FORMULARY EXCEPTION POLICY

POLICY: Opioids Transmucosal – Fentora Formulary Exception Policy
- Fentora® (fentanyl buccal tablet – Teva, authorized generic)

REVIEW DATE: 12/29/2023

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:

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

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

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is(are) covered as medically necessary when the following criteria is(are) met. Any other exception is considered not medically necessary:

CRITERIA

1. **Breakthrough Pain in Patients with Cancer:** Approve for 6 months 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, and hydromorphone.

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 fentanyl citrate oral transmucosal lozenge (Actiq, generic) [verification of therapies required]; OR

ii. Patient cannot tolerate the sugar content of fentanyl citrate oral transmucosal lozenge (Actiq, generic).
Note: Examples of intolerance to the sugar content of fentanyl citrate oral transmucosal lozenge include patients who are glucose intolerant, diabetic, or at high risk of dental caries.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	**Approval duration:** Changed from 1 year to 6 months. **Breakthrough Pain in Patients with Cancer:** Removal of Abstral (obsolete) as an option in the formulary criteria. Changed examples of patients who cannot tolerate the sugar content of fentanyl citrate oral transmucosal lozenge (Actiq, generic) to a note.	12/02/2022
Annual Revision	No criteria changes.	12/29/2023