

ABSTRAL (fentanyl sublingual tablets)

Pre - PA Allowance

None

Prior-Approval Requirements

Age 18 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:

- a. 60mg of oral morphine/day
- b. 25mcg transdermal fentanyl/hour
- c. 8mg oral hydromorphone/day
- d. 25mg oral oxymorphone/day
- e. 30mg oral oxycodone/day
- f. or an equianalgesic dose of another opioid for a week or longer
- g. However, lower dosage requirements may achieve tolerance in renal impaired or elderly patients.
- 3. Prescribing healthcare professional should be knowledgeable of, and skilled in, the use of Schedule II opioids to treat cancer pain
- 4. Patient and prescribing healthcare professional are enrolled in TIRF REMS Access program.
- 5. **Initial dose** of Abstral must be for 100mcg, even if patient is already established on another fentanyl product other than Actiq
 - a. Actiq 200mcg converts to Abstral 100mcg
 - b. Actiq 400mcg converts to Abstral 200mcg
 - c. Actiq 600mcg converts to Abstral 200mcg



Federal Employee Program.

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- d. Actiq 800mcg converts to Abstral 200mcg
- e. Actiq 1200mcg converts to Abstral 200mcg
- f. Actiq 1600mcg converts to Abstral 400mcg

Prior - Approval Limits

Dosage 100 mcg: Up to 4 units / day

Duration 6 months

Prior - Approval Renewal Requirements

Age 18 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 knowledgeable of, and skilled in, the use of Schedule II opioids to treat cancer pain
- 3. Prescriber and patient are enrolled in TIRF REMS program

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

Prior - Approval Renewal Limits

Dosage 100 mcg: Up to 4 units / day or

200 mcg: Up to 4 units / day or 300 mcg: Up to 4 units / day or 400 mcg: Up to 4 units / day or 600 mcg: Up to 4 units / day or 800 mcg: Up to 4 units / day

Duration 6 months



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