Subsys

**Description**

Subsys (fentanyl sublingual spray)

**Background**

Subsys has one indication, the management of breakthrough cancer pain in patients with malignancies who are already receiving, and are tolerant to, opioid therapy for their underlying persistent cancer pain (1). Subsys should only be prescribed by oncologists and pain specialists who are knowledgeable in the use of Schedule II opioids for cancer pain (1).

Subsys has a high potential for abuse, addiction, and diversion. Subsys prescribing guidelines indicate that if more than 4 units are required per day, the dosage of the underlying opioid therapy should be titrated. During titration periods, the patient may require more than 4 units per day (1).

**Regulatory Status**

FDA-approved indication: Subsys is an opioid agonist indicated for the management of breakthrough cancer pain in patients 18 years of age and older who are already receiving and who are tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain. Patients must remain on around-the-clock opioids when taking Subsys (1).

**Limitations of use:**
Subsys may be dispensed only to patients enrolled in the TIRF REMS Access program (1).

Subsys has a boxed warning regarding the risk of fatal respiratory depression in patients treated with Subsys, including following use in opioid non-tolerant patients and improper dosing.
Subsys is contraindicated in the management of acute or postoperative pain, including headache/migraine and in opioid non-tolerant patients. Subsys cannot be substituted mcg per mcg for other fentanyl products. The substitution of Subsys for any other fentanyl product may result in fatal overdose (1).

Safety and effectiveness in pediatric patients under the age of 18 have not been established (1).

Related policies
Abstral, Actiq, Butorphanol, Butrans, Duragesic, Extended Release Opioid Drugs, Fentanyl Powder, Fentora, Immediate Release Opioid Drugs, IR Opioid Combo Drugs, Lazanda, Methadone, Opioid Powders, Opioid Step Policy, Suboxone Drug Class, Subsys

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Subsys may be considered medically necessary for the management of breakthrough cancer pain in patients age 18 years old and older and if the conditions indicated below are met. All initial PA requests must be for 100mcg, even if patient is already established on another fentanyl product.

Subsys is considered investigational in patients below 18 years of age and for all other indications.

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 ALL of the following:
  1. Patient has been on around-the-clock opioid analgesia for underlying persistent cancer pain
2. 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 oral 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.

3. 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 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
   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 Renewal 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 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

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Dosage: Subsys 100mcg – up to 4 units/day
Duration: 6 months

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)

Duration: 6 months

Rationale

Summary

Subsys, a short-acting opioid, is indicated only for the management of breakthrough cancer pain in patients with malignancies who are already receiving and tolerant to opioid therapy for their underlying persistent cancer pain. Subsys should only be prescribed by oncologists and pain management specialists who are knowledgeable in the use of Schedule II opioids for cancer pain (1).

Prior authorization is required to ensure the safe, clinically appropriate and cost effective use of Subsys while maintaining optimal therapeutic outcomes.
Section: Prescription Drugs  Effective Date: April 1, 2019
Subsection: Analgesics and Anesthetics  Original Policy Date: April 1, 2012
Subject: Subsys  Page: 5 of 5

References

Policy History

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<td>April 2012</td>
<td>Renal patients may require lower doses. REMS changed to TIRF REMS</td>
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Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 15, 2019 and is effective on April 1, 2019.