

Bulletin #678

February 28, 2007

BENEFIT CHANGES TO NBPDP

This update to the New Brunswick Prescription Drug Program (NBPDP) Formulary is effective February 28, 2007.

Included in this bulletin:

- **Regular Benefit Additions**
- **Special Authorization Additions and Revised Criteria**
- **Drugs Reviewed and Not Listed**
- **Clozapine maximum allowable price (MAP)**

If you would prefer to receive bulletins electronically rather than in hard copy, please send a message to BC_nbpdp@medavie.bluecross.ca or call 1-800-332-3691. Bulletins are also available on the NBPDP web page: www.gnb.ca/0051/0212/index-e.asp

If you have any questions or concerns, please contact our office at 1-800-332-3691.

Yours truly,

Debbie LeBlanc
New Brunswick Prescription Drug Program

REGULAR BENEFIT ADDITIONS

Drug/Form/Route/Strength		Brand Name	DIN	Manufacturer	Plans	\$
Amlodipine Besylate		No longer requires special authorization				
Tab	Orl	5mg Norvasc [®]	878928	PFI	AEFVW	AAC
		10mg Norvasc [®]	878936	PFI	AEFVW	AAC
Gliclazide						
Tab	Orl	80mg Diamicon [®]	765996	SEV	ABEFGVW	MAP
		Gen-Gliclazide	2229519	GPM		
		Novo-Gliclazide	2238103	NOP		
		Apo-Gliclazide	2245247	APX		
		Sandoz Gliclazide	2254719	SDZ		
Glimepiride						
Tab	Orl	1mg Amaryl [®]	2245272	SAV	ABEFGVW	MAP
		Sandoz Glimepiride	2269589	SDZ		
		ratio-Glimepiride	2273101	RPH		
		Novo-Glimepiride	2273756	NOP		
		Co Glimepiride	2274248	COB		
		2mg Amaryl [®]	2245273	SAV	ABEFGVW	MAP
		Sandoz Glimepiride	2269597	SDZ		
		ratio-Glimepiride	2273128	RPH		
		Novo-Glimepiride	2273764	NOP		
		Co Glimepiride	2274256	COB		
		4mg Amaryl [®]	2245274	SAV	ABEFGVW	MAP
		Sandoz Glimepiride	2269619	SDZ		
		ratio-Glimepiride	2273136	RPH		
		Novo-Glimepiride	2273772	NOP		
		Co Glimepiride	2274272	COB		
Triptorelin Pamoate						
Pws	IM	3.75mg Trelstar [®] SR	2240000	PAL	AEFVW	AAC
		11.25mg Trelstar [®] LA	2243856	PAL	AEFVW	AAC

SPECIAL AUTHORIZATION ADDITIONS

Amlodipine/Atorvastatin (*Caduet™*)

5/10mg, 5/20mg, 5/40mg,
5/80mg, 10/10mg, 10/20mg,
10/40mg, 10/80mg tablets

For the treatment of patients who have been titrated to a stable combination of the separate components, amlodipine and atorvastatin.

Note: If the beneficiary has had a claim for both amlodipine and atorvastatin reimbursed by NBPDP in the previous 6 months, the claim for Caduet™ will automatically be reimbursed without requiring special authorization.

Treprostinil

(*Remodulin™*)

1mg/mL, 2.5mg/mL,
5mg/mL, 10mg/mL solution

For the treatment of patients with primary pulmonary hypertension or pulmonary hypertension secondary to collagen vascular disease, with New York Heart Association class III or IV disease who have both:

1. failed to respond to non-prostanoid therapies and
 2. who are not candidates for epoprostenol therapy because of:
 - prior recurrent complications with central line access (e.g. infection, thrombosis) or,
 - inability to operate the complicated delivery system of epoprostenol or,
 - they reside in an area without ready access to medical care, which could complicate problems associated with an abrupt interruption of epoprostenol.
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SPECIAL AUTHORIZATION – REVISED CRITERIA

Olanzapine (*Zyprexa®*)

2.5mg, 5mg, 7.5mg,
10mg, 15mg tablets

(*Zyprexa Zydys®*)

5mg, 10mg tablets

- For the acute and maintenance treatment of schizophrenia and related psychotic disorders.
- For the acute treatment of manic or mixed episodes in bipolar I disorder in patients with intolerance or a history of failure to one other atypical antipsychotic.
- For maintenance treatment in patients with bipolar disorder who are currently stabilized on olanzapine.

Advice from a psychiatrist is suggested prior to starting therapy. Prescriptions written by New Brunswick psychiatrists do not require special authorization. Subsequent refills ordered by other practitioners will not require special authorization.

DRUGS REVIEWED AND NOT LISTED

The reviews of the following products found that they did not offer a therapeutic and/or cost advantage over existing therapies. Requests for coverage through special authorization will not be considered.

Gliclazide	<i>Diamicron[®]MR</i>	30mg modified release tablets
Insulin detemir	<i>Levemir[®]</i>	100units/mL Penfill cartridges
Pegaptanib	<i>Macugen[™]</i>	0.3mg/90µL prefilled syringe
Pegvisomant	<i>Somavert[™]</i>	10mg, 15mg, 20mg vial
Pregabalin	<i>Lyrica[®]</i>	25mg, 50mg, 75mg, 150mg, 300mg capsules

This following product has been approved for listing. However, it cannot be listed since it is not currently marketed in Canada.

Pantoprazole Magnesium	<i>Pantoloc M[™]</i>	40mg tablets
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CLOZAPINE – NOTICE OF MAP

All brands of clozapine are currently reimbursed at actual acquisition cost. **Effective May 15, 2007**, a maximum allowable price (MAP) will be applied to clozapine. This advance notice is being provided to allow sufficient time to transfer those patients who are not currently receiving a lower cost brand from one manufacturer-specific clozapine registry system to another.

The following MAPs will be effective May 15, 2007.

Drug / Strength	Interchangeable Brand	DIN	Manufacturer	MAP
Clozapine 25mg tablet	Clozaril [®]	894737	NVR	\$0.6594
	Gen-Clozapine	2247243	GPM	
	Apo-Clozapine	2248034	APX	
Clozapine 100mg tablet	Clozaril [®]	894745	NVR	\$2.6446
	Gen-Clozapine	2247244	GPM	
	Apo-Clozapine	2247035	APX	

Information from Health Canada's June 2004 Advisory for Health Care Professionals regarding the monitoring of patients taking clozapine is attached and is available at:

http://www.hc-sc.gc.ca/dhp-mps/alt_formats/hpfb-dgpsa/pdf/medeff/clozapine_hpc-cps_e.pdf.



The Health Products and Food Branch (HPFB) posts on the Health Canada web site safety alerts, public health advisories, press releases and other notices as a service to health professionals, consumers, and other interested parties. These advisories may be prepared with Directorates in the HPFB which includes pre-market and post-market areas as well as market authorization holders and other stakeholders. Although the HPFB grants market authorizations or licenses for therapeutic products, we do not endorse either the product or the company. Any questions regarding product information should be discussed with your health professional.

**Health Canada releases important information on
the dispensation of CLOZAPINE products in Canada**

June 22, 2004

Subject: Monitoring of patients taking clozapine in Canada

Dear Health Care Professional,

The Marketed Health Products Directorate (MHPD) and the Therapeutic Products Directorate (TPD) would like to draw your attention to important upcoming revisions to the Product Monographs of all clozapine products marketed in Canada. These revisions will strengthen the labelling and address ongoing issues around patient consent for the sharing of information between registries. As you know, monitoring of patients with the use of registries is the risk mitigation strategy in place to address the known risk of agranulocytosis.

Revisions to clozapine Product Monographs will emphasize the following:

- 1. the switching of a patient from one brand of clozapine to another must not be done by a pharmacist unless he/she obtains a new, registry-specific patient registration form filled out by the prescribing physician.**
- 2. the physician has to inform his/her patient about the potential sharing of information between clozapine registries and document if there is consent from the patient to allow it, in order to ensure the safe use and continuous monitoring of patients taking clozapine.**
- 3. the responsibility of physicians concerning the sending of the mandatory laboratory results (white blood cell counts and differential) to the appropriate registry will be limited to informing the laboratory where the patient's haematological results have to be sent.**
- 4. weekly monitoring of neutrophils and white cell counts for four weeks at the end of the treatment is necessary only in case of cessation of all clozapine treatment.**

Due to a significant risk of agranulocytosis, patients on clozapine and their treating physicians and dispensing pharmacists have to be enrolled in registries, which are currently specific to each market authorization holder. Patients must undergo regular haematological tests to

monitor their total white blood-cell and absolute neutrophil counts. Between 1991 and 2003, clozapine was distributed by a single manufacturer, and patients were monitored by this manufacturer's specific registry. The introduction of generic clozapine in the last year has led to the establishment of other registries.

After consultations with representatives from market authorization holders, the Canadian Psychiatric Association (CPA), the Schizophrenia Society of Canada and the National Association of Pharmacy Regulatory Authorities (NAPRA), Health Canada is taking the following steps to ensure the safe use and continuous monitoring of patients taking clozapine in Canada:

- inclusion of a statement in the registry-specific Patient Registration Form signed by the treating physician certifying that the patient has been informed of the necessary sharing of information between clozapine registries to enable continuous monitoring and safe use of the medication. The inclusion of this text in the Patient Registration Form is necessary to overcome ongoing problems with the exchange of information between registries, caused in part by some potential implications of the "Personal Information Protection and Electronic Documents Act" (PIPEDA), the federal legislation protecting personal information in the private sector, including health information. As a preventive measure and to avoid any confusion, physicians may also ask patients already on clozapine to fill out the updated Patient Registration Form.
- A "Questions and Answers" patient information leaflet, prepared in collaboration with the Schizophrenia Society of Canada, is also provided to help physicians to document the actual consent from the patient on information exchange between registries.
- Appropriate revision of clozapine Product Monographs to reflect the above.

Any questions related to a clozapine product or a registry should be directed to the company concerned. Any further questions on clozapine Products Monographs' updates should be addressed to the Therapeutic Products Directorate (TPD), by phone: (613) 957-0368, by fax: (613) 952-7756 or by email: TPD-General-DPT-Général@hc-sc.gc.ca. Any further questions related to this letter should be addressed to the Marketed Health Products Directorate (MHPD): (613) 946-5140, by fax: (613) 946-6011 or by email: mhpd_dpssc@hc-sc.gc.ca.

The implementation of these steps will permit the achievement of a more efficient network of independent registries, and therefore improve the continuity of care of patients treated with clozapine.

We thank you in advance for your collaboration in the implementation of these changes.

original signed by

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Marketed Health Products Directorate

original signed by

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Q & As Regarding Patient Consent for information sharing

1. Why does my blood need to be monitored if I am taking clozapine?

Clozapine has been associated with a serious condition that reduces white blood cell counts (agranulocytosis). Due to the risk of developing this condition, regular blood testing of white blood cell counts must take place for individuals on clozapine, to ensure that the white blood cell counts remains within the normal range.

2. Why does my doctor need my consent?

The medication you are taking, clozapine, is produced by several different suppliers. Each supplier has a different monitoring system to ensure patient safety. Should your doctor and/or pharmacist (with the approval of your doctor) change the brand of clozapine you are taking, you will be transferred to a different monitoring system. If this happens, it is very important that your new supplier is able to access your past white blood cell counts results in order to help your doctor ensure that you are properly monitored.

It is also important to check with all registries at the start of the treatment that you have not experienced in the past a decrease of your white blood cell count with clozapine. Your consent is needed to allow this verification and sharing of information to take place.

3. Why is personal information such as my initials, birth date, gender and health card number being collected and used for identification purposes?

This information will be collected and used for several reasons. Since this information is specific to you, it helps to ensure that your test results are not mixed up with those of another person on the same medication. Using this information also avoids the need to use your full name and therefore protects your privacy.

4. Can my personal information be used for other purposes?

No. Your information will only be used to ensure that you are properly monitored while using any brand of clozapine.

5. Where can I find information on the protection of health related personal information in the private sector?

Information on this topic can be found on the website of Industry Canada, at the following address:

<http://www.e-com.ic.gc.ca/epic/internet/inecic-ceac.nsf/en/gv00235e.html>.