

## FORMULARY EXCEPTION POLICY

**POLICY:** Opioids Transmucosal – Subsys Formulary Exception Policy

- Subsys® (fentanyl sublingual spray – Insys)

**REVIEW DATE:** 09/21/2021

**Verification of Therapies Required:** Previous trials of other fentanyl transmucosal therapies are required to be verified by a clinician in the ESI Coverage Review Department when noted in the criteria as [verification of therapies required].

**Approval Duration:** All approvals are provided for the duration noted below.

### CRITERIA

**1. Breakthrough Pain in Patients with Cancer:** Approve for 1 year if the patient meets the following criteria (A, B and C):

A) Patient meets ONE of the following conditions (i or ii):

- i. Patient is unable to swallow, has dysphagia, esophagitis, mucositis, or uncontrollable nausea/vomiting; OR
- ii. Patient is unable to take two other short-acting narcotics secondary to allergy or severe adverse events; AND

Note: Examples of short-acting narcotics include immediate-release formulations of oxycodone, morphine sulfate, hydromorphone, etc.

B) Patient is on or will be on an oral or transdermal long-acting narcotic, or the patient is on intravenous, subcutaneous, or spinal (intrathecal, epidural) narcotics; AND

Note: Examples of long-acting narcotics include Duragesic, OxyContin, and morphine extended-release. Examples of intravenous, subcutaneous, or spinal narcotics include morphine sulfate, hydromorphone, and fentanyl citrate.

C) Patient meets ONE of the following conditions (i or ii):

- i. The patient has tried two of the following, if two are formulary (or one if only one is formulary or none if none are formulary): fentanyl citrate oral transmucosal lozenge (Actiq, generics), Abstral, Fentora, or Lazanda [verification of therapies required]; OR
- ii. In patients who cannot tolerate the sugar content of fentanyl citrate oral transmucosal lozenge (Actiq, generics) [e.g., patients who are glucose intolerant, diabetic, at high risk of dental carries], the patient has tried two of the following, if two are formulary (or one if only one is formulary or none if none are formulary): Abstral, Lazanda, or Fentora [verification of therapies required].

### HISTORY

Type of Revision	Summary of Changes	Date
Annual Revision	No criteria changes.	05/08/2020
Annual Revision	<b>Breakthrough Pain in Patients with Cancer:</b> Removed the statement “In the professional opinion of specialist physicians reviewing the data, we have adopted this criterion” from criteria. Changed examples of narcotics to notes.	09/21/2021