

NOTICE FROM THE EXECUTIVE OFFICER

February 4, 2013

RE: FINAL Reminder Regarding the Funding Status of Oxycodone Controlled Release Tablet – OxyNEO

This is a reminder that the automatic coverage (“grandfathering”) of OxyNEO (oxycodone controlled release tablet) for Ontario Drug Benefit (ODB) recipients who were previously receiving OxyContin ends **February 28, 2013**. This notice outlines the requirements to obtain continued coverage for OxyNEO beyond this date.

Effective March 1, 2013, an approval under the Exceptional Access Program (EAP) will be required for OxyNEO coverage. A request must be submitted to the EAP and patients must meet the funding criteria. *(Please see the EAP criteria for OxyNEO below).*

The Ministry is accepting EAP requests for continued funding. Please note that the turnaround time for EAP requests varies according to the volume of requests received and other factors. To prevent an interruption in coverage for recipients for whom OxyNEO continues to be an appropriate therapy, **prescribers should submit EAP requests to the ministry immediately to request coverage beyond February 28, 2013.**

We have developed a list of questions and answers below regarding the funding status of OxyNEO. This may assist you in determining the requirements for ongoing funding of OxyNEO for your patient after the automatic coverage period ends on February 28, 2013. We encourage you to read this document in its entirety.

Questions & Answers

What is required for ODB recipients who were transitioned from OxyContin to OxyNEO under the ODB program?

ODB recipients who had been reimbursed for OxyContin in the 6 months prior to February 29, 2012 received automatic coverage for OxyNEO for a period of one year. If coverage for OxyNEO is required beyond February 28, 2013, an EAP approval will be required AND recipients must meet the criteria for “Initial Requests” described below, including documentation of the prior use and failure or intolerance with one other listed long-acting opioid therapy. Subsequent requests must meet the criteria for “Renewal Requests”.

Is OxyNEO 80mg funded for any ODB recipient under the Exceptional Access Program (EAP)?

No. This strength is only available to cancer patients or palliative care patients under the

Facilitated Access mechanism.

What is the Ontario Drug Benefit (ODB) funding status of OxyNEO?

OxyNEO is funded through the Exceptional Access Program (EAP) and through the Facilitated Access to Palliative Care Drugs mechanism.

(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:

Initial Requests

- 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 (*the name of the previous product and reason for discontinuation must be documented on the request*).

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.*

Renewal Requests

- 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 (initial and renewal requests)

(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 the 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 (no renewals)

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

Why are the 60mg and 80mg strengths of OxyNEO not 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.

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

What is the Facilitated Access mechanism?

Specific products used to treat ODB-eligible recipients receiving palliative care are reimbursed under the Ontario Public Drug Programs, through its Facilitated Access process. Under this process, certain physicians are exempt from obtaining approval for these products 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 a period of up to one year. After the first year, ongoing OxyNEO coverage must be requested through the EAP.

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 Carlene Nash, Ontario Medical Association, (416)599-2580 ext. 3265 or Toll free: 1-800-268-7215 ext. 3265 Fax: (416) 340-2944. Web: www.oma.org

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

If an ODB recipient 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 an ODB recipient 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 for a period of up to one year. After the first year, ongoing OxyNEO coverage must be requested through the EAP.

Is generic oxycodone funded through the Exceptional Access Program (EAP)?

No. Generic long-acting oxycodone products are not available for public funding. Moreover, there are no generic long-acting oxycodone products that have been deemed interchangeable with OxyNEO or OxyContin.

For more information regarding the new regulatory requirements for long-acting oxycodone drug products, please visit the ministry website at:
http://www.health.gov.on.ca/en/public/programs/drugs/ons/oxy_faq.aspx

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