

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: <input type="checkbox"/> Male <input type="checkbox"/> Female <input type="checkbox"/> _____	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:

<input type="checkbox"/> iLet insulin pump	Date ____/____/____ (MM/DD/YYYY)	iLet insulin pump: <input type="checkbox"/> Lifetime (i.e., 99 yrs.) <input type="checkbox"/> _____
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INSULIN CARTRIDGE: <input type="checkbox"/> iLet Cartridge Kit 10-pack	CARTRIDGE AND INFUSION SET CHANGE FREQUENCY: <input type="checkbox"/> Every 3 days (Qty. 30 + 3 refills) <input type="checkbox"/> Every 2 days (Qty. 50 + 3 refills) <input type="checkbox"/> Every 1 day (Qty. 90 + 3 refills)	DEXCOM G6 CGM SUPPLIES: <input type="checkbox"/> Sensors - change every 10 days. (Qty. 9 + 3 refills) <input type="checkbox"/> Transmitter - change every 90 days. (Qty. 1 + 3 refills) <input type="checkbox"/> Receiver - (Qty. 1) or DEXCOM G7 CGM SUPPLIES: <input type="checkbox"/> Sensors - change every 10 days. (Qty. 9 + 3 refills) <input type="checkbox"/> Receiver - (Qty. 1)	Pump & CGM Supplies: <input type="checkbox"/> 1 year <input type="checkbox"/> _____
INFUSION SET TYPE: <input type="checkbox"/> Contact Detach: 6mm Steel needle, 23" tube length <input type="checkbox"/> Inset: 6mm Teflon cannula, 23" tube length <input type="checkbox"/> Patient preference of above			

Pharmacy Prescription Information Boxes next to quantity, infusion set type, frequency of change, and refills must be checked.

iLet Bionic Pancreas Qty <input type="checkbox"/> #1 Use to treat diabetes Refills: none	iLet Monthly Supplies Qty: QS x 3 months Change cartridge and infusion set per training Refills: <input type="checkbox"/> None, _____ (specific number), <input type="checkbox"/> 1 year	Infusion Set type (select one): <input type="checkbox"/> Inset (Teflon), <input type="checkbox"/> Contact Detach (steel) Frequency of infusion set change: <input type="checkbox"/> q1-2 days, <input type="checkbox"/> q2 days, <input type="checkbox"/> q3 days
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CURRENT THERAPY

ICD-10 DIAGNOSIS CODE <input type="checkbox"/> Type 1 diabetes without complications (E10.9) <input type="checkbox"/> Type 1 diabetes with complications (E10.65) <input type="checkbox"/> Other: _____	DATE OF DIAGNOSIS: ____/____/____ (MM/YYYY)	MOST RECENT HbA1c Result _____% Date ____/____/____ (MM/DD/YYYY)	MOST RECENT WEIGHT ____ (lbs) Date ____/____/____ (MM/DD/YYYY)
<input type="checkbox"/> Patient/Caregiver has completed comprehensive diabetes education and is motivated to maintain optimal glucose control.			
<input type="checkbox"/> Patient/Caregiver has the ability to operate and can use an insulin pump to manage blood glucose.			
<input type="checkbox"/> Blood glucose logs indicate blood glucose is checked as required or CGM used appropriately.			

Complete one of the sections below:

<input type="checkbox"/> Multiple Daily Injections <input type="checkbox"/> Patient performs multiple daily injections consisting of 3-4 or more injections per day and is able to self-adjust insulin doses. <input type="checkbox"/> Variations in the day-to-day schedule and/or exercise prevent the achievement of successful glycemic control with multiple daily injections. <input type="checkbox"/> Despite frequent therapy adjustments, the patient experiences suboptimal glycemic control-evidenced by wide glycemic fluctuations ranging from _____ to _____ mg/dl.	<input type="checkbox"/> Insulin Pump <input type="checkbox"/> 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 <input type="checkbox"/> n/a)
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DIABETES COMPLICATIONS (CHECK ALL THAT APPLY)

<input type="checkbox"/> Dawn phenomenon (AM hyperglycemia)	<input type="checkbox"/> Hypoglycemia unawareness	<input type="checkbox"/> Nocturnal hypoglycemia	<input type="checkbox"/> Retinopathy	<input type="checkbox"/> Neuropathy
<input type="checkbox"/> Nephropathy <input type="checkbox"/> History of ER/hospital visits: <input type="checkbox"/> DKA; <input type="checkbox"/> Severe Hypoglycemia; <input type="checkbox"/> 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)
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X

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iLet GLUCOSE TARGET SETTING

<input type="checkbox"/> Usual <input type="checkbox"/> Higher Certified iLet Trainer may adjust glucose target at initial follow up calls: <input type="checkbox"/> Yes <input type="checkbox"/> 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. ***
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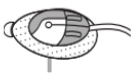




PRESCRIBER'S ORDERS FOR MANAGEMENT OF HYPERGLYCEMIA AND KETONES

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.		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.
you think your infusion set is not working.			ZONE 2 	Urine Ketones: Trace - Moderate OR Blood Ketones: 0.6 - 2.5 mmol/L
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	ZONE 3 		Urine Ketones: Large OR Blood Ketones: 2.5 mmol/L or higher
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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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)
X	