

Fentanyl

Product:

FENTANYL 12.5mcg/hr
TRANSDERMAL PATCH (Duragesic 12®)

Class of drugs:

Opioid analgesic (pain reliever)

Indication:

Control of moderate to
severe chronic pain

Manufacturer:

Janssen-Ortho Inc.

CED Recommendation

The CED recommended that fentanyl 12.5mcg/hr transdermal patch (Duragesic 12) not be listed on the Ontario Drug Benefit Formulary on the basis that there are other strengths of Duragesic patches available on the Formulary, and this strength is proportionately more expensive than the listed generic products at higher strengths.

Executive Officer Decision

Based on the CED's recommendation, the Executive Officer decided not to list the fentanyl 12.5mcg/hr transdermal patch (Duragesic 12).

Status

No funding through the Ontario Public Drug Programs.

Highlights of Recommendation:

- ◆ Fentanyl 12.5mcg/hr transdermal patch (Duragesic 12) is a new strength of the fentanyl skin patch and is used to treat chronic moderate-to-severe pain. Duragesic and generic fentanyl patches are currently listed on the Ontario Drug Benefit (ODB) Formulary in 25, 50, 75, and 100mcg/hr strengths.
- ◆ In general, fentanyl skin patches are used when oral long-acting pain medications cannot be used. Fentanyl 12.5mcg/hr transdermal patch (Duragesic 12) provides half the dose of the lowest strength fentanyl patch listed (25mcg/hr) and may be useful when starting treatment.
- ◆ Fentanyl 12.5mcg/hr transdermal patch (Duragesic 12), priced at \$4.25 per patch, provides 12.5mcg of fentanyl per hour. This is the same price as the 25mcg/hr generic fentanyl patch, which provides double the dose.
- ◆ **Overall, the Committee noted that there are other strengths of Duragesic patches available on the Formulary and this strength is not proportionately priced compared to the 25mcg/hr generic fentanyl patch.** Therefore, the Committee recommended that fentanyl 12.5mcg/hr transdermal patch (Duragesic 12) not be listed on the ODB Formulary.

Background:

Many different medical conditions can cause chronic pain. Standard treatment varies, according to the underlying cause of the pain, but very often it includes some form of drug therapy.

Fentanyl belongs to a group of medications called strong opioid analgesics, which are painkillers.

Fentanyl 12.5mcg/hr transdermal patch (Duragesic 12) is a thin, rectangular patch that a patient sticks on his or her skin. The patch delivers fentanyl to the bloodstream for constant pain control. It is intended for patients with chronic pain who require continuous treatment over a long period of time.

Fentanyl 12.5mcg/hr transdermal patch (Duragesic 12) is a new formulation of the existing product line of Duragesic patches, currently on the Formulary at higher strengths.

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Detailed Discussion:

- ◆ The manufacturer, Janssen-Ortho Inc., asked the Ministry of Health and Long-Term Care to consider listing the fentanyl 12.5mcg/hr transdermal patch (Duragesic 12) on the Ontario Drug Benefit Formulary.
- ◆ The patch delivers 12.5mcg of fentanyl per hour, although the product is labelled Duragesic 12 rather than Duragesic 12.5 to avoid potential confusion with the 125mcg/hour strength.
- ◆ The Committee questioned the clinical need for fentanyl 12.5mcg/hr transdermal patch (Duragesic 12) as a starting dose.
- ◆ The dose produced by the fentanyl patches can be manipulated by adjusting its contact area to the skin.
- ◆ The Committee noted that the use of fentanyl transdermal patches in Ontario has increased substantially over the past several years. The number of fentanyl transdermal patches prescribed appears to continue to exceed the usage the Committee would anticipate, based on the current Limited Use criteria.
- ◆ The proposed price in the manufacturer's submission for fentanyl 12.5mcg/hr transdermal patch (Duragesic 12) is \$4.25 per patch. With the introduction of generic fentanyl transdermal patches, the current Drug Benefit Price of generic fentanyl 25mcg/hr is also \$4.25 per patch. As such, Duragesic 12 is proportionately more expensive than the higher strengths of generic fentanyl patches on the Formulary.
- ◆ Common side effects include constipation, nausea, drowsiness and dizziness.
- ◆ Overall, the Committee recommended that the fentanyl 12.5mcg/hr transdermal patch (Duragesic 12) not be listed on the Formulary.

CEDAC Recommendation:

(<http://www.cadth.ca/index.php/en/cdr/recommendations>):

The Canadian Expert Drug Advisory Committee (CEDAC) did not review the fentanyl 12.5mcg/hr transdermal patch (Duragesic 12).



Ministry of
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