Ministry of Health & Long-Term Care

Pressure Modification Devices Policy and Administration Manual

Assistive Devices Program
Ministry of Health & Long-Term Care

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www.health.gov.on.ca/adp

Ontario

Table of Amendments

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

Section	Change	Date
115.02	Updated to align with the new Authorizer Agreement.	October 1, 2014
305	Added manufacturer warranty requirements.	October 1, 2014
405	Added manufacturer warranty requirements.	October 1, 2014
505	Added manufacturer warranty requirements.	October 1, 2014
110	Added definitions of Nurse Practitioner and Physician; added Nurse Practitioner to the Prescriber definition.	April 1, 2014
410.04	Added Specialist Physician and Nurse Practitioner.	April 1, 2014
415.01	Added Specialist Physician and Nurse Practitioner.	April 1, 2014
415.02	Added Specialist Physician and Nurse Practitioner.	April 1, 2014
400 - 425	Updated to provide clearer policy statements regarding eligibility, devices funded, warranty information, different assessment situations and procedures and designated funding periods. Information about non-elastic compression garments has been added.	July 2, 2015
Various Sections	Updated definitions and references for Authorizer and Certified Orthotist.	August 1, 2015
900	Added policy regarding Manufacturers as Vendors.	September 22, 2015

Table of Contents

Introduction

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Part 1: Pressure Modification Devices Policy and Administration Manual

100 Purpose of the Manual

The purpose of this Manual is to present the policies and procedures for the funding of Pressure Modification Devices in one document. This Manual is intended to complement the Policies and Procedures Manual for the Assistive Devices Program (ADP Manual).

This Manual forms part of the agreement between the Ministry of Health and Long-Term Care and the Vendor, and the agreement between the Ministry of Health and Long-Term Care and the Authorizer. The Ministry reserves the right to revise this Manual.

100.01 Intended Target Audience

This Manual is intended to be used by Authorizers and Vendors who have an agreement with the Assistive Devices Program (ADP) to provide Pressure Modification Devices.

105 Protecting Personal Health Information

Authorizers and 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 **Application Form** means the Application for Funding Pressure Modification Devices form provided by the Program and used to request ADP funding assistance for a listed device.

110.02 **Authorizer** means a health care professional who assesses the Applicant to determine ADP funding eligibility and completes an assessment of the Applicant/Client to determine what Pressure Modification Devices are appropriate for them.

110.03 **Burn Team** means a team of health professionals registered with the ADP to authorize pressure garments and pressure orthoses for the management of hypertrophic scars. Team members must meet together with the client in a permanent location.

110.04 **Certified Fitter** means an individual who holds a training certificate recognized by the ADP and issued by a manufacturer of pressure modification devices. The certified fitter is employed by a Vendor of pressure modification devices and can measure, fit and educate clients requiring custom-fitted or custom- made pressure garments for hypertrophic scar management, custom-fitted or custom-made lymphedema compression garments or sleeves and/or sequential extremity pumps/accessories.

110.05 **Certified Orthotist** means a person who has successfully completed the certification exams for Certified Orthotist through the Canadian Board for Certification of Prosthetists and Orthotists (CBCPO) and who is registered as a "Certified Orthotist" who is a member in good standing with Orthotics Prosthetics Canada (OPC).

110.06 **Chronic Lymphedema** means, for the purposes of Funding purposes, a condition which has been present for at least six (6) months**.**

- **Primary Lymphedema** means an inherited condition of the lymphatic system which prevents the system's normal functioning and transport of fluid. The condition may be present at various times in life. Secondary causes of lymphedema must be excluded. For the purposes of Funding, the conditions of hemangioma, lymphangioma and Klippel- Trenaunay Syndrome are included in this definition.

- **Secondary Lymphedema** means a malfunction of the lymphatic system, secondary to an acquired abnormality which prevents the normal transport of fluid in the lymphatic system. This results in chronic swelling of an extremity.

110.07 **Chronic Use** means the need for a pressure modification device for management of hypertrophic scars or chronic lymphedema for more than six (6) months of regular daily use.

110.08 **Custom-fitted Pressure Garment for Hypertrophic Scar Management** means a pressure garment manufactured first, then fitted and adjusted to the client directly.

110.09 **Custom-made Pressure Garment for Hypertrophic Scar Management** means a pressure garment fabricated according to individualized measurements of the client's body. Once made the garment is fitted to the client directly.

110.10 **Custom-fitted Lymphedema Compression Garment** means a compression garment manufactured first, then fitted and adjusted to the client directly.

110.11 **Custom-made Lymphedema Compression Garment** means a compression garment fabricated according to individualized measurements of the client's body. Once made the garment is fitted to the client directly.

110.12 **Daily** means over a period of twenty-four (24) hours.

110.13 **Family Physician** means a Physician whose certificate of registration or medical license is in general practice or family practice.

110.14 **General Practitioner in Oncology (GPO)** means a general practitioner who provides oncology care in the primary care setting or who functions in the role of a GPO at a Cancer Care Centre or an Oncology Associate.

110.15 **Gynecologic Oncologist** means an obstetrician gynecologist who provides oncology care.

110.16 **Hypertrophic Scarring** means scarring that is secondary to deep partial thickness or full thickness traumatic skin loss which may be due to chemical, electrical, thermal or infectious agents, or friction burns.

110.17 **Lymphedema Team** means a team of health professionals registered with the ADP to prescribe and authorize sequential extremity pumps and accessories for individuals with primary lymphedema. The team may elect to prescribe and authorize compression garments and sleeves as well.

110.18 **Manual** means the Pressure Modification Devices Policy and Administration Manual.

110.19 **Manufacturer/Distributor Representative** means an employee of a manufacturer or distributor, registered with the ADP as a Vendor of pressure modification devices. The manufacturer/distributor representative is employed by a Vendor of pressure garments for hypertrophic scar management, lymphedema compression garments and sleeves and/or sequential extremity pumps.

110.20 **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 practice in Ontario.

