M.O., 2003-13

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 2 December 2003

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

THE MINISTER OF HEALTH AND SOCIAL SERVICES,

CONSIDERING section 60 of the Act respecting prescription drug insurance (R.S.Q., c. A-29.01);

CONSIDERING Order 1999-014 dated 15 September 1999 of the Minister of State for Health and Social Services and Minister of Health and Social Services 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 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 hereto.

Québec, 2 December 2003

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)

1. The Regulation respecting the List of medications covered by the basic prescription drug insurance plan is amended, in the List of medications attached thereto, by inserting the following in Appendix III entitled "Products for Which the Wholesaler's Mark-Up is Limited to a Maximum Amount" before the line concerning the medication "GLEEVEC":

"Roche Fuzeon 60".

2. The List of medications attached to the Regulation is amended:

(1) by inserting the following in Appendix IV entitled "Exceptional Medications, With Recognized Indications for Payment Purposes" after the medication "DRESSING – SODIUM CHLORIDE" and the accompanying indications:

"ENFUVIRTIDE:

◆ for treatment, in association with other antiretrovirals, of HIV-infected persons,
- whose current viral load is greater than or equal to 5 000 copies/mL while having been treated for at least three months with an association of antiretrovirals,

and
- for whom a laboratory test showed sensitivity to only one antiretroviral or to none.

The maximum duration of the initial authorization is five months.

* The Regulation respecting the List of medications covered by the basic prescription drug insurance plan, made by Minister's 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 Minister's Orders 2003-008 dated 20 June 2003 (2003, *G.O.* 2, 2022), 2003-010 dated 10 September 2003 (2003, *G.O.* 2, 2915A) and 2003-12 dated 28 October 2003 (2003, *G.O.* 2, 3288) of that Minister. For previous amendments, refer to the *Tableau des modifications et Index sommaire*, Éditeur officiel du Québec, 2003, updated to 1 September 2003.

Upon subsequent requests, the physician must provide a recent viral load measurement showing a beneficial effect, specifically, a reduction of at least 0.5 log compared with the viral load measurement obtained before the enfuvirtide treatment began. Authorizations will then have a maximum duration of six months;

◆ for treatment, in association with other antiretrovirals, of HIV-infected persons,
- whose current viral load is greater than or equal to 5 000 copies/mL and is greater than or equal to the previous value, obtained at an interval of at least three months, while having been treated with an association of three or more antiretrovirals during the interval between the two viral load measurements,

and
- who previously received at least two other antiretroviral treatments that resulted in a documented virological failure, after at least three months of treatment for each of the associations,

and
- who have tried, since the beginning of their antiretroviral therapy, at least one nucleoside reverse transcriptase inhibitor, one non-nucleoside reverse transcriptase inhibitor and one protease inhibitor, except in the presence of a class resistance.

The maximum duration of the initial authorization is five months.

Upon subsequent requests, the physician must provide a recent viral load measurement showing a beneficial effect, specifically, a reduction of at least 0.5 log compared with the viral load measurement obtained before the enfuvirtide treatment began. Authorizations will then have a maximum duration of six months;";

(2) by inserting the following in the "Exceptional Medications" section after the medication "DRESSING – SODIUM CHLORIDE" and the accompanying indications:

CODE	BRAND NAME	MANUFACTURER	PKG. SIZE	COST OF PKG. SIZE	UNIT PRICE
ENFUVIRTIDE P					
S.C. Inj. Pd.				108 mg	
02247725	Fuzeon	Roche	60	2385.60	39.7600

3. This Regulation comes into force on 10 December 2003.

6044