EXPRESS SCRIPTS®

FORMULARY EXCEPTION POLICY

POLICY: Opioids Transmucosal – Subsys® (fentanyl sublingual spray – Insys)

DATE REVISED: 04/11/2019

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,[8] or uncontrollable nausea/vomiting (In the professional opinion of specialist physicians reviewing the data, we have adopted this criterion); OR
     - **ii.** Patient is unable to take two other short-acting narcotics (e.g., oxycodone, morphine sulfate, hydromorphone, etc.) secondary to allergy or severe adverse events (In the professional opinion of specialist physicians reviewing the data, we have adopted this criterion); AND
   - **B)** Patient is on or will be on an oral or transdermal long-acting narcotic (e.g., Duragesic, OxyContin, morphine extended-release), or the patient is on intravenous, subcutaneous, or spinal (intrathecal, epidural) narcotics (e.g., morphine sulfate, hydromorphone, 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
New Policy	--	03/02/2018
Annual revision	No changes to criteria.	04/11/2019