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:
☐ iLet insulin pump

ORDER START DATE:
Date ____/____/____ (MM/DD/YYYY)

LENGTH OF NEED:
iLet insulin pump:
☐ Lifetime (i.e., 99 yrs.) ☐ _____

Pump & CGM Supplies:
☐ 1 year ☐ _____

CARTRIDGE AND INFUSION SET CHANGE FREQUENCY: Consider approximate total daily dose (TDD) when selecting to ensure user has enough supplies. Cartridge holds 165 units after prime.

☐ Every 3 days: TDD < ~50 units (Qty. 30 + 3 refills)
☐ Every 2 days: TDD ~50 to ~75 units (Qty. 50 + 3 refills)
☐ Every 1 day: TDD > ~75 units (Qty. 90 + 3 refills)

INSULIN CARTRIDGE: ☐ iLet Cartridge Kit 10-pack

CARTRIDGE ADAPTER: ☐ iLet Connect Adapter 10-pack

INFUSION SET TYPE:
☐ Contact Detach: 6mm Steel needle, 23″ tube length
Inset: 6mm Teflon cannula
☐ 23″ tube length
☐ 32″ tube length
☐ Patient preference

CHOOSE CGM TYPE:

FREESTYLE LIBRE 3 PLUS CGM SUPPLIES
☐ Sensors – change every 15 days. (Qty. 6 + 3 refills)
☐ Reader (Qty. 1)

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)

DEXCOM G7 CGM SUPPLIES:
☐ Sensors – change every 10 days. (Qty. 9 + 3 refills)
☐ Receiver (Qty. 1)

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) X	DATE (MM/DD/YYYY)

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iLet GLUCOSE TARGET SETTING

If no options are selected, Certified iLet Trainer will use their judgement for target setting and adjustments

☐ Usual ☐ Higher

Certified iLet Trainer may adjust glucose target at 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. *The ketone action plan prescribed here will be considered valid for the lifetime use of the device unless otherwise noted.*

For questions or concerns, contact Beta Bionics Customer Care at: 1-855-745-3800

Ketone Action Plan

Beta Bionics

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.
- 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

LA000059C

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. At the time of the injection, **DISCONNECT** from the iLet and pause it for 1 hour and 30 minutes. 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, **RECONNECT** to the iLet , and **RESUME** insulin dosing. 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	