110.21 **Occupational Therapist (OT)** means a regulated health professional registered as a practicing member in good standing with the College of Occupational Therapists of Ontario.

110.22 **Oncology Associate** means a physician, other than an Oncologist, who holds Royal College of Physicians and Surgeons of Canada certification and provides oncology care.

110.23 **Personal Health Information** means the personal information as defined in Section 4 of the *Personal Health Information Protection Act, 2004*.

See the ADP Manual Part 7, Personal Health Information and Part 3, Policy 320, Release of Information About Previous Funding for more details.

110.24 **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.

110.25 **Physiotherapist (PT)** means a regulated health professional registered as a practicing member in good standing with the College of Physiotherapists of Ontario.

110.26 **Prescriber** means a Specialist Physician, Family Physician, General Practitioner in Oncology (GPO), Gynecologic Oncologist or Nurse Practitioner who prescribes Pressure Modification Devices.

110.26 **Pressure Modification Device** means an assistive device that produces external pressure to an individual's body to help manage the effects of hypertrophic scarring or chronic lymphedema.

For ADP funding purposes Pressure Modification Devices include:

1. Pressure garments and pressure orthoses for the management of hypertrophic scars,

2. Compression garments and sleeves for chronic lymphedema, and

3. Sequential extremity pumps and accessories for primary lymphedema.

110.27 **Registered Massage Therapist (RMT)** means a regulated health care professional registered as a practicing member in good standing with the College of Massage Therapists of Ontario.

110.28 **Registered Nurse (RN)** means a regulated health care professional registered as a practicing member in good standing with the College of Nurses of Ontario.

110.29 **Specialist Physician** means:

- A Physician who prescribes pressure modification devices for hypertrophic scar management and holds a certificate in plastic surgery, physiatry or general surgery, and/or

- A Physician who prescribes lymphedema compression devices and holds a certificate in cardiovascular surgery, vascular surgery, plastic surgery, medical oncology, radiation oncology, internal medicine, pediatrics, physiatry, orthopedic surgery or general surgery.

Note: A GPO, Gynecologic Oncologist, wound care specialist or dermatologist with applicable experience may apply for Prescriber status for lymphedema compression garments.

110.29 **Style** means a particular design, shape or pattern of garment. See Section 110 of the ADP Manual for more definitions.

115 Roles and Responsibilities

In the process of confirming eligibility for funding assistance, the Applicant/Client, the Authorizer, the Certified Fitter and the Vendor have specific roles and certain rights and responsibilities. Additional information may be found in the ADP Manual, the Authorizer Agreement and the Vendor Agreement.

115.01 Roles and Responsibilities of the Applicant/Client

- Has the right to choose from the list of Authorizers, any Authorizer in their community;

- Provides the necessary and accurate information to the Authorizer;

- Makes an informed decision based on the accurate and complete information provided by the Authorizer, Certified Fitter and the Vendor during the assessment and the ADP application process;

- Determines whether or not to proceed with an application for ADP Funding and choice of Vendor;

- Provides the necessary and accurate information on the Application Form, Section 1, “Applicant’s Biographical Information”;

- Carefully reviews all of the information in the Application Form, Section 3, “Applicant’s Consent and Signature”, prior to signing the form;

- Has the right to seek a second opinion if he/she disagrees with the Authorizer’s or Certified Fitter’s assessment of his/her needs;

- Is responsible for paying his/her 25 percent (25%) portion of the Approved Price for the Pressure Modification Devices directly to the Vendor.

115.02 Roles and Responsibilities of the Authorizer

- Different roles and responsibilities exist for Authorizers, depending on the type of Pressure Modification Device and the service delivery model/situation. Details of these situations are found in each applicable section of this Manual;

- Is the gatekeeper to the Program and assumes the leadership role in the assessment process, confirmation of the Applicant’s eligibility and completion of the Application Form in a timely fashion;

- Will provide the Applicant with accurate information about the ADP policies and procedures, eligibility criteria and the estimated cost to purchase the Authorized Device;

- Will provide the Applicant with the applicant information sheet;

- Will provide the Applicant with a list of Vendors serving his/her community and advise Applicants to consider more than one Vendor to compare options, service plans and, if relevant, prices. Lists are available on the ADP website;

- Maintains current knowledge of the Pressure Modification Devices that he/she is registered to authorize;

- Identifies the need for Pressure Modification Devices as part of the Client assessment process and authorizes the Devices that meet the needs of the Client;

- Provides the Applicant/Client with the Approved Price for the Pressure Modification Devices and explains any additional costs not covered by the ADP that the Applicant may expect to incur, if a Certified Fitter is not available;

- Schedules regular follow-up appointments with the Client to check the fit of the Pressure Modification Devices and the manner in which the Client is wearing and maintaining the Devices, if a Certified Fitter is not available;

- Is responsible for ensuring that any Client with a suspected change in medical condition is referred back to his/her Physician for medical review;

- Must not submit an Application Form to the Program for an individual who does not meet the ADP eligibility criteria;

- Must continue to meet all conditions specified in his/her executed Authorizer Agreement and all applicable Manuals.

115.03 Roles and Responsibilities of the Certified Fitter

- Different roles and responsibilities exist for Certified Fitters, depending on the type of Pressure Modification Device and the service delivery model/situation. Details of these situations are found in each applicable section of this Manual;

- Is a gatekeeper to the Program and assumes a leadership role in the assessment process, confirmation of the Applicant's eligibility and completion of the Application Form in a timely fashion;

- Will provide the Applicant with accurate information about the ADP policies and procedures, and eligibility criteria;

- Will provide the Applicant with the applicant information sheet;

- Will provide the Applicant with a list of Vendors serving his/her community and advise Applicants to consider more than one Vendor to compare

options, service plans and, if relevant, prices. Lists are available on the ADP website;

- Maintains current knowledge of the Pressure Modification Devices that he/she is registered for with the Assistive Devices Program;

- Identifies the need for Pressure Modification Devices as part of the Client assessment process and authorizes the Devices that meet the needs of the Client;

- Provides the Applicant/Client with the Approved Price for the Pressure Modification Devices and explains any additional costs not covered by the ADP that the Applicant may expect to incur, if assessing the Client and fitting the Devices;

- Schedules regular follow-up appointments with the Client to check the fit of the Pressure Modification Devices and the manner in which the Client is wearing and maintaining the Devices, if assessing the Client and fitting the Devices;

- Is responsible for ensuring that any Client with a need for a different size or style of compression garment is referred back to the Authorizer;

- Is responsible for ensuring that any Client with a suspected change in medical condition is referred back to his/her Physician for medical review;

- Must not submit an Application Form to the Program for an individual who does not meet the ADP eligibility criteria.

