Cigna National Preferred Formulary Coverage Policy

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Prior Authorization
Opioids – Fentanyl Transmucosal Drugs

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INSTRUCTIONS FOR USE
The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer’s particular benefit plan document (Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document) may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer’s benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer’s benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

NPF Coverage Policy

Drugs Affected

- Abstral® (fentanyl sublingual tablet)
- Actiq® (oral transmucosal fentanyl citrate, generics)
- Fentora® (fentanyl buccal tablet, authorized generic)
- Lazanda® (fentanyl nasal spray)
- Subsys® (fentanyl sublingual spray)

Cigna covers fentanyl transmucosal drugs as medically necessary when the following criteria are met for FDA Indications or Other Uses with Supportive Evidence:

Prior authorization is recommended for prescription benefit coverage of fentanyl transmucosal drugs. All approvals are provided for the duration noted below.
FDA Indication(s)

1. **Breakthrough Pain in Individuals with Cancer.** Approve for 1 year if the individual meets the following criteria (A and B):
   
   A) Individual meets ONE of the following conditions (i or ii):
      i. Individual is unable to swallow, has dysphagia, esophagitis, mucositis, or uncontrollable nausea/vomiting; OR
      ii. Individual 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) Individual is on or will be on an oral or transdermal long-acting narcotic, or the individual is on intravenous, subcutaneous, or spinal (intrathecal, epidural) narcotics.
   
   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.

Conditions Not Covered

Fentanyl transmucosal drugs are considered experimental, investigational or unproven for ANY other use including the following (this list may not be all inclusive):

1. **Acute and/or Postoperative Pain.** This includes surgery/post-surgery, trauma/post-trauma, acute medical illness (acute abdominal pain, pelvic pain, muscle spasm). Actiq (generics), Abstral, Fentora, Lazanda, and Subsys are contraindicated for use in the management of acute or postoperative pain, including migraine headache pain. A case series reported the efficacious out individual use (75% reduction in pain intensity at 2 hours; n = 18) of Actiq for the management of treating an acute, refractory migraine headache in 20 individuals. Actiq was used as a rescue medication for management of a moderate to severe migraine after ineffective treatment with the individuals’ usual antimigraine therapy. All of these individuals were managed by a headache clinic and had undergone a full evaluation of their medical history, vital signs, and physical and neurological examinations. In addition, all 20 individuals had been previously treated with multiple other therapies (e.g., 5-hydroxytryptamine [5-HT] receptor agonists, ergots, antiemetics, prescription and over-the-counter analgesics, and anti-inflammatory drugs) and all had previously received out individual opioid therapies in an attempt to manage their migraine pain. All individuals were also known responders to use of parenteral opioid therapy. Side effects reported included nausea (n = 3), vomiting (n = 1), somnolence (n = 2), itching (n = 1), and dry mouth (n = 1). Controlled research is needed to fully determine the role of Actiq for the management of acute, refractory migraine.

Background

Overview

The transmucosal fentanyl drugs are indicated only for the management of breakthrough pain in patients with cancer who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain.

Actiq (generics), Abstral, Fentora, and Subsys are immediate-release oral transmucosal formulations of fentanyl citrate. Lazanda is a nasal spray intended for intranasal transmucosal administration. Patients considered opioid tolerant are those who are taking at least 60 mg of oral morphine daily, at least 25 mcg of transdermal fentanyl/hour, at least 30 mg of oxycodone daily, at least 8 mg oral hydromorphone daily, at least 25 mg oral oxymorphone daily, or an equianalgesic dose of another opioid for a week or longer. The appropriate dosing and safety of Actiq (generics) in opioid tolerant children with breakthrough cancer pain have not been established in those below 16 years of age. The safety and efficacy of Abstral, Fentora, Subsys, and Lazanda have not been established in pediatric patients below 18 years of age.
The transmucosal fentanyl drugs are contraindicated in the management of acute or postoperative pain and in patients with known intolerance or hypersensitivity to any components or the drug fentanyl. In addition, these products must not be used in opioid non-tolerant patients (contraindicated). The transmucosal fentanyl drugs are approved for use only in the care of cancer patients and only by healthcare professionals (oncologists and pain specialists) who are knowledgeable of and skilled in the use of Schedule II opioids to treat cancer pain. Because of the risk of misuse, abuse, addition, and overdose, these products are available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the Transmucosal Immediate-Release Fentanyl (TIRF) REMS ACCESS program. Under the TIRF REMS ACCESS program, outpatients, prescribers who prescribe to outpatients, pharmacies, and distributors must enroll in the program.

References


Last Revision Details

| Annual Revision | Breakthrough Pain in Patients with Cancer: 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. | 10/21/2020 |

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