

Insulin Pump Therapy Program - Clinical Criteria

A patient must meet both the eligibility criteria as outlined in the *Insulin Pump Therapy Program - Eligibility Criteria*, and the clinical criteria, as outlined herein, developed by Alberta Health Services (AHS) in order to participate in the Insulin Pump Therapy (IPT) Program (IPTP). The eligibility and clinical criteria may be changed from time to time, and the IPTP may be changed or discontinued at any time. Enrollment as an IPTP participant does not guarantee continued coverage for an insulin pump and/or diabetic supplies. The IPTP is delivered by AHS through an authorized Adult or Pediatric Insulin Pump Therapy (IPT) Clinic (Clinic), with claims administration by Alberta Blue Cross (ABC) and administrative support from Alberta Health (AH).

1. Definitions

- **Clinic Team:** A diabetes physician specialist with expertise in insulin pumps and diabetes healthcare professionals: a Registered Nurse, Registered Dietitian or Registered Pharmacist, more than one of which is certified in the insulin pump.
- **IPTP participant:** a patient who is enrolled in the IPTP on or after January 14, 2019.
- **Type 1 diabetes:** diabetes that is primarily a result of pancreatic beta cell destruction with consequent insulin deficiency, which is prone to ketoacidosis. This form includes cases due to an autoimmune process and those for which the etiology of beta cell destruction is unknown¹.
- **Type 3c diabetes:** diabetes due to impairment in pancreatic endocrine function related to pancreatic exocrine damage due to acute, relapsing and chronic pancreatitis (of any etiology), cystic fibrosis, hemochromatosis, pancreatic cancer, and pancreatectomy, and rare causes such as neonatal diabetes due to pancreatic agenesis².

2. Objectives

- a. To optimize health outcomes in terms of both safety and effectiveness for individuals with diabetes using IPT, and;
- b. To facilitate responsible utilization and appropriate allocation of resources available for the care of patients with type 1 or type 3c diabetes.

3. Target population

Residents of Alberta eligible for coverage under the Alberta Health Care Insurance Plan and who meet all the program eligibility criteria as outlined in the *Insulin Pump Therapy Program - Eligibility Criteria*.

¹ Punthakee et al., (2018) *Diabetes Canada 2018 Clinical Practice Guidelines for the Prevention and Management of Diabetes in Canada*: Definition, Classification and Diagnosis of Diabetes, Prediabetes and Metabolic Syndrome. Can J Diabetes 2018;42(Suppl 1):S88-S103.

² Gudipaty et al.,(2015), Pancreatogenic (Type 3c) Diabetes. Pancreapedia: Exocrine Pancreas Knowledge Base <<http://www.pancreapedia.org/>>, DOI:10.3998/panc.2015.35<<http://dx.doi.org/10.3998/panc.2015.35>

4. Starting IPT

4.1 Indications for IPT

For the avoidance of doubt, all patients with Level 1-4 indications for IPT, including those with a Level 3.2 or 4.1 indication, are required to satisfy the requirements outlined in the *Insulin Pump Therapy Program - Eligibility Criteria*.

Level 1:

- 1.1. Problematic hypoglycemia (*Choudhary et al 2015 Diabetes Care 38 (6), 1016-1029*
<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4439532/>)
- 1.2. Impaired awareness of hypoglycemia (*e.g., as indicated by a Clarke or Gold score $\geq 4/7$*).
- 1.3. Inability to achieve acceptable glycemic control with Flexible Insulin Therapy (FIT) using Multiple Daily Injections (MDI).
- 1.4. Development and progression of microvascular complications where glycemic control is inadequate.

Level 2:

- 2.1 Unpredictable variation in activity levels (sport or occupational) where ability to adjust basal insulin delivery is required to improve glycemic control or minimize risk of hypoglycemia.
- 2.2 Strong dawn phenomenon where increases to basal (analog) insulin to achieve Fasting Plasma Glucose (FPG) < 7 mmol/L have caused nocturnal hypoglycemia.
- 2.3 Age < 12 years and MDI is considered to be impractical or inappropriate by the Clinic Team.

