

Northeast Florida Pediatric Diabetes Center (PDC) at Wolfson Children's Hospital with
Collaboration from Nemours Children's Health Jacksonville, FL

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Northeast Florida Pediatric Diabetes Center Insulin Pump Policy (pp.1-6)



Date of Implementation: 3/1/24

Date of Last Review: 02/29/24 by all Nemours Faculty.

Background:

- Continuous subcutaneous insulin infusion (CSII) pump therapy can be used safely and effectively in youth with type 1 diabetes. (T1D) to assist with achieving targeted glycemic control.
- Insulin pump therapy can assist with reducing episodes of hypoglycemia.
- Insulin pumps reduce chronic complications of T1D in youth, even when compared to those with similar hemoglobin A1c (HbA1c) levels on multiple daily injection (MDI) therapy
 - Insulin pump therapy is appropriate for youth with diabetes, regardless of age.
 - Infusion set failures are common and must be recognized early so as to avoid episodes of diabetic ketoacidosis (DKA)
 - Sensor augmented pump (SAP) therapy is superior in children and adolescents over MDI with self-monitoring of blood glucose (SMBG) in reduction of HbA1c without an increase in hypoglycemia or severe hypoglycemia. However, this benefit is mediated by adherence to sensor therapy, with at least 60% use being associated with these findings.
 - Automated insulin delivery (closed loop) systems improve TIR, including minimizing hypoglycemia and hyperglycemia.
 - Automated insulin delivery systems have proven to be especially beneficial in attaining targeted control in the overnight period.
 - There exists a wide spectrum of cell phone apps to aid patients with diabetes. Use of evidence-based apps has shown glycemic benefit for adult patients with type 2, but not T1D.
 - Bolus calculators, either on insulin pumps or as phone apps for MDI users, aid patients with diabetes in determining carbohydrate and correction dosing. Their use is associated with improved glycemic control in patients with T1D and should be encouraged for all patients.
 - Automated algorithmic adjustment with four recently approved closed loop systems have received FDA approval. It is important you see our CDCES team before and 1-2 weeks after starting these systems as they do require some additional education and settings may need to be adjusted depending on the system.
 - Routine downloading of diabetes devices (blood glucose monitors, pumps, or CGM) is associated with better glycemic control, though overall rates of patients downloading their devices are extremely low.
 - Telemedicine, whereby patients or providers, receive care from a specialist remotely through video conferencing may assist with improving glycemic control and increase the frequency of visits

for patients with diabetes living in remote or rural locations.

- Setting realistic expectations for the integration of diabetes technologies is paramount to the success of patients as they adopt new technologies.

- Identification and counseling of potential barriers to adoption of new technologies or continued use of devices is critical.

Indications for insulin pump use (Reference #3):

Conditions under which insulin pumps should be considered

- Recurrent severe hypoglycemia
- Wide fluctuations in blood glucose levels regardless of A1c
- Suboptimal diabetes control (ie, A1c exceeds target range for age)
- Microvascular complications and/or risk factors for macrovascular complications
- Good metabolic control but insulin regimen that compromises lifestyle

Circumstances in which insulin pumps may be beneficial

- Young children and especially infants and neonates
- Children and adolescents with pronounced dawn phenomenon
- Children with needle phobia
- Pregnant adolescents, ideally preconception
- Ketosis prone individuals
- Competitive athletes

Pump Initiation Criteria:

We strongly encourage the use and adoption of advanced diabetes technology including automated insulin delivery devices (AID) which are also known as artificial pancreas technology in all patients with type 1 diabetes mellitus and particularly in those children less than 7 years of age. When patients, families and prescribers are interested in starting insulin pump therapy we will offer the following resources before, during and after initiation of insulin pump therapy. Our diabetes center will utilize on-line videos/podcasts starting April 1st, 2024, which families can watch or listen to, as a tool to aid them in their decisions about which FDA approved insulin pump, they would like to choose.

Competencies in managing diabetes will be assessed prior to ordering the insulin pump for your child. We expect reasonable glucose monitoring with

either CGM and/or fingerstick glucose, ability to check blood and/or urine ketones and having completed sick day training with adequate familiarity and knowledgeable regarding the use of the ketone action plan (see last page).

The decision to start insulin pumps will be made by your physician and ARNP in clinic, coupled with the PDC assessments from our educator team: The five major criteria will be as follows: (exceptions will be considered on a case-by-case basis by Drs. Benson or Mortensen).

- 1) Diagnosed with diabetes mellitus type 1 and ~3-6 months from diagnosis.
- 2) Deemed “carbohydrate aware”, with 2 of a possible 6 completed assessment quizzes dealing with carbohydrate counting in person with CDCES prior to starting pump therapy (see video link below for a basic review ahead of the in-person meeting at the PDC):
<https://www.youtube.com/watch?v=am6ga3tSnpk>
- 3) Able to recognize symptoms of hyperglycemia and hypoglycemia and treat appropriately with competence in the use of the ketone action plan.
- 4) Approved by your physician and ARNP to begin the pump ordering process.
- 5) Completion of pump readiness session, carbohydrate counting quizzes and be able to competently use the ketone action plan at the PDC pump readiness session after watching the four main pump overview educational videos/podcasts.

