

Drug formulary listing decision – BUPRENORPHINE IN TREATMENT OF CHRONIC PAIN

BUPRENORPHINE TRANSDERMAL PATCH - BUTRANS® AND BUPRENORPHINE BUCCAL SOLUBLE FILM - BELBUCA®

Indication(s)

The management of pain severe enough to require daily, continuous, long-term opioid treatment that is opioid-responsive and for which alternative options are inadequate.

Formulary Status

The Drug Advisory Committee (DAC) recommended that buprenorphine transdermal patch and buprenorphine buccal soluble film not be listed on any WSIB formularies.

WSIB accepts the DAC recommendation for listing.

Recommendation highlights

- Buprenorphine is an opioid with mixed agonist-antagonist activity at opioid receptors.
- Buprenorphine transdermal patch and buccal film have been investigated and approved for the treatment of chronic pain only; as such, they are not indicated for the treatment of opioid use disorder.
- The DAC considered external, independent reviews of randomized-controlled trials of buprenorphine transdermal patch and buprenorphine buccal film in treatment of chronic pain in its decision. The magnitude of analgesic effect of buprenorphine transdermal patch relative to placebo is small. Buprenorphine transdermal patch has been demonstrated non-inferior to other opioids, but there are no published head-to-head comparative trials. The evidence for efficacy of buprenorphine buccal film is limited to one trial that met inclusion criteria but remains unpublished.
- Main adverse effects of buprenorphine transdermal patch and buccal film are similar to

other opioids with reported lower incidence of constipation. The unique mixed agonist-antagonist activity of buprenorphine may contribute to a lower incidence of respiratory depression.

- Guidelines indicate that there is lack of evidence to recommend buprenorphine transdermal patch or buccal film over other opioids.
- There is also insufficient evidence at this time to support using buprenorphine over other opioids during opioid tapering and discontinuation attempts.
- Results from published pharmacoeconomic analyses of buprenorphine in chronic pain are likely not relevant to the Canadian working population covered by WSIB and the analyses had many methodological flaws.
- The daily cost of both buprenorphine transdermal patch and buccal film is generally higher than for other opioids.
- Both buprenorphine transdermal patch and buccal film are not covered by Ontario Drug Benefit Program.
- In summary, based on published evidence, jurisdictional review, guidelines' review and cost analysis provided in the external reviews, DAC recommended that buprenorphine transdermal patch and buprenorphine buccal film NOT be listed on any WSIB formularies.

Products available in Canada:

- Buprenorphine transdermal system (BuTrans®) 5 mcg/hr, 10 mcg/hr, 15 mcg/hr, 20 mcg/hr
- Buprenorphine buccal soluble film (Belbuca®) 75 mcg, 150 mcg, 300 mcg, 450 mcg, 600 mcg, 750 mcg, 900 mcg