

Insulin Pump and Supplies Policy and Administration Manual

Assistive Devices Program
Ministry of Health & Long-Term Care

May 2016

www.health.gov.on.ca/adp

Table of Amendments

This page will list all substantive changes to policies and procedures listed in the Manual.

Section	Change	Date
605	Requests for Replacement Device	June 2011
915	Subcontracting	January 2012
110	Added definition of Nurse Practitioner, Physician and Prescriber	April 1, 2014
300, 320 325, 400, 410, 505, 805.01, 805.02, Appendix B, Appendix C, Appendix D	Updated based on new definition of Prescriber	April 1, 2014
200.02	Added manufacturer warranty requirements	October 1, 2014
900	Added policy regarding Manufacturers as Vendors	September 11, 2015
110	Added definitions	October 19, 2015
115	Added information to the Roles and Responsibilities of the Applicant/Client and the DEP	October 19, 2015

410	Renamed the policy to Annual Renewal of the Supplies Grant	October 19, 2015
710	Renamed the policy to Insulin Pump Supplies Grant and updated the policy statements	October 19, 2015
715	Renamed the policy to Grant Amounts and Payments and added new policy statements	October 19, 2015
720	Added a new policy entitled Ongoing Grant Payments for Supplies	October 19, 2015
805	Renamed the policy to Renewal Letter for Insulin Pump Supplies Grant for Children and Adults	October 19, 2015
1000	Added Contact Information	October 19, 2015

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Introduction

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Part 1: Introduction to Insulin Pump and Supplies Policy and Administration Manual

100 Purpose of the Manual

The purpose of the Policy and Administration Manual is to present in one document the policies and procedures for Funding an insulin pump and Supplies. The Policy and Administration Manual is intended to complement the ADP Manual.

This Manual forms part of the agreement between the Ministry of Health and Long-Term Care and the Vendor and the understanding between the Ministry of Health and Long-Term Care and Diabetes Education Programs. The Ministry reserves the right to revise this Manual.

100.01 Intended Target Audience

The Assistive Devices Program (ADP) intends the Policy and Administration Manual to be used by the following:

- health professionals from the Diabetes Education Programs who treat individuals with type 1 diabetes; and
- Vendors who have an Agreement with the ADP to provide insulin pumps and services.

105 Protecting Personal Health Information

Vendors must comply with all applicable privacy laws governing information regarding their Clients.

See the ADP Manual, Policy 700, Protection of Personal Information and Personal Health Information.

110 Definitions

Capitalized terms used in this Manual shall have the meaning associated with them as set out in the ADP Manual or such meanings as described below:

- 110.01 **Diabetes Education Program** means a specialized multi-disciplinary team registered with the ADP and comprised of health professionals that provide diabetes education, treatment and follow-up resources to individuals with diabetes.
- 110.02 **Grant** means the financial assistance provided directly to the Client and intended to cover some of the costs of purchasing Supplies.
- 110.03 **Insulin Pump Therapy** means a method of administering insulin subcutaneously by means of a portable, battery-operated, programmable pump specially designed for this purpose.
- 110.04 **Insulin Pump Therapy Education Program** means a Diabetes Education Program that provides a multi-disciplinary team approach in the identification of suitable insulin pump candidates and provides education to assist individuals to understand the principles of Insulin Pump Therapy including the mechanical and technical aspects of the insulin pump.

- 110.05 **Medical Eligibility Criteria** means medical conditions that determine eligibility for Funding insulin pumps and Supplies.
- 110.06 **Nurse Practitioner** means a professional who holds a valid certificate of registration from the College of Nurses of Ontario (CNO) as a Registered Nurse in the Extended Class and entitled to practise in Ontario.
- 110.07 **Physician** means a member of the College of Physicians and Surgeons of Ontario who is qualified to practice medicine in Ontario under the *Medicine Act*, 1991, S.O. 1991, c. 30 or any successor legislation thereto.
- 110.08 **Prescriber** means a Physician or Nurse Practitioner registered as a Prescriber with a Diabetes Education Program.
- 110.09 **Renewal Date** means the date on which a Grant expires and a new Grant period begins.
- 110.10 **Renewal Form** means the form with which the Diabetes Education Program confirms the Client's ongoing eligibility for a Grant.
- 110.11 **Supplies** means the items that are required in order for the Client to use the insulin pump.

For more definitions, see the ADP Manual, Policy 110, Definitions.

115 Roles and Responsibilities

In the process of confirming eligibility for Funding, the Applicant/Client, the Diabetes Education Program and the Vendor have specific roles and certain rights and responsibilities.

Additional information may be found in the ADP Manual and the Vendor Agreement.

115.01 Roles and Responsibilities of the Applicant/Client

- Using information provided by the Diabetes Education Program and the Vendor will decide whether to proceed with an application for Funding, his/her choice of Vendor and his/her choice of make and model of insulin pump.
- Should carefully review all the information on the Application Form, Section 3 – “Applicant’s Consent and Signature” prior to signing Section 3.
- Has the right to seek a second opinion if he/she disagrees with the Diabetes Education Program’s assessment of his/her needs.
- Is responsible for paying for the Supplies directly to the Vendor.
- Is responsible for returning the Renewal Form to the ADP to enable the ADP to determine ongoing eligibility and payments.
- Is responsible for providing updated information to the ADP regarding their name, address and/or Health number at the contact information provided in policy 1000 of this Manual.
- Is responsible for providing updated information to the Ministry of Health and Long-Term Care’s Financial Management Branch in Kingston regarding their banking information at the contact information provided in policy 1005 of this Manual.
- Is responsible for monitoring their Grant payments and for contacting the ADP, should an issue be identified.
- Is responsible for retaining original receipts for 2 years after the purchase date of the insulin pump and Supplies.
- Agrees that he/she may be required to temporarily return to insulin injections in the event of pump failure.

