PRIOR AUTHORIZATION POLICY

POLICY: Opioids – Fentanyl Transmucosal Drugs Prior Authorization Policy
- Actiq® (oral transmucosal fentanyl citrate – Teva, generic)
- Fentora® (fentanyl buccal tablet – Teva, authorized generic [brand obsolete])
- Lazanda® (fentanyl nasal spray – West Therapeutic Development [obsolete as of 12/30/2022])
- Subsys® (fentanyl sublingual spray – West Therapeutic Development [obsolete as of 6/1/2024])

REVIEW DATE: 11/13/2024

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. EACH COVERAGE REQUEST SHOULD BE REVIEWED ON ITS OWN MERITS. MEDICAL DIRECTORS ARE EXPECTED TO EXERCISE CLINICAL JUDGMENT AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. 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.

CIGNA NATIONAL FORMULARY COVERAGE:

OVERVIEW

The transmucosal immediate-release fentanyl (TIRF) 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.[1-5]

Actiq (generic), Fentora, and Subsys are immediate-release oral transmucosal formulations of fentanyl citrate.[1-4] Lazanda is a nasal spray intended for intranasal transmucosal administration.[5] 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 one week or longer. The appropriate dosing and safety of Actiq (generic) in opioid-tolerant children with breakthrough cancer pain have not been established in those below 16 years of age.[1,3] The safety and efficacy of Fentora, Subsys, and Lazanda have not been established in pediatric patients below 18 years of age.[2,4,5]

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.[1-5] In addition, these products must not be used in patients who are not opioid tolerant (contraindicated). The transmucosal fentanyl drugs are approved for use only in the care of cancer patients and only by healthcare professionals[1-4] (oncologists and pain specialists)[2,3,5] 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 TIRF REMS ACCESS program. Under the TIRF REMS ACCESS program, outpatients, prescribers who prescribe to outpatients, pharmacies, and distributors must enroll in the program.

On September 16, 2024, the FDA stated that according to manufacturers of TIRF medicines, **production of all TIRF medicines will be discontinued on September 30, 2024**. Due to this discontinuation, the TIRF REMS will no longer accept new enrollments for patients, prescribers, or pharmacies. As of September 16, 2024, there were fewer than 150 patients receiving treatment with TIRF medicines. Patients who are currently on a TIRF medicine may continue treatment under the REMS while TIRF medicine supply remains available. Prescribers should work with their patients to transition to other non-TIRF treatment. The TIRF REMS will remain in place as long as the manufacturers' new drug applications or abbreviated new drug applications are approved, regardless of the marketing status of the products. Of note, **the FDA did not request this discontinuation**.

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of fentanyl transmucosal drugs. All approvals are provided for the duration noted below.

- **Actiq® (oral transmucosal fentanyl citrate – Teva, generic)**
- **Fentora® (fentanyl buccal tablet – Teva, authorized generic [brand obsolete])**
- **Lazanda® (fentanyl nasal spray – West Therapeutic Development [obsolete as of 12/30/2022])**
- **Subsys® (fentanyl sublingual spray – West Therapeutic Development [obsolete as of 6/1/2024])**

is(are) covered as medically necessary when the following criteria is(are) met for fda-approved indication(s) or other uses with supportive evidence (if applicable):

FDA-Approved Indication

1. **Breakthrough Pain in a Patient with Cancer.** Approve for 1 year if the patient meets BOTH of the following (A and B):
   - **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 an intravenous, subcutaneous, or spinal (intrathecal, epidural) narcotic.

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

CONDITIONS NOT COVERED

- **Actiq® (oral transmucosal fentanyl citrate – Teva, generic)**
- **Fentora® (fentanyl buccal tablet – Teva, authorized generic [brand obsolete])**
- **Lazanda® (fentanyl nasal spray – West Therapeutic Development [obsolete as of 12/30/2022])**
- **Subsys® (fentanyl sublingual spray – West Therapeutic Development [obsolete as of 6/1/2024])**

is(are) considered experimental, investigational, or unproven for ANY other use(s) including the following (this list may not be all inclusive; criteria will be updated as new published data are available):

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 (generic), Fentora, Lazanda, and Subsys are contraindicated for use in the management of acute or postoperative pain, including migraine headache pain.[1-5]

2. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Actiq® oral transmucosal [prescribing information]. Parsippany, NJ: Teva; December 2023.
2. Fentora® buccal tablet [prescribing information]. Parsippany, NJ: Teva; December 2023.
3. Oral Transmucosal Fentanyl Citrate (OTFC) [prescribing information]. Parsippany, NJ: Teva; January 2024.
4. Subsys® sublingual spray [prescribing information]. Northbrook, IL: West Therapeutic Development; March 2021.
5. Lazanda® nasal spray [prescribing information]. Northbrook, IL: West Therapeutic Development; March 2021.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	11/15/2023
Annual Revision	**Abstral:** Abstral was removed from the policy because it has been obsolete > 3 years.	11/13/2024

APPENDIX A

Note: This list is not inclusive. As new STCs become available, they will roll into this policy and the list will be updated periodically.

STC*	STC Description
0470	ANTINEOPLASTIC - ALKYLATING AGENTS
0471	ANTINEOPLASTIC - ANTIMETABOLITES
0472	ANTINEOPLASTIC - VINCA ALKALOIDS
0473	ANTIBIOTIC ANTINEOPLASTICS
0475	ANTINEOPLASTICS, MISCELLANEOUS
6323	ANTINEOPLASTIC - ANTIANDROGENIC AGENTS
7235	ANTINEOPLASTICS ANTIBODY/ANTIBODY-DRUG COMPLEXES
7977	ANTINEOPLASTIC IMMUNOMODULATOR AGENTS
8254	ANTINEOPLASTIC LHRH(GNRH) AGONIST, PITUITARY SUPPR.
8460	ANTINEOPLASTIC LHRH(GNRH) ANTAGONIST,PITUIT.SUPPRS
8569	ANTINEOPLASTIC EGF RECEPTOR BLOCKER MCLON ANTIBODY
8585	ANTINEOPLAST HUM VEGF INHIBITOR RECOMB MC ANTIBODY
9150	ANTINEOPLASTIC SYSTEMIC ENZYME INHIBITORS
B759	ANTINEOPLAST, HISTONE DEACETYLASE (HDAC) INHIBITORS
C232	ANTINEOPLASTIC - MTOR KINASE INHIBITORS
C370	ANTINEOPLASTIC - EPOTHILONES AND ANALOGS
C532	ANTINEOPLASTIC - TOPOISOMERASE I INHIBITORS
C593	ANTINEOPLASTIC - AROMATASE INHIBITORS
D426	ANTINEOPLASTIC - IMMUNOTHERAPY, THERAPEUTIC VAC
D560	ANTINEOPLASTIC - HALICHONDRIN B ANALOGS
D687	CYTOTOXIC T-LYMPHOCYTE ANTIGEN (CTLA-4) RMC ANTIBODY
E039	ANTINEOPLASTIC - JANUS KINASE (JAK) INHIBITORS
E150	ANTINEOPLASTIC - HEDGEHOG PATHWAY INHIBITOR
E600	ANTINEOPLASTIC - VEGF-A,B AND PLGF INHIBITORS
F495	ANTINEOPLASTIC - INTERLEUKIN-6(IL-6)INHIB,ANTIBODY
F501	ANTINEOPLASTIC - VEGFR ANTAGONIST
F665	ANTINEOPLASTIC, ANTI-PROGRAMMED DEATH-1 (PD-1) MAB
G545	ANTINEOPLASTIC - IMMUNOTHERAPY, VIRUS-BASED AGENTS
G575	ANTINEOPLASTIC - MEK1 AND MEK2 KINASE INHIBITORS
G590	ANTINEOPLASTIC - ANTI-CD38 MONOCLONAL ANTIBODY
G607	ANTINEOPLASTIC - ANTI-SLAMF7 MONOCLONAL ANTIBODY
G802	ANTINEOPLASTIC- B CELL LYMPHOMA-2(BCL-2) INHIBITORS
G857	ANTI-PROGRAMMED CELL DEATH-LIGAND 1 (PD-L1) MAB
H018	ANTINEOPLASTIC, PDGFR-ALPHA BLOCKER MC ANTIBODY
H214	ANTINEOPLASTIC COMB-KINASE AND AROMATASE INHIBIT
H289	ANTINEOPLASTIC-ISOCITRATE DEHYDROGENASE INHIBITORS
H309	ANTINEOPLASTIC – ANTIBIOTIC AND ANTIMETABOLITE
H317	ANTINEOPLASTIC – CD22 ANTIBODY-CYTOTOXIC ANTIBIOTIC
H324	ANTINEOPLASTIC- CD19 DIR. CAR-T CELL IMMUNOTHERAPY
H329	ANTINEOPLASTIC – CD33 ANTIBODY-CYTOTOXIC ANTIBIOTIC
H617	ANTINEOPLASTIC – BRAF KINASE INHIBITORS
H768	ANTINEOPLASTIC-CD22 DIRECT ANTIBODY/CYTOTOXIN CONJ
H868	ANTINEOPLASTIC-CD123-DIRECTED CYTOTOXIN CONJUGATE
I054	ANTINEOPLASTIC-SELECT INHIB OF NUCLEAR EXP (SINE)

I264	ANTINEOPLASTIC – PROTEIN METHYLTRANSFERASE INHIBITORS

* Excluding topical products

APPENDIX B

ICD-10 Codes
Cancer-related codes
C00. * to D09. *
D3A.* to D48. *
E34.0*
Q85.0*

*Indicates the inclusion of subheadings.