HYDROMORPHONE HCL PROLONGED RELEASE

**Indication(s)**
The management of moderate to severe chronic pain in adults who require around the clock treatment.

**DAC Recommendation**
The Drug Advisory Committee (DAC) has recommended that hydromorphone HCL prolonged release (PR) NOT be listed on any WSIB formulary as there are no trials providing evidence that it demonstrates an advantage to long-acting opioids comparators currently listed on WSIB formularies.

**The WSIB Decision**
Based on the DAC’s recommendation, the WSIB has decided NOT to list hydromorphone HCL PR (Jurnista®) on any WSIB formulary.

**Formulary Status**
Hydromorphone HCL PR (Jurnista®) is not listed on any WSIB formularies at this time.

**Recommendation Highlights**
- Hydromorphone HCL prolonged release (PR) is a long-acting opioid marketed under the brand name Jurnista®.
- A systematic review by the Common Drug Review (CDR) of one randomized controlled trial concluded that there was a lack of evidence demonstrating any therapeutic advantage for hydromorphone HCL PR compared with other less-costly long-acting opioid formulations.
- There is no evidence demonstrating any safety advantage for hydromorphone HCL PR compared to any other long-acting opioid formulations.
- There is a lack of evidence to support the effect hydromorphone HCL PR on clinically important outcomes such as quality of life and function in patients with chronic pain compared to other long-acting hydromorphone formulations.
- There is a lack of evidence to support that the OROS® osmotic controlled-release delivery technology for hydromorphone HCL PR is associated with a lower risk of abuse compared to other opioids.
- Hydromorphone HCL PR is more costly than Hydromorph Contin® and most other long-acting opioid formulations.
- The DAC concluded that the CDR review of the clinical efficacy, safety, and cost-effectiveness of hydromorphone HCL PR did not indicate any therapeutic or non-therapeutic advantage over appropriate long-acting opioid comparators available in Canada. Consequently, the DAC recommended that hydromorphone HCL PR (Jurnista®) NOT be listed on any WSIB formulary.
Background

Hydromorphone is a semi-synthetic morphine derivative which binds to opioid receptors in the CNS and other tissues, producing various pharmacological effects, including pain relief.

Hydromorphone hydrochloride prolonged-release (PR) is marketed by Janssen Ortho Inc in Canada under the brand name of Jurnista®. It is approved for the treatment of moderate to severe chronic pain in adults requiring around the clock treatment.

Summary of Committee Considerations

The DAC considered a systematic review by the Common Drug Review (CDR) and the recommendation of the Canadian Expert Drug Advisory Committee (CEDAC). The CDR is part of the federally and provincially funded Canadian Agency for Drugs and Technologies (CADTH) and was set up to provide objective, rigorous reviews and evidence-based listing recommendations for participating Canadian public drug plans.

The CDR review included one double-blind randomized controlled trial. This trial is unpublished and was sponsored by the manufacturer. A total of 169 adult patients with chronic pain were included in the study. To be eligible, patients required strong oral or transdermal opioids, or were suitable to advance to step three of the WHO analgesic ladder. Types of pain reported by enrolled patients included musculoskeletal (57%), neuropathic (35%), sympathetic (55%) and cancer pain (2%).

A two-week run-in phase stabilized patients on hydromorphone immediate-release. Those patients (n=113) who achieved a stable dose between 20mg and 60mg daily, and had three or fewer rescue doses for two consecutive days were then further randomized into three groups. One group (n=34) continued at the same dose using hydromorphone HCL PR (Jurnista®). Another group (n=40) received half their dose of hydromorphone HCL PR. The third group (n=39) continued on the same dose of immediate-release hydromorphone. This portion of the study was conducted for seven days.

The primary outcome for this trial was the change in total daily use of breakthrough pain medication. Reduction in pain and adverse events were also identified a priori and were reviewed. The use of breakthrough medication increased in all groups, with no significant difference between groups. There were no statistically significant differences between groups for any other efficacy outcomes. Quality of life, treatment compliance, and functional outcomes were not assessed. The trial did not measure abuse and diversion potential.

Adverse events for the immediate- and prolonged-release hydromorphone groups were similar.

No trials assessing cost or cost-effectiveness were included.

The CDR noted that although hydromorphone HCL PR is the only hydromorphone product approved for once-daily use, there is no evidence demonstrating improved compliance or quality of life with once-daily versus twice-daily dosing (e.g., Hydromorph Contin®).

The Canadian Expert Drug Advisory Committee (CEDAC) has recommended that hydromorphone HCL PR not be listed on provincial formularies. The Ontario Drug Benefit Program does not fund hydromorphone HCL PR as a general benefit.

Based on the available evidence, the DAC concluded that there was no compelling evidence demonstrating a therapeutic or non-therapeutic advantage for hydromorphone HCL PR over other available opioid formulations. There are numerous other opioids available through the WSIB Drug Benefit Program that meet the needs of the majority of injured/ill workers. Therefore, the DAC recommended that hydromorphone HCL PR (Jurnista®) not be listed on any WSIB formulary.

Revised: January 29, 2013