115.02 Roles and Responsibilities of the Diabetes Education Program

- Is the gatekeeper to the Program and assumes the leadership role in the assessment process, confirmation of the eligibility, and completion of the Application Form.
- Will provide the Eligible Person with accurate information about ADP policies, eligibility criteria, and procedures, so the Eligible Person can make a well-informed decision regarding submitting an application to the Program.
- Will provide the Eligible Person with a list of Vendors serving his/her community.
- Will identify the need for an insulin pump as part of the Eligible Person's assessment process.
- Will work with the Vendor to ensure appropriate assessment and trial pumps are obtained.
- Will authorize the pump that meets the Eligible Person's requirements.
- Will not submit an application for Funding to the Program for an individual who does not meet the Medical Eligibility Criteria.
- Will complete the Renewal Form for the Client.

115.03 Roles and Responsibilities of the Vendor

- To have employees trained in the use of the type of insulin pump, which the ADP has authorized the Vendor to sell and to provide instructions
- for the effective use, care, and maintenance of this insulin pump.
- Must provide Applicant/Client the assessment and trial pump requested by the Diabetes Education Program and for a reasonable length of time.

- Will work cooperatively with the Applicant/Client and the Diabetes Education Program to ensure that the choice of insulin pump is appropriate to meet the individual's basic requirements.
- Must notify the Diabetes Education Program when the Vendor has delivered the insulin pump to the Applicant/Client, so the Diabetes Education Program can complete appropriate follow-up.
- Must keep an adequate stock of the insulin pump the Program has authorized the Vendor to sell, honour manufacturer warranties, and provide after sale service.
- Must continue to meet all conditions specified in their executed Vendor Agreement and the Manuals.

Devices Covered

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Part 2: Device Covered

200 Devices Covered

200.01 Insulin pumps approved for Funding are listed in the Product Manual. The ADP provides Funding for the following items.

- insulin pumps
- the Supplies associated with the use of an insulin pump

200.02 In order to list an **insulin pump** with the Program the manufacturer/distributor responsible for the product in the Ontario market must warranty the product for a minimum of 5 years from the date the Client purchased the Device.

205 Insulin Pumps

Only those makes and models of insulin pumps listed in the Product Manual are available for Funding.

Note: The Applicant must pay the Vendor directly for any non-ADP funded items he/she may choose to purchase.

All insulin pumps funded by the Program must be new. The Vendor cannot supply any insulin pump or any related component that has been previously used, rebuilt or refurbished.

For greater certainty, insulin pumps that manufacturers or dealers have loaned to any other person or entity for promotional or educational purposes do not qualify as new pumps.

210 Repairs/Batteries

The ADP does not provide Funding towards the cost of repairs, maintenance and/or replacement batteries for any Device.

Applicant Eligibility Criteria for Insulin Pump and Supplies

3

Part 3: Applicant Eligibility Criteria for Insulin Pump and Supplies

300 Prescriber

The ADP will only fund an insulin pump and the Supplies when prescribed by a Physician or Nurse Practitioner registered with the ADP as a Prescriber with a Diabetes Education Program.

The ADP will only register a Physician or Nurse Practitioner as a Prescriber for insulin pumps and Supplies, if the Physician or Nurse Practitioner is an adult or pediatric diabetes specialist.

305 Applicant Identified as Ineligible by ADP

An Applicant may be deemed ineligible if the criteria for his/her access to the Program are not met or where information supplied in connection with an Application Form is insufficient, incomplete and/or inaccurate.

In cases of denial, the Vendor, the Applicant and the Prescriber will be advised of the reason.

310 Pediatric Medical Eligibility Criteria for Insulin Pump and Supplies

Children and youth eighteen (18) years of age and under with type 1 diabetes will be eligible for Funding if they meet the following Medical Eligibility Criteria:

- has type 1 diabetes and has been on injection therapy for 1 year prior to the initiation of Insulin Pump Therapy;
- has demonstrated that they have three A1c levels from the previous year and that the last two A1c levels, taken prior to Insulin Pump Therapy initiation, are less than or equal to 10%;
- has demonstrated to a pediatric Diabetes Education Program an ongoing commitment to blood glucose (BG) monitoring before each meal and before bedtime and a commitment to establishing an ongoing record of BG test results;
- has demonstrated to the pediatric Diabetes Education Program appropriate insertion site rotation;
- has demonstrated to the pediatric Diabetes Education Program appropriate sick day knowledge and management - not more than one diabetic ketoacidosis (DKA) in the previous six (6) months;
- has demonstrated to the pediatric Diabetes Education Program the ability to self-assess and take action on blood glucose results by carbohydrate counting and sick day management;
- receives appropriate ongoing family support;
- maintains regular diabetes clinic attendance (at least three (3) visits in the previous year);

- has or will participate in an insulin pump education program; and
- signs an agreement with the pediatric Diabetes Education Program that they will adhere to the terms established by the pediatric Diabetes Education Program for the continuation of Insulin Pump Therapy.

315 Pediatric Renewal Medical Ineligibility Criteria for Insulin Pump Supplies

Children and youth eighteen (18) years of age and under with type 1 diabetes will be ineligible for continued Funding for insulin pump Supplies under the following circumstances:

- occurrence of more than one episode of diabetic ketoacidosis (DKA) within the last twelve (12) months;
- inadequate frequency of blood glucose testing to ensure safe and effective use of the insulin pump;
- A1c greater than 10% for the last two readings;
- inadequate frequency of set changes to ensure healthy insertion sites;
- consistent pattern of ineffective pump management; and
- fewer than three (3) diabetes clinic visits in the last twelve (12) months.

