SECTION	SUBJECT		PAGE		
HIGH COST DRUG	Fentanyl patch (e.g. Duragesic® MAT)		1 of 4		
			YY	MM	DD
		Original	99	05	09
		Revised	07	04	10
		Revised	08	01	31
		Revised	16	01	28

PREAMBLE

Opioids are an important component of the pharmaceutical armamentarium for management of chronic pain. The superiority of analgesic effect of one opioid over another is not generally suggested by evidence; rather, agents tend to be differentiated clinically in terms of tolerance and ability to obtain desired analgesia without undue adverse effects.

Transdermal fentanyl (via patch) is different from other long-acting opioids in its mode of delivery and potency. It is a significantly potent opioid and is best reserved for individuals who either need a topical delivery form or who have not achieved therapeutic goals with other opioid analgesics.

Because serious or life-threatening hypoventilation could occur, transdermal fentanyl is not recommended in opioid-naïve patients, at any dose. Use in non-opioid tolerant patients, or initiating at a dose higher than the opioid equivalent to which the patient is tolerant at the time of the switch, may lead to fatal respiratory depression.

Note: Due to extensive information required for safe and effective use, the reader is referred to a current fentanyl patch product monograph for further drug information.

POINTS OF EMPHASIS

1. Fentanyl, like other opioids, is a high alert medication.

2. Health professionals responsible for care of a resident on fentanyl patches should accept responsibility for the safe use of this drug product. Physician, pharmacists and nurses should regularly familiarize themselves with the product monograph, best practice, and safety considerations, including knowledge of detection and management of respiratory depression, including the use of naloxone.

3. The fentanyl patch is not appropriate for mild to moderate, intermittent, or unstable pain where there is a requirement for titration to attempt to achieve pain control. Rapid titration is not recommended with fentanyl and should be avoided. The peak analgesic effect of the first dose takes 24-72 hours to be seen. For this reason, overlap with short-acting analgesics can be used as breakthrough until analgesic effect has been attained. It is also recommended that the fentanyl dose be titrated no sooner than three days after initial application, or six days after subsequent dosage increases.

4. It takes, on average, 17 hours or longer for the fentanyl serum levels to fall by 50% after patch removal. Thus, the effects of the medication can continue for 17-34 hours or more following removal due to the effect of a subcutaneous depot of fentanyl. Residents will require monitoring for at least 24 hours after downward titration or removal. This is particularly important following an adverse reaction.

SECTION	SUBJECT		PAGE		
HIGH COST DRUG	Fentanyl patch (e.g. Duragesic® MAT)		2 of 4		
			YY	MM	DD
		Original	99	05	09
		Revised	07	04	10
		Revised	08	01	31
		Revised	16	01	28

5. It is recommended fentanyl patches be used cautiously when used in combination with other opioid analgesics, CNS depressants or drugs that affect the metabolism of fentanyl (e.g. CYP 3A4 inhibitors increase or prolong the effect of fentanyl [e.g. erythromycin, clarithromycin, diltiazem, verapamil, amiodarone]). Concomitant use may result in an increase in fentanyl serum concentrations, adverse event or side effects.

6. Application of a heat source to the patch (*e.g.* heating pad, hot packs) may result in increased release and absorption because of increased skin permeability. Fever may also enhance this effect.

7. Despite that matrix-type patches have the ability to be cut, or that a partial dose can be achieved by occluding a portion of the patch with an impermeable material, this practice is **not recommended**. With opioids, exact dosing is critical and modification may result in unpredictable rate of delivery, inaccurate dosing, or accidental exposure to the drug. Modifying or altering fentanyl patches is not supported in the product monograph or by ISMP Canada.

8. It is recommended policies and procedures are in place to safely and securely receive, store, administer, and discard patches. The documentation process clearly communicates the date, time, and location of patch administration, and the date, time, and location of patch removal (*e.g.* by providing prompts on the MAR).

    i. Safe and secure disposal of fentanyl patches: upon removal from resident, immediately follow disposal procedures as stipulated by site policy and procedure. Only then should the new patch be placed on the resident. **The patch should never be placed temporarily on a bedside table or bed rail while applying a new patch, or disposed of in a garbage can.**

    ii. Fentanyl patches contain significant amount of drug. Accidental exposure to used (or unused) fentanyl patch can be especially harmful, and in some cases fatal.

9. It is recommended an alert be provided on the MAR for patients receiving more than one fentanyl patch (i.e. more than one fentanyl patch required to obtain the prescribed dose), and/or a different medication patch (e.g. nicotine, nitroglycerin, hormone replacement).

SECTION	SUBJECT		PAGE		
HIGH COST DRUG	Fentanyl patch (e.g. Duragesic® MAT)		3 of 4		
			YY	MM	DD
		Original	99	05	09
		Revised	07	04	10
		Revised	08	01	31
		Revised	16	01	28

PROTOCOLS

Fentanyl patches are approved for use under one of the following conditions:

Protocol 1

For treatment of persistent, severe chronic pain in residents who require continuous around-the-clock analgesia for an extended period of time, and who are already receiving opioid therapy at a total daily dose of at least 60 mg/day* oral morphine equivalents.

Patients must have tried and failed with at least two discrete courses of therapy with two of the following agents, unless contraindicated: morphine, hydromorphone and oxycodone.

- A failed opioid trial occurs when dosage titration to achieve pain control is not possible due to unacceptable or non-resolving side effects which are impairing function such as uncontrollable nausea & vomiting, distressing hallucinations, sedation, or cognitive impairment.
- A discrete course is defined as a separate treatment course, which may involve more than one agent, used during a period of time to manage the patient's pain.

*Some practitioners have used 30 mg/day oral morphine equivalents as a starting point, but that dosing is not supported in the product monograph and therefore not recommended by the P&T committee. Insufficient opioid tolerance may lead to fatal respiratory depression. See product monograph for further details[1].

Protocol 2

For ongoing management of persistent, severe, chronic pain in residents who have been stabilized on the fentanyl patch prior to admission to the facility. These residents are eligible for continued funding on the fentanyl patch upon a full review of the safety, appropriateness, and effectiveness of its use.

- The period of stabilization may vary with each resident; the physician and pharmacist should use clinical judgement to evaluate whether the resident has used transdermal fentanyl for sufficient duration prior to admission to the facility. Recent starts and opioid rotations within the previous 0-4 weeks should be reviewed carefully.
- If there is no indication for selecting transdermal fentanyl as the opioid drug and route of choice, opioid rotation to an oral agent could be considered.

PROCEDURE

Assessment and documentation in the patient record by a clinical pharmacist is required prior to initial drug provision (new admission or new start), change in fentanyl dose, change to other opioid therapy (scheduled opioids), and/or significant change in patient's status. The HCD-08 form is required to be submitted to AHS for initial drug provision and dose changes. By submitting the application, the care team and pharmacist have given reasonable consideration to consent, alternative therapeutic options

(including formulary alternatives), and risks/benefits. Compliance with the protocol and procedure is necessary for drug cost reimbursement.

FORMULARY LINKS

Fentanyl patch (HCD-08) Form

REFERENCES

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