Clinical Policy: fentanyl oral transmucosal (Actiq)
Reference Number: HIM.PA.45
Effective Date: 12/14
Last Review Date:
Line of Business: Health Insurance Marketplace

Coding Implications
Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description
Fentanyl (Actiq®) is an opioid agonist.

FDA approved indication
Actiq is indicated for the management of breakthrough pain in cancer patients 16 years of age and older who are already receiving and who are tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain.

Limitations of use:
- Not for use in opioid non-tolerant patients
- Not for use in the management of acute or postoperative pain, including headache/migraine or dental pain
- As a part of the Transmucosal Immediate Release Fentanyl Risk Evaluation and Mitigation Strategy (TIRF REMS) Access program, Actiq may be dispensed only to outpatients enrolled in the program. For inpatient administration of Actiq (e.g., hospitals, hospices, and long-term care facilities that prescribe for inpatient use), patient and prescriber enrollment is not required.

Policy/Criteria
** Provider must submit documentation (including office chart notes and lab results) supporting that member has met all approval criteria **

I. Initial Approval Criteria

A. Cancer Pain (must meet all)**:**

1. Diagnosis of cancer;
2. Prescribed for the management of breakthrough pain;
3. Member is currently receiving an extended-release opioid analgesic;
4. Failure of 2 formulary short-acting narcotic analgesic unless all are contraindicated or clinically significant adverse effects are experienced;
5. Dose does not exceed 4 lozenges per day.

Approval duration: 12 months

B. Other diagnoses/indications

1. Refer to HIM.PHAR.21 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized);

II. Continued Therapy

A. Cancer Pain (must meet all)**:**

1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
2. Documentation of positive response to therapy;
3. If request is for a dose increase, new dose does not exceed 4 lozenges per day.

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. Currently receiving medication via health plan benefit and documentation supports positive response to therapy; or
2. Refer to HIM.PHAR.21 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized)

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policy – HIM.PHAR.21 or evidence of coverage documents

IV. Appendices/General Information

Appendix A: Abbreviation Key
FDA: Food and Drug Administration
REMS: Risk Evaluation and Mitigation Strategy
TIRF: Transmucosal Immediate Release Fentanyl

V. References

1. Actiq [Prescribing Information] North Wales, PA: Teva Pharmaceuticals; December 2016. Available at: http://www.accessdata.fda.gov/drugsatfda_docs/label/2016/020747s043s044lbl.pdf. Accessed January 12, 2017.
2. Fentanyl drug monograph. Clinical Pharmacology. Accessed January 2017. http://clinicalpharmacology-ip.com

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Changed guidelines to new format.	05/16	05/16
Clinical changes made to criteria -Updated criterion related to "Documented severe chronic pain requiring around-the-clock-analgesia" to "Currently receiving an extended-release opioid analgesic" -Added requirement related to trial and failure of 2 formulary short acting narcotic analgesics unless contraindicated or clinically significant side effects are experienced Non-clinical changes -Converted to new template	01/17	

Reviews, Revisions, and Approvals	Date	P&T Approval Date
-Added quantity limit -References updated		

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

Note: For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.