320 Adult Medical Eligibility Criteria for Insulin Pump and Supplies

Adults 19 years of age and older with type 1 diabetes will be eligible for Funding if they meet the following Medical Eligibility Criteria:

- has been on a basal/bolus regimen for at least 1 year prior to the initiation of Insulin Pump Therapy;
- has demonstrated to the adult Diabetes Education Program the ability to self-assess and take action based on blood glucose results by carbohydrate counting, administering correction boluses and sick day management; and
- has demonstrated to the adult Diabetes Education Program a commitment to long-term diabetes follow-up through regular assessments by diabetes educators, and Prescribers at intervals deemed appropriate by the adult Diabetes Education Program.

325 Adult Renewal Medical Eligibility Criteria for Insulin Pump Supplies

Adults 19 years of age and older with type 1 diabetes will be eligible for continued Funding for insulin pump Supplies if they meet the following Medical Eligibility Criteria at the time of the annual renewal:

- has continued to demonstrate an ongoing commitment to blood glucose (BG) monitoring at a minimum of four times a day;
- has continued to demonstrate successful sick day management;
- has demonstrated that they have benefited from Insulin Pump Therapy, which is defined as one of the following:
 - improved quality of life;
 - improved A1c results;
 - reduction in the number of hypoglycaemic events;

- reduction in the number of diabetic ketoacidosis (DKA) episodes;
or
- improved management of the “dawn phenomenon”; and
- has demonstrated a commitment to long-term diabetes follow-up through regular assessments by diabetes educators, and Prescribers at intervals deemed appropriate by the Diabetes Education Program.

330 Transition from Pediatric to Adult Funding Assistance

- 330.01 At the time of their 19th birthday, Clients who have received Funding for an insulin pump and Supplies are eligible for continued Funding.
- 330.02 At that time, Clients who are 19 years of age must meet the adult Renewal Medical Eligibility Criteria (**see 325**). An adult Diabetes Education Program that offers an Insulin Pump Therapy Education Program must assess the Client.
- 330.03 The ADP database will automatically generate an adult renewal letter two months prior to the Client’s anniversary date. The ADP bases the anniversary date on the date the ADP receives the initial Application Form.

Confirmation of Eligibility for Insulin Pump and Supplies Required

4

Part 4: Confirmation of Eligibility for Insulin Pump and Supplies Required

400 Acceptable Evidence of Medical Eligibility Criteria

A Diabetes Education Program must assess the Applicant. The Diabetes Education Program will determine if the Applicant is an appropriate candidate for Insulin Pump Therapy and meets the Medical Eligibility Criteria (**see 310 and 320**).

A Prescriber, registered as a Prescriber with the Diabetes Education Program must certify that the Applicant has type 1 diabetes, has demonstrated a clinical need for Insulin Pump Therapy and has participated in a diabetes education program.

405 Initiation of 90-Day Trial Period

When the ADP receives a fully completed initial Application Form from an Applicant who meets the general and Medical Eligibility Criteria, the Applicant will receive Funding for the 90-day trial period.

The purpose of the 90-day trial period is to determine if the Applicant is a suitable candidate for Insulin Pump Therapy.

The 90-day trial period begins on the date the Applicant initiated Insulin Pump Therapy.

Once the ADP has approved the Application Form, the Client will be eligible to receive full Funding for the cost of the insulin pump and will receive the first installment of the annual insulin pump Supplies Grant.

410 Annual Renewal of the Supplies Grant

To renew Funding for the insulin pump Supplies Grant, the Diabetes Education Program must continue to assess the Client. The Diabetes Education Program will determine if the Client continues to be an appropriate candidate for Insulin Pump Therapy and if they continue to meet the pediatric and adult renewal Medical Eligibility Criteria (**see 300, 315 and 325**).

The Prescriber must certify that the Client has type 1 diabetes, continues to demonstrate a clinical need for Insulin Pump Therapy, meets the renewal Medical Eligibility Criteria and complies with the requirements of the Diabetes Education Program.

See policy 700 for more details regarding the renewal process and funding for Supplies.

Diabetes Education Program

5

Part 5: Diabetes Education Program

500 Diabetes Education Program Status

A Diabetes Education Program wishing to prescribe an insulin pump that is funded by the ADP must be registered as an ADP clinic.

505 ADP Clinic Status

In order to maintain active ADP clinic status, a Diabetes Education Program must provide an Insulin Pump Therapy Education Program to Eligible Persons and ensure that the ADP has an updated list of Prescribers who are actively prescribing Insulin Pump Therapy.

510 Guidelines for an Diabetes Education Program

See Appendix B for the minimum criteria established for a Pediatric Diabetes Education Program registered with the ADP.

See Appendix C for the minimum criteria established for an adult Diabetes Education Program registered with ADP.

515 Maintaining Up To Date Clinic List

Within ten (10) days of any change in personnel actively involved in assessing or prescribing Insulin Pump Therapy, the Diabetes Education Program must provide the ADP with an up to date record of information.

See Appendix D for Diabetes Education Program Registration Form.

520 Record Keeping

Accurate record keeping is essential. The Program may ask to see the Diabetes Education Program's clinical assessment findings to confirm the Applicant/Client's eligibility and/or as part of the Program's audit review procedures.

525 Status of Application Report

The ADP will generate a monthly report that the Program will mail to the Diabetes Education Program. The report will list the Application Forms received by the Program and include the following information:

- Applicant/Client's name;
- Applicant/Client's health card number;
- ADP unique claim number assigned;
- codes requested (including quantity); and
- status of the Application Form.

Device Eligibility

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Part 6: Device Eligibility

600 Funding Periods

The ADP expects an insulin pump to remain useful for a minimum period of time. The minimum period of time for an insulin pump is five (5) years.

