Beta Bionics

Fax Completed Form to: **1-800-786-0720**

STATEMENT OF MEDICAL NECESSITY AND PRESCRIPTION ORDER

Confidential Patient Health Information

This form serves as a prescription and Statement of Medical Necessity for the Beta Bionics insulin infusion system and all related diabetes supplies to be provided by Beta Bionics or authorized distributors.

PATIENT ORDER INFORMATION (CHECK ITEM(S) BEING PRESCRIBED)

PATIENT NAME (FIRST, MIDDLE, LAST)	SEX: ☐Male ☐Female ☐_____	DATE OF BIRTH (MM/DD/YYYY)	PARENT/GUARDIAN (FIRST, LAST)	
PATIENT STREET ADDRESS	CITY	STATE	ZIP CODE	PHONE NUMBER

ITEM BEING PRESCRIBED:	ORDER START DATE:	LENGTH OF NEED:
☐ iLet insulin pump	Date ____/____/____ (MM/DD/YYYY)	iLet insulin pump: ☐ Lifetime (i.e., 99 yrs.) ☐ _____

INSULIN CARTRIDGE:

☐ iLet Cartridge Kit 10-pack

INFUSION SET TYPE:

☐ Contact Detach: 6mm Steel needle, 23" tube length
☐ Inset: 6mm Teflon cannula, 23" tube length
☐ Patient preference of above

CARTRIDGE AND INFUSION SET CHANGE FREQUENCY:

☐ Every 3 days (Qty. 30 + 3 refills)
☐ Every 2 days (Qty. 50 + 3 refills)
☐ Every 1 day (Qty. 90 + 3 refills)

DEXCOM G6 CGM SUPPLIES:

☐ Sensors – change every 10 days. (Qty. 9 + 3 refills)
☐ Transmitter – change every 90 days. (Qty. 1 + 3 refills)
☐ Receiver – (Qty. 1)

or

DEXCOM G7 CGM SUPPLIES:

☐ Sensors – change every 10 days. (Qty. 9 + 3 refills)
☐ Receiver – (Qty. 1)

Pump & CGM Supplies:

☐ 1 year
☐ _____

CURRENT THERAPY

ICD-10 DIAGNOSIS CODE	DATE OF DIAGNOSIS:	MOST RECENT HbA1c	MOST RECENT WEIGHT
☐ Type 1 diabetes without complications (E10.9) ☐ Type 1 diabetes with complications (E10.65) ☐ Other: _____	____/_____ (MM/YYYY)	Result _____% Date ____/____/____ (MM/DD/YYYY)	_____ (lbs) Date ____/____/____ (MM/DD/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 of the sections below:

☐ 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
☐ Nephropathy	☐ Neuropathy	☐ History of ER/hospital visits: ☐ DKA; ☐ Severe Hypoglycemia; ☐ Other: _____ Date(s): _____	

PRESCRIBER INFORMATION

PRESCRIBING PROVIDER NAME	NPI#	PRACTICE NAME		
OFFICE STREET ADDRESS	CITY	STATE	ZIP CODE	PHONE NUMBER
FAX NUMBER	EMAIL ADDRESS			

Prescribing Provider Attestation and Signature/Date

I certify that I am the prescribing provider identified above and have reviewed all of the order information above. Any statement on my letterhead attached hereto has been reviewed by me. I certify that all 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 marked above. I understand the indications for use and associated warnings and precautions of the Beta Bionics® products I have prescribed herein. A copy of this order will be retained as part of the patient's medical record.

PRESCRIBER SIGNATURE: (SIGNATURE STAMPS ARE NOT ACCEPTABLE)	DATE (MM/DD/YYYY)
X	

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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 "Usual" glucose target. Consider starting on 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

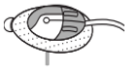
Because the iLet determines all doses of insulin, the management of ketosis is different when using the iLet as compared to other insulin pumps, including hybrid closed-loop systems.

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.	
your CGM glucose has been above 300 mg/dL for 90 minutes.	 High Glucose Glucose has been above 300 mg/dL for more than 90 minutes
your CGM glucose is above 400 mg/dL.	 HIGH

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

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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 provider 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: ***If no options are selected, the default ketone action plan above will be used***

☐ 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)
X	