FENTANYL TRANSMUCOSAL AGENTS

Generic	Brand	HICL	GCN	Exception/Other
FENTANYL CITRATE	ACTIQ ABSTRAL FENTORA ONSOLIS	01747		ROUTE = BUCCAL, SUBLINGUAL

GUIDELINES FOR USE

1. Does the patient have a diagnosis of cancer?

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Is the patient on a maintenance dose of controlled release pain medication (MS Contin, Oxycontin, Oramorph SR, Duramorph, Roxanol SR, Duragesic, Avinza or the generic forms of any of these drugs)?

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

3. Has the patient tried or does the patient have a contraindication to at least one immediate-release oral pain agent (morphine sulfate immediate-release [MSIR], Percodan, Percocet, Vicodin, Tylenol with Codeine, Dilaudid, Demerol or the generic forms of any of these)?

   If yes, continue to #5.
   If no, continue to #4.

4. Does the patient have difficulty swallowing tablets or capsules?

   If yes, continue to #5.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

5. Is the request for generic fentanyl citrate lozenge?

   If yes, **approve for 6 months with a quantity limit of #120 per month.**
   APPROVAL TEXT: See the approval text at the end of the guideline.
   If no, continue to #6.

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GUIDELINES FOR USE (CONTINUED)

6. Has the patient tried or does the patient have a contraindication to generic fentanyl citrate lozenge?

   If yes, **approve for 6 months with a quantity limit of #120 per month.**
   APPROVAL TEXT: See the approval text at the end of the guideline.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

APPROVAL TEXT: Please note that this drug has an important FDA safety warning. For more information, please ask your doctor or pharmacist.

DENIAL TEXT: Our guideline for **FENTANYL TRANSMUCOSAL AGENTS** requires a diagnosis of cancer-related pain, and concurrent use with a controlled-release pain medication (MS Contin, Oxycontin, Oramorph SR, Duramorph, Roxanol SR, Duragesic, Avinza or the generic forms of any of these drugs), a trial of an oral immediate-release pain medication (morphine sulfate immediate-release [MSIR], Percodan, Percocet, Vicodin, Tylenol with Codeine, Dilaudid, Demerol or the generic forms of any of these), AND a trial of generic fentanyl citrate lozenge, which also requires a prior authorization.

RATIONALE
To ensure use of transmucosal fentanyl is consistent with indication.

FDA APPROVED INDICATIONS
ABSTRAL is an opioid analgesic indicated only for the management of breakthrough pain in patients with cancer, 18 years of age and older, who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain.

ACTIQ is indicated for breakthrough cancer pain in patients 16 years and older with malignancies who are already receiving and who are tolerant to opioid therapy for persistent cancer pain. Patients must remain on around-the-clock opioids when taking Actiq.

FENTORA is indicated for breakthrough pain in patients with cancer who are already receiving and who are tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain. Patients considered opioid tolerant are those who are taking around-the-clock medicine consisting of at least 60 mg of oral morphine daily, at least 25 mcg of transdermal fentanyl/hour, at least 30 mg of oxycodone daily, at least 8 mg of oral hydromorphone daily or an equianalgesic dose of another opioid daily for a week or longer. This product must not be used in opioid non-tolerant patients because life-threatening hypoventilation and death could occur at any dose in patients not on a chronic regimen of opioids.

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FDA APPROVED INDICATIONS (CONTINUED)
FENTORA is contraindicated in the management of acute or postoperative pain. Fentora is intended to be used only in the care of opioid tolerant cancer patients and only by healthcare professionals who are knowledgeable of and skilled in the use of Schedule II opioids to treat cancer pain.

ONSOLIS is indicated for the management of breakthrough pain in patients with cancer, 18 years of age and older, who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain.

REFERENCES

- Cephalon, Inc. Actiq package insert. Frazer, PA. September 2009.
- Cephalon, Inc. Fentora package insert. Frazer, PA. January 2011.
- Meda Pharmaceuticals, Inc. Onsolis package insert. Somerset, NJ July 2009.
- ProStrakan Inc. Abstral package insert. Bedminster, NJ. January 2011.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 01/01/15
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P&T Approval: 11/14