605 Requests for Replacement Device

Clients who have received an ADP funded insulin pump and continue to meet the general (see ADP Manual, Policy 300, Eligibility Criteria for Program Benefits) and Medical Eligibility Criteria (see Part 3, Applicant Eligibility Criteria for Insulin Pump and Supplies) are eligible to re-apply for Funding after the designated funding period has expired, if there is:

- a documented change in the Client's medical status and the ADP funded insulin pump no longer meets the Client's basic needs; or
- damage due to normal use and wear, and the Client confirms that the insulin pump is no longer under warranty and the cost of the repair is more than one third of the original purchase price.

610 Warranty

The Vendor must provide the Client with the written manufacturer's warranty at the time of purchase.

The manufacturer is responsible for honouring warranties even in those situations where an insulin pump has been purchased from a Vendor that is no longer in business, i.e. the Vendor has been sold, closed or has declared bankruptcy.

Funding to replace insulin pumps that are not in good working order is not available when the manufacturer's warranty is still in effect.

Funding and Payment

7

Part 7: Funding and Payment

700 Funding Amount for ADP Clients

The Program pays 100% of the Approved Price for an insulin pump listed in the Product Manual.

The Vendor **may not sell** the insulin pump to the Client for more than the Approved Price.

The Vendor **may sell** the insulin pump to the Client for **less** than the Approved Price.

See the ADP Manual, Policy 905, Rebates.

705 Delivery of Device

The Vendor will provide the Authorized Device together with a fully itemized invoice to the Client, advise the Client regarding the warranty and after-purchase services offered, and provide a copy of the manufacturer's warranty and user manual for the Device.

710 Insulin Pump Supplies Grant

710.01 The ADP provides a Grant to help pay for the Supplies associated with the use of an insulin pump.

710.02 The Applicant may purchase their Supplies from any retailer that sells these products.

715 Renewal of Annual Financial Supply Grant

The Client must continue to meet the Medical Eligibility Criteria in order to continue to receive the annual supply grant.

The ADP will send a renewal letter directly to the Client every year. The Client must complete the renewal letter with his/her Diabetes Education Program to maintain eligibility for the supply grant.

715 Grant Amounts and Payments

- 715.01 Clients are eligible to receive an annual Grant in the amount of \$2400 towards the purchase of Supplies.
- 715.02 Once an Application Form has been reviewed and approved by the ADP, the ADP will provide the first Grant payment directly to the Client for the approved Grant amount.
- 715.03 The Grant is paid in four (4) equal installments in each 12-month period.
- 715.04 Direct deposit is encouraged for provision of the payments of Grant funding. The Application for Direct Bank Payment form is available on the ADP website:

http://www.health.gov.on.ca/en/public/programs/adp/adp_fm.aspx

Alternately, the Client may submit a letter that requests direct deposit and includes the Client's name, Health number or Grant claim number, as well as a void cheque.

If the Client has arranged direct deposit for a different ADP Grant, payments will automatically be made by direct deposit.

If arrangements are made for direct deposit, future Grant payments will be made in this way.

715.05 Where the Program has discontinued the provision of Grant payments to a Client and no payments have been made for a period of one (1) year, the Client must submit a new Application Form in order to re-apply for Grant payments.

715.06 In certain limited circumstance, the ADP will consider requests to provide retroactive Grant payments. These circumstances are:

- Cancellations due to returned mail, declined direct deposits or OHIP database mismatches.

A maximum of one (1) year of retroactive Grant payments, from the date of request, may be made. The Client must have continued to meet the ADP eligibility criteria throughout the year.

The Client must submit written documentation outlining their specific situation to the ADP. The ADP will advise the Client of its decision.

715.07 The Client must retain a copy of any receipts related to the Supplies for a period of two (2) years.

720 Ongoing Grant Payments for Supplies

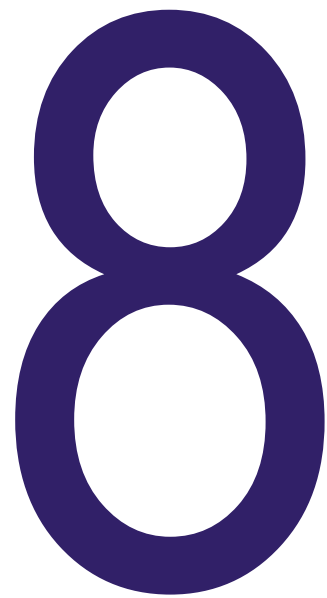
720.01 When assessing an Applicant's eligibility to receive the Grant, the ADP verifies that information on the Application Form matches the Health number, last name, date of birth and gender information in the Ministry of Health and Long-Term Care's Registered Persons Data Base (OHIP database). As well, the system confirms that the Applicant/Client is not deceased and is entitled to the receipt of insured services in Ontario. If there is a mismatch of information or if the information is not confirmed, the Applicant will be deemed ineligible and no payment will be made to the individual.

- 720.02 If a cheque or electronic funds transfer (EFT, otherwise known as direct deposit) letter is returned to the ADP, or if an EFT is declined/returned, the Grant will be cancelled.
- 720.03 It is the responsibility of the Client to monitor the receipt of Grant payments. If a problem with payments is identified, the Client must contact the ADP directly to provide the update/change in writing. See policy 1000 of this Manual for contact details.
- 720.04 It is the responsibility of the Client to notify the ADP in writing of a change in name, address, Health number or any other relevant information.
- 720.05 It is the responsibility of the Client to notify the Financial Management Branch in Kingston, in writing, of a change in bank account information. See policy 1005 of this Manual for contact details.
- 720.06 The ADP will cancel a Grant when it receives written notification that a Client no longer requires the Grant, is no longer eligible for the Grant or that the Client is deceased. The Client or Agent must submit documentation that includes the Client's name, Health number or Grant claim number and a request to cancel the Grant. This information may be submitted by letter, fax or email. If the Client is deceased, a copy of the death certificate must also be submitted.
- 720.07 A Renewal Form will be mailed to the Client by the ADP every year. The Client must complete this form with his/her Diabetes Education Program and return the original form to the ADP in order to confirm their continued eligibility to receive the Grant for the following year.
- 720.08 Renewal Forms must be returned to the ADP prior to the Grant's Renewal Date in order to prevent payment delays. Renewal Forms received after the Renewal Date will result in delays in the processing of Grant payments.
- 720.09 If the submitted Renewal Form is fully and correctly completed and if the Client continues to meet the eligibility criteria, the ADP will process the Renewal Form and the Client will continue to receive the Grant payments.
- 720.10 If the submitted Renewal Form is incomplete, a copy of the incomplete Renewal Form will be mailed to the Client, highlighting the required missing

