

Drug formulary listing decision - HYPNOTICS

HYPNOTICS: ZOPICLONE, ZOLPIDEM, TRAZODONE AND TRYPTOPHAN

Indication(s)

Zopiclone and sublingual zolpidem (oral disintegrating tablet, ODT- Sublinox®): GABA agonists for short-term symptomatic relief of insomnia

Trazodone: symptomatic relief of depression

Tryptophan: essential serotonergic amino acid for adjunctive treatment of bipolar affective disorders

Formulary Status

The Drug Advisory Committee recommended that:

- (i) zopiclone and trazodone be listed on the Burn (05WS), Cancer (19WS) and Psychotraumatic (22WS) formularies
- (ii) tryptophan not be listed as a hypnotic on any WSIB formulary - it should continue to be listed on Psychotraumatic (22WS) formulary for the treatment of psychiatric disorders;
- (iii) and zolpidem ODT not be listed on any WSIB formulary.

WSIB accepts the DAC recommendation for listing.

Recommendation highlights

- ♦ External, independent reviews of randomized, controlled trials, systematic reviews and meta-analyses show few meaningful differences in efficacy between zopiclone, zolpidem and benzodiazepines.
- ♦ Although there are several published RCTs for oral zolpidem, which is not available in Canada, there were no studies comparing sublingual zolpidem against treatments for insomnia available in Canada
- ♦ Due to potential for dependence, complex sleep

behaviours and next-day psychomotor impairment, zopiclone and zolpidem should only be used short-term.

- ♦ Trazodone possesses sedative and antidepressant properties. It is associated with a lower risk of dependence and abuse.
- ♦ No rigorous evidence supporting the use of tryptophan in insomnia was located.
- ♦ Information on the efficacy of hypnotics to improve sleep parameters or increase productivity or functional ability in setting of work-related injury is unavailable.
- ♦ Current guidelines suggest use of hypnotics only after non-pharmacologic measures have been considered. Methodological issues limit the studies available to guide the choice of hypnotic.
- ♦ No pharmacoeconomic studies assessing the use of hypnotics were located. The Ontario Drug Benefit Program funds trazodone as general benefit and zopiclone under Exceptional Access Program. Zolpidem ODT (Sublinox®) and tryptophan are not covered. Zolpidem ODT is more costly than zopiclone, trazodone, tryptophan and benzodiazepines.
- ♦ The DAC concluded that: (i) zopiclone and trazodone may be useful in the short-term treatment of insomnia; and (ii) tryptophan and zolpidem ODT lack rigorous evidence for use in insomnia.

Products available in Canada:

Trazodone - Desyre[®], various generics
Tryptophan – various generics
Zopiclone- Imovane[®], various generics
Zolpidem - Sublinox[®], various generics