Certificate of Medical Necessity

1. Patient Information

Patient Name: _____ Telephone: _____

Date of Birth: _____ Patient ID Number: _____

This certificate serves as a Prescription and Statement of Medical Necessity for the above referenced patient for the following items:

☐ Insulin pump supplies for a lifetime need*
☐ Insulin pump supplies and CGM supplies for a lifetime need*
☐ CGM supplies for a lifetime need*

2. Diagnosis ICD 10

DX Code: ☐ E10.9 Type 1 without Complications ☐ E11.65 Type 2 w/ Hyperglycemia ☐ E10.65 Type 1 w/ Hyperglycemia ☐ Other: _____ MUST BE an ICD 10 code

3. Management and Assessment

Date last seen: Month _____ Day _____ Year _____ Fluctuation of BG values: _____ mg/dL to _____ mg/dL

On insulin pump: ☐ Yes ☐ No Purchase date: Month _____ Year _____ HbA1c: _____% Date: _____

☐ Patient/Parent has completed a comprehensive diabetes education program, including carbohydrate counting
☐ For at least six months, patient has been on multiple daily injections at least 3 times per day and is able to self-adjust insu lin doses
☐ BG logs on file show BG is checked 4 or more times a day for the past two months

4. Clinical Indications

☐ Patient has recurring episodes of severe hypoglycemia despite appropriate modifications in insulin regimen and adherence with frequent finger stick self-monitoring
☐ History of severe glycemic excursions (commonly associated with brittle diabetes, hypoglycemic unawareness, nocturnal hypoglycemia, extreme insulin sensitivity and/or very low insulin requirements)
☐ Dawn phenomenon
☐ Diabetic ketoacidosis

Please also attach medical documentation proving medical necessity
(example: chart notes from patient's most recent appointment)

☐ History of suboptimal glycemic control during preconception or pregnancy
☐ Poor glycemic control evidenced by CGMS diagnostic sensing
☐ Patient has been hospitalized or has required assistance from others for a low blood sugar; Date: _____
☐ Retinopathy ☐ Neuropathy ☐ Nephropathy

The following conditions support the medical necessity of an insulin pump replacement:

_____

5. Infusion Set and Cartridge Changes

Prescribed for a lifetime

Infusion sets and cartridges - check box for frequency and quantity:

☐ Every 2 days - Quantity 50 ☐ Every 2-3 days - Quantity 40
☐ Every 3 days - Quantity 30
☐ Every 1 day - Quantity 90 Reason: _____
☐ Other: _____ Quantity: _____ Reason: _____

6. CGM Supplies

Prescribed for 12 months

A9277 Transmitter ☐ 2/365

A9276 Sensors ☐ 365/365 (1 unit = 1 day)

Directions for use: Site change per manufacturer recommendation, up to 90 days unless otherwise noted. Up to 90-day supply unless otherwise noted.

7. Testing Supplies - How many times per day the patient is expected to check his/her blood glucose

Estimated number of strips and lancets prescribed for a 90-day period (check the appropriate box):

☐ 4/day=400; ☐ 5/day=450; ☐ 6/day=550; ☐ 7/day=650; ☐ 8/day=750; ☐ 9/day=850;
☐ 10/day=900; ☐ Other: _____

Testing supplies prescribed for a 12-month period (check the appropriate box):

☒ Meter; ☒ Lancets; ☒ Control solution; ☒ Lancing device; ☒ Batteries; ☒ Strips;
☒ Transparent film; ☒ Skin barrier swabs; ☒ Alcohol wipes; ☒ Spring powered device for lancet

I certify that the above information is correct.

Healthcare Provider's Signature: _____ Date Signed: _____

Healthcare Provider Information (Printed):

Healthcare Provider: _____ **Office Contact:** _____

Address: _____ City: _____ State: _____ ZIP: _____

Phone Number: _____ Fax Number: _____ NPI: _____

This document serves as a Prescription and Statement of Medical Necessity for the above referenced patient for an Animas® Vibe® insulin pump, supplies, diabetes supplies, and/or Dexcom G4® Sensor and Transmitter.
The Animas® Vibe™ insulin pump and Continuous Glucose Monitoring (CGM) system is not approved for pediatric use in the US. The Animas® Vibe™ insulin pump and Continuous Glucose Monitoring (CGM) system, providing a new management solution for adults living with diabetes, is approved for patients 18 and older in the US.

AuBurn Pharmacy: _____
Fax: _____