115.04 Roles and Responsibilities of the Prescriber

- The Specialist Physician prescribes the initial Pressure Modification Device;

- The Prescriber provides the medical diagnosis;

- The Specialist Physician or Family Physician or Nurse Practitioner prescribes replacement Pressure Modification Compression Garments required every two (2) years and/or due to a change in medical condition at any time;

- As an active member of a Hypertrophic Scar Management Team, prescribes garments and orthoses;

- As an active member of a Lymphedema Management Team, provides the medical clearance for the trial assessment of the sequential extremity pump and with other team members, reviews the Applicant's response and gives final approval as to the Device's suitability;

- As an active member of the Lymphedema Management Team, prescribes any replacement sequential extremity pumps or accessories.

Devices

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Part 2: Devices

200 Devices Covered

200.01 Pressure Modification Devices for Hypertrophic Scar Management

The Program provides Funding for specified pressure garments and pressure orthoses for the management of Hypertrophic Scarring.

See section 305 for more detail.

200.02 Pressure Modification Devices for Lymphedema Management

The Program provides Funding for specified graduated compression garments and compression sleeves for the management of Chronic Lymphedema.

The ADP provides Funding for Sequential Extremity Pumps and accessories for the management of Primary Lymphedema.

See sections 405 and 505 for more detail.

The ADP will fund the pressure gradient for compression garments that is clinically required by the Applicant, as determined by the Authorizer and/or Certified Fitter.

Clients must purchase ADP funded Pressure Modification Devices from a Vendor.

205 Non-Eligible Pressure Modification Devices

The Program does not provide Funding for the following:

a. Pressure Modification Devices used for:

   i. Post-operative use or any use for less than six (6) months duration;

   ii. Acute physical conditions of less than six (6) months duration;

   iii. Venous insufficiency or thrombo-embolosis;

b. Pressure inserts, silastic elastomer and dressings for hypertrophic scar management or vascular conditions;

c. Elastic compression bandages and wraps;

d. Pressure Modification Devices implanted or inserted into the body;

e. Pressure Modification Devices purchased from non-registered suppliers;

f. Hyperbaric pressure chamber treatments.

210 Repairs/Batteries

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

215 Individual Identified as Ineligible by Authorizer

An Application for Pressure Modification Devices form, requesting ADP funding, must **not** be submitted to the ADP if, after assessing the requirements of his/her client, the Authorizer confirms that the individual does not meet the ADP eligibility criteria.

220 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 will be advised of the reason.

Management of Hypertrophic Scars – Garments/Orthoses

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Part 3: Management of Hypertrophic Scars – Garments/Orthoses

300 Eligibility

An individual who has Hypertrophic Scarring and requires a pressure garment and/or a pressure orthosis for a minimum of six (6) months of regular daily use is eligible for ADP Funding.

305 Devices Covered

The following Devices for the management of hypertrophic scars are eligible for Funding:

- Specified pressure garments custom-made to a Client's measurements and fitted to the individual;
- Specified pressure garments pre-manufactured and then custom-fitted to the individual;
- Specified pressure orthoses molded to the Client.

For all pressure garments and pressure orthoses funded by the Program, the Vendor may only provide Devices for which the manufacturer provides a warranty that is typical in the industry for that type of garment and orthosis.

The minimum warranty must be thirty (30) days.

The warranty period is determined from the date that the pressure garments and pressure orthoses are dispensed to the Client.

The procedure for manufacturers or Authorizers to apply for ADP approval of a new and/or updated garment or orthosis is available upon request from the Program.

Each authorization of pressure garments for hypertrophic scar management consists of **two (2) outfits**, one to wash and one to wear.

Each prescription/authorization of pressure orthoses for hypertrophic scar management consists of one (1) pressure orthosis.

310 Authorization of Garments and Orthoses

An individual who requires a Pressure Modification Device for hypertrophic scar management and who is accessing the ADP for the first time, or who has had a change in medical condition, must be assessed by a Burn Team.

310.01 Burn Team

The Burn Team prescribes and authorizes pressure garments and/or pressure orthoses for the management of hypertrophic scars.

Every Authorizer must be affiliated with a Burn Team.

The Team must consist of at least:

- A Specialist Physician, licensed to practise medicine in Ontario, who holds a certificate in the specialty of plastic surgery, physiatry, or general surgery. The Physician acts as the Prescriber of the pressure garments and/or pressure orthoses, and
- An Occupational Therapist (OT) and/or Physiotherapist (PT) who is an Authorizer for compression garments.

Team members must meet together with the Client in a permanent location.

Burn Team membership may also include:

- A Certified Orthotist, employed by a Vendor of custom-made or custom-fitted pressure orthoses, and who is an Authorizer for pressure orthoses. The Certified Orthotist's membership on the Team will depend on whether the Team wants to prescribe and authorize these Devices.

- A Certified Fitter and Manufacturer/Distributor Representative, employed by a Vendor for pressure garments, may be affiliated with Burn Teams if he/she is measuring and fitting pressure garments. The Certified Fitter and Manufacturer/Distributor Representative must be registered with the ADP for pressure garments for hypertrophic scar management.

