iLet Insulin Pump & Dexcom CGM System

Prescription & Certificate of Medical Necessity

PATIENT INFORMATION

Patient Name: _____ Date of Birth: _____

Patient Address: _____

Patient Email: _____ Phone: _____

ITEMS BEING PRESCRIBED

Pump Type *Choose 1*	☐ iLet Starter Kit, Commercial, 1/Kit (E0784/E2103) **Dispense Qty:** ☐ 1 **Refills:** ☐ 0 **Sig:** Use to treat diabetes **Length of Need:** ☐ Lifetime (99 yrs)	☐ iLet Starter Kit, Government, 1/Kit (E0784/E2103) **Dispense Qty:** ☐ 1 **Refills:** ☐ 0 **Sig:** Use to treat diabetes **Length of Need:** ☐ Lifetime (99 yrs)
Insulin Cartridge	☐ iLet Cartridge Kit, 10/Bx (A4232/A4225) **Dispense Qty:** ☐ 90 ☐ 50 ☐ 30 ☐Other: _____ **Refills:** ☐ 4 ☐ Other: _____ **Sig**: Change cartridge per training **Length of Need:** ☐ 1 Year ☐ Other: _____	**Cartridge Change Frequency:** ☐ Every 3 days (Qty. 30) ☐ Every 2 days (Qty. 50) ☐ Every 1 day (Qty. 90) ☐ Every _____ day(s) (Qty. _____)
Infusion Set *Choose 1*	☐ iLet Inset (Teflon Cannula) Infusion Set Kit, 6mm, 23" Grey, 10/Bx (A4231) ☐ iLet Contact Detach (Steel) Infusion Set Kit, 6mm, 23", 10/Bx (A4231) ☐ Patient Preference on Above **Dispense Qty:** ☐90 ☐50 ☐30 ☐Other: _____ **Refills:** ☐4 ☐Other: _____ **Sig**: Change infusion set per training **Length of Need:** ☐ 1 Year ☐Other: _____	**Infusion Set Change Frequency:** ☐ Every 3 days (Qty. 30) ☐ Every 2 days (Qty. 50) ☐ Every 1 day (Qty. 90) ☐ Every _____ day(s) (Qty. _____)
CGM Products *Check all that apply*	☐ Dexcom G7 Receiver (A9278/E2103) *DME ONLY: 1/365* **Dispense Qty:** ☐1 **Refills:** ☐0 ☐Other: _____ **Sig:** Use to check glucose daily.	☐ Dexcom G7 Sensors (A9276/A4239) *DME ONLY: 9/90* **Dispense Qty:** ☐9 (90 days) ☐Other:_____ **Refills:** ☐4 ☐Other:_____ **Sig:** Site change per manufacturer recommendation, every 10 days. ☐ Dexcom G7 15 Day Sensors (A9276/A4239) *DME ONLY: 6/90* **Dispense Qty:** ☐6 (90 days) ☐Other:_____ **Refills:** ☐4 ☐Other:_____ **Sig:** Site change per manufacturer recommendation, every 15 days.

CURRENT THERAPY

ORDER START DATE:_____

ICD-10 Diagnosis Code:	**Date of Diagnosis:**	**Most Recent HbA1c:**
☐ Type 1 diabetes without complications (E10.9) ☐ Type 1 diabetes with complications (E10.65) ☐ Other:_____	_____ (MM/YYYY)	Result: _____% Date:_____ (DD/MM/YYYY)

☐ Patient/Caregiver has completed comprehensive diabetes education and is motivated to maintain optimal glucose control.

☐ Patient/Caregiver has the ability to operate and can use an insulin pump to manage blood glucose.

☐ Blood glucose logs indicate blood glucose is checked as required or CGM used appropriately.

Complete One:

☐ Multiple Daily Injections ☐ Patient performs multiple daily injections consisting of 3-4 or more injections per day and is able to self-adjust insulin doses. ☐ Variations in the day-to-day schedule and/or exercise prevent the achievement of successful glycemic control with multiple daily injections. ☐ Despite frequent therapy adjustments, the patient experiences suboptimal glycemic control evidenced by wide glycemic fluctuations ranging from _____ to _____ mg/dl.	☐ Insulin Pump ☐ Current pump functionality no longer meets the patient's medical needs and/or is out of warranty. ☐ Mechanical or medical reasons for replacement: _____ Out of warranty date:_____ (or ☐ N/A)

DIABETES COMPLICATIONS (Check all that apply)

☐ Dawn phenomenon (AM hyperglycemia)	☐ Hypoglycemia unawareness	☐ Nocturnal hypoglycemia	☐ Retinopathy	☐ Neuropathy
☐ Nephropathy	☐ History of ER/hospital visits: ☐DKA; ☐Severe hypoglycemia; ☐Other: _____ Dates: _____			

This document serves as a Prescription and Statement of Medical Necessity for the above referenced patient for a Personal Diabetes Manager and supplies. I certify that I am the physician identified in the below section and I certify that the medical necessity information contained in this document is true, accurate and complete, to the best of my knowledge, and I understand that any falsification, omission, or concealment of material fact in that section may subject me to civil or criminal liability.

