

NOTICE FROM THE EXECUTIVE OFFICER

February 17, 2012

RE: Important Notice Regarding Change in Funding Status of Oxycodone Controlled Release Tablet – (Discontinuation of OxyContin and introduction of OxyNEO)

Effective March 1, 2012 Purdue Pharma is withdrawing its current formulation of oxycodone controlled release tablet, OxyContin, and introducing OxyNEO.

I am writing to inform you of the changes that the Ministry of Health and Long-Term Care (“ministry”) will implement as a result of the introduction of OxyNEO. These changes are based on extensive discussions with practicing pain specialists, addiction experts and other health care providers, and are designed to balance appropriate use, patient care and the growing problem of opioid addiction in Ontario.

We have developed a list of questions and answers below to facilitate an understanding of this new change. We encourage you to read this document in its entirety, as it sets out important information that relates to a number of Ontario Drug Benefit (ODB) Formulary listing changes for oxycodone controlled release tablets that will come into effect on **February 29, 2012**.

Frequently Asked Questions

1. What is the Ontario Drug Benefit (ODB) funding status of OxyContin and OxyNEO?

Effective February 29, 2012, the ministry will remove OxyContin from the Ontario Drug Benefit Formulary/Comparative Drug Index (“ODB Formulary”). **OxyNeo will be funded through the Exceptional Access Program (EAP) and through the Facilitated Access to Palliative Care Drugs mechanism.** There will also be a one-year transition period for patients currently receiving OxyContin. Details are provided below.

Existing ODB recipients of OxyContin:

ODB recipients who have had a claim submitted to the ODB program for OxyContin between September 1, 2011 and February 28, 2012, will receive automatic coverage for OxyContin for 1 month. All coverage for OxyContin will cease on April 2, 2012. In addition, these patients will receive automatic coverage for OxyNEO (10mg, 15mg, 20mg, 30mg, 40mg and 80mg) for a period of one year (February 29, 2012 to February 28, 2013).

If coverage for OxyNEO is required beyond February 28, 2013, an EAP approval will be required. (*Please see EAP criteria for OxyNEO below.*)

Prescribers are asked to note that the current turnaround time for EAP requests is approximately three months. For patients in whom OxyNEO continues to be an appropriate therapy, it is recommended that prescribers submit EAP requests to the ministry at least three months in advance of February 28, 2013. The ministry will send out reminder notices throughout the year.

All other ODB patients requiring OxyNEO:

For all other ODB patients requiring oxycodone controlled release tablet starting February 29, 2012, OxyNEO will be funded as follows:

(1) Exceptional Access Program (EAP)

OxyNEO 10mg, 15mg, 20mg, 30mg and 40mg tablets will be considered through the EAP for patients with chronic pain according to the following criteria:

New Patients

- For the treatment of chronic pain in patients who have experienced intolerance or have failed an adequate trial (for example, three months) of at least one other listed long-acting opioid product.

Note: Physicians should consider best practice guidelines for the safe and effective use of opioids in chronic non-cancer pain, such as the Canadian Guideline for Safe and Effective Use of Opioids for Chronic Non-Cancer Pain (available at: <http://nationalpaincentre.mcmaster.ca/opioid/>).

The diagnosis for which the pain management is required must be documented;

All concomitant pain medication therapy must be documented;

Other medications with potential for abuse or interaction with opioid therapy should be documented.

Renewals

- Treatment continues to be appropriate for the management of the patient's chronic pain.

All concomitant pain medication therapy must be documented;

Other medications with potential for abuse or interaction with opioid therapy should be documented.

Note: OxyNEO 60mg and 80mg tablets are not funded.

Approval period: one year (new and renewals)

(2) Facilitated Access to Palliative Care Drug Products (Part VI-b of the ODB Formulary)

OxyNEO 10mg, 15mg, 20mg, 30mg, 40mg and 80mg tablets for cancer patients or palliative care patients for whom the prescriber is registered on the Palliative Care Facilitated Access List will be funded with the following criteria:

- For the treatment of cancer-related pain, or pain in patients receiving end-of-life palliative care; AND
- The patient has experienced intolerance or has failed an adequate trial (for example, three months) of at least one other listed long-acting opioid product.

Note: For reimbursement of OxyNEO via the Facilitated Access mechanism, prescribers must be registered on the Palliative Care Facilitated Access List. To facilitate the reimbursement process at the pharmacy, the prescriber is asked to indicate “Cancer”, “Palliative” or “P.C.F.A.”, on the prescription to signify that the patient meets the above-noted eligibility criteria. This would be an indication to the pharmacist that these medications may be reimbursed under this mechanism.

Note: If prescriber is not registered on the Palliative Care Facilitated Access List, a request for funding of OxyNEO must be made through the EAP process based on the EAP criteria noted above.

Note: OxyNEO 60mg tablets are not funded.

Approval period: one year

Additional information on the Facilitated Access Mechanism can be found on Part VI of the ODB Formulary.

2. Why are the 60mg and 80mg strengths of OxyNEO not being funded through the Exceptional Access Program (EAP)?

The ministry noted that the "watchful dose" recommended in the *Canadian Guideline for Safe and Effective Use of Opioids for Chronic Non-Cancer Pain* is 200mg/day morphine equivalent. The guideline states that “the potential for adverse psychological and physical effects, the potential for misuse, and questionable efficacy are all factors that should be considered in limiting the dose and increasing the frequency of follow-up visits. Some studies reported safety concerns or questionable efficacy of higher daily doses of opioids.” (<http://nationalpaincentre.mcmaster.ca/opioid>)

As part of the review for OxyNEO, the Committee to Evaluate Drugs (CED) noted that the 60mg and 80mg strengths, when used twice daily, would approach or exceed this watchful dose. Because of these concerns and the availability of alternative opioids, the CED recommended that the 60mg and 80mg strengths of OxyNEO not be funded for chronic non-cancer pain.

