

M.O., 2005-011**Order of the Minister of Health and Social Services making the Regulation to amend the Regulation respecting the List of medications covered by the basic prescription drug insurance plan dated 28 July 2005**

An Act respecting prescription drug insurance (R.S.Q., c. A-29.01; 2002, c. 27)

THE MINISTER OF HEALTH AND SOCIAL SERVICES,

CONSIDERING that the agreement on the administration of the “Patients d’exception” program by the Régie de l’assurance maladie du Québec attached as a Schedule to Décret 2678-83 dated 21 December 1983, as amended by Décret 971-66 dated 7 August 1996, ends on 30 August 2005;

CONSIDERING section 60 of the Act respecting prescription drug insurance (R.S.Q., c. A-29.01; 2002, c. 27, s. 22, 3rd par.);

CONSIDERING Order 1999-014 of the Minister of State for Health and Social Services and Minister of Health and Social Services dated 15 September 1999 making the Regulation respecting the List of medications covered by the basic prescription drug insurance plan;

CONSIDERING that it is necessary to amend the List of Medications attached as a Schedule to that Regulation;

CONSIDERING that the Conseil du médicament has been consulted on the draft Regulation;

MAKES the Regulation to amend the Regulation respecting the List of medications covered by the basic prescription drug insurance plan, the text of which is attached to this Order.

Québec, 28 July 2005

PHILIPPE COUILLARD,
Minister of Health and Social Services

Regulation to amend the Regulation respecting the List of medications covered by the basic prescription drug insurance plan*

An Act respecting prescription drug insurance (R.S.Q., c. A-29.01, s. 60; 2002, c. 27, s. 22, 3rd par.)

1. The Regulation respecting the List of medications covered by the basic prescription drug insurance plan is amended by inserting the following sections after section 5.1 in the List of Medications in Schedule 1 to the Regulation:

“6. Conditions, cases and circumstances on or in which the cost of any other medication is covered by the basic plan, except the medications or classes of medications specified below

6.1. Objective

The purpose of this measure is to provide for the payment, in exceptional circumstances, of a medication that is not on the List or an exception medication prescribed for a therapeutic indication not specified on the List for that medication, on or in the conditions, cases and circumstances described below, and to provide for coverage under the basic prescription drug insurance plan of the cost of the medication and the cost of the pharmaceutical services provided by a pharmacist to an eligible person.

* The Regulation respecting the List of medications covered by the basic prescription drug insurance plan, made by Order 1999-014 dated 15 September 1999 (1999, *G.O.* 2, 3197) of the Minister of State for Health and Social Services and Minister of Health and Social Services, was last amended by the regulations made by Minister’s Orders 2003-010 dated 10 September 2003 (2003, *G.O.* 2, 2915A), 2003-012 dated 28 October 2003 (2003, *G.O.* 2, 3288), 2003-013 dated 2 December 2003 (2003, *G.O.* 2, 3472), 2004-002 dated 19 January 2004 (2004, *G.O.* 2, 828), 2004-006 dated 15 April 2004 (2004, *G.O.* 2, 1376), 2004-008 dated 17 June 2004 (2004, *G.O.* 2, 2028), 2004-013 dated 21 September 2004 (2004, *G.O.* 2, 2864), 2004-015 dated 15 November 2004 (2004, *G.O.* 2, 3157), 2004-019 dated 13 December 2004 (2004, *G.O.* 2, 3613), 2005-001 dated 20 January 2005 (2005, *G.O.* 2, 491) and 2005-006 dated 13 May 2005 (2005, *G.O.* 2, 1381). For previous amendments, refer to the *Tableau des modifications et Index sommaire*, Québec Official Publisher, 2005, updated to 1 March 2005.

6.2. Conditions, cases and circumstances

6.2.1. Conditions

A medication that is not on the List, or an exception medication prescribed for a therapeutic indication not specified on the List for that medication, is covered by the basic prescription drug insurance plan on an exceptional basis when no other pharmacological treatment specified on the List or medical treatment whose cost is covered under the Health Insurance Act (chapter A-29) can be considered because the treatment is contraindicated, there is significant intolerance to the treatment, or the treatment is ineffective due to the clinical condition of the eligible person.

The medication to which section 6 applies must be

(1) manufactured and marketed in Canada and, subject to the fourth paragraph of this section, have been assigned a DIN by Health Canada;

(2) an extemporaneous preparation consisting of ingredients marketed in Canada; or

(3) a sterile preparation made by a pharmacist from sterile pharmaceutical products marketed in Canada, at least one of which is not specified on the List for parenteral administration or ophthalmic use.

The medication is covered by the basic plan if it satisfies every condition specified for both of the following criteria:

(1) severity of the medical condition; and

(2) chronicity, treatment of an acute infection, and palliative care.

An exception medication referred to in Appendix 4 may be covered by the basic plan even if it has not been assigned a DIN by Health Canada, insofar as its coverage is not subject to any exclusion set out in the List.

6.2.1.1. Severity of the medical condition

The medication is to be used to treat a severe medical condition of an eligible person for whom there is a specific necessity of an exceptional nature to use the medication, recorded in the person's medical file.

“Severe medical condition” means a symptom, illness or severe complication arising from the illness with consequences that pose a serious health threat, such as significant physical or psychological injury, with a high

probability that the person will require the use of a number of services in the health network such as frequent medical services or hospitalization if the medication is not administered, and whose severity is, as the case may be,

(1) immediate, in that it already severely restricts the afflicted person's activities or quality of life or would, according to the current state of scientific knowledge, lead to significant functional injury or the person's death; or

(2) foreseeable in the short term, in that its evolution or complications could affect the eligible person's morbidity or mortality risk.

If, however, the consequences of the severe medical condition are significant functional psychological injury, the injury must be immediate and as a consequence already severely restrict the eligible person's activities or quality of life.

6.2.1.2. Chronicity, treatment of an acute severe infection, and palliative care

The medication is to be used, as the case may be,

(1) to treat a chronic medical condition or a complication or manifestation arising from the chronic medical condition provided its degree of severity satisfies subparagraph 1 or 2 of the second paragraph of section 6.2.1.1;

(2) to treat an acute severe infection; or

(3) notwithstanding the degree of severity criteria in section 6.2.1.1, to provide for the administration of a medication required for final phase ambulatory palliative care in the case of a terminal illness.

6.3. Exclusions

Despite the conditions being satisfied for coverage by the basic prescription drug plan under section 6.2.1 as a medication not on the List or as an exception medication prescribed for a therapeutic indication not specified on the List for that medication, a request for payment authorization must be denied for the following medications:

(1) medications prescribed to treat infertility;

(2) medications prescribed for aesthetic or cosmetic purposes;

(3) medications prescribed to treat alopecia or baldness;

- (4) medications prescribed to treat erectile dysfunction;
- (5) medications prescribed to treat obesity;
- (6) medications prescribed for cachexia and to stimulate appetite; and
- (7) oxygen.

6.4. Price paid by the Régie de l'assurance maladie du Québec

The price of a medication to which section 6 applies, and for which the Régie de l'assurance maladie du Québec assumes payment for persons whose coverage under the basic plan is provided by the Régie, is the actual purchase price paid for the medication by the pharmacist.

6.5. Payment authorization and duration of authorization

The prescriber must send

(1) to the Régie de l'assurance maladie du Québec, in the case of persons whose coverage by the basic plan is provided by the Régie, a request for prior authorization on the duly completed form provided by the Régie;

(2) to the insurer or administrator of the employee benefit plan, in the case of persons whose basic plan coverage is provided by insurers transacting group insurance or by administrators of private-sector employee benefit plans, if it is required by the applicable group insurance contract or benefit plan, a prior request for authorization duly completed in accordance with the terms and conditions of the contract or plan, as the case may be.

If the request is accepted, the medication for which payment authorization is sought is covered only for the period authorized by the Régie, the insurer or the administrator of the employee benefit plan, as the case may be.”.

2. Requests for authorization sent to the Régie de l'assurance maladie du Québec before 1 September 2005 under the “Patients d'exception” program administered by the Régie de l'assurance maladie du Québec under Décret 2678-83 dated 21 December 1983, as amended by Décret 971-96 dated 7 August 1996, will be processed in accordance with the terms and conditions of the agreements attached to those Orders in Council.

3. This Regulation comes into force on 1 September 2005.

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