

#### SUBSYS

oloyee Program. (fentanyl sublingual spray)

## **Pre - PA Allowance**

None

# Prior Approval Poquiroments

# **Prior-Approval Requirements**

Age 18 years of age or older

## Diagnosis

Patient must have the following:

Breakthrough cancer pain – type or location of cancer must be specified

### **AND**

- 1. Patient has been on around-the-clock opioid analgesia for underlying persistent cancer pain
- Patient is tolerant to opioid therapy.Patients are considered opioid tolerant if they are taking at least:
  - a. 60mg of oral morphine/day
  - b. 25mcg transdermal fentanyl/hour
  - c. 30mg ooral oxycodone daily
  - d. 8 mg oral hydromorphone daily
  - e. or an equianalgesic dose of another opioid daily for a week or longer.
  - f. However, lower dosage requirements may achieve tolerance in renal impaired or elderly patients.
- Prescriber is an oncologist or pain management specialist who is knowledgeable and skilled in the use of schedule II opioids to treat cancer pain.
- 4. Patient and prescribing healthcare professional are enrolled in TIRF REMS Access program
- 5. Initial dose of Subsys must be 100mcg even if converting from another immediate release fentanyl product other than Actiq
  - a. Actiq 200mcg convert to Subsys 100mcg
  - b. Actiq 400mcg convert to Subsys 100mcg



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- c. Actiq 600mcg convert to Subsys 200mcg
- d. Actiq 800mcg convert to Subsys 200mcg
- e. Actiq 1200mcg convert to Subsys 400mcg
- f. Actiq 1600mcg convert to Subsys 400mcg

## **Prior - Approval Limits**

**Dosage** Subsys 100mcg – up to 4 units/ day

**Duration** 6 months

# Prior - Approval Renewal Requirements

Age 18 years of age or greater

## **Diagnosis**

Patient must have the following:

Breakthrough cancer pain – type or location of cancer must be specified

## AND ALL of the following:

- 1. Patient has remained on around-the-clock opioid therapy
- 2. Prescriber is an oncologist or pain specialist
- 3. Prescriber and patient are enrolled in TIRF REMS Access program

All requests are subject to approval by a secondary review by a clinical specialist for final coverage determination

# Prior – Approval Renewal Limits

**Dosage** Subsys 100mcg – up to 4 units/day, or

Subsys 200mcg - up to 4 units/day, or

Subsys 400mcg - up to 4 units/day, or

Subsys 600mcg – up to 4 units/day, or

Subsys 800mcg – up to 4 units/day, or

Subsys 1200mcg – up to 4 doses/day (8 X 600mcg per day per

packaging), or

Subsys 1600mcg – up to 4 doses/ day (8 X 800mcg per day per

packaging)



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**Duration** 6 months