DRUG QUANTITY MANAGEMENT POLICY - PER DAYS

POLICY: Fentanyl Transdermal Patch Drugs Duration Limit

DATE REVIEWED: 01/31/2021

DRUGS AFFECTED:

- fentanyl transdermal system – 12 mcg/hr, 25 mcg/hr, 37.5 mcg/hr, 50 mcg/hr, 75 mcg/hr, 100 mcg/hr (Duragesic® - Janssen Pharmaceutical, Inc., generics)
- fentanyl transdermal system - 12 mcg/hr, 25 mcg/hr, 37.5 mcg/hr, 50 mcg/hr, 62.5 mcg/hr, 75 mcg/hr, 87.5 mcg/hr, 100 mcg/hr - generics)

Table 1. Quantity Limits[1,2]

Medication Name and Strength	*Quantity per 30 days*
Duragesic (fentanyl) 12 mcg/hr, 25 mcg/hr, 37.5 mcg/hr, 50 mcg/hr, 75 mcg/hr, 100 mcg/hr	15 transdermal systems (patches)
Fentanyl transdermal system 12 mcg/hr, 25 mcg/hr, 37.5 mcg/hr, 50 mcg/hr, 62.5 mcg/hr, 75 mcg/hr, 87.5 mcg/hr, 100 mcg/hr	15 transdermal systems (patches)

OVERVIEW

The initial quantity limit supplies a sufficient quantity for the fentanyl transdermal system products to be utilized for the management of pain in patients, severe enough to require daily, around-the-clock, long-term opioid treatment in patients with a cancer diagnosis. This Drug Quantity Management Policy is designed to complement the coverage provided by *Opioids Long-Acting Prior Authorization Policy*.

The fentanyl transdermal system products are intended to be used only by healthcare professionals (oncologists and pain specialists) who are knowledgeable of and skilled in the use of Schedule II opioids to treat cancer pain. Fentanyl transdermal system products are contraindicated in the management of acute or postoperative pain and in non-opioid tolerant patients.[1-2]

The recommended starting dose when converting from other opioids to Duragesic is intended to minimize the potential for overdosing patients with the first dose. Concomitant use of opioids with benzodiazepines or other central nervous system (CNS) depressants, including alcohol, may result in profound sedation, respiratory depression, coma, and death. Concomitant prescribing of Duragesic/fentanyl transdermal systems and benzodiazepines or other CNS depressants should be reserved for use in patients for whom alternative treatment options are inadequate. Dosages and durations should be limited to the minimum effective. Patients should be followed for signs and symptoms of respiratory depression and sedation. Discontinue all other around-the-clock opioid drugs when Duragesic/fentanyl transdermal system therapy is initiated. While there are useful tables of opioid equivalents readily available, there is substantial inter-patient variability in the relative potency of different opioid drugs and products. As such, it is preferable to underestimate a patient's 24-hour fentanyl requirements and provide rescue medication (e.g., immediate release opioid) than to overestimate the 24-hour fentanyl requirements which could result in adverse reactions. There are tables available within the prescribing information that assist in converting patients from their existing opioid therapy to Duragesic/fentanyl transdermal system.

The dosing interval for Duragesic/fentanyl transdermal system is 72 hours. Do not increase the dose for the first time until at least 3 days after the initial application. Titrate the dose based on the daily dose of

supplemental opioid analgesics required by the patient on the second or third day of the initial application. It may take up to 6 days for fentanyl levels to reach equilibrium on a new dose. Therefore, evaluate patients for further titration after no less than two 3-day applications before any further increase in dosage is made. Base dosage increments on the daily dosage of supplementary opioids, using the ratio of 45 mg/24 hours of oral morphine to a 12 mcg/hour increase in Duragesic/fentanyl transdermal system dose.

A small proportion of adult patients may not achieve adequate analgesia using a 72-hour dosing interval and may require systems to be applied at 48 hours rather than at 72 hours, only if adequate pain control cannot be achieved using a 72-hour regimen. An increase in the dose should be evaluated before changing dosing intervals in order to maintain patients on a 72-hour regimen. Therefore, a quantity of fentanyl transdermal systems of 15 patches will be covered per 30 days without prior authorization.

CRITERIA

All approvals are provided for 12 months in duration unless otherwise noted below

Duragesic (generic) 12 mcg/hr, 25 mcg/hr, 37.5 mcg/hr, 50 mcg/hr, 75 mcg/hr transdermal system

Recommended not to override the quantity. For patients requesting greater quantities because they are titrating doses up, they should be referred to the next higher strength patch.

Fentanyl transdermal system - 12 mcg/hr, 25 mcg/hr, 37.5 mcg/hr, 50 mcg/hr, 62.5 mcg/hr, 75 mcg/hr, 87.5 mcg/hr

Recommended not to override the quantity. For patients requesting greater quantities because they are titrating doses up, they should be referred to the next higher strength patch.

Duragesic (generic) 100 mcg/hr transdermal system

1. For patients who need doses of greater than 100 mcg/hr, a sufficient quantity of the 100 mcg/hr transdermal systems may be approved to allow for up to 400 mcg/hr with every 48 hour dosing (60 transdermal systems or patches per 30 days).
2. For patients needing greater than 400 mcg/hr every 48 hours, approve the requested quantity if:
    a. the prescribing physician confirms that the patient is currently on the requested dose and is stable, OR;
    b. the patient's dose is being titrated up to the requested dose and the dose is necessary to control the patient's pain.

REFERENCES

1. Duragesic® transdermal system [prescribing information]. Titusville, NJ: Janssen Pharmaceuticals, Inc.; October 2019.
2. Fentanyl transdermal system [prescribing information]. Morgantown, WV: Mylan Pharmaceuticals, Inc.; November 2019.
3. Opioids Long-Acting prior authorization policy. , Inc. Updated 04/29/2020.