

Clinical Policy: External Diabetic Devices (Omnipod)

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Line of Business: Medicaid

[Coding Implications](#)

[Revision Log](#)

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

Description

The following are insulin delivery systems* requiring prior authorization:

- Omnipod DASH® Insulin Management System
- Omnipod® 5 Automated Insulin Delivery System
- Omnipod GO™ Insulin Delivery Device

**If request is for an insulin delivery system that is also a continuous glucose monitor, additional approval criteria apply. Refer to the Continuous Glucose Monitor policy for the relevant line of business.*

FDA Approved Indication(s)

Omnipod DASH Insulin Management System

- Use: Subcutaneous delivery of insulin at set and variable rates for the management of diabetes mellitus in persons requiring insulin.
- Populations: Appropriate for use in type 1 diabetes, insulin-requiring type 2 diabetes, gestational diabetes, and latent autoimmune diabetes. Omnipod DASH can be used by people of all ages. See <https://www.myomnipod.com/healthcareproviders/about-omnipod/prescribe>.
- Components: 1) Adhesive disposable pump (DASH Pod), 2) handheld DASH Personal Diabetes Manager (PDM) device, 3) compatible Contour® Next One blood glucose meter (BGM)
 - Contour Next test strips and control solution are used with the Contour Next One BGM for quantitative measurement of blood glucose (BG) in fresh capillary whole blood drawn from the fingertips or palm.*
- Connectivity: Wireless Bluetooth communication between the DASH Pod, DASH PDM, Contour Next BGM and, if desired, an iPhone (iPhone application does not include insulin management - view only).**
- User guide and related resources: <https://www.omnipod.com/current-podders/resources/omnipod-dash>

Omnipod 5 Automated Insulin Delivery System

- Use: Subcutaneous delivery of insulin at set and variable rates for the management of diabetes mellitus in persons requiring insulin.

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- Populations: The Omnipod 5 Alternate Controller Enabled (ACE) Pump is intended for the management of diabetes mellitus in persons requiring insulin. The SmartAdjust technology is intended for use in patients aged 2 years and older with type 1 diabetes and patients aged 18 years and older with type 2 diabetes. The SmartBolus Calculator is intended for use in patients aged 2 years and older with diabetes requiring rapid-acting U-100 insulin.
- Components: 1) Omnipod 5 ACE Pump (an adhesive disposable pump, or Pod), 2) Omnipod 5 App (on a provided Controller or installed on a compatible smartphone), 3) Dexcom G6[®] or G7[®] continuous glucose monitoring (CGM) system (must be obtained separately)
- Connectivity: Wireless *Bluetooth communication* between the Pod, Dexcom G6 or G7 CGM, and provided Controller or compatible smartphone (<https://omnipod.com/compatibility>)
- User guide and related resources: https://www.omnipod.com/sites/default/files/Omnipod-5_User-guide.pdf

Omnipod GO Insulin Delivery Device

- Use: Subcutaneous delivery of insulin at preset basal rates for the management of type 2 diabetes mellitus in persons requiring insulin.
- Populations: Adults with type 2 diabetes requiring basal insulin.
- Components: Adhesive disposable pump (Omnipod GO Pod)
- Connectivity: None
- User guide and related resources: <https://www.omnipod.com/current-podders/resources>

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation[®] that V-Go, Omnipod DASH, Omnipod 5, Omnipod GO, and InPen are **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Requests for Omnipod GO (must meet all):

1. Request is for Omnipod GO;
2. Diagnosis of type 2 diabetes mellitus;
3. Prescribed by or in consultation with an endocrinologist;
4. Age \geq 18 years;
5. One of the following (a or b):
 - a. Member is currently receiving basal insulin therapy;
 - b. Both of the following (i and ii):
 - i. Member requires insulin therapy as evidenced by HbA1c $>$ 10% or blood glucose \geq 300 mg/dL;
 - ii. Failure of an antidiabetic agent (*see Appendix B for examples*), unless clinically significant adverse effects are experienced or all are contraindicated;

