VENTURA COUNTY
HEALTH CARE PLAN

DRUG QUANTITY MANAGEMENT POLICY – PER DAYS

POLICY: Opioids – Fentanyl Transdermal Products Drug Quantity Management Policy – Per Days
- Duragesic® (fentanyl transdermal system – Janssen, generic)
- fentanyl transdermal system – generic only

REVIEW DATE: 04/20/2022

OVERVIEW

Transdermal fentanyl systems are indicated for the **management of pain severe enough to require daily, around-the-clock, long-term opioid treatment** and for which alternative treatment options are inadequate.[1,2]

Dosing

When converting to transdermal fentanyl from other opioids, the recommended starting dose is intended to minimize the potential for overdose.[1,2] The use of transdermal fentanyl systems should be limited to the minimum effective dose and duration. When transdermal fentanyl systems are started, all other around-the-clock opioids should be discontinued.

The dosing interval for transdermal fentanyl systems is 72 hours.[1,2] The initial dose should not be increased for at least 3 days after the initial application. The dose is titrated 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, patients should not be evaluated for further dose titration until at least two 3-day applications have occurred. Dose increases should be based 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 fentanyl transdermal patch dose.

A small proportion of adult patients may not achieve adequate analgesia using a 72-hour dosing interval and may require system to be applied at 48 hour intervals.[1,2] Application every 48 hours is only intended for patients without adequate pain control 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.

Availability

Transdermal fentanyl systems are available as Duragesic as well as generic transdermal fentanyl systems.[1,2] The Duragesic brand product has been recently discontinued; however, supply may still be available. There are some differences between the Duragesic product and generic transdermal fentanyl system related to available strengths and patch size.

Duragesic has been available in the following strengths: 12 mcg/hour, 25 mcg/hour, 75 mcg/hour, and 100 mcg/hour.[1] The patch sizes range from 5.5 cm^2 to 44 cm^2.

Generic fentanyl transdermal systems are available in the following strengths: 12 mcg/hour, 25 mcg/hour, 37.5 mcg/hour, 50 mcg/hour, 62.5 mcg/hour, 75 mcg/hour, 87.5 mcg/hour or 100 mcg/hour of fentanyl.[2] Each of the systems is a different size ranging from 3.13 cm^2 to 25 cm^2.

For both the Duragesic and generic transdermal fentanyl systems, the lowest labeled strength, 12 mcg/hr, is actually 12.5 mcg/hour, but is labeled as 12 mcg/hour to distinguish it from a possible 125 mcg/hour dosage that could be prescribed by using multiple transdermal systems.[1,2]

Duragesic and generic transdermal fentanyl systems are supplied in cartons containing five individual child-resistant packaged systems.[1,2] The generic fentanyl system are also supplied in cartons containing one individually packaged system.

POLICY STATEMENT

This Drug Quantity Management program has been developed to prevent stockpiling and waste, as well as address potential order entry error, of fentanyl transdermal products. If the Drug Quantity Management rule is not met for the requested medication at the point of service, coverage will be determined by the Criteria below. All approvals are provided for 1 year in duration.

Automation: None.

Drug Quantity Limits

Product	Strength and Form	Maximum Quantity per 30 Days
Duragesic® (fentanyl transdermal system, generic)	12 mcg/hour	15 systems
	25 mcg/hour	
	50 mcg/hour	
	75 mcg/hour	
	100 mcg/hour	
Fentanyl transdermal system (generic only)	12 mcg/hour	15 systems
	25 mcg/hour	
	37.5 mcg/hour	
	50 mcg/hour	
	62.5 mcg/hour	
	75 mcg/hour	
	87.5 mcg/hour	
	100 mcg/hour	

CRITERIA

Approval of additional quantities of the transdermal fentanyl products is recommended in patients with a diagnosis of cancer and pain severe enough to require daily, around-the-clock, long-term opioid treatment if the patient meets ONE of the following criteria.

Duragesic (generic), fentanyl transdermal system 12 mcg/hr, 25 mcg/hr, 37.5 mcg/hr, 50 mcg/hr, 62.6 mcg/hr, 75 mcg/hr, 87.5 mcg/hr
No overrides recommended.
Note: For patients requesting greater quantities because they are up-titrating doses, they should be referred to the next higher strength patch.

Duragesic (generic), fentanyl transdermal patch 100 mcg/hr
1. If the patient needs a dose greater than 100 mcg/hr, approve the requested quantity per 30 days.

REFERENCES

1. Duragesic® transdermal system [prescribing information]. Titusville, NJ: Janssen Pharmaceuticals; March 2021.
2. Fentanyl transdermal system [prescribing information]. Morgantown, WV: Mylan Pharmaceuticals; March 2021.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	Reviewed by Clinical Specialists. No change to criteria.	01/31/2021
Annual Revision	Duragesic 37.5 mcg/hr patches (brand) were removed; these are no longer available. **Duragesic (generic), fentanyl transdermal patch 100 mcg/hr.** For patients requiring a dose greater than 100 mcg/hr, criteria were updated to approve the requested quantity per 30 days. Previously, criteria approved "a quantity sufficient to allow for up to a 400 mcg/hr with every 48 hour dosing". Criteria for patients requiring a dose greater than 400 mcg/hr every 48 hours was removed (no longer needed based on the change for patients requiring a dose greater than 100 mcg/hr). Previously, the requested quantity was approved if the patient required a dose greater than 400 mcg/hr every 48 hours and the patient met one of the following: 1) The patient was currently on the requested dose and was stable, according to the prescriber; or 2) The medication was being up titrated to the requested dose and the dose was necessary to control the patients pain.	04/20/2022