Level 3:

- 3.1 Strong desire/motivation for pump therapy in patients achieving acceptable control with FIT using MDI.
- 3.2 Current/Previous insulin pump users not funded through the IPTP with acceptable glycemic control.

Level 4:

- 4.1 Clinical Exception. Situations where, in the view of the Clinic Team, a patient requires IPT to mitigate risk from extremely poor glycemic control or prevent recurrent hospital admission, and where alternative approaches have been exhausted.

4.2 Qualifications for receiving IPT

The following are required of patients, as well as their parent(s) or legal guardian(s) in cases where the patient is a minor under the age of 18 or an adult with legal guardian(s):

- a. Successful completion of diabetes management education and the IPTP insulin pump therapy learning module and demonstrated competence in FIT and/or strategies to prevent severe hypoglycemia as determined by the Clinic Team.
- b. Adequate trial of FIT with modern insulin analogs supervised by an experienced multidisciplinary care team. At the discretion of the IPT prescribing physician, this qualification may be waived in the case of pediatric patients whose abilities do not allow

them to obtain the full benefit of FIT training. Full documentation supporting this waiver must be provided.

- c. Active involvement in diabetes self management.
- d. Patient assessment at the Clinic.

4.3 Requirements for IPT Start

- a. Completion of assessment of starting basal rates, insulin:carbohydrate ratios, and insulin sensitivity at the Clinic.
- b. Completion of pump training and demonstration of competence with using their selected pump to maximize safe use.

5. IPT Review and Continuation

To optimize IPTP participant safety and maximize the clinical benefits of IPT, IPTP participants will be reviewed at least once a year by the Clinic Team. The goal of the review process is to help maintain people on IPT by providing ongoing education, support and coaching, and promote active self management.

5.1. Responsibilities of IPTP participants

- a. Regular follow-up with a primary care physician or other health care professionals for routine diabetes care (e.g., regular A1C, surveillance for complications).
- b. Demonstration of active involvement in diabetes self-management including provision of insulin pump information to the Clinic upon request.
- c. Where the indication for IPT is Level 4 Clinical Exception, IPTP participants will be required to undergo a full clinical assessment in the Clinic and will be reviewed at least annually to ensure that any clinical factors are identified and addressed.

5.2. Factors that may require further clinical support for IPTP participants

- a. Increase in A1C levels greater than 1.5% or A1C levels higher than 10%.
- b. Recurrent admissions to hospital for unexplained diabetic ketoacidosis.
- c. Episodes of severe hypoglycemia.
- d. Failure to engage consistently in active self management.
- e. Excessive basal rates associated with risk for hypoglycemia if meals are omitted or delayed.
- f. Physical, psychological, or cognitive deficits, or changes in social situation, where the individual (or family) may find it more challenging to manage pump therapy safely.

5.3. IPT Discontinuation Criteria

- 5.3.1. An IPTP participant may be discontinued from the program where it is determined, at the discretion of the Clinic Team, that the patient meets one or more of the following Discontinuation Criteria:
 - a. The patient does not meet IPTP eligibility criteria outlined in the *Insulin Pump Therapy Program – Eligibility Criteria*.
 - b. Persistent failure to meet the outlined responsibilities of IPTP participants, particularly demonstration of active involvement with diabetes self management.

- c. Unwillingness to work with the Clinic Team to address one or several of the factors that may require additional clinical support as outlined in 4.2.
- d. Where continuation of IPT would be clinically unsafe as determined by the IPTP participant's IPT prescriber.
- e. Where the IPTP participant (or their primary caretaker) is unable to safely operate and/or manage IPT.
- f. Illegal or unethical behaviour (e.g., illegal re-selling of supplies, wastage or fraud).

5.3.2 IPTP participants discontinued from the IPTP will be sent a Letter of Discontinuance and will not be entitled to further coverage after the effective date of discontinuance specified in the letter. If a person wishes to be considered for re-enrollment, they will have to apply for re-enrollment in the IPTP; satisfy all eligibility criteria as outlined in the *Insulin Pump Therapy Program – Eligibility Criteria* and all clinical criteria as outlined herein; and have received another Confirmation Letter with a new effective enrollment date, confirming that such person is an IPTP participant from such new effective enrollment date.

The effective date of this document is January 15, 2019.