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6. Medical justification supports necessity of an insulin delivery system (i.e., rationale why member cannot self-inject daily basal insulin – for example, the member has severe arthritis and no caregivers are available to assist with insulin administration);
7. Number of Pods does not exceed 10 per month.*
**For requests exceeding 10 Pods per month, a clinical rationale with documentation to support the higher quantity is required.*

Approval duration: 6 months

B. All Other Requests (must meet all):

1. Request is for Omnipod DASH, Omnipod 5;
2. Diagnosis of diabetes mellitus;
3. Prescribed by or in consultation with an endocrinologist;
4. If request is for Omnipod 5, age ≥ 2 years;
5. Member has utilized one of the following insulin administration methods for at least the last 6 months (a or b):
 - a. Continuous insulin delivery system (*see Appendix B for examples*);
 - b. Multiple daily insulin injections (meets i and ii):
 - i. Administration of at least 3 daily injections of a basal and bolus insulin regimen (*see Appendix B for examples of basal [intermediate- or long-acting] and bolus [short- or rapid-acting] insulin*);
 - ii. History of suboptimal blood sugar control despite appropriate management – examples of suboptimal control include, but are not limited to, any of the following (1-6):
 - 1) Repeated hypoglycemic events (BG < 70 mg/dL);
 - 2) Repeated episodes of diabetic ketoacidosis;
 - 3) Wide blood sugar excursions;
 - 4) Hypoglycemia unawareness;
 - 5) Glycosylated hemoglobin level (HbA1c) ≥ 7.0 ;
 - 6) “Dawn phenomenon” with fasting blood sugars repeatedly > 200 mg/dL;
6. Member has monitored BG ≥ 4 times a day for at least the last 6 months;
7. Omnipod DASH/Omnipod 5: Both of the following (i and ii):
 - i. Number of Pods does not exceed 10 per month;*
**For requests exceeding 10 Pods per month, a clinical rationale with documentation to support the higher quantity is required.*
 - ii. Number of devices does not exceed 1 per 4 years;
- b. **Approval duration:** Omnipod DASH/Omnipod 5 (Pods – 6 months, device – 30 days),

C. Other diagnoses/indications (must meet 1 or 2):

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
 - a. For drugs on the PDL, the no coverage criteria policy: CP.PMN.255; or
 - b. For drugs NOT on the PDL, the non-formulary policy: CP.PMN.16; or

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2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.PMN.53.

II. Continued Therapy

A. Diabetes Mellitus (must meet all):

1. Member meets one of the following (a or b):
 - a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
 - b. Member is currently receiving medication and is enrolled in a state and product with continuity of care regulations (*refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B*);
2. Member is responding positively to therapy;
3. Member is adherent to provider follow-up visits and training;
4. Omnipod DASH/Omnipod 5/Omnipod GO: Both of the following (i and ii):
 - i. Number of Pods does not exceed 10 per month;*

**For requests exceeding 10 Pods per month, a clinical rationale with documentation to support the higher quantity is required.*
 - ii. Omnipod DASH/Omnipod 5 only: Number of devices does not exceed 1 device per 4 years;
- b. **Approval duration: Medicaid:** Omnipod DASH/Omnipod 5 (Pods – 12 months, device – 30 days), Omnipod GO (Pods – 12 months)

B. Other diagnoses/indications (must meet 1 or 2):

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
 - a. For drugs on the PDL, the no coverage criteria policy: CP.PMN.255; or
 - b. For drugs NOT on the PDL, the non-formulary policy: CP.PMN.16; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.PMN.53.

III. Diagnoses/Indications for which coverage is NOT authorized:

- A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – CP.PMN.53 for Medicaid, or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

ACE: alternate controller enabled

BG: blood glucose

BGM: blood glucose meter

CGM: continuous glucose monitoring

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CSII: continuous subcutaneous insulin infusion
FDA: Food and Drug Administration
GLP-1: glucagon-like peptide-1
MDI: multiple daily doses of insulin

PDM: Personal Diabetes Manager
Pod: tubeless insulin pump
T1DM: type 1 diabetes mellitus
T2DM: type 2 diabetes mellitus

Appendix B: Therapeutic Alternatives

This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
CONTINUOUS INSULIN DELIVERY SYSTEMS <u>Insulin pumps (with tubing [automated options available])</u> <ul style="list-style-type: none"> MiniMed™ System (530G, 630G, 670G) MiniMed™ Paradigm Revel™ t:slim™ X2 Insulin Pump <u>Insulin pumps (without tubing)</u> <ul style="list-style-type: none"> Omnipod DASH Insulin Management System Omnipod 5 Automated Insulin Delivery System Omnipod GO Insulin Delivery Device <u>Insulin patches</u> <ul style="list-style-type: none"> V-Go 20, 30, 40 Wearable Insulin Delivery Device (disposable) 	Varies	Varies
INSULIN Human Insulin <u>Short-acting:</u> <ul style="list-style-type: none"> Regular insulin (HumuLIN® R U-500, HumuLIN® R U-500 KwikPen®, HumuLIN® R [OTC], NovoLIN® R ReliOn [OTC], NovoLIN® R [OTC]) <u>Intermediate-acting:</u> <ul style="list-style-type: none"> Insulin NPH (HumuLIN® N KwikPen® [OTC], HumuLIN® N [OTC], NovoLIN® N ReliOn [OTC], NovoLIN® N [OTC]) <u>Intermediate-acting and short-acting combinations:</u> <ul style="list-style-type: none"> Insulin NPH and regular insulin (HumuLIN® 70/30, HumuLIN® 70/30 KwikPen®, NovoLIN® 70/30) Insulin Analogs <u>Rapid-acting</u> <ul style="list-style-type: none"> Insulin glulisine (Apidra, Apidra SoloStar®) Insulin lispro (Admelog, Admelog SoloStar®, HumaLOG®, HumaLOG Junior KwikPen®, HumaLOG KwikPen®, Lyumjev®) Insulin aspart (Fiasp®, Fiasp FlexTouch®, NovoLOG®, NovoLOG FlexPen®, NovoLOG PenFill®) <u>Intermediate-acting and short-acting combinations:</u> <ul style="list-style-type: none"> Insulin aspart protamine and insulin aspart (NovoLOG Mix® 70/30, NovoLOG Mix 70/30 FlexPen®) Insulin lispro protamine and insulin lispro (HumaLOG Mix®, HumaLOG Mix® 50/50, HumaLOG Mix 50/50 KwikPen®, HumaLOG Mix® 75/25, HumaLOG Mix 75/25 KwikPen®) <u>Long-acting</u>	Varies	Varies

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Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
<ul style="list-style-type: none"> Insulin glargine (Basaglar KwikPen[®], Lantus[®], Lantus SoloStar[®], Toujeo Max SoloStar[®], Toujeo SoloStar[®]) Insulin detemir (Levemir[®], Levemir FlexTouch[®]) Insulin degludec (Tresiba[®], Tresiba FlexTouch[®]) 		
ANTIDIABETIC AGENTS <ul style="list-style-type: none"> Biguanide: metformin Sulfonylureas: glipizide, glimepiride, glyburide Thiazolidinedione: pioglitazone GLP-1 receptor agonists: dulaglutide (Trulicity[®]), exenatide ER (Bydureon[®], Bydureon BCise[®]), exenatide IR (Byetta[®]), liraglutide (Victoza[®]), liraglutide/insulin degludec (Xultophy[®]), lixisenatide/insulin glargine (Soliqua[®]), semaglutide (Ozempic[®], Rybelsus[®]), tirzepatide (Mounjaro[™]) SGLT2 inhibitors: bexagliflozin (Brenzavvy[™]), canagliflozin (Invokana[®]), canagliflozin/metformin (Invokamet[®], Invokamet[®] XR), dapagliflozin (Farxiga[®]), dapagliflozin/metformin (Xigduo[®] XR), dapagliflozin/saxagliptin (Qtern[®]), empagliflozin (Jardiance[®]), empagliflozin/linagliptin (Glyxambi[®]), empagliflozin/linagliptin/metformin (Trijardy[™] XR), empagliflozin/metformin (Synjardy[®], Synjardy[®] XR), ertugliflozin/sitagliptin (Steglujan[™]), sotagliflozin (Inpefa[™]) DPP-4 inhibitors: alogliptin (Nesina[®]), alogliptin/metformin (Kazano[®]), alogliptin/pioglitazone (Oseni[®]), linagliptin (Tradjenta[®]), linagliptin/metformin (Jentadueto[®], Jentadueto[®] XR), saxagliptin (Onglyza[®]), saxagliptin/metformin (Kombiglyze[®] XR), sitagliptin (Januvia[®], Zituvio[™]), sitagliptin/metformin (Janumet[®], Janumet[®] XR, Zituvimet[™]) 	Varies	Varies

