

ONSOLIS
(fentanyl buccal film)

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:
 - 60mg of oral morphine/day
 - 25mcg transdermal fentanyl/hour
 - 8mg oral hydromorphone/day
 - 25mg orally oxymorphone/day
 - 30mg oral oxycodone/day
 - 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 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 Onsolis must be for 200mcg, even if patient is already established on another fentanyl product

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Prior - Approval Limits

Dosage 200 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

Prior – Approval *Renewal* Limits

Dosage 200 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, or
1200 mcg: Up to 4 units / day

Duration 6 months