M.O., 2002-013

Order of the Minister of State for 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 15 October 2002

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

THE MINISTER OF STATE FOR HEALTH AND SOCIAL SERVICES AND MINISTER OF HEALTH AND SOCIAL SERVICES,

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

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 consultatif de pharmacologie 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, 15 October 2002

FRANÇOIS LEGAULT,
Minister of State for Health and Social Services and 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, par. 2)

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, in Appendix III entitled "Products for which the wholesaler's mark-up is limited to a maximum amount":

(1) by inserting the following after the line concerning the medication "DILAUDID-XP":

"W.A.C.	Enbrel S.C. Inj. Pd. 25 mg	4 vials";

(2) by inserting the following after the line concerning the medication "TOBI":

"Actelion	Tracleer Tab. 62.5 mg	60 tablets
Actelion	Tracleer Tab. 125 mg	60 tablets".

2. The List of medications, attached to that Regulation, is amended in Appendix IV entitled "Exceptional medications, with recognized indications for payment purposes":

(1) by inserting the following after the medication "BISACODYL" and the accompanying indications:

"BOSENTAN

◆ for treatment of pulmonary arterial hypertension (WHO functional class III) that is either primary or secondary to sclerodermia and that is symptomatic despite the optimal conventional treatment;

The person must be evaluated and followed up on by physicians working at designated centres specializing in the treatment of pulmonary arterial hypertension;";

* 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 2002-005 dated 11 June 2002 (2000, *G.O.* 2, 2733) and 2002-011 dated 13 September 2002 (2002, *G.O.* 2, 4885) of that Minister. For previous amendments, refer to the *Tableau des modifications et Index sommaire*, Éditeur officiel du Québec, 2002, updated to 1 September 2002.

(2) by inserting the following after the medication "ESTRADIOL-17B/NORETHINDRONE ACETATE" and the accompanying indications and before the medication "ETIDRONATE DISODIUM":

"ETANERCEPT

◆ for treatment of moderate or severe rheumatoid arthritis;

Upon initiation of treatment or if the person has been receiving the drug for less than five months:
- the person must, prior to the beginning of treatment, have eight or more joints with active synovitis and one of the following five elements must be present:
  – a positive rheumatoid factor;
  – radiologically measured erosions;
  – a score of more than 1 on the health assessment questionnaire (HAQ);
  – an elevated C-reactive protein level;
  – an elevated sedimentation rate;

and
- the disease must still be active despite treatment with two disease-modifying anti-rheumatic drugs, used either concomitantly or not, for at least three months each. Unless there is a significant intolerance or contraindication, one of the two drugs must be:
  – methotrexate at a dose of 20 mg or more per week;
  or
  – leflunomide at a dose of 20 mg per day.

The initial request is authorized for a maximum of five months.

When requesting continuation of treatment, the physician must provide information establishing the treatment's beneficial effects, specifically:
- a decrease of at least 20% in the number of joints with active synovitis and one of the following four elements:
  – a decrease of 20% or more in the C-reactive protein level;
  – a reduction of 20% or more in the sedimentation rate;
  – an improvement of 0.20 in the HAQ score;
  – a return to work.

The first request for continuation of treatment is authorized for six months and the following requests will be authorized for twelve months.

Authorizations for etanercept are given for a dose of 25 mg twice per week.

◆ for treatment of moderate or severe juvenile idiopathic arthritis (juvenile rheumatoid arthritis and juvenile chronic arthritis) of the polyarticular or systemic type;

Upon initiation of treatment or if the person has been receiving the drug for less than five months:
- the person must, prior to the beginning of treatment, have five or more joints with active synovitis and one of the following two elements must be present:
  – an elevated C-reactive protein level;
  – an elevated sedimentation rate;

and
- the disease must still be active despite treatment with methotrexate at a dose of 15 mg/M^2 or more (maximum 20 mg per dose) per week for at least three months, unless there is intolerance or a contraindication.

The initial request is authorized for a maximum of five months.

When requesting continuation of treatment, the physician must provide information establishing the treatment's beneficial effects, specifically:
- a decrease of 20% or more in the number of joints with active synovitis and one of the following six elements:
  – a decrease of 20% or more in the C-reactive protein level;
  – a reduction of 20% or more in the sedimentation rate;
  – an improvement of 0.13 in the childhood health assessment questionnaire (CHAQ) score or a return to school;
  – an improvement of at least 20% in the physician's overall assessment (visual analogue scale);
  – an improvement of at least 20% in the patient's or parent's overall assessment (visual analogue scale);
  – an improvement of 20% or more in the number of joints with limited movement.

The first request for continuation of treatment is authorized for six months and the following requests will be authorized for 12 months.

Authorizations for etanercept are given for 0.4 mg/kg (maximum 25 mg) twice per week;";

(3) by inserting the following indication after the indications accompanying the medication "IMATINIB MESYLATE":

"◆ for treatment of an inoperable, recidivant or metastatic gastrointestinal stromal tumour with presence of the c-kit receptor (CD117);

The initial authorization is for a daily dose of 400 mg for a duration of six months.

