

## FORMULARY EXCEPTION POLICY

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

- Fentora® (fentanyl buccal tablet – Teva/Cephalon, authorized generic)

**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) or Abstral [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 caries], the patient has tried the following, if it is formulary (or none if it is not formulary): Abstral [verification of therapies required].

### HISTORY

| Type of Revision  | Summary of Changes                                                                                                                                                                                                                       | Review Date |
|-------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------|
| Annual Revision   | No criteria changes.                                                                                                                                                                                                                     | 05/08/2020  |
| Selected Revision | <b>Breakthrough Pain in Patients with Cancer:</b> Removal of Lazanda and Subsys as options in the formulary criteria.                                                                                                                    | 05/18/2020  |
| 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  |