

Drug formulary listing decision - NABILONE

NABILONE

Indication(s)

The management of severe nausea and vomiting associated with cancer chemotherapy.

Formulary Status

The Drug Advisory Committee (DAC) recommended that generic nabilone (0.5mg and 1mg capsules) be listed on Musculoskeletal (02WS), Central Nervous System/Peripheral Nervous System (03WS), Burn (05WS), Cancer (19WS) and Serious Injury Services (27WS) formularies.

WSIB accepts the DAC recommendation for listing.

Recommendation highlights

- Nabilone is a synthetic cannabinoid which acts as an agonist at endogenous cannabinoid receptors.
- Nabilone has an official indication for chemotherapy-associated nausea and vomiting, but has been used off-label for treatment of neuropathic pain associated with musculoskeletal injury, spinal cord injury and psychiatric indications such as post-traumatic stress syndrome (PTSD).
- External, independent reviews of randomized controlled studies in 2009 and 2016 have shown that, compared to placebo, nabilone demonstrated limited efficacy in treatment of fibromyalgia pain; improved select measures of spasticity after spinal cord injury; and produced mixed results in patients with anxiety or PTSD-related nightmares, conditions relevant to WSIB. In studies using an active comparator, nabilone was somewhat efficacious for sleep disturbance in fibromyalgia (comparator amitriptyline) and offered a modest clinical effect on neuropathic pain (comparator dihydrocodeine). Limitations in trial design make the possible therapeutic advantages of nabilone inconclusive. There were no new randomized controlled studies since the last review.
- Canadian Pain Society 2014 Consensus Statement on Chronic Neuropathic Pain

classifies nabilone as a third-line agent for the management of chronic neuropathic pain, and the College of Family Physicians 2018 Simplified Guidelines for Medical Cannabinoids suggest nabilone may be used for refractory neuropathic pain if more than three other prescribed analgesics have failed to provide adequate treatment of pain symptoms. There are no guidelines published that consider or endorse nabilone as treatment option for PTSD or other psychiatric indications.

- Nabilone has a significant side effect profile, and a discussion with patients regarding the safety and appropriateness of nabilone is recommended prior to initiating therapy. Health Canada has issued a warning on the use of cannabis and cannabinoids due to possibility of physical and psychological dependence, cognitive and memory impairment and changes in mood. There is also potential for drug interaction with other central nervous system depressants.
- While the daily cost of generic nabilone is more than typical first- or second-line therapeutic agents for the treatment of neuropathic pain, 0.5 and 1 mg capsules are considered within reason for allowing expanded access as a third-line agent.
- Nabilone (0.5mg and 1mg capsules) is covered by the Ontario Drug Benefit Program.
- Based on the published evidence and guideline recommendations, the DAC recommended generic nabilone be listed on formularies accessed by those with neuropathic pain, spinal cord injuries, burns, cancer and serious injuries.

Products available in Canada:

Nabilone 0.25 mg, 0.5 mg and 1 mg capsules (Cesamet® and generics)