If you are interested in learning more about what it takes to be a successful pumper, watch the videos (about 4 hours of content) below and then complete an in-person 1 hour assessment with the CDCES at the PDC at Nemours. It is important that anyone thinking about using an insulin pump understands exactly what is involved and how to use this technology safely.

NOTE: The pump process could take as long as 2-3 months.

The following videos/podcasts cover the four main automated insulin delivery systems currently on the market in the USA and then complete a pre-pump readiness assessment with the PDC:

- 1) Beta Bionics Ilet Pump: <https://www.youtube.com/watch?app=desktop&v=CNq1tz4ct60>
- 2) Medtronic 780G: <https://diabetes-connections.com/the-minimed-780g-a-deep-dive-into-medtronics-most-advanced-system/>
- 3) Omnipod-5: <https://diabetes-connections.com/we-really-listened-to-what-people-wanted-a-look-at-omnipod-5-with-horizon/>
- 4) Tandem Control IQ with T-slim X2 or the Mobi pump: https://www.youtube.com/watch?v=HTx7p2OoD_A

Before, During & After Pump Initiation Review Sessions:

- 1) Watch the videos and then complete a 1-hour in-person assessment at the PDC at Nemours **BEFORE** starting pump therapy.
- 2) **AFTER** pump therapy is started, you will have an in person visit with the PDC at Nemours 1-2 weeks after starting the pump to adjust pump settings and if needed, to remedy any challenges you may be having with your insulin pump effectiveness. We aim to improve your glucose time in range (TIR) on your AGP report with a goal of ~70% TIR, while we keep rates of hypoglycemia below ~5% and hyperglycemia less than ~25% of the time you are wearing your CGM.
- 3) We would strongly encourage a TH visit as well with your provider who prescribed the insulin pump 3-6 weeks **AFTER** starting the pump to review your CGM data and pump settings to make further adjustments with your insulin pump system to optimize control and improve your glucose TIR. It is expected that changes in your pump settings will be necessary very often the first 4-8 weeks to help the glucose control algorithms in your pump computer to help you achieve optimal control. Without early adjustments and adequate support, many users of these complex insulin pump devices may be prematurely discontinued early.

Ketone Action Plan with Insulin Pump:

Hyperglycemia with Insulin Pump

If your glucose has been over 300 mg/dL for 2 hours or more, check ketone levels and follow the steps in the chart below...

Ketone levels:

0.1-0.9 mmol/L = normal to small ketones	<ol style="list-style-type: none">1. Give correction bolus via insulin pump2. Recheck glucose and ketone levels in 2 hours<ol style="list-style-type: none">a. If your glucose is still over 250 mg/dL AND ketone levels are below 1.0 mmol/L, change infusion set and give correction bolus with new infusion set every 2 hours until glucose is below 180 mg/dLb. If your glucose is still over 250 mg/dL AND ketone levels are 1.0 mmol/L or more, follow the instructions below based on the ketone levelc. If glucose is below 250 mg/dL, you may continue using your current infusion set. Give correction bolus every 2 hours until glucose is below 180 mg/dL
1.0-2.5 mmol/L = moderate to large ketones	<ol style="list-style-type: none">1. Give injection of insulin by syringe or pen NOW (not through pump) You will need more insulin than your usual correction dose because of the ketones. Talk to your diabetes care team about how to calculate your dose.2. Change infusion set3. Drink water4. Recheck glucose and ketone levels every 2 hours and give correction bolus with new infusion set every 2 hours after syringe/pen injection until ketones are below 1.0 mmol/L and glucose is below 180 mg/dL
> 2.5 mmol/L = extra large ketones	<ol style="list-style-type: none">1. Give injection of insulin by syringe or pen NOW (not through pump) You will need more insulin than your usual correction dose because of the ketones. Talk to your diabetes care team about how to calculate your dose.2. Change infusion set3. Follow ALL steps for "ketones 1.0-2.5 mmol/L" and CALL your diabetes care team if ketone levels are not decreasing 2 hours after you gave insulin dose by syringe/pen

Go to the ER or CALL 911 if experiencing confusion, frequent vomiting, or rapid breathing

Bibliography:

- 1) Consensus Recommendations for the Use of Automated Insulin Delivery Technologies in Clinical Practice. *Endocrine Reviews*, 2023, 44, 254–280.
- 2) Self-reported insulin pump prescribing practices in pediatric type 1 diabetes. *Pediatr Diabetes*. 2021; 22:758–765.
- 3) ISPAD Clinical Practice Consensus Guidelines 2018: Diabetes technologies. *Pediatric Diabetes* October 2018; 19 (Suppl. 27): 302–325.