310.02 Burn Team Roles and Responsibilities:

- Assess the individual's need for an ADP funded pressure garment and/or pressure orthosis for hypertrophic scar management;

- Prescribe and authorize the initial pressure garment and/or pressure orthosis;

- Confirm the Applicant's need for a Pressure Modification Device to the Vendor;

- The OT, PT, Certified Fitter or Manufacturer/Distributor Representative fits the pressure garment to the Applicant and provides any necessary follow-up;

- The OT and/or PT in consultation with the Certified Orthotist, Certified Fitter or Manufacturer/Distributor Representative is involved in training the Applicant in how to apply, remove, use, care for and maintain the Device, and

- Provide education to the Applicant about hypertrophic scar management.

315 Assessment Procedures

315.01 Client First Access

For first access to the ADP an assessment must be completed by all Burn Team members.

When an Application Form for garments is submitted to the ADP, a funding package will be automatically approved. On approval, a Client will be approved for funding of **identical garments** for a two (2) year period.

The Vendor will invoice the applicable codes during the two (2) year designated funding period as replacement garments are required, as assessed by the Certified Fitter. No additional Application Forms are required during the designated funding period.

See below for assessment requirements for replacement garments.

315.02 Client Repeat Access

Devices may be replaced when the Client's current Device is no longer usable. Pressure Modification Devices which jeopardize the Client's safety or no longer meet the Client's needs as a result of physiological growth, atrophy, change in medical condition, or normal wear (except where such wear and tear, in the opinion of the Ministry, is excessive or arises from the Client's failure to take reasonable care) are eligible for replacement Funding.

Compression garments that are required as a result of normal wear (except where such wear and tear, in the opinion of the Ministry, is excessive or arises from the Client's failure to take reasonable care) and that are no longer providing the required compression, are eligible for replacement Funding.

For replacement garments, where the **identical garment** is being prescribed **within the 2 years**, the Client must be assessed by the Certified Fitter and/or Manufacturer/Distributor Representative.

When an **identical garment** is required, an Application Form is **not** required within the 2 year designated funding period. The Vendor will submit an invoice to the Financial Management Branch.

For replacement garments, if there are **any changes (style, size, fabric, etc.)**, an assessment must be completed by an Authorizer and the Certified Fitter, if the latter is available. In these cases, a new Application Form must be completed.

For all replacement Devices due to a **change in the Client's medical condition**, an assessment must be completed by a Burn Team Physician.

A Client with a suspected change in medical condition should be referred back to the Burn Team's Specialist Physician for a medical review.

A new Application Form must be completed when a replacement Device is required due to a **change in medical condition** or if the Client requires a change in the type of Device. The reason for the replacement **must** be checked on the Application Form.

315.03 Loss or Damage

The ADP does not provide Funding for a replacement Device if the Device is lost, stolen or damaged beyond repair where such wear and tear, in the opinion of the Ministry, is excessive or arises from the Client's failure to take reasonable care.

315.04 Pressure Garments Measured and Fitted by a Burn Team Therapist (OT/PT)

The Authorizer measures the Applicant and checks off the Device type(s) on the Application Form. The Authorizer then provides the details of the required garments to the Certified Fitter at the Vendor location and orders the garments from a Vendor for hypertrophic scar management.

The Vendor mails the garments to the Authorizer, who then fits them to the Applicant and educates him/her about their proper use and care and provides the warranty information.

The Authorizer ensures that all required information is completed on the Application Form and obtains the signature of the Applicant on the 'receipt of goods' form. Both forms are mailed to the Vendor.

315.05 Pressure Garments Authorized by an OT/PT and Measured and Fitted by a Certified Fitter or Manufacturer/Distributor Representative

The Authorizer assesses the Applicant and checks off the Device type(s) on the Application Form. The Authorizer then refers the Applicant to the Certified Fitter or Manufacturer/Distributor Representative and communicates the Applicant's Pressure Modification Device needs to them.

The Certified Fitter or Manufacturer/Distributor Representative measures the Applicant for the appropriate garments, fits them to the Applicant and educates him/her about their proper use and care.

The Vendor ensures that all required information is completed on the Application Form and obtains the signature of the Applicant on the 'receipt of goods' form.

The Certified Fitter provides the Applicant with the warranty and care instructions.

315.06 Pressure Orthoses Authorized by Both the OT/PT and the Certified Orthotist

The OT or PT assesses the Applicant's need for occupational therapy or physiotherapy intervention. In this role, the OT or PT is acting as a Rehabilitation Assessor.

The Certified Orthotist assesses the Applicant's needs and checks off the required Device type(s) on the Application Form. The Certified Orthotist, in the role of the Authorizer, ensures that the authorized Device is properly fabricated, fitted and dispensed to the Applicant.

320 Designated Funding Periods

Garments – a maximum of five (5) authorizations is allowed in a 12 month period. Each authorization consists of two (2) outfits, one to wash and one to wear. An outfit consists of a one-layered set of garments worn at one time.

Pressure Orthosis – replacement allowed after one (1) year from the Authorizer's assessment date for a previously funded similar device.

325 Warranty

There are two types of warranties: (i) Normal Use, and (ii) Satisfactory Fit.

325.01 Warranty Under Normal Use

The Vendor must warrant the garment/orthosis against breakage or tearing for:

- Thirty (30) days for a Custom-made or Custom-fitted Compression Garment for hypertrophic scar management.
- Thirty (30) days for all orthoses.

The warranty must be provided to the Client in writing.

325.02 Warranty for Satisfactory Fit

Whoever fits the garment/orthosis to the Client must warrant satisfactory fit of the Device for a minimum of one (1) month from the date the garment/orthosis was delivered to the Client, unless there is a relevant change in the Client's size due to growth, atrophy or a change in medical condition.

During the warranty period, the Vendor/manufacturer will provide all services including repairs or replacement of the authorized garment/orthosis free of charge.

When there is repeated technical failure, the garment/orthosis will be replaced by the issuer of the warranty. Repair and service of Devices are the responsibility of the Vendor, manufacturer or service designate.

The ADP does not contribute towards the cost of repairs under any circumstances.

Management of Lymphedema - Graduated Compression Garments / Sleeves

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Part 4: Management of Lymphedema - Graduated Compression Garments / Sleeves

400 Eligibility

An individual who has Chronic Primary or Secondary Lymphedema and requires a graduated compression garment for a minimum of six (6) months of regular daily daytime use is eligible for Funding.

An individual who has Chronic Lymphedema and requires the use of a compression sleeve for longer than six (6) months of regular nightly use, in conjunction with the use of graduated compression garments is eligible for Funding. In these cases the Applicant's edema cannot be managed effectively with the use of nighttime bandaging.

Contributing factors may include:

- A high density edema,
- Multiple skin folds,
- Complicated shape of the extremity, and/or
- The individual's inability to apply the bandages.

405 Devices Covered

The following Devices, for the management of Chronic Lymphedema, are eligible for ADP Funding:

- Specified graduated compression garments custom-made to a Client's measurements and fitted to the individual,

- Specified graduated compression garments pre-manufactured and then custom-fitted to the individual,

- Specified compression sleeves and accessories.

For all compression garments and compression sleeves funded by the Program, the Vendor may only provide Devices for which the manufacturer provides a warranty that is typical in the industry for that type of garment and sleeve.

The required minimum warranty periods are as follows:

- for elastic garments, thirty (30) days;

- for non-elastic garments, six (6) months; and

- for compression sleeves, ninety (90) days.

The warranty period for elastic compression garments is determined from the date that the garment is shipped from the manufacturer to the Vendor. For non-elastic compression garments and compression sleeves, the warranty period is determined from the date of purchase.

The procedure for manufacturers to apply for ADP approval of a new and/or updated garment or sleeve is available upon request from the Program.

Each authorization of graduated compression garments for lymphedema management consists of **two (2) identical** outfits, one to wash and one to wear.

Each authorization of compression sleeves consists of one sleeve per extremity. One gauge is allowed during the five (5) year designated funding period.

410 Authorization of Compression Garments/Sleeves

Different situations exist for authorization of compression garments and/or sleeves. The following section outlines these different situations.

410.01 Garments Measured and Fitted by an Authorizer (OT/PT/RN/RMT)

The Authorizer measures the Applicant and orders the garments from the Vendor.

The Vendor mails the garments to the Authorizer, who then fits them to the Applicant and educates him/her about their proper use and care.

The Authorizer ensures that all required information is completed on the Application Form and obtains the signature of the Applicant on the 'receipt of goods' form. Both forms are mailed to the Vendor.

410.02 Garments Measured by an Authorizer and Fitted by a Certified Fitter and/or Manufacturer/Distributor Representative (First Access, Change of Size/Garment Style or Change in Medical Condition)

The Authorizer measures the Applicant and checks off on the Application Form the garment type(s) required.

The Certified Fitter or Manufacturer/Distributor Representative measures the Applicant for the appropriate garments, fits them to the Applicant and educates him/her about their proper use and care.

The Vendor ensures that all required information is completed on the Application Form and obtains the signature of the Applicant on the 'receipt of goods' form.

The Certified Fitter provides the Applicant with the warranty and care instructions.

410.03 Garments Measured and Fitted by a Certified Fitter or Manufacturer/Distributor Representative (Identical Garment Replacement)

The Certified Fitter or Manufacturer/Distributor Representative measures the Applicant for the appropriate garments. If within the two (2) year designated funding period, no Application Form submission is required. See policy 415 for information about the Funding packages.

The Certified Fitter or Manufacturer/Distributor Representative fits the garments to the Applicant and educates him/her about their proper use and care.

The Vendor provides the warranty and care instructions and invoices the ADP and the Applicant.

410.04 Compression Sleeves

The Authorizer determines the Applicant's clinical requirement for the compression sleeve(s).

The Authorizer confirms that the Applicant's edema cannot be managed effectively with the use of nighttime bandaging, in conjunction with daily use of graduated compression garments.

The Authorizer confirms the Applicant's need for the compression sleeve(s) with his/her Specialist Physician, Family Physician or Nurse Practitioner.

This consultation must be documented in the Authorizer's clinical notes.

The Authorizer refers the Applicant to a Vendor who employs a Certified Fitter trained to assess and dispense compression sleeves. The Certified Fitter measures the Applicant for the appropriate compression sleeve(s) and educates the Applicant about their proper use and care.

If a Vendor or Certified Fitter is not available, the Authorizer orders the appropriate compression sleeve(s), fits the Applicant and educates them about their proper use and care.

415 Assessment Procedures

415.01 Client First Access

For first access to the ADP, the Specialist Physician/GPO/Gynecologic Oncologist acts as Prescriber for graduated compression garments and sleeves for lymphedema management. The Prescriber need not be a member of an ADP Lymphedema Team.

Individuals who are accessing the ADP for the first time for garments or sleeves must also be assessed by an Authorizer for graduated compression garments (OT, PT, RN or RMT).

When an Application Form for garments is submitted to the ADP and approved, a Funding package for **identical garments** for a two (2) year period will be automatically approved.

Individuals who are accessing the ADP for Funding for compression sleeves must be assessed by an Authorizer for Pressure Modification Devices. If the Applicant has previously accessed funding for garments for lymphedema management within the past two (2) years, the Specialist Physician or Family Physician or Nurse Practitioner (Prescriber) assessment is not required. In these cases, the Authorizer must consult with the Specialist Physician or Family Physician or Nurse Practitioner (Prescriber) and document this consultation.

415.02 Client Repeat Access

Devices may be replaced when the Client's current Device is no longer usable. Pressure Modification Devices which jeopardize the Client's safety or no longer meet the Client's needs as a result of physiological growth, atrophy, change in medical condition, or normal wear (except where such wear and tear, in the opinion of the Ministry, is excessive or arises from the Client's failure to take reasonable care) are eligible for replacement Funding.

Compression garments that are required as a result of normal wear (except where such wear and tear, in the opinion of the Ministry, is excessive or arises from the Client's failure to take reasonable care) and that are no longer providing the required compression, are eligible for replacement Funding.

415.03 Compression Garments

For replacement garments, the Client must be assessed on a biannual basis (every 2 years) by their Specialist Physician or Family Physician or a Nurse Practitioner Prescriber), an Authorizer and a Certified Fitter, if the latter is available.

When an **identical garment** is being replaced **within the designated funding period of 2 years**, the Client must be assessed by the Certified Fitter. An application Form is **not** required in these situations. The Vendor submits an invoice to the Financial Management Branch with the applicable codes after the Certified Fitter has assessed the Client and has dispensed the replacement garments.

For any replacement garments that are **not an identical** replacement, the Client must be reassessed by an Authorizer and a Certified Fitter, if the fitter is available. A Physician or Nurse Practitioner reassessment may also be required, depending on the reason for replacement.

For replacement garments required due to a **change of size or style**, including fabric changes, size changes, compression level changes, changes from custom to custom-fitted styles and/or changes from elastic or non-elastic garments, **at any time**, the Client must be assessed by an Authorizer and a Certified Fitter, if the fitter is available.

For replacement garments required due to a **change in medical condition at any time**, the Client must be assessed by their Specialist Physician or Family Physician or a Nurse Practitioner (Prescriber), the Authorizer and the Certified Fitter, if the latter is available.

A new Application Form must be completed when a replacement Device is required due to a **change in size or style or a change in medical condition** at any time. The reason for the replacement must be checked on the Application Form.

415.04 Compression Sleeves

For replacement compression sleeves at any time, a Client must be assessed by an Authorizer for Pressure Modification Devices for lymphedema management.

If a Certified Fitter is available, they may also assess the Client. The Client must be assessed by their Specialist Physician or Family.

Physician or Nurse Practitioner (Prescriber) if the reason for replacement is change in medical condition**.**

An Application Form must be completed for all replacement compression sleeves.

415.05 Loss or Damage

The ADP does not provide Funding for a replacement Device if the Device is lost, stolen or damaged beyond repair where such wear and tear, in the opinion of the Ministry, is excessive or arises from the Client's failure to take reasonable care.

420 Designated Funding Periods

Garments

Elastic Compression Garments - a maximum of three (3) authorizations are allowed in a twelve (12) month period. Each authorization consists of two (2) identical outfits, one to wash and one to wear. An outfit consists of a one-layered set of garments worn at one time.

Non-Elastic Compression Garments - a maximum of two (2) authorizations are allowed in a twelve (12) month period. Each authorization consists of two (2) identical outfits, one to wash and one to wear.

Compression Sleeves and Gauge - the designated funding period is five (5) years. Clients must be encouraged to utilize the refurbishing/restoration program offered by the manufacturer.

425 Warranty

There are two types of warranties:

- Normal Use, and
- Satisfactory Fit.

425.01 Warranty Under Normal Use

The Vendor must warrant the garment/sleeve against breakage or tearing for:

- Thirty (30) days from the date that the garment is shipped from the manufacturer to the Vendor for an Elastic Custom-made or
- Custom-fitted Compression Garment;
- Six (6) months from the date the purchase of a Non-Elastic Compression Garment;
- Ninety (90) days from the date of purchase for manufacturer defects for a compression sleeve. This warranty should be confirmed with the specific manufacturer.

The warranty must be provided to the Client in writing.

425.02 Warranty for Satisfactory Fit

Whoever fits the garment to the Client and the Vendor who dispenses the garment/sleeve must warrant satisfactory fit of the garment/sleeve for a minimum of one (1) month after delivery of the garment/sleeve to the Client, unless there is a relevant change in the Client's size due to growth or atrophy or a change in medical condition.

During the warranty period, the Vendor will provide all services including repairs or replacement of the garment/sleeve or any components free of charge.

When there is repeated technical failure, the Device will be replaced by the issuer of the warranty. Repair and service of Devices are the responsibility of the Vendor, manufacturer or service designate.

The ADP does not contribute towards the cost of repairs under any circumstances.

Management of Lymphedema – Sequential Extremity Pumps and Accessories

5

Part 5: Management of Lymphedema – Sequential Extremity Pumps and Accessories

500 Eligibility

Individuals who have a diagnosis of Primary Lymphedema are eligible for Funding for a sequential extremity pump and accessories.

The individual must require the sequential extremity pump for a minimum of five (5) days out of seven (7) per week, and a minimum of two (2) hours per day.

The individual must require the sequential extremity pump and accessories for longer than six (6) months of regular use.

505 Devices Covered

The following Devices, for the management of Primary Lymphedema, are eligible for ADP Funding:

- Specified sequential extremity pumps and their accessories.

For all sequential extremity pumps and accessories funded by the Program, the Vendor may only provide Devices and accessories for which the manufacturer provides a minimum warranty of one (1) year.

The warranty period is determined from the date that the Device and accessories are dispensed to the Client.

The procedure for manufacturers to apply for ADP approval of a new and/or updated sequential extremity pump or accessories is available upon request

from the Program.

Each authorization consists of one (1) sequential extremity pump per Applicant, one (1) sleeve/boot per affected limb, and additional required accessories.

510 Accessories for Sequential Extremity Pumps not Funded by the ADP

Individuals may request Funding for accessories for a sequential extremity pump that was not funded by the ADP.

The Authorizer must confirm and document during the assessment that:

- The Applicant meets the eligibility criteria for funding for a sequential extremity pump;
- The pump is on the ADP approved manufacturer list of Devices;
- The pump is in good condition, and
- With the accessories requested, the pump will continue to meet the Applicant's needs.

The Applicant must be assessed by a Lymphedema Team.

515 Authorization of Pumps and Accessories

An individual who requires a sequential extremity pump and accessories for the management of lymphedema must be assessed by a Lymphedema Team. The Team may also prescribe and authorize graduated compression garments and sleeves.

515.01 Lymphedema Team

The Lymphedema Team prescribes and authorizes sequential extremity pumps and accessories for the management of lymphedema.

The Team must consist of at least:

- A Physician, licensed to practise medicine in Ontario who holds a certificate in the specialty of cardiovascular surgery, vascular surgery, radiation oncology, medical oncology, internal medicine, paediatrics, orthopaedic surgery, plastic surgery, physiatry, or general surgery, and

- An OT and/or PT who is an Authorizer for lymphedema compression garments and sequential extremity pumps/accessories, and

- A representative of a Vendor for sequential extremity pumps and accessories affiliated with the team.

All members must request that their names be added to the membership of a Lymphedema Team. Applications to register Lymphedema Teams are available from the Program.

Where possible, the team members must meet together with the Applicant in a permanent location. Alternately, the team members may meet individually with the Applicant and subsequently consult regarding the outcome of their assessments and their recommendations. All clinical findings and recommendations must be documented in their clinical notes.

515.02 Lymphedema Team Responsibilities

- The Specialist Physician provides medical clearance for a trial assessment with the sequential extremity pump;

- The Authorizer assesses the Applicant's response to the sequential extremity pump. A trial series of pump downs plus regular volumetric or circumferential measurements of the Applicant's affected limb, before and after the application of the pump, will help to determine whether the Applicant will respond to this modality;

- The team reviews the Applicant's response to the sequential extremity pump and gives final approval as to the Device's suitability;

- The Authorizer and Certified Fitter or Manufacturer/Distributor Representative provide training to the Applicant in how to apply, remove, use, care for, and maintain the pump;

- The team schedules regular follow-up visits with the Client to check the Client's progress and the performance of the sequential extremity pump and accessories. Adjustments to the Device may be made or further training in its use may be provided as needed;

- The team evaluates the need for changes to the compression Device and refers any Client with a suspected change in medical condition back to the Team's Specialist Physician for medical review.

520 Assessment Procedures

520.01 Client First Access

For first access to the ADP an assessment must be completed by a Lymphedema Team.

520.02 Client Repeat Access

Regardless of the reason for replacement of a sequential extremity pump and/or accessory, the Client must be assessed by a Lymphedema Team.

The reason for replacement **must** be checked on the Application Form.

All replacements of sleeves/boots for sequential extremity pumps due to a change in the Client's size or medical condition can be prescribed and authorized by **any** Lymphedema Team.

Devices may be replaced when the Client's current Device is no longer usable. Pressure Modification Devices which jeopardize the Client's safety or no longer meet the Client's needs as a result of physiological growth, atrophy, change in

medical condition, or normal wear (except where such wear and tear, in the opinion of the Ministry, is excessive or arises from the Client's failure to take reasonable care) are eligible for replacement Funding.

A Client with a suspected change in medical condition should be referred back to the Lymphedema Team's Specialist Physician for a medical review.

520.03 Loss or Damage

The ADP does not provide Funding for a replacement Device if the Device is lost, stolen or damaged beyond repair where such wear and tear, in the opinion of the Ministry, is excessive or arises from the Client's failure to take reasonable care.

525 Designated Funding Periods

- Sequential Extremity Pumps - five (5) years.
- Accessories - three (3) years.

530 Warranty

There are two types of warranties:

- Normal Use, and
- Satisfactory Fit.

530.01 Warranty under Normal Use

The Vendor of Pressure Modification Devices will warrant the Device, in writing, against breakage or tearing under normal use for:

- One (1) year for sequential extremity pumps;

- One (1) year for accessories (sleeves and boots) for the sequential extremity pumps.

During the warranty period, the Vendor will provide or cause to be provided any service including repairs or replacement of the Device or any accessories free of charge.

When there is repeated technical failure, the Device will be replaced by the issuer of the warranty. Repair and service of sequential extremity pumps is the responsibility of the Vendor, manufacturer or service designate.

The ADP does not contribute towards the cost of repairs under any circumstances.

Funding and Payment

6

Part 6: Funding and Payment

600 Policies

No payment of an approved Device shall be made by the Ministry to anyone other than a Vendor in respect of Pressure Modification Devices. The Vendor must be registered to provide a specific type of Pressure Modification Device, as noted below.

Vendors must be registered in the specific subcategory:

- Hypertrophic Scar Management – Garments
- Hypertrophic Scar Management – Orthoses
- Lymphedema Management – Garments and Sleeves
- Lymphedema Management – Sequential Extremity Pumps

Lists of Vendors in specific geographic areas can be obtained from the ADP website at:

http://www.health.gov.on.ca/en/pro/programs/adp

Detailed information about payment is found in the **ADP Manual: Part 9, Invoice Processing and Payment.**

605 Funding Amount for ADP clients

The Program will pay seventy-five per cent (75%) of the Approved Price for Pressure Modification Devices listed in the Product Manual.

Vendors may **not** bill the Client more than the Approved Price for the Device. Vendors **may** charge the Client **less** than the Approved Price.

The Vendor **must** charge the Client twenty-five per cent (25%) of the Approved Price and invoice the ADP for 75% of the Approved Price.

Note: Should the Vendor charge the Client less than the Approved Price, or provide a rebate or discount to the Client for their Devices, both the Client portion (25%) and the ADP portion (75%) must be adjusted accordingly.

610 Funding for Ministry of Community and Social Services (MCSS) Benefits Recipients

Co-payment for clients receiving Social Assistance Benefits:

- Ontario Works (OW)
- Ontario Disability Support Program (ODSP)
- Assistance to Children with Severe Disabilities (ACSD)

For Clients receiving social assistance benefits through OW, ODSP or ACSD as of the date reviewed and approved by an Authorizer, the ADP will pay one hundred per cent (100%) of the Approved Price for all Device codes.

615 Delivery of Devices

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

Note: The Vendor must notify the Authorizer regarding provision of the Pressure Modification Device to allow his/her follow-up to be completed, if applicable.

620 Expiry Date of the Application for Pressure Modification Devices

The Application Form is considered current and valid for one (1) year from the Authorizer assessment date.

Note: The expiry date will NOT be extended. After the expiry date a new assessment must be completed and a new Application Form must be submitted to the Program.

Note: The Authorizer assessment date must precede the delivery of the Pressure Modification Device(s) to the Client.

Invoicing Procedures

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Part 7: Invoicing Procedures

700 Guide to Completing the Invoice

Refer to the ADP Manual, Part 9, Invoice Processing and Payment for details.

705 ADP Processing Errors

In the event of an ADP processing error being identified following Funding approval, the ADP will co-operate with the Authorizer and Client to make any necessary corrections.

The Authorizer must notify the ADP in writing of the error(s) along with a request for the approval to be amended.

710 Authorizer Prescription Errors & Omissions

In the event of an Authorizer prescription error and/or omission being identified following Funding approval, the ADP will co-operate with the Authorizer to make any necessary corrections.

The Authorizer must return a copy of the page of the Application Form to the ADP with the errors highlighted along with a request for the approval to be amended.

715 Client Refusal of Delivered Devices

In the event of Client refusal either at the time of delivery or immediately thereafter, the ADP will work co-operatively with the Client, Authorizer and Vendor to resolve the situation.

Authorizers

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Part 8: Authorizers

800 Authorizer Status

Occupational Therapists, Physiotherapists, Certified Orthotists, Registered Nurses or Registered Massage Therapists wishing to be registered with the Program for Pressure Modification Devices must be registered as Authorizers in the specific Device category.

Certified Fitters, wishing to be registered with the Program as fitters for Pressure Modification Devices must be registered as Fitters in the specific Device category.

805 Hypertrophic Scar Management Authorizers

The following individuals may be registered as authorizers:

- OT/PT – garments
- Certified Orthotists – orthotics

Certified Fitters may be registered as Fitters for garments.

OT/PT's may be registered as Rehabilitation Assessors for orthotics.

810 Lymphedema Management Authorizers

The following individuals may be registered as Authorizers:

- OT/PT/RN/RMT – garments and sleeves
- OT/PT – sequential extremity pumps

Certified Fitters may be registered as fitters for garments, sleeves and sequential extremity pumps.

815 General Authorizer Policies

Detailed information about Authorizer registration, policies and procedures, are found in the **ADP Manual, Part 4, General Authorizer and Vendor Policies** and **Part 5, Authorizers**.

820 Requirements for Authorizer Status

Under the Pressure Modification Devices Category, all Regulated Health Professionals must hold a valid certificate of registration from their respective Colleges and must be licensed to practise in Ontario. This includes Occupational Therapists, Physiotherapists, Registered Nurses and Registered Massage Therapists.

An Authorizer for pressure orthoses for hypertrophic scar management must be a Certified Orthotist who has met all registration requirements with the Program.

Certified Fitters are required to have completed one ADP recognized manufacturers' course in each area of registration. These areas are hypertrophic scar management compression garments, lymphedema management compression garments, lymphedema management sleeves and sequential extremity pumps for lymphedema management.

Vendors

9

Part 9: Vendors

900 Vendor Status

Vendors wishing to submit a request for funding to the Ministry for Pressure Modification Devices must be registered as Vendors in the Device category.

Vendors must be register separately for the following categories.

1. Hypertrophic Scar Management – Garments
2. Hypertrophic Scar Management – Orthotics
3. Lymphedema Management – Garments and Sleeves
4. Lymphedema Management – Sequential Extremity Pumps

Vendors applying for registration status for Pressure Modification Devices must provide a letter from each of the manufacturers whose products they intend to sell through the ADP, confirming that they are an authorized dealer.

Vendors applying for registration status must submit the names of staff members who have **professional qualifications to fabricate and/or fit particular devices** and proof of such qualifications.

900.01 Manufacturers As Vendors – Hypertrophic Scar Management

Despite policy 605 in the ADP Manual, Manufacturers and Distributors as Vendors, manufacturers of compression garments and pressure orthoses for hypertrophic scar management may apply to become ADP registered Vendors.

An ADP registered Vendor must meet, on an ongoing basis, the device specific requirements to become registered with the ADP. See policy 600, Becoming Registered and Maintaining Vendor Status with the Program, in the ADP Manual and the Vendor Registration section on the ADP website.

900.02 Manufacturers As Vendors – Lymphedema Management

Despite policy 605 in the ADP Manual, Manufacturers and Distributors as Vendors, manufacturers of compression garments, compression sleeves and sequential extremity pumps for lymphedema management may apply to become ADP registered Vendors if they have access to and offer for sale one (1) other manufacturer's products that qualify as Devices under the Program.

The manufacturer must meet all other requirements under policy 605.

An ADP registered Vendor must meet, on an ongoing basis, the device specific requirements to become registered with the ADP. See policy 600, Becoming Registered and Maintaining Vendor Status with the Program, in the ADP Manual and the Vendor Registration section on the ADP website.

905 Staffing Requirements for Vendors

Vendors of Pressure Modification Devices are required to have at least one full time Certified Fitter who is registered with the ADP in the respective area of the Pressure Modification Devices Category on staff.

Vendors of pressure orthoses for hypertrophic scar management are required to have at least one full time Certified Orthotist on staff.

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

Registering an ADP Clinic/Team

10

Part 10: Registering an ADP Clinic / Team

1000 Hypertrophic Scar Management Team (Burn Team)

See Policy 310.01 for membership details.

An application to register a Burn Team must be completed. The application can be requested from the Program.

The Burn Team will be issued a clinic/team registration number that must be used on the Application for Funding Pressure Modification Devices form for first access and whenever applicable.

1005 Lymphedema Management Clinic/Team (Lymphedema Team)

See Policy 510.01 for membership details.

An application to register a Lymphedema Team must be completed. The application can be requested from the Program.

The Lymphedema Team will be issued a clinic/team registration number that must be used on the Application for Funding Pressure Modification Devices form for any sequential extremity pump or accessories application.

Contact Information

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Part 11: Contact Information

1100 Program Addresses

1100.01 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

1100.02 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