Certificate of Medical Necessity

Insulet Corporation
600 Technology Park Drive, Ste. 200
Billerica, MA 01821
Fax: 877-467-8538
MyOmniPod.com

omnipod®

1. Patient Information

Patient Name (Last, First) _____

Street _____

City _____ State _____ ZIP Code _____

Date of Birth (Month/Day/Year) ___/___/___

Today's Date (Month/Day/Year) ___/___/___

Home Phone Number ___–___

☐ New pump with pump supplies*

☐ Replacement pump with pump supplies*

* Based on payer criteria, additional information may be required

2. Diagnosis Information and Test Results

Date Diagnosed (Month/Day/Year) ___/___/___ | Recent HbA1C ____% | Date (Month/Day/Year) ___/___/___ | C-peptide results *(if available)* | Range low | Range high | Date (Month/Day/Year) ___/___/___

To be completed by the physician

Patient Diagnosis:

- ☐ Type 1 DM without complications (E 10.9/250.01)
- ☐ Type 1 DM with complications (E 10.65/250.03)
- ☐ Type 2 DM without complications (E 11.9/250.00)
- ☐ Type 2 DM with complications (E 11.65/250.02)
- ☐ Gestational (0 99.810/648.80)
- ☐ Other: _____

The following clinical indications are present (Check <u>all</u> that apply):

- ☐ Dawn Phenomenon (.65)
- ☐ Diabetic Ketoacidosis (.10)
- ☐ Frequent or severe Hypoglycemia without coma (.649)
- ☐ Nocturnal Hypoglycemia without coma (.649)
- ☐ Gastroparesis (.43)
- ☐ Hypoglycemia Unawareness without coma (.649)
- ☐ Nephropathy (.21)
- ☐ Neuropathy (.40)
- ☐ Retinopathy with macular edema (.311)
- ☐ Post-renal transplant (.22)
- ☐ Wide fluctuations in blood glucose values: _____ to _____ mg/dL
- ☐ Other: _____

The following existing conditions support the start of OmniPod® insulin pump therapy (Check <u>all</u> that apply):

- ☐ Patient has phobia regarding or aversion to needles.
- ☐ Patient/caregiver is motivated, as well as physically and intellectually able to operate the insulin pump.
- ☐ Work and/or exercise regimen (competitive or prescribed) requires pump to withstand prolonged frequent exposure to water.
- ☐ Tubing poses occupational hazard for patient.
- ☐ Patient's current pump therapy technology is out of warranty or its functionality does not meet the patient's medical needs.
- ☐ Blood glucose logs in file show blood glucose is checked 4 or more times a day for the past 2 months.
- ☐ Due to impaired vision, patient requires adjustable, high-contrast back-lit colored screen display, not available on current pump.
- ☐ Patient has been on multiple daily injections at least 3 times per day for at least 6 months, and is able to self-adjust insulin doses.
- ☐ Patient has taken or is enrolled in a comprehensive diabetes education program, including carbohydrate counting, which is used to calculate bolus for meals and adjustments to glucose levels.

3. Physician's Order for OmniPod®

Dispense one OmniPod® Insulin Management System with lifetime of supplies.

- E0784: OmniPod® Personal Diabetes Manager (PDM)
- A9274: External Ambulatory Insulin Delivery System (Pods)

To be completed by the physician

Replace insulin pump supplies every (check one): ☐ 48 Hours - 50 Pods/90 days ☐ 72 Hours - 40 Pods/90 days ☐ Other: _____

Sig: As directed. **Refill:** PRN

Physician Name (Last, First) _____ NPI# _____

Street _____ Phone Number ___–___ Fax Number ___–___

City _____ State _____ ZIP Code _____ Email Address _____

Physician Attestation: I certify that I am the Physician identified on this form. I have reviewed the Certificate of Medical Necessity. Any statement on my Letterhead attached hereto, has been reviewed and signed by me. I certify that the medical necessity information is true, accurate and complete, to the best of my knowledge. The patient's record contains supporting documentation which substantiates the utilization and medical necessity of the products listed and will be provided to the distributor upon request. I understand that any falsification, omission, or concealment of material fact in that section may subject me to civil or criminal liability. A copy of this order will be retained as part of the patient's medical record.

_____ Date (Month/Day/Year) ___/___/___

Physician Signature. Please note: Signature stamps are NOT acceptable.

Fax completed form to **877-467-8538** or mail it to address listed above. If you have any questions, call 800-591-3455.