

Please fax completed form to (416) 327-7526 or toll-free 1 866 811-9908 or mail to the above address. (Do not mail if request is faxed).

The Ministry of Health and Long-Term Care (the "Ministry") considers requests for coverage of drug products not listed in the Ontario Drug Benefit Formulary under Section 8 of the *Ontario Drug Benefit Act*, R.S.O. 1990 c. O.10 (Individual Clinical Review). This form is intended to facilitate requests for Plavix under Section 8. The ministry may request additional documentation to support the request. Please ensure that all appropriate information for each section is provided to avoid delays.

Section 1 – Prescriber Information		Section 2 – Patient Information	
First name	Last name	First name	Last name
Mailing address Street no. Street name			
City		Postal code	
Fax no. ()	Telephone no. ()	Date of birth	Health Number

- Initial request** (complete part 1 or 3 below)
 Renewal request (previous Section 8 approval) (complete part 1 below)
 Ongoing therapy (previously met Limited Used criteria) (complete part 2 below)

Section 3 – Clinical Information (attach an additional sheet to provide other relevant information or if more space is required)

- 1. Secondary prevention of vascular ischemic events** – the patient experienced the following clinically significant vascular event:
- myocardial infarction
 unstable angina
 peripheral vascular surgery
 stroke/transient ischemic attack
 peripheral vascular disease with gangrene
 other (specify) _____

Date of vascular event: _____

Rationale for Plavix use:

- patient had the above vascular event while being treated with ASA or ticlopidine
 patient is intolerant or allergic to ASA or ticlopidine (describe the intolerance or allergy) _____
 other (specify) _____

2. Ongoing therapy (previously met Limited Use criteria)

Current Limited Use (LU) criteria allow for **up to 12 months** of coverage for patients immediately post-hospitalization for non-ST segment acute coronary syndrome (ACS) **OR** immediately pre- or post-percutaneous coronary intervention (PCI).

Rationale for ongoing Plavix use beyond twelve months:

3. Other (provide rationale for use and relevant clinical information including concomitant medications)

Diagnosis _____ Date of vascular event _____

Other information _____

The information on this form is collected by the Ministry of Health and Long-Term Care under the authority of s.13 of the Ontario Drug Benefit Act R.S.O. 1990 c. O.10. The information is collected for the purpose of considering whether special coverage of an unlisted drug should be approved under section 8 of the *Ontario Drug Benefit Act*, and will be used and disclosed for this purpose. It may also be used and disclosed for the administration of the Ontario Drug Benefit program. If you have any questions about the collection of this information, call the Ontario Drug Programs Help Desk at 1 800 668-6641 or contact the Director, Drug Programs Branch, 5700 Yonge St., 3rd Floor, Toronto ON M2M 4K5.

Prescriber signature	CPSO number	Date
_____	_____	_____

Ontario Drug Benefit (ODB) Plan Plavix (clopidogrel) Reimbursement

Limited Use listing for ACS and PCI

The Drug Quality and Therapeutics Committee (DQTC) has recommended that Plavix (clopidogrel) be listed as a Limited Use (LU) benefit in the Formulary for certain indications. This change takes effect September 4, 2003.

In light of the data from the CURE, PCI-CURE, and CREDO trials, the DQTC felt that the evidence supports the efficacy of clopidogrel for peri or post-percutaneous coronary interventions (PCI) as well as for acute coronary syndromes (ACS), including non-ST elevation myocardial infarction and unstable angina. The DQTC noted that clopidogrel, in combination with daily ASA therapy, appears to be cost-effective for these indications. The committee further noted that there is currently no published evidence to support the use of clopidogrel beyond 12 months for either PCI or ACS.

Limited Use criteria (effective September 4, 2003):

375 For patients immediately post-hospitalization* for non-ST segment elevation acute coronary syndrome (ACS)**:
Note: approval for 12 months

376 For patients immediately pre- or post- percutaneous coronary intervention (PCI)***:
Note: approval for 12 months

* The first prescription must be written by a physician at the hospital where the patient was hospitalized.

** ACS, as defined by the CURE study, includes hospitalized patients with unstable angina or non-ST segment elevation myocardial infarctions.

*** Therapy may be initiated up to 10 days prior to PCI.

While the first prescription must be written by a physician based at the hospital where the patient was hospitalized, subsequent prescriptions may be written by any physician responsible for the patient's ongoing care. The hospital must be identified on the first prescription as this information is required by the dispensing pharmacist to allow the patient to receive an initial supply of medication.

The Health Network System (HNS) will limit patients to a maximum of 365 days supply under the LU criteria. The LU approval will remain active on the HNS for 14 months to allow patients adequate time to obtain this supply. Patients who experience recurrent events within this 14 month period will still be limited to the maximum 365 day supply. Once the 14 month period has elapsed, a new LU prescription may be written if applicable. For patients who do not qualify for continued reimbursement under the LU criteria, additional coverage may be considered under the Individual Clinical Review (Section 8) mechanism.

Individual Clinical Review (ICR, Section 8)

Patients who do not qualify for Limited Use reimbursement of clopidogrel may still obtain coverage through the ICR mechanism. ICR requests are considered for the following indications:

- Secondary prevention of vascular ischemic events for patients who have experienced a vascular ischemic event while being treated with ASA or ticlopidine.
- Secondary prevention of vascular ischemic events for patients who are intolerant or allergic to ASA or ticlopidine.

Requests for other indications may be considered on a case-by-case basis. Please submit appropriate clinical information for consideration. *The ministry has prepared an ICR request form for clopidogrel which is on the reverse of this notice.* Copies may be viewed and downloaded from www.health.gov.on.ca/english/public/forms/form_menus/odb_fm.html or ordered by calling 1 888 310-9008. It is important to ensure all of the relevant patient information is provided. If not, consideration of your request may be delayed. Please note that ICR coverage cannot be made retroactive. Please send requests by Fax to (416) 327-7526, or toll-free 1 866 811-9908.

Cost comparison of Antiplatelet Drugs

Drug/comparator	Price (\$)	Average daily use	Average annual cost (\$)
Plavix	2.4000	75mg daily	876.00
Aggrenox*	0.7750	200mg/25mg bid	565.75
Ticlopidine*	0.6885	250mg bid	502.61
ASA EC 325mg	0.0147	325mg daily	5.37

*Listed as a Limited Use benefit. The reimbursement criteria are available in the current edition of the formulary. Please refer to the individual product monographs for prescribing information.

Please refer to the Fall 2003 Drug Programs Branch bulletin for a more detailed discussion. Your feedback is welcomed. References are available upon request. Please contact us at:

Drug Programs Branch
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