BOSTON MEDICAL CENTER HEALTHNet PLAN

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WELL SENSE HEALTH PLAN

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Pharmacy Medical Necessity Policy

Continuous Subcutaneous Insulin Infusion – Unified Formulary

Policy Number: 9.339
Version Number: 1.2
Version Effective Date: 1/1/2022

Product Applicability	☐ **All Plan+ Products**
Well Sense Health Plan ☐ New Hampshire Medicaid	**Boston Medical Center HealthNet Plan** ☒ MassHealth ACO ☒ MassHealth MCO ☐ Qualified Health Plans/ConnectorCare/Employer Choice Direct ☐ Senior Care Options
Benefit	☒ Pharmacy Benefit ☐ Medical Benefit

Note: Disclaimer and audit information is located at the end of this document.

Policy

Reference Table

Products that require PA*	No PA
Omnipod®[PD]	
Omnipod Dash®[PD]	
V-Go®[PD]	

***Other forms of CSII may be available through DME. Prior authorizations received for a continuous subcutaneous insulin infusion should be faxed back.**

[PD] Preferred Drug. In general a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class is required.

The following NDCs are included within the rebate agreement and will usually reject at the pharmacy as prior authorization required. Any NDC that is not listed here is not included in the rebate agreement and therefore will usually reject at the pharmacy level.

Omnipod® and Omnipod Dash®
08508-3000-01 Omnipod 5 Intro kit (GSN)
08508-1120-05 Omnipod 5 Pack Pod (GSN 061024)
08508-3000-21 Omnipod 5 Refill 5 Pack (GSN)
08508-2000-11 Omnipod Dash Intro Kit (GSN)
08508-2000-05 Omnipod Dash 5 Pack Pods (GSN 061024)
08508-2000-00 Omnipod Dash PDM Kit (GSN: 070933)
08508-1140-02 Omnipod Starter Kit (GSN 063929)

V-Go®
08560-9400-03 V-Go 20-unit disposable device (GSN 068529)
08560-9400-02 V-Go 30-unit disposable device (GSN 068533)
08560-9400-01 V-Go 40-unit disposable device (GSN 068534)

Approval Criteria:

Omnipod® *Omnipod Dash®* *V-Go®*	**Initial Prior Authorization Requests:** 1. Member has a diagnosis of diabetes mellitus; **AND** 2. Member's current treatment plan involves testing blood glucose at least 4 times per day; **AND** 3. **ONE** of the following: a. Member is currently receiving multiple daily insulin injections (at least three) or an insulin pump; **OR** b. The provider submits documentation that the member is not receiving daily insulin injections due to physical disability, visual impairment, cognitive impairment, or age less than 18 years old **AND** 4. Member's A1c is greater than 7.0% or value that does not meet documented target treatment; **AND** 5. **ONE** of the following: a. Frequent hypoglycemia; **OR** b. Fluctuations of more than 100 mg/dL in blood glucose before mealtime; **OR** c. Dawn phenomenon with fasting blood sugars frequently exceeding 200 mg/dL; **OR** d. History of severe glycemic excursions **AND** 6. **If the request is for V-Go®**: member is ≥18 years of age **Reauthorization criteria:** 1. Member has a diagnosis of diabetes mellitus; **AND** 2. The provider submits documentation of improvement in

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	diabetic control/relative stability (e.g., provider attestation or A1c improvement or improvement in hypoglycemia or hyperglycemia can be considered to meet this requirement)
Duration of Authorization:	**Initial:** Prior authorization may be issued for **3 months.** **Reauthorization:** Prior authorization may be issued for **1 year.**

Appendix:

Responsibility and Accountability

Policy History

Original Approval Date	Original Effective Date	Policy Owner	Approved by
5/13/2021	7/1/2021	Pharmacy Services	Pharmacy & Therapeutics (P&T) Committee

Policy Revisions History			
Review Date	**Summary of Revisions**	**Revision Effective Date**	**Approved by**
5/13/2021	Created policy for MH Unified Formulary, policy date 3/15/21	7/1/2021	P&T Committee
6/4/2021	State updates to NDCs for Omnipod based on products available	9/1/2021	P&T Committee
10/1/2021	MH UPPL Update: Guideline updated to clarify preferred products	1/1/2022	P&T Committee

Next Review Date

5/2022

Other Applicable Policies

References

1. American Diabetes Association. Standards of Medical Care in Diabetes-2021: Diabetes Technology. Diabetes Care. 2021;44(Suppl 1): S85-S99.

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Disclaimer Information

Medical Policies are the Plan's guidelines for determining the medical necessity of certain services or supplies for purposes of determining coverage. These Policies may also describe when a service or supply is considered experimental or investigational, or cosmetic. In making coverage decisions, the Plan uses these guidelines and other Plan Policies, as well as the Member's benefit document, and when appropriate, coordinates with the Member's health care Providers to consider the individual Member's health care needs.

Plan Policies are developed in accordance with applicable state and federal laws and regulations, and accrediting organization standards (including NCQA). Medical Policies are also developed, as appropriate, with consideration of the medical necessity definitions in various Plan products, review of current literature, consultation with practicing Providers in the Plan's service area who are medical experts in the particular field, and adherence to FDA and other government agency policies. Applicable state or federal mandates, as well as the Member's benefit document, take precedence over these guidelines. Policies are reviewed and updated on an annual basis, or more frequently as needed. Treating providers are solely responsible for the medical advice and treatment of Members.

The use of this Policy is neither a guarantee of payment nor a final prediction of how a specific claim(s) will be adjudicated. Reimbursement is based on many factors, including member eligibility and benefits on the date of service; medical necessity; utilization management guidelines (when applicable); coordination of benefits; adherence with applicable Plan policies and procedures; clinical coding criteria; claim editing logic; and the applicable Plan – Provider agreement.

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