Considerations</a> .....	6
<a href="#">Clinical Evidence</a> .....	6
<a href="#">U.S. Food and Drug Administration</a> .....	7
<a href="#">References</a> .....	7
<a href="#">Policy History/Revision Information</a> .....	8
<a href="#">Instructions for Use</a> .....	9

Related Policy
<ul style="list-style-type: none"> <li><a href="#">Durable Medical Equipment, Orthotics, Medical Supplies, and Repairs/Replacements (for Pennsylvania Only)</a></li> </ul>

## 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](#).

When used according to [U.S. Food and Drug Administration \(FDA\)](#) labeled indications, contraindications, warnings, and precautions, other external continuous subcutaneous insulin infusion pumps are proven and medically necessary in certain circumstances.

For medical necessity clinical coverage criteria, refer to the InterQual® CP: Durable Medical Equipment, Continuous Glucose Monitors, Insulin Pumps and Automated Insulin Deliver Technology.

[Click here to view the InterQual® criteria.](#)

**External continuous subcutaneous insulin infusion pumps are medically necessary for managing individuals with diabetes due to other causes that require intensive insulin therapy (insulin-treated at least 3 times a day).** Examples include, but are not limited to cystic fibrosis-related diabetes, post-transplantation diabetes, or diabetes following pancreatic surgery.

**The following [devices](#) are unproven and not medically necessary for managing individuals with diabetes due to insufficient evidence of efficacy:**

- Implantable insulin pumps
- 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

*CPT® is a registered trademark of the American Medical Association*

HCPCS Code	Description
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 nonadjunctive, 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), one 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
E2102	Adjunctive, nonimplanted continuous glucose monitor (CGM) or receiver
E2103	Nonadjunctive, nonimplanted continuous glucose monitor (CGM) or receiver
S1030	Continuous noninvasive glucose monitoring device, purchase (For physician interpretation of data, use CPT code)
S1031	Continuous noninvasive glucose monitoring device, rental, including sensor, sensor replacement, and download to monitor (For physician interpretation of data, use CPT code)

HCPCS Code	Description
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
E11.3399	Type 2 diabetes mellitus with moderate nonproliferative diabetic retinopathy without macular edema, unspecified eye

Diagnosis Code	Description
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
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

Diagnosis Code	Description
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
O24.414	Gestational diabetes mellitus in pregnancy, insulin controlled
O24.415	Gestational diabetes mellitus in pregnancy, controlled by oral hypoglycemic drugs
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
O24.425	Gestational diabetes mellitus in childbirth, controlled by oral hypoglycemic drugs

Diagnosis Code	Description
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
O24.435	Gestational diabetes mellitus in the puerperium, controlled by oral hypoglycemic drugs
O24.439	Gestational diabetes mellitus in the puerperium, unspecified control

## Description of Services

Diabetes mellitus can be classified into the following general categories (ADA, 2024):

- Type 1 diabetes [due to autoimmune beta-cell destruction, usually leading to absolute insulin deficiency, including latent autoimmune diabetes in adults (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 or other types of diabetes occurring throughout pregnancy, such as type 1 diabetes). 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, 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 erectile dysfunction. 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. Glycemic status can be assessed by blood glucose monitoring (BGM), continuous glucose monitoring (CGM) and laboratory testing of hemoglobin A1c (HbA1c) (ADA, 2024).

### Insulin Delivery

Standard external insulin pumps connect to flexible plastic tubing that ends with a needle inserted just under the skin. 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).

## Benefit Considerations

For details regarding repair and replacement coverage, refer to the Coverage Determination Guideline titled [Durable Medical Equipment, Orthotics, Medical Supplies, and Repairs/Replacements \(for Pennsylvania Only\)](#).

## Clinical Evidence

### Insulin Delivery

#### *Insulin Pumps for Diabetes Due to Other Causes*

Specific types of diabetes due to other causes may require intensive insulin management. Examples include cystic fibrosis-related diabetes, post-transplantation diabetes, or diabetes following pancreatic surgery. Although the evidence is limited, professional societies state that insulin pumps may be considered in these populations with insulin deficiency that require multiple daily injections (ADA, 2024; McCall et al., 2023).

#### *Implantable Insulin Pumps*

At this time, implantable insulin pumps are only available in a clinical trial setting.



## ***Nonprogrammable Transdermal Insulin Delivery***

There is insufficient evidence in the clinical literature demonstrating the safety and efficacy of nonprogrammable wearable disposable insulin delivery devices in the management of individuals with diabetes. Larger, well-designed studies with long-term follow-up and comparative effectiveness data are needed.

## **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 codes LZG or QFG): <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm>. (Accessed March 13, 2024)

For information on automated insulin delivery systems or 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 March 13, 2024)

No implantable insulin pumps have received FDA approval at this time.

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

- Beta Bionics iLet
- Insulet Omnipod 5
- Insulet Omnipod DASH
- Medtronic MiniMed 630G
- Medtronic MiniMed 770G
- Medtronic MiniMed 780G
- Sooil Dana Diabecare
- Tandem Mobi
- 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 March 13, 2024)

CGM Models (this is not an exhaustive list):

- Abbott FreeStyle Libre 2
- Abbott FreeStyle Libre 3
- Abbott FreeStyle Libre 14-Day
- 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 March 13, 2024)

## **References**

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## Policy History/Revision Information

Date	Summary of Changes
10/01/2024	<p><b>Coverage Rationale</b>  <b><i>Insulin Delivery</i></b></p> <ul style="list-style-type: none"> <li>Replaced language indicating “other external insulin pumps <i>that deliver insulin by continuous subcutaneous infusion</i> are proven and medically necessary for managing individuals with type 1 or insulin-requiring type 2 diabetes” with “other external <i>continuous subcutaneous</i> insulin infusion pumps are proven and medically necessary <i>in certain circumstances when used according to U.S. Food and Drug Administration (FDA) labeled indications, contraindications, warnings, and precautions</i>”</li> <li>Revised language pertaining to medical necessity clinical coverage criteria: <ul style="list-style-type: none"> <li>Added reference to the InterQual® CP: Durable Medical Equipment, Continuous Glucose Monitors, Insulin Pumps, and Automated Insulin Delivery Technology</li> <li>Removed reference to the InterQual® Client Defined, CP: Durable Medical Equipment, Insulin Pump, Ambulatory (Custom) - UHG</li> </ul> </li> <li>Added language to indicate external continuous subcutaneous insulin infusion pumps are medically necessary for managing individuals with diabetes due to other causes that require intensive insulin therapy (insulin-treated at least 3 times a day); examples include, but are not limited to cystic fibrosis-related diabetes, post-transplantation diabetes, or diabetes following pancreatic surgery</li> <li>Revised list of unproven and not medically necessary devices; removed “insulin infuser ports”</li> </ul> <p><b>Applicable Codes</b></p> <ul style="list-style-type: none"> <li>Removed HCPCS codes A4211 and E1399</li> <li>Removed coding clarification pertaining to HCPCS code E1399</li> <li>Added ICD-10 diagnosis codes O24.414, O24.420, O24.424, O24.425, O24.429, and O24.434</li> </ul> <p><b>Supporting Information</b></p> <ul style="list-style-type: none"> <li>Updated <i>Description of Services, Clinical Evidence, FDA, and References</i> sections to reflect the most current information</li> <li>Archived previous policy version CS024PA.AC</li> </ul>



## 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<sup>®</sup> 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.