An authorization for a daily dose of 600 mg may be obtained with evidence of a progression of the disease, confirmed by imaging, after a minimum of three months of treatment at a daily dose of 400 mg.

When making subsequent requests, the physician must provide evidence of a complete or partial response or of stabilization of the disease, confirmed by imaging.

Authorizations will be for six-month periods;";

(4) by inserting the following indications after the indications accompanying the medication "INFLIXIMAB":

"◆for treatment of moderate or severe rheumatoid arthritis;

Upon initiation of treatment or if the person has been receiving the drug for less than five months:
- the person must, prior to the beginning of treatment, have eight or more joints with active synovitis and one of the following five elements must be present:
  – a positive rheumatoid factor;
  – radiologically measured erosions;
  – a score of more than 1 on the health assessment questionnaire (HAQ);
  – an elevated C-reactive protein level;
  – an elevated sedimentation rate;

and
- the disease must still be active despite treatment with two disease-modifying anti-rheumatic drugs, used either concomitantly or not, for at least three months each. Unless there is a significant intolerance or contraindication, one of the two drugs must be:
  – methotrexate at a dose of 20 mg or more per week;
  or
  – leflunomide at a dose of 20 mg per day.

The initial request is authorized for a maximum of five months.

When requesting continuation of treatment, the physician must provide information establishing the treatment's beneficial effects, specifically:
- a decrease of at least 20% in the number of joints with active synovitis and one of the following four elements:
  – a decrease of 20% or more in the C-reactive protein level;
  – a reduction of 20% or more in the sedimentation rate;
  – an improvement of 0.20 in the HAQ score;
  – a return to work.

The first request for continuation of treatment is authorized for six months and the following requests will be authorized for twelve months.

Authorizations for infliximab are given for three doses of 3 mg/kg, with the possibility of increasing the dose to 5 mg/kg after three doses or in the 14th week;

◆ for treatment of moderate or severe juvenile idiopathic arthritis (juvenile rheumatoid arthritis and juvenile chronic arthritis) of the polyarticular or systemic type;

Upon initiation of treatment or if the person has been receiving the drug for less than five months:
- the person must, prior to the beginning of treatment, have five or more joints with active synovitis and one of the following two elements must be present:
  – an elevated C-reactive protein level;
  – an elevated sedimentation rate;

and
- the disease must still be active despite treatment with methotrexate at a dose of 15 mg/M^2 or more (maximum 20 mg per dose) per week for at least three months, unless there is intolerance or a contraindication.

The initial request is authorized for a maximum of five months.

When requesting continuation of treatment, the physician must provide information establishing the treatment's beneficial effects, specifically:
- a decrease of at least 20% in the number of joints with active synovitis and one of the following six elements:
  – a decrease of 20% or more in the C-reactive protein level;
  – a reduction of 20% or more in the sedimentation rate;
  – an improvement of 0.13 in the childhood health assessment questionnaire (CHAQ) score or a return to school;
  – an improvement of at least 20% in the physician's overall assessment (visual analogue scale);
  – an improvement of at least 20% in the patient's or parent's overall assessment (visual analogue scale);
  – an improvement of 20% or more in the number of joints with limited movement.

The first request for continuation of treatment is authorized for six months and the following requests will be authorized for 12 months.

Authorizations for infliximab are given for three doses of 3 mg/kg, with the possibility of increasing the dose to 5 mg/kg after three doses or in the 14th week;".

3. The List of medications, attached to that Regulation, is amended by substituting the package size costs and unit prices indicated hereinafter for the unit prices and package size costs of the following medications:

	CODE	BRAND NAME	MANUFACTURER	PKG. SIZE	COST OF PKG. SIZE	UNIT PRICE
8:12.02						
AMINOGLYCOSIDES						
TOBRAMYCINE SULFATE P						
	Inj. Sol.		40 mg/mL **P.P.B.**			
*	00325449	Nebcin	Lilly	2 mL	4.82	
92:00						
UNCLASSIFIED THERAPEUTIC AGENTS						
COLCHICINE						
	Tab.		0,6 mg			
*	00572349	Colchicine	Odan	500	97.50	0.1950
	Tab.		1 mg			
*	00621374	Colchicine	Odan	100	37.80	0.3780
EXCEPTIONAL MEDICATIONS						
EPOETIN ALFA P						
	Syringe		10 000 UI/1,0 mL			
*	02231587	Eprex	J.O.I.	6	803.70	133.9500

4. The List of medications, attached to that Regulation, is amended in the "Exceptional Medications" section:

(1) by inserting the following after the medication "BISACODYL" and the accompanying information:

BOSENTAN P						
	Tab.		62.5 mg			
+	02244981	Tracleer	Actelion	60	3594.00	59.9000
	Tab.		125 mg			
+	02244982	Tracleer	Actelion	60	3594.00	59.9000

(2) by inserting the following after the medication "ESTRADIOL-17B, ESTRADIOL-17B/NORETHINDRONE ACETATE" and the accompanying information and before the medication "ETIDRONATE SODIUM":

ETANERCEPT P						
	S.C. Inj. Pd.		25 mg			
+	02242903	Enbrel	W.A.C.	4	660.00	165.0000

5. This Regulation comes into force on 23 October 2002.

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