information. If the Client is not eligible to receive the Grant based on the information provided on the form, the ADP will advise the Client in writing.

- 720.11 Individuals will not continue to be eligible to receive Grant payments where a Renewal Form has not been received by the ADP within one (1) year after the expiry of the Renewal Date. A new Application Form must be submitted to the Program if the Client wishes to re-apply for the Grant.

Application for Funding Insulin Pump and Supplies



Part 8: Application for Funding Insulin Pump and Supplies

800 Guide to Completing the Application Form

For more information on completing the Application Form, see the ADP Manual, Part 8, Application Forms.

Refer to Appendix A (Insulin Pump and Supplies Application for Process Flow Chart Assistive Devices Program) for further assistance.

805 Renewal Letter for Insulin Pump Supplies Grant Children and Adults

There are two separate renewal letters.

1. Insulin Pump Supplies for Children Funding Renewal Letter: Children and youth, 18 years of age and under, must use this form when renewing their annual Grant.
2. Insulin Pump Supplies for Adults Funding Renewal Letter: Adults, 19 years of age and over, must use this letter when renewing their annual Grant.

The Renewal Letter is completed and submitted to the Program when the Diabetes Education Program has completed the annual re-assessment and if the Client continues to meet the Medical Eligibility Criteria (**see 315 and 325**).

The ADP will automatically generate the Renewal Letters three months prior to the Client's anniversary date. The ADP bases the anniversary on the date the ADP received the initial Application Form.

805.01 Children Renewal

The Renewal Letter consists of the following:

- the payee name and address;
- the Client's name (if different from the payee's name);
- ADP reference number; and
- date the ADP issued the renewal letter.

A Prescriber who is associated with one of the pediatric Diabetes Education Programs must complete the Children's Renewal Letter. The Prescriber must indicate that the child or youth has:

- has had no more than one episode of diabetic ketoacidosis (DKA) within the last 12 months;
- has had adequate frequency and recording of blood glucose testing to ensure safe and effective use of the insulin pump;
- has had A1c levels less than or equal to ten per cent for the last two readings at a minimum interval 3 months;
- has had adequate frequency of set changes to ensure healthy insertion sites;
- has shown a consistent pattern of effective pump management; and
- has had a minimum of three diabetes clinic visits in the last twelve months.

805.02 Adult Renewal

The Renewal Letter consists of the following:

- the payee name and address;
- the Client's name (if different from the payee's name);
- ADP reference number; and
- date the ADP issued the renewal letter.

A Prescriber who is associated with one of the adult Diabetes Education Programs must complete the Adult Renewal Letter. The Prescriber must indicate that the adult has:

- has had adequate frequency and recording of blood glucose testing to ensure safe and effective use of the insulin pump;
- has continued to demonstrate successful sick day management;
- has shown a consistent pattern of effective pump management; and
- has continued with regular diabetes assessments as deemed appropriate by the diabetes team.

805.03 See policy 720, Ongoing Grant Payments, for additional details regarding the Renewal Letter and procedures.

Vendors

9

Part 9: Vendors

900 Vendor Status

Vendors wishing to submit a request for funding to the Ministry for an insulin pump must be registered as Vendors in the Device category.

900.01 Manufacturers As Vendors

Despite subsection (b) and (c) of section 605.00 in the ADP Manual, any manufacturer of insulin pumps may apply for Vendor registration status for insulin pumps.

New and existing manufacturers operating as Vendors must demonstrate an ability to meet the requirements of Policy 600 in the ADP Manual.

905 Device Care and Maintenance / Repairs

The Vendor must have employees trained in the use of the insulin pump the ADP has authorized the Vendor to sell.

The Vendor must provide instructions to Clients regarding the effective use, care, and maintenance of the insulin pump the ADP has authorized the Vendor to sell.

The ADP does not provide Funding towards the cost of repairs or maintenance for insulin pumps. The cost of repairs during the warranty period will depend on the terms of the warranty. The cost of repairs after the warranty period expires is the responsibility of the Client.

910 General Vendor Policies

Detailed information about Vendor registration and policies and procedures is found in the ADP Manual in the following areas:

- Part 4, General Authorizer and Vendor Policies;
- Part 6, Vendors;
- Part 7, Personal Health Information, and
- Part 9, Invoice Processing and Payment.

Note in Particular:

- i. Policy 405, Conflict of Interest
- ii. Policy 415, Advertising
- iii. Policy 420, Referrals
- iv. Policy 600, Applying for Registration – New Vendor
- v. Policy 601, Applying for Registration – Additional Vendor Location or Additional Category of Devices
- vi. Policy 602, Maintaining Registration as a Vendor
- vii. Policy 615, Relationships of Hospitals and Vendors
- viii. Policy 620, Vendors Sharing Proceeds with Long-Term Care Homes
- ix. Policy 640, Informing Persons of the Program
- x. Policy 660, Refusal to Supply for Safety Reasons
- xi. Policy 665, Warranties of Purchased Devices
- xii. Policy 670, Repairs of Purchased Devices

- xiii. Policy 700, Protection of Personal and Personal Health information
- xiv. Policy 905, Rebates

The ADP Manual is available at:

http://www.health.gov.on.ca/en/pro/programs/adp/policies_procedures_manuals/docs/pp_adp_manual.pdf

915 Subcontracting

Further to 655.01 of the ADP Manual, a Vendor may use a subcontractor to provide an insulin pump directly to a Client.