3. Why is the ministry making the Ontario Drug Benefit (ODB) funding of oxycodone controlled release tablet more restrictive?

Recent studies suggest that increased rates of opioid prescribing, particularly oxycodone, is contributing significantly to opioid-related harms and deaths. Issues identified in these studies include excessive prescribing, escalating misuse, escalating diversion of drugs away from intended medical purposes, increases in addictions, and increases in opioids-related deaths.

Ontario has the highest rate of narcotics use in Canada. Between 1991 and 2009, the number of prescriptions in Ontario for oxycodone drugs rose by 900 per cent. Each year in Ontario, between 300 and 400 people die from overdoses involving prescription opioids. The opioid most commonly found on post-mortem analyses in recent years is oxycodone.

Furthermore, analyses conducted by the ministry on the prescribing and utilization of oxycodone controlled release tablets through the ODB Program found that the majority of utilization of this drug is outside the current Limited Use criteria.

With the introduction of OxyNEO, the ministry consulted its expert advisory committee, the Committee to Evaluate Drugs (CED), on how the ODB Program should fund this drug. The CED noted that while the new OxyNEO formulation is reported to be more tamper-resistant, concerns remain about the safety of OxyNEO and the significant potential for misuse or overuse by ingesting the tablet whole. The CED noted that listing OxyNEO as a Limited Use benefit will make it easily accessible and allow for continued misuse or overuse resulting in opioid-related harm, similar to that observed with OxyContin. The CED recommended that OxyNEO be funded through the Exceptional Access Program (EAP) according to specific criteria.

Based on the CED's recommendation and discussions with pain specialists, addiction experts and other health care professionals, the ministry is moving forward with restricted funding for OxyNEO as outlined above.

The ministry will continue to monitor the utilization of oxycodone and other opioids to determine if further actions and changes are warranted.

4. What is the Exceptional Access Program?

The Exceptional Access Program (EAP) facilitates patient access in exceptional circumstances to drugs not listed on the Formulary or where Formulary drugs were ineffective, not tolerated, or where no listed alternative was available. To apply through the EAP, a physician must submit a request documenting complete and relevant medical information to the ministry, and provide the clinical rationale for requesting the unlisted drug and reasons why covered benefits are not suitable. All requests are reviewed according to the guidelines recommended by the CED and approved by the Executive Officer, and include a thorough assessment of the patient's specific case and clinical circumstances, as provide by the physician, as well as the available scientific evidence.

For more information about the EAP, please visit the ministry website at:
http://www.health.gov.on.ca/english/providers/program/drugs/eap_mn.html

5. What is the Facilitated Access mechanism?

Specific products used to treat ODB-eligible patients undergoing palliative care are reimbursed under the Ontario Public Drug Programs, through its Facilitated Access process. Under this process, a select group of participating physicians are exempt from obtaining approval under Exceptional Access Program (EAP).

In order to participate in the Facilitated Access to Palliative Care Drugs process, physicians must be registered by the Ontario Medical Association (OMA) and must meet pre-defined criteria as determined by the OMA. Physicians who are not registered through this process must obtain approval for OxyNEO through the EAP.

To facilitate the reimbursement process for OxyNEO at the pharmacy, the prescriber is asked to indicate “Cancer”, “Palliative” or “P.C.F.A.”, on the prescription to signify that the patient meets the above-noted eligibility. This would be an indication to the pharmacist that these medications may be reimbursed under this mechanism.

For further information regarding the list of physicians and/or the criteria physicians require to be included on the list, please contact Dr. Howard Burke, c/o Ina Nesbitt, Ontario Medical Association: (416) 340-2234, or via email at Ina.Nesbitt@oma.org

6. If a patient has a prescription for OxyContin, is the pharmacist able to interchange/substitute the prescription for OxyNEO?

No. In Ontario, OxyNEO and OxyContin have not been designated as interchangeable. Therefore, a new prescription for OxyNEO would be required in this case.

7. What is the pharmacy process for submitting Ontario Drug Benefit (ODB) claims for OxyNEO?

If the patient has an EAP approval for OxyNEO, a claim may be submitted to the ODB program through the normal process using the approved DIN(s).

If the patient is receiving OxyNEO through the Facilitated Access (FA) mechanism, the dispenser must use the PINs outlined below when submitting the claim. When a FA claim is submitted, the Health Network System will validate the prescriber identification (through the prescriber’s licence number).

PIN	Product
09857408	OxyNEO 10mg CR Tab
09857409	OxyNEO 15mg CR Tab
09857410	OxyNEO 20mg CR Tab

09857411	OxyNEO 30mg CR Tab
09857412	OxyNEO 40mg CR Tab
09857413	OxyNEO 80mg CR Tab

To facilitate the reimbursement process for OxyNEO at the pharmacy, the prescriber is asked to indicate “Cancer”, “Palliative” or “P.C.F.A.”, on the prescription to signify that the patient meets the above-noted eligibility. This would be an indication to the pharmacist that these medications may be reimbursed under this mechanism. A list of prescribers currently registered through the Facilitated Access to Palliative Care Drugs process will be sent to pharmacies through the OneMail system.

8. Who can I contact if I have additional questions?

If you require further clarification or have questions regarding this matter, please send your question(s) to PublicDrugPrgrms.moh@ontario.ca or call the telephone numbers provided below.

For pharmacies:

Please call ODB Pharmacy Help Desk at: 1-800-668-6641

For all other Health Care Providers and the Public:

Please call ServiceOntario, Infoline at 1-866-532-3161

TTY 1-800-387-5559.

In Toronto, TTY 416-327-4282