Therapeutic alternatives are listed as Brand name[®] (generic) when the drug is available by brand name only and generic (Brand name[®]) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s):
 - Omnipod DASH, Omnipod 5, and Omnipod GO are not recommended for people who are:
 - Unable to monitor glucose as recommended by their healthcare provider (*at least 4 blood glucose tests per day for Omnipod DASH*)
 - Unable to maintain contact with their healthcare provider
 - Unable to use the System according to instructions
 - Omnipod 5 is additionally not recommended for people who:
 - Are taking hydroxyurea as it could lead to falsely elevated CGM values and result in over-delivery of insulin that can lead to severe hypoglycemia
 - Do not have adequate hearing and/or vision to allow recognition of all functions of the Omnipod 5 System, including alerts, alarms, and reminders
 - Omnipod GO is additionally not recommended for people who:
 - Do not have adequate hearing and/or vision to allow recognition of Pod lights and sounds that signify alerts and alarms

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InPen is not intended for anyone unable or unwilling to:

- Test blood glucose levels as recommended by a healthcare provider
- Maintain sufficient diabetes self-care skills
- Visit a healthcare provider regularly
- Boxed warning(s): none reported

V. Dosage and Administration

Drug Name	Dosing Regimen	Maximum Dose
Omnipod DASH Insulin Management System <i>See User Guide for more information:</i> https://www.omnipod.com/current-podders/resources/omni-pod-dash	<ul style="list-style-type: none"> ● Initial Omnipod DASH System use <ul style="list-style-type: none"> ○ Provider recommends initial program settings and meets with patient and Omnipod System Trainer to program the PDM device and first Pod. ● Filling the Pod <ul style="list-style-type: none"> ○ The Pod is filled with insulin FDA approved for insulin pumps (i.e., the following rapid-acting U100 insulin analogs: insulin glulisine (Apidra), insulin lispro (Admelog, HumaLOG, Lyumjev), insulin aspart (Fiasp, NovoLOG)). ○ Pod capacity accommodates 85 to 200 units of insulin depending on patient need (<i>for initial programming, each Pod must be filled with at least 85 units of insulin</i>). ● Pod priming <ul style="list-style-type: none"> ○ The PDM device and Pod are placed next to each other so that the PDM may prime the Pod. ● Pod placement <ul style="list-style-type: none"> ○ For site selection, see User Guides. ● Pod activation <ul style="list-style-type: none"> ○ The Pod features an insulin-providing cannula that inserts automatically with the press of an “activate” button on the PDM device. ● Pod replacement <ul style="list-style-type: none"> ○ The Pod may remain on the skin from 1 to 3 days after which a new Pod should be filled, primed, applied, and activated. 	200 units per day (1 Pod)
Omnipod 5 Automated Insulin Delivery System	<ul style="list-style-type: none"> ● There is no tubing with the Pod allowing placement almost anywhere an injection would be given. The Pod may be worn for up to 3 days and can be filled with up to 200 units of U-100 rapid-acting insulin (minimum 85 units). <ul style="list-style-type: none"> ○ The Pod, SmartAdjust technology, and SmartBolus Calculator are compatible with the following U-100 insulins: NovoLOG, HumaLOG, and AdmeLOG. ● The Omnipod 5 App allows the patient to select a basal profile, target glucose and bolus settings, activate and deactivate the Pod, connect with the Dexcom G6/G7 CGM, and select insulin delivery mode ● The Omnipod 5 System communicates with the Dexcom G6/G7 CGM System. CGM values and trends from the Dexcom G6/G7 are used for automated insulin delivery in Automated Mode, as well as bolus calculations in both 	200 units per day (1 Pod)

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Drug Name	Dosing Regimen	Maximum Dose
	<p>Automated and Manual Mode. The Dexcom G6/G7 sensor must be started in the Dexcom app in order to use CGM values and trends in the Omnipod 5 System.</p> <ul style="list-style-type: none"> There are 2 modes of operation: Automated and Manual. <ul style="list-style-type: none"> In Automated mode, SmartAdjust technology adjusts insulin every 5 minutes to bring the glucose value to the customized glucose target, or Target Glucose. The adjustment is based on a prediction of where your glucose will be 60 minutes in the future and considers your CGM value and trend, adaptive basal rate, and insulin that is still working in your body. In Manual mode, the Omnipod 5 System delivers insulin based on user-defined Basal Programs. During Manual Mode, there is no automated adjustment of insulin delivery. 	
Omnipod GO	<ul style="list-style-type: none"> The Pod is a tubeless, waterproof system that can be filled with insulin. Insulin is delivered through a canula via subcutaneous infusion at a preset basal rate in one 24-hour time period for 3 days (72 hours). <ul style="list-style-type: none"> Compatible U-100 insulins: NovoLog, Fiasp, Humalog, Admelog, Lyumjev Basal rates: <ul style="list-style-type: none"> 10 units per day (0.42 U/hr) 15 units per day (0.63 U/hr) 20 units per day (0.83 U/hr) 25 units per day (1.04 U/hr) 30 units per day (1.25 U/hr) 35 units per day (1.46 U/hr) 40 units per day (1.67 U/hr) The Pod needs to be changed at least once every 3 days. 	40 units per day (1 Pod)

VI. Product Availability

Drug Name	Availability
Omnipod DASH Insulin Management System <i>All Omnipod DASH components (Pod, PDM, compatible BGM) have Bluetooth connectivity that is compatible with the iPhone.</i>	<ul style="list-style-type: none"> Omnipod Pack 5 (packs of 5 Pods) Starter Kit (PDM DASH device plus a separate but compatible Contour® Next One BGM)* <i>*The compatible Contour Next One BGM must be used with Ascensia Contour® Next test strips and control solution; however, patients may choose to use other blood glucose testing methods with manual entry into the PDM device.</i>
Omnipod 5 Automated Insulin Delivery System	<ul style="list-style-type: none"> Omnipod 5 Intro Kit (Omnipod 5 Controller and Pods plus a separate but compatible Dexcom G6 or G7 CGM) Omnipod 5 Refill 5 Pack Pods
Omnipod GO	<ul style="list-style-type: none"> Packs of 5 Pods: Omnipod GO-10, Omnipod GO-15, Omnipod GO-20, Omnipod GO-25, Omnipod GO-30, Omnipod GO-35, Omnipod GO-40

VII. References

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V-Go

FDA 510(k) device summary

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Omnipod DASH, Omnipod 5, Omnipod GO

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InPen

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Coding Implications

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPSC Codes	Description*
A9274	External ambulatory insulin delivery system, disposable, each, includes all supplies and accessories (Suggest NDC level or Invoice pricing) (Pod)
E0784	External ambulatory infusion pump, insulin (PDM device)
A4211	Supplies for self-administered injection

**A9274 and E0784: Omnipod System (note: these codes do not apply to Omnipod DASH or Omnipod 5, which are available only through pharmacy distribution); A9274: V-Go; A4211: not specific but can be applied to InPen.*

Note: S5561 (Insulin delivery device, reusable pen) does NOT apply to InPen.

NDCs	Description
08508200005	Omnipod DASH 5 Pack Pods
08508200000	Omnipod DASH PDM Kit
08508200032	Omnipod DASH Intro Kit
08508300021	Omnipod 5 G6 Refill 5 Pack Pods
08508300001	Omnipod 5 G6 Intro Kit
08508300050	Omnipod 5 G7 Intro Kit (Gen 5)
08508300053	Omnipod 5 G7 Pods (Gen 5)

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	05.25	

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health

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plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions, and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment, or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members, and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note:

For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

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