PHYSICIAN INFORMATION

Physician name: _____ NPI: _____

Hospital/Clinic: _____ Phone: _____

Address: _____ Fax: _____

Signature: _____ Date: _____

Phone: (207) 784-3700 | **Fax: (207) 795-7622** | **www.MyBedard.com** | **Refer through Parachute Health**

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iLet GLUCOSE TARGET SETTING

☐ Usual ☐ Higher Certified iLet Trainer may adjust glucose target at initial follow up calls: ☐ YES ☐NO	Note for HCPs: Most patients should start using the iLet at the "Higher" glucose target ONLY for those who have a higher A1C (e.g., > 10%), are transitioning from a long-acting insulin, or have very low insulin requirements. ***For patients with higher A1Cs or transitioning from long-acting insulin, consider target reduction to "usual" after the first few days of iLet therapy.***

PRESCRIBER'S ORDERS FOR MANAGEMENT OF HYPERGLYCEMIA AND KETONES

Because the iLet determines all doses of insulin, the management of ketosis is different when using the iLet as compared to other insulin pumps, including hybrid closed-loop systems.
The iLet Bionic Pancreas System comes with a recommended ketone action plan. Review the plan below and indicate the patient should follow the instructions as written or provide alternative recommendations in the section below. The certified iLet trainer will review these recommendations with the patient during the iLet training and initiation visit. For questions or concerns, contact Beta Bionics Customer Care at: 1-855-745-3800

KETONE ACTION PLAN

Test your BG and ketones if:	
You are nauseous, vomiting or have diarrhea.	
You think your infusion set is not working.	
You CGM glucose has been above 300 mg/dL for 90 minutes.	
Your CGM glucose is above 400 mg/dL.	

Always keep these supplies with you:
- Glucose meter and strips
- Urine ketone strips OR blood ketone meter and strips
- Extra CGM sensor
- Extra infusion set and cartridge
- Insulin vial and syringe, or insulin pen and pen needle

Zone 1 	**Urine Ketones:** Negative **OR** **Blood Ketones:** less than 0.6 mmol/L	**Check to make sure:** • Your iLet is charged, has insulin, and is displaying CGM values. • Your infusion set is in place and not leaking. **Continue to monitor your BG:** • If your BG is still high after 90 minutes, check ketones again.
Zone 2 	**Urine Ketones:** Trace - Moderate **OR** **Blood Ketones:** 0.6 - 2.5 mmol/L	1. **CHANGE** your iLet infusion set. 2. **DRINK** extra fluids. 3. **RECHECK** BG and ketones in 90 minutes. • If BG is less than 180 mg/dL and ketones are in **ZONE 1**, you do not need to do anything else. • If BG is more than 180 mg/dL and ketones are not in **ZONE 1, GO TO ZONE 3.**
Zone 3 	**Urine Ketones:** Large **OR** **Blood Ketones:** 2.5 mmol/L or higher	**CALL YOUR HEALTHCARE PROVIDER IMMEDIATELY!** If your healthcare providers has told you to take an insulin injection, it is important to follow these steps: 1. **DISCONNECT** from the iLet at the time of the injection. 2. Give the injection of rapid acting insulin as instructed by your healthcare provider. 3. **DRINK** extra fluids. 4. **RECHECK** BG and ketones in 90 minutes. • If BG is less than 180 mg/dL and ketones are in **ZONE 1, CHANGE** your iLet infusion set and **RECONNECT** to the iLet. • If your BG is more than 180 mg/dL and ketones are not in **ZONE 1, CALL YOUR HEALTHCARE PROVIDER, GO TO THE EMERGENCY ROOM, OR CALL 911.**

Select One:

☐ I agree with the ketone action plan above.
☐ I agree with the ketone action plan with the noted modifications.
☐ I DO NOT agree with the ketone action plan and recommend the alternative plan below.

Ketone Action Plan Modifications or Alternative Plan:

☐ I have confirmed the patient has the prescriptions needed to comply with this plan including an alternative method of insulin delivery in the event iLet therapy is discontinued (i.e., blood ketone testing strips, insulin prescriptions including long-acting, etc.)

Prescriber Signature (signature stamps are not acceptable): _____ Date (MM/DD/YYYY) _____

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