The Vendor shall obtain the prior written consent of the Ministry prior to subcontracting this responsibility, which consent shall be in the sole discretion of the Ministry and subject to any terms and conditions that the Ministry determines, including the following.

- The Vendor agrees that it shall remain liable for the acts and omissions of the subcontractors.
- The Vendor shall advise the subcontractor of their obligations under the Vendor Agreement and Manuals and shall ensure their compliance with the applicable terms of the Vendor Agreement and the Manuals.
- In addition to any other liabilities of the Vendor pursuant to the Vendor Agreement, Manuals or otherwise at law or in equity, the Vendor shall be liable for all damages, costs, expenses, losses, claims or actions arising from any breach of the Vendor Agreement or Manuals resulting from the actions of the subcontractor.
- Nothing contained in these Manuals or the Vendor Agreement shall create a contractual relationship between any subcontractor and the Ministry.

- These obligations shall survive the termination or expiry of the Vendor Agreement.

Contact Information

10

Part 10: Contact Information

1000 Program Addresses

1000.01 Assistive Devices Program

Assistive Devices Program
Ministry of Health and Long-Term Care
5700 Yonge Street, 7th Floor
Toronto, Ontario M2M 4K5

Email: adp@ontario.ca

Telephone: Toronto area (416) 327-8804
Toll free: 1-800-268-6021
TTY: 1-800-387-5559
Fax: (416) 327-8192 or (416) 327-8963

Public Website:
<http://www.health.gov.on.ca/adp>

Health Professionals Website:
<http://www.health.gov.on.ca/en/pro/programs/adp>

1000.02 Financial Management Branch

Ministry of Health and Long-Term Care
Financial Management Branch, Program Payments Unit
P.O. Box 48
49 Place d'Armes, 2nd Floor
Kingston Ontario K7L 5J3

Telephone: In Kingston (613) 548-6477
Toll free: 1-800-267-9458
Fax: (613) 548-6514

Appendices

A-D

Appendix A: Insulin Pump and Supplies Application for Process Flow Chart

Assistive Devices Program (ADP)

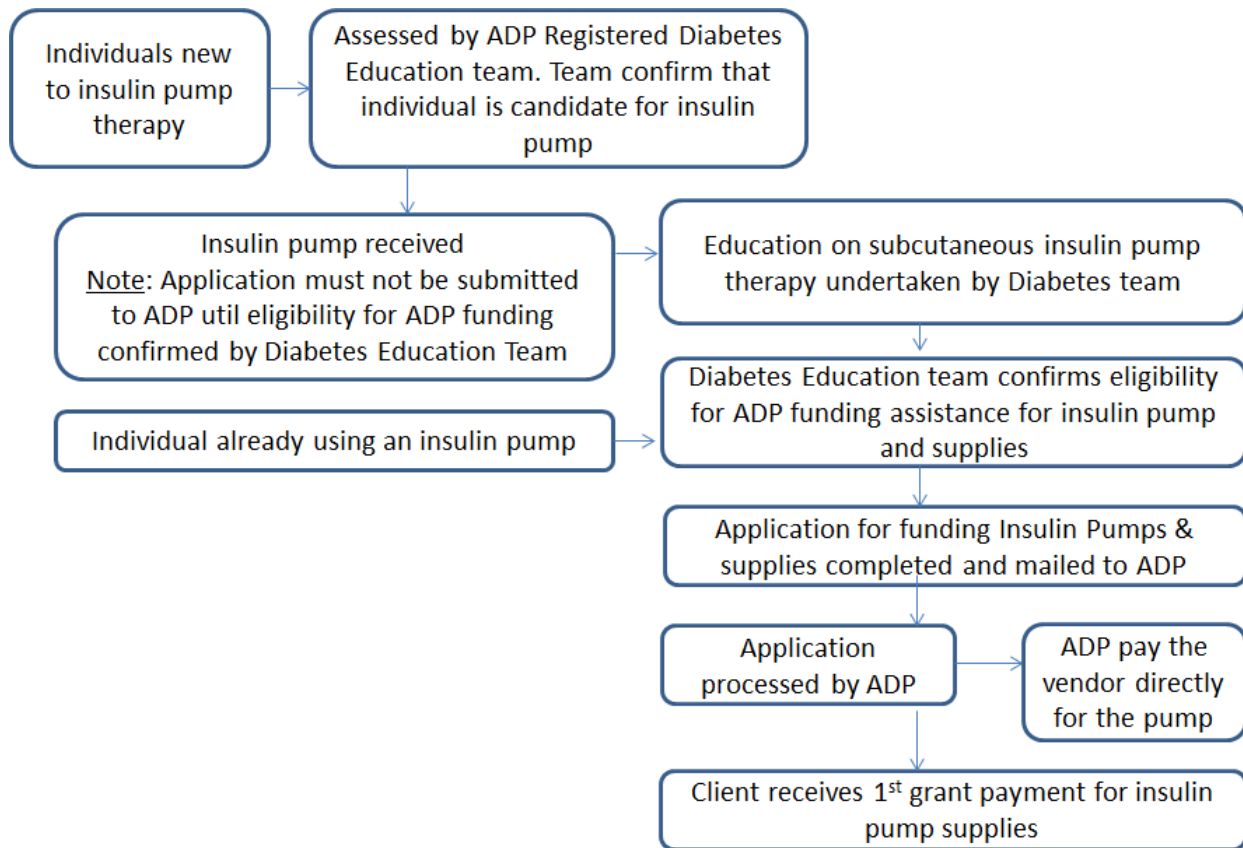


Figure: Flow chart for submission of funding applications for insulin pump and insulin pump supplies

Appendix B: Minimum Criteria for a Paediatric Diabetes Education Program

The minimum standard for paediatric diabetes team members is a multi-disciplinary team that consists of a Physician specialist or Nurse Practitioner, a registered nurse and a registered dietician.

1. Multi-disciplinary team and their roles

Working with clients and families, the role of the multi-disciplinary team is to:

- assess the readiness for pump therapy;
- provide the required education, and ongoing support;
- ensure adequate pump training; and
- monitor the effectiveness of pump therapy.

Physician or Nurse Practitioner

- identifies appropriate candidates for pump therapy
- suggests, prescribes and monitors insulin pump therapy

Registered Nurse (Paediatric Diabetes Educator)

- designs, implements and monitors an individual nursing care plan with the client/family

- acts as primary liaison between the healthcare team and the client/family

Registered Dietician (Paediatric Diabetes Educator)

- designs, implements and monitors individual nutrition care plans with an emphasis on carbohydrate counting education

2. Pre-Assessment Phase of Pump Therapy

The pre-assessment phase of pump therapy” phase begins when insulin pump therapy is being considered as a possible treatment option for diabetes, identified by either the client/family or the diabetes team. *At the end of the “pre-pump” phase, a decision is made whether to initiate insulin pump therapy or not.*

The multidisciplinary team provides information about pump therapy that should include:

- description of how a pump works;
- potential advantages and disadvantages;
- family and school considerations;
- initial and ongoing costs;
- client expectations of pump management;
- steps involved to initiate pump therapy; and
- expectations for on-going follow-up.

Assessment of the client and family’s readiness for pump therapy should include:

- adherence to current diabetes management regimen demonstrated by:

- accurate insulin administration and dose adjustment;
- frequent blood glucose checks;
- adherence to meal plan and carbohydrate counting;
- logbook recording;
- recognition and proper treatment of hypoglycemia;
- illness management;
- ketone testing and DKA prevention;
- regular clinic attendance; and
- good problem-solving skills;
- willingness to carry out activities required for pump therapy;
- parental support and involvement;
- a plan for dealing with school and day care issues; and
- financial means to pay for portion of costs not covered by ADP program.

3. Middle Phase of Pump Therapy

The “middle phase of pump therapy” begins once insulin pump therapy has been chosen as the treatment option. *This phase ends approximately 6 weeks after successful initiation and establishment of insulin pump therapy.*

Prior to pump initiation, the team must ensure that the client has received adequate education and preparation, which is demonstrated by an understanding of the principles of insulin pump therapy, including:

- advantages, disadvantages and realistic expectations;

- the goals of insulin pump therapy;
- the requirement for frequent blood glucose and ketone checks;
- record keeping and pattern recognition;
- insulin dose adjustment;
- the potential risks (ex. DKA) and how to avoid them;
- the management of illness/hyperglycemia;
- treatment and prevention of hypoglycemia;
- exercise;
- safety issues;
- frequency of clinic appointments;
- who and when to call for help; and
- special considerations for:
 - pre-teen and teen issues;
 - travel plans; and
 - ordering pump supplies and prescriptions.

Pump education must occur as per the guidelines of the selected pump company.

4. Ongoing Phase of Pump Therapy

The “ongoing phase of pump therapy” begins approximately 6 weeks after the successful establishment of pump therapy and is *ongoing until either pump*

therapy is discontinued or the client is transferred to adult services prior to their 19 birthday. This phase addresses the ongoing management of pump therapy.

Client should be seen in follow-up by the pediatric diabetes team every 3-4 months. Ongoing follow-up should include the following.

Review and evaluation of glycemic control and pump historical data (downloaded)

- include nocturnal blood glucose assessment
- make adjustments to basal rate, insulin to carbohydrate ratio and correction factor as required
- discuss adequacy of glycemic control and whether pump therapy is achieving glycemic goals

Review and education as required

- treatment of lows
- DKA prevention
- illness management guidelines (including when/who to call)

Assessment of insertion sites

- address site issues as required
- review insertion technique and site rotation as indicated

Nutritional assessment

- assess growth and development

- review carbohydrate counting and effectiveness of insulin to carbohydrate ratio as required

Adjustments for physical activity

Identification of school-related issues

- transition and changes

Ongoing education

- goals for control
- normal growth and development
- changes in lifestyle
- new technologies

Appendix C: Minimum Criteria for an Adult Diabetes Education Program

The minimum standard for adult diabetes team members is a multi-disciplinary team that consists of a Physician or Nurse Practitioner, a registered nurse and a registered dietician.

1. Multi-disciplinary team and their roles

Working with clients and caregivers, the role of the multi-disciplinary team is to:

- assess the readiness for pump therapy;
- provide the required education and ongoing support;
- ensure adequate pump training; and
- monitor the effectiveness of pump therapy.

Physician or Nurse Practitioner

- identifies appropriate candidates for pump therapy;
- suggests, prescribes and monitors insulin pump therapy.

Registered Nurse (Adult Diabetes Educator)

- designs, implements and monitors an individual nursing care plan and the initiation and follow-up of insulin pump therapy with the client/caregiver;
- provides pump training to client/caregiver or oversees the technical training in the event that training is provided by a representative of the manufacturer;
- provides ongoing follow-up and education;

- acts as primary liaison between the healthcare team and the client/caregiver.

Registered Dietician (Adult Diabetes Educator)

- designs, implements and monitors individual nutrition care plans with an emphasis on carbohydrate counting education.

2. Pre-Assessment Phase of Pump Therapy

The pre-assessment phase begins when insulin pump therapy is being considered as a possible treatment option for diabetes and ends once the 90-day trial period for an insulin pump begins.

The multidisciplinary team, with special consideration for lifestyle, supports the client/caregiver in:

- the decision process regarding insulin pump therapy;
- identifying and working through issues that may impact the success of pump therapy;
- developing coping strategies;
- addressing financial concerns and identifying available resources; and
- ensuring appropriate referral to a social worker as required.

The multidisciplinary team provides information about pump therapy, which should include:

- description of how a pump works;
- potential advantages and disadvantages;
- initial and ongoing costs;

- client expectations of pump management;
- steps involved to initiate pump therapy; and
- expectations for on-going follow-up.

Assessment of the client and caregiver's readiness for pump therapy should include:

- adherence to current diabetes management and basal/bolus regimen demonstrated by:
 - accurate insulin administration and dose adjustment within a basal/bolus regimen;
 - frequent blood glucose checks (minimum 4 times per day);
 - adherence to carbohydrate counting using Carbohydrate to Insulin Ratio;
 - logbook recording;
 - recognition and proper treatment of hypoglycaemia;
 - sick day management;
 - ketone testing and DKA prevention;
 - regular clinic attendance; and
 - good problem-solving skills;
- willingness to carry out activities required for pump therapy; and
- financial means to pay for portion of costs not covered by ADP.

3. Initiation and Trial Phase of Pump Therapy

The Initiation and Trial Phase begins once the 90-day trial period for insulin pump therapy starts. At the start of the Initiation and Trial Phase, the application requesting funding assistance can be completed and sent to the ADP.

Pump education for the mechanical/technical aspects of therapy must occur as per the guidelines of the selected pump company. It is recognized that some adult diabetes centres utilize technical training in the use of insulin pumps offered by insulin pump manufacturers. In this case, the Registered Nurse must oversee the technical training offered by the manufacturer.

Prior to pump initiation, the team must ensure that the client has received adequate education and preparation, which is demonstrated by an understanding of the principles of insulin pump therapy, including:

- advantages, disadvantages and realistic expectations;
- the goals of insulin pump therapy;
- the requirement for frequent blood glucose and ketone checks including record keeping and pattern recognition;
- insulin dose adjustment;
- the potential risks (ex. DKA) and how to avoid them;
- the management of illness/hyperglycemia;
- treatment and prevention of hypoglycaemia;
- appropriate insertion site changes and rotation;
- exercise;
- safety issues;

- frequency of clinic appointments;
- who and when to call for help; and
- special considerations for:
 - travel plans; and
 - ordering pump supplies and prescriptions.

This phase concludes at the end of the 90-day trial period. If it has been determined by the client or the multidisciplinary team that the client is not an

appropriate candidate for pump therapy, the pump must be returned to the manufacturer by the client for a refund (to be credited to the ADP). An unsuccessful trial period does not prevent the client from re-considering pump therapy as a treatment option later.

4. Ongoing Phase of Pump Therapy

The Ongoing Phase begins once the 90-day trial period is concluded and the multidisciplinary team has determined that the client is an appropriate candidate for pump therapy. This phase addresses the ongoing management of pump therapy and is ongoing until pump therapy is discontinued.

The client should be seen in follow-up by the adult diabetes program every 3-4 months or as determined by the client and multi-disciplinary team. Ongoing follow-up should include the following.

Review and evaluation of glycemic control and pump historical data (downloaded)

- include nocturnal blood glucose assessment
- make adjustments to basal rate, Carbohydrate to Insulin Ratio and correction ratio as required
- discuss adequacy of glycemic control and whether pump therapy is achieving glycemic goals

Review and education as required for the following:

- treatment of lows
- DKA prevention
- illness management guidelines (including when/who to call)

Assessment of insertion sites for the following:

- address site issues as required
- review insertion technique and site rotation as indicated

Nutritional assessment for the following:

- assess changes in weight
- review carbohydrate counting and effectiveness of Carbohydrate to Insulin Ratio as required

Adjustments for physical activity

Ongoing education for the following:

- goals for control
- changes in lifestyle
- new technologies

Renewal of funding assistance for Insulin supplies including

- assessment of the client to determine if they continue to meet the medical eligibility criteria (view receipts to ensure funding is used for the purpose intended)
- completion of Assistive Devices Program's renewal application

Appendix D: Diabetes Education Program Registration Form

Please answer all the questions (please print) and return the form to:

Program Coordinator, Medical Supplies
Assistive Devices Program
5700 Yonge Street, 7th Floor
Toronto Ontario M2M 4K5

Name of Diabetes Education Centre: _____

Address: _____

Telephone Number: _____

Fax Number: _____

E-mail Address: _____

Do you have an adult insulin pump education program?

- Yes
- No

Do you have a pediatric insulin pump education program?

- Yes
- No

Name of Centre's Program Manager/Coordinator and professional status:

Name(s) of physician and specialty, and/or Nurse Practitioner.

Name of Physician and/or Nurse Practitioner	Specialty	Business Tele.	OHIP Billing #

Name(s) of Diabetes Nurse Educator.

Name	Prof. designation	Business Tel #	College Reg. #

Name(s) of Registered Dietician

Name	Business Tel #	College Reg. #

What geographic area does this centre serve?

How many individuals with type 1 diabetes were assessed at your centre in the previous 12 months?

Of the individuals assessed by your centre in the past 12 months, how many were suitable candidates for insulin pump therapy?

Please indicate who provides the mechanical/technical training for the use of the insulin pump.

- Centre staff
- Manufacturer staff

What are your regularly scheduled days and hours of operation?

Does your centre have satellite locations?

- Yes
- No

If yes, please list the name of the centre and addresses:

Name: _____

Address: _____

Hours of Operation: _____