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5.70.002

Section:	Prescription Drugs	**Effective Date:**	January 1, 2025
Subsection:	Analgesics and Anesthetics	**Original Policy Date:**	November 1, 2009
Subject:	Actiq	**Page:**	1 of 5

Last Review Date: December 13, 2024

Actiq

Description

Actiq (oral transmucosal fentanyl citrate)

Background
Actiq is indicated only for the management of breakthrough cancer pain in patients with malignancies, who are already receiving, and are tolerant to, opioid therapy for their underlying persistent cancer pain. Actiq should only be prescribed by oncologists and pain specialists who are knowledgeable in the use of Schedule II opioids for cancer pain (1).

Actiq has a high potential for abuse, addiction, and diversion. Actiq prescribing guidelines indicate that if more than 4 units are required per day, the dosage of the underlying opioid therapy should be titrated**.** During titration periods, the patient may require more than 4 units per day (1).

Regulatory Status
FDA-approved indication: Actiq is an opioid agonist indicated for the management of breakthrough cancer pain in 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 (1).

Actiq has a boxed warning regarding the risk of fatal respiratory depression in patients treated with Actiq, including following use in opioid non-tolerant patients and improper dosing. Actiq is contraindicated in the management of acute or postoperative pain, including headache/migraine and in opioid non-tolerant patients. Actiq cannot be substituted mcg per mcg for other fentanyl

products. The substitution of Actiq for any other fentanyl product may result in fatal overdose. Outpatients, prescribers, and distributers must be enrolled in the TIRF REMS Access program (1).

Safety and effectiveness of Actiq in pediatric patients less than 16 years of have not been established (1).

Related policies
Abstral, Buprenorphine and Methadone Powders, Fentanyl Powder, Fentora, Methadone, Opioid Drugs, Suboxone Drug Class, Subsys

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Actiq may be considered **medically necessary** if the conditions indicated below are met.

Actiq may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 16 years of age or older

Diagnosis

Patient must have the following:

Breakthrough cancer pain – type or location of cancer must be specified

AND ALL of the following:

1. Patient is already receiving around the clock opioid therapy for underlying persistent cancer pain
2. Patient is tolerant to opioid therapy.
   Patients are considered opioid tolerant if they are taking at least:
   - 60mg oral morphine/day
   - 25mcg transdermal fentanyl/hr

- 30mg of oral oxycodone daily
- 8 mg oral hydromorphone daily
- 25mg oral oxymorphone daily
- or an equianalgesic dose of another opioid for a week or longer. However, lower dosage requirements may achieve tolerance in renal impaired or elderly patients.

3. Prescribing health care professional is an oncologist or pain specialist who is knowledgeable of and skilled in the use of Schedule II opioids to treat cancer pain.
4. Patient and prescriber are enrolled in TIRF REMS Access program.
5. **Initial dose** of Actiq must be 200mcg even if converting from another immediate release fentanyl product

Prior – Approval *Renewal* Requirements

Age 16 years of age or older

Diagnosis

Patient must have the following:

Breakthrough cancer pain – type or location of cancer must be specified

AND ALL of the following:

1. Patient has remained on around-the-clock opioid therapy
2. Prescriber is an oncologist or pain specialist
3. Patient and prescriber are enrolled in TIRF REMS program

All requests are subject to approval by a secondary review by a clinical specialist for final coverage determination.

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Dosage 200mcg - up to 4 units / day

Duration 6 months

Prior – Approval *Renewal* Limits

Dosage
Actiq 200mcg – up to 4 units/ day or
Actiq 400mcg – up to 4units/ day or
Actiq 600mcg – up to 4units/ day or
Actiq 800mcg – up to 4units/ day or
Actiq 1200mcg- up to 4 units/ day or
Actiq 1600mcg- up to 4 units/ day

Duration 6 months

Rationale

Summary
Actiq, a short-acting opioid, is indicated only for the management of breakthrough cancer pain in patients with malignancies who are already receiving and tolerant to opioid therapy for their underlying persistent cancer pain. Actiq should only be prescribed by oncologist and pain management specialists who are knowledgeable in the use of Schedule II opioids for cancer pain (1).

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of Actiq while maintaining optimal therapeutic outcomes.

References
1. Actiq [package insert]. Parsippany, NJ: Cephalon, Inc; December 2023.

Policy History

Date	Action
November 2009	Criteria was updated to include the definition of opioid tolerant per the prescribing information. The time frame for initiation and renewal was changed to be consistent for all fentanyl products.
October 2011	Decreased dosage limit from 6 units/day to 4 units/day. Added a requirement of at least one week of around-the-clock opioid analgesia. Removed hematologist from accepted specialist prescribing physicians. Added requirement of enrollment in REMS

April 2012	Added renal patients may require lower dose. Changed reference from REMS to TIRF REMS.
September 2012	Annual editorial review and reference update
June 2013	Annual editorial review and reference update
June 2014	Annual editorial review and reference update and addition of type/location of cancer
March 2016	Annual editorial review and reference update. Addition of subject to secondary review by clinical specialist Policy number changed from 5.02.02 to 5.70.02.
March 2017	Annual editorial review. Addition of age to renewal requirements.
March 2018	Annual editorial review and reference update
March 2019	Annual editorial review
March 2020	Annual review
March 2021	Annual editorial review and reference update
March 2022	Annual review and reference update
March 2023	Annual review and reference update. Changed policy number to 5.70.002
December 2023	Annual review
March 2024	Annual review and reference update
December 2024	Annual review

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on December 13, 2024 and is effective on January 1, 2025.