



STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

FENTANYL SUBLINGUAL SPRAY

Generic	Brand	HICL	GCN	Exception/Other
FENTANYL SUBLINGUAL SPRAY	SUBSYS		31187 31188 31189 31192 31193 31596 31597	

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.

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GUIDELINES FOR USE (CONTINUED)

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

If yes, continue to #6.

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

6. Has the patient tried or does the patient have a contraindication to Abstral, Fentora, or Onsolis?

If yes, **approve for 6 months with a quantity limit of #120 per month.**

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

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

DENIAL TEXT: Our guideline for **FENTANYL SUBLINGUAL SPRAY** 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 AND a trial of Abstral, Fentora, or Onsolis, all of which may also require a prior authorization.

RATIONALE

To ensure the use of fentanyl sublingual spray is consistent with the FDA approved indication.

FDA APPROVED INDICATIONS

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

REFERENCES

- Insys Therapeutics, Subsys package insert. Phoenix, AZ. January 2012.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 01/01/15

Created: 04/12

Client Approval: 10/14

P&T Approval: 11/14