

Market Applicability/Effective Date														
Market	FL & FHK	FL MMA	FL LTC	GA	KS	KY	LA	MD	NJ	NV	NY	TN	TX	WA
Applicable	X	NA	NA	X	NA	X	X	X	X	X	X	NA	NA	X

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Transmucosal Immediate Release Fentanyl (TIRF) Agents

Override(s)	Approval Duration
Prior Authorization Quantity Limit	1 year

Medications	Quantity Limit	Comments
*Fentanyl citrate lozenge - Generic	4 units per day	Preferred
*Actiq (fentanyl citrate) lozenge- Brand	4 units per day	Non-Preferred
Abstral (fentanyl) sublingual tablets	4 tablets per day	
Fentora (fentanyl) buccal tablets	4 tablets per day	
Lazanda (fentanyl citrate) nasal spray	1 bottle per day	
Onsolis (fentanyl) buccal film	4 units per day	
Subsys (fentanyl) sublingual spray	4 units per day	

APPROVAL CRITERIA

Requests for Transmucosal Immediate Release Fentanyl (TIRF) may be approved for individuals who meet the following criteria:

- I. Individual has a diagnosis of active cancer (i.e. metastatic or locally invasive cancