DRUG QUANTITY MANAGEMENT POLICY – PER DAYS

POLICY: Opioids – Fentanyl Transdermal Products Drug Quantity Management Policy – Per Days
- Fentanyl transdermal system –generic only

REVIEW DATE: 04/02/2025

INSTRUCTIONS FOR USE

THE FOLLOWING COVERAGE POLICY APPLIES TO HEALTH BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. CERTAIN CIGNA COMPANIES AND/OR LINES OF BUSINESS ONLY PROVIDE UTILIZATION REVIEW SERVICES TO CLIENTS AND DO NOT MAKE COVERAGE DETERMINATIONS. REFERENCES TO STANDARD BENEFIT PLAN LANGUAGE AND COVERAGE DETERMINATIONS DO NOT APPLY TO THOSE CLIENTS. COVERAGE POLICIES ARE INTENDED TO PROVIDE GUIDANCE IN INTERPRETING CERTAIN STANDARD BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. PLEASE NOTE, THE TERMS OF A CUSTOMER'S PARTICULAR BENEFIT PLAN DOCUMENT [GROUP SERVICE AGREEMENT, EVIDENCE OF COVERAGE, CERTIFICATE OF COVERAGE, SUMMARY PLAN DESCRIPTION (SPD) OR SIMILAR PLAN DOCUMENT] MAY DIFFER SIGNIFICANTLY FROM THE STANDARD BENEFIT PLANS UPON WHICH THESE COVERAGE POLICIES ARE BASED. FOR EXAMPLE, A CUSTOMER'S BENEFIT PLAN DOCUMENT MAY CONTAIN A SPECIFIC EXCLUSION RELATED TO A TOPIC ADDRESSED IN A COVERAGE POLICY. IN THE EVENT OF A CONFLICT, A CUSTOMER'S BENEFIT PLAN DOCUMENT ALWAYS SUPERSEDES THE INFORMATION IN THE COVERAGE POLICIES. IN THE ABSENCE OF A CONTROLLING FEDERAL OR STATE COVERAGE MANDATE, BENEFITS ARE ULTIMATELY DETERMINED BY THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT. COVERAGE DETERMINATIONS IN EACH SPECIFIC INSTANCE REQUIRE CONSIDERATION OF 1) THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT IN EFFECT ON THE DATE OF SERVICE; 2) ANY APPLICABLE LAWS/REGULATIONS; 3) ANY RELEVANT COLLATERAL SOURCE MATERIALS INCLUDING COVERAGE POLICIES AND; 4) THE SPECIFIC FACTS OF THE PARTICULAR SITUATION. EACH COVERAGE REQUEST SHOULD BE REVIEWED ON ITS OWN MERITS. MEDICAL DIRECTORS ARE EXPECTED TO EXERCISE CLINICAL JUDGMENT WHERE APPROPRIATE AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. WHERE COVERAGE FOR CARE OR SERVICES DOES NOT DEPEND ON SPECIFIC CIRCUMSTANCES, REIMBURSEMENT WILL ONLY BE PROVIDED IF A REQUESTED SERVICE(S) IS SUBMITTED IN ACCORDANCE WITH THE RELEVANT CRITERIA OUTLINED IN THE APPLICABLE COVERAGE POLICY, INCLUDING COVERED DIAGNOSIS AND/OR PROCEDURE CODE(S). REIMBURSEMENT IS NOT ALLOWED FOR SERVICES WHEN BILLED FOR CONDITIONS OR DIAGNOSES THAT ARE NOT COVERED UNDER THIS COVERAGE POLICY (SEE "CODING INFORMATION" BELOW). WHEN BILLING, PROVIDERS MUST USE THE MOST APPROPRIATE CODES AS OF THE EFFECTIVE DATE OF THE SUBMISSION. CLAIMS SUBMITTED FOR SERVICES THAT ARE NOT ACCOMPANIED BY COVERED CODE(S) UNDER THE APPLICABLE COVERAGE POLICY WILL BE DENIED AS NOT COVERED. COVERAGE POLICIES RELATE EXCLUSIVELY TO THE ADMINISTRATION OF HEALTH BENEFIT PLANS. COVERAGE POLICIES ARE NOT RECOMMENDATIONS FOR TREATMENT AND SHOULD NEVER BE USED AS TREATMENT GUIDELINES. IN CERTAIN MARKETS, DELEGATED VENDOR GUIDELINES MAY BE USED TO SUPPORT MEDICAL NECESSITY AND OTHER COVERAGE DETERMINATIONS.

CIGNA NATIONAL FORMULARY COVERAGE:

OVERVIEW

Fentanyl transdermal systems are indicated for the **management of severe and persistent pain** in opioid-tolerant patients, that requires an extended treatment period with a daily opioid analgesic and for which alternative treatment options are inadequate.[1]

Dosing

When converting to transdermal fentanyl from other opioids, the recommended starting dose is intended to minimize the potential for overdose.[1] 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] 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] 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

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.[1] Each of the systems is a different size ranging from 3.13 cm^2 to 25 cm^2.

For 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]

Transdermal fentanyl systems are supplied in cartons containing five individual child-resistant packaged systems.[1] 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.

Drug Quantity Limits

Product	Strength and Form	Retail Maximum Quantity per 30 Days	Home Delivery Maximum Quantity per 90 Days
Fentanyl transdermal system	12 mcg/hour	15 systems	45 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		

***Opioids – Fentanyl Transdermal Products Drug Quantity Management Policy – Per Days* product(s) is(are) covered as medically necessary when the following criteria is(are) met. Any other exception is considered not medically necessary.**

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.

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: A patient requesting a greater quantity due to dose up-titration should be referred to the next higher strength patch.

Fentanyl transdermal system 100 mcg/hr
1. If the patient requires a dose greater than 100 mcg/hr, approve the requested quantity for a 30-day supply at retail or a 90-day supply at home delivery.

REFERENCES

1. Fentanyl transdermal system [prescribing information]. Morgantown, WV: Mylan; December 2023.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	Policy was updated to reflect the existing quantity limits when a product is obtained via home delivery. No criteria changes.	04/24/2023
Annual Revision	No criteria changes.	04/30/2024
Annual Revision	Duragesic transdermal system (brand only) was removed from the policy (obsolete).	04/02/2025