

Insulin Pump Therapy Program Eligibility Criteria

A patient must meet both the eligibility criteria, as outlined herein, and the clinical criteria developed by Alberta Health Services (AHS) as outlined in the *Insulin Pump Therapy Program - Clinical Criteria* 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 diabetes supplies. The IPTP is delivered by AHS through an authorized AHS clinic serving Adult or Pediatric IPT patients (Clinic), with claims administration by Alberta Blue Cross (ABC) and administrative support from Alberta Health (AH).

Definitions

- **Clinic Team:** Consists of a diabetes physician specialist with expertise in insulin pumps and the following diabetes healthcare professionals: a Registered Nurse, Registered Dietitian or Registered Pharmacist, more than one of which is certified in the management of patients who use insulin pumps.
- **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 unknown (1).
- **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 as well rare causes such as neonatal diabetes due to pancreatic agenesis (2).

Eligibility Criteria

To be eligible for enrollment, and for continued enrollment, as an IPTP participant, an individual must meet all the following:

- a. be a resident of Alberta who is enrolled or eligible for coverage under the Alberta Health Care Insurance Plan.
- b. be diagnosed with Type 1 diabetes or Type 3c diabetes and be under the care of a physician or nurse practitioner for the condition.
- c. meet and continue to meet the clinical criteria as set out in the Insulin Pump Therapy Program - Clinical Criteria.
- d. complete a pre-insulin pump information session.
- e. complete an IPT education plan.

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>>

- f. attend at least one assessment at a Clinic.
- g. complete a Patient Responsibility Form.
- h. have completed an Eligibility Notification Form.
- i. have been sent a Confirmation Letter.
- j. participate in required reviews and ongoing clinical monitoring by the Clinic Team.
- k. have not been sent a Letter of Clinical Ineligibility.
- l. have not been sent a Discontinuation Letter.

Enrollment and Continued Eligibility Process

- a. Patients must complete a pre-insulin pump information session arranged through a Clinic.
- b. Patients must then seek and obtain an appointment at a Clinic to undergo an assessment by a Clinic Team.
- c. Patients will be assessed by the Clinic Team for the following:
 - i. A Clinic IPT prescriber will assess whether the patient meets the clinical criteria; and
 - ii. Patients will be required to participate in ongoing clinical monitoring and to complete an IPT education plan.
- d. Patients who meet all eligibility and clinical criteria must also complete a Patient Responsibility Form.
- e. Upon receipt of a completed Patient Responsibility Form, the Clinic will complete an IPTP Eligibility Notification Form for the patient and fax the form to Alberta Blue Cross (ABC).
- f. Upon receipt and confirmation of the contents of the IPTP Eligibility Notification Form, ABC will mail a Confirmation Letter to the patient and the Clinic to confirm the patient's enrollment in the IPTP. Upon issuance of the Confirmation Letter by ABC, the patient will be deemed to have been enrolled as an IPTP participant effective as of the date stated in the IPTP participant's Confirmation Letter.
- g. The Confirmation Letter will also advise the IPTP participant as follows:
 - i. The products that are eligible for funding.
 - ii. Information on how to obtain an insulin pump and IPT supplies.
- h. Adult IPTP participants must participate in annual reviews as required by the Clinic. IPTP participants under the age of 18 must participate in semi-annual reviews as required by the Clinic.
- i. Patients who do not meet the clinical criteria as outlined in the *Insulin Pump Therapy Program – Clinical Criteria* will be sent a Letter of Clinical Ineligibility from the Clinic.
- j. An IPTP participant may be discontinued from the IPTP where it is determined, by a Clinic Team, that the patient meets one or more of the clinical criteria for discontinuation, as outlined in the *Insulin Pump Therapy Program – Clinical Criteria*.
 - i. The Clinic will fax a Patient Discontinuation Form to ABC to terminate IPT supply coverage for the patient. Discontinued IPT Users will be sent an AHS Patient Discontinuation Letter from the Clinic indicating that they are no longer eligible for coverage under the IPT Program, effective from the date specified in the Discontinuation Letter.

IPTP participants enrolled prior to January 15, 2019

- a. Notwithstanding section 2, IPTP participants enrolled in the IPTP prior to January 15, 2019 and who have received an insulin pump provided under the IPTP prior to January 15, 2019 will continue to receive coverage for an insulin pump and IPT supplies under the IPTP provided they meet the clinical criteria as outlined in the *Insulin Pump Therapy Program - Clinical Criteria* as assessed at their annual clinical review, and provided they meet all eligibility criteria in section 2 other than those specified in sections 2(d), 2(e), 2(h), and 2(i).
- b. Notwithstanding section 2, IPTP participants enrolled in the IPTP prior to January 15, 2019 and who have not received an insulin pump provided under the IPTP prior to January 15, 2019 will continue to receive coverage only for IPT supplies until the end on the date outlined in their Confirmation Letter. After this date, such IPTP

participant will be deemed to have been discontinued as an IPTP participant, will not be entitled to further coverage, and will be sent a Discontinuation Letter unless, prior to such date, they have applied for re-enrollment in the IPTP; have satisfied all eligibility criteria and all clinical criteria as outlined in the *Insulin Pump Therapy Program – Clinical Criteria*; 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.

Coverage

- a. Subject to section 4(a) and (b), IPTP participants are eligible, from the date stated in their Confirmation Letter, for an insulin pump every five years and IPT supplies to support its use, unless they are discontinued from the IPTP.
- b. The Minister, in its sole discretion, may refuse to pay claims from an IPTP participant made for an insulin pump and/or IPT for any reason, including but not limited to, where a request for an insulin pump or IPT is as a result of wastage or fraud.
- c. Insulin Pumps:
 - i. The IPTP provides coverage for the following insulin pumps:
 - Insulet Canada Corporation
 - Omnipod Insulin Management System
 - Omnipod DASH Insulin Management System
 - Medtronic Canada
 - Minimed 630G Insulin Pump System
 - Minimed 670G Insulin Pump System
 - Minimed 770G Insulin Pump System
 - Minimed 780G Insulin Pump System
 - Tandem Diabetes Care Canada, Inc.
 - T:slim X2 Insulin Pump with Basal IQ technology
 - T:slim X2 Insulin Pump with Control IQ technology
 - Ypsomed Canada Inc.
 - YpsoPump Insulin Pump
 - ii. IPTP participants are eligible for a replacement insulin pump every five years from the date the previous insulin pump was delivered from the insulin pump manufacturer.
 - iii. Insulin pumps must be obtained directly from one of the approved insulin pump manufacturers, on a direct bill basis, to be covered under the IPTP.
 - iv. Insulin pumps covered under the IPTP come with a warranty from the insulin pump manufacturer.
 - v. Where the IPTP participant has a defective insulin pump, the IPTP participant will contact the insulin pump manufacturer for replacement or repair pursuant to the terms and conditions of the insulin pump manufacturer's warranty.
 - vi. Where an insulin pump manufacturer refuses to provide a replacement insulin pump or repair a defective insulin pump, the IPTP participant will contact ABC, who will contact the Pharmaceutical and Health Benefits Branch of AH. The Executive Director, Pharmaceutical and Health Benefits Branch, AH at their sole discretion may authorize ABC to provide coverage for a new replacement insulin pump for the IPTP participant.
- d. IPT Supplies:
 - i. IPTP participants will receive coverage for the following IPT supplies, subject to the limits below, unless they are discontinued from the IPTP:

Insulin Pump Supplies

 - Insulet Pump Supplies
 - 100 units of pods per 100 days

- Medtronic Pump Supplies
 - 100 units of infusion sets per 100 days
 - 100 units of insulin cartridges/ reservoirs/ pods per 100 days
 - 1 unit of serter per year
- Tandem Pump Supplies
 - 100 units of infusion sets per 100 days
 - 100 units of insulin cartridges/ reservoirs/ pods per 100 days
- YpsoMed Pump Supplies
 - 100 units of infusion sets per 100 days
 - 100 units of insulin cartridges/ reservoirs/ pods per 100 days
 - 1 unit of serter per year

Other Diabetes Management Supplies

- Skin preparation (dressings, skin adhesives and adhesive removers): up to \$100 per year
 - Blood glucose test strips: up to 700 units per 100 days
 - Blood ketone test strips: up to 20 units per 100 days
 - Blood ketone test meter: up to 1 unit every 2 years
 - Lancets: up to 700 units per 100 days
 - Insulin syringes or Pen tip needles: up to 100 units per 100 days
- ii. IPT supplies must be obtained from a licensed pharmacy in Alberta and/or one of the approved insulin pump manufacturers, on a direct bill basis, to be covered under the IPTP.
- iii. Where an IPTP participant wishes to obtain an exception to the IPT supply limits set out above, the IPTP participant, prior to obtaining any IPT supplies above the supply limit, shall make a request for an exception as follows:
- a. Contact a pharmacy or insulin pump manufacturer from whom the supplies are sought to be obtained, and request that they make an exception request on behalf of the IPTP participant to ABC.
 - b. ABC will then contact the Pharmaceutical and Health Benefits Branch of AH. The Executive Director, Pharmaceutical and Health Benefits Branch, AH at its sole discretion may authorize ABC to provide coverage for IPT supplies outside of the above-mentioned limits. Exceptions will be considered on a case-by-case basis if there is a demonstrated medical need.
 - c. ABC will inform the IPTP participant whether an exception has been granted and the particulars of the exception.
- e. Coverage under the IPTP is provided on a direct bill basis to pharmacies and/or insulin pump manufacturers only. IPTP participants will not be reimbursed for IPT supplies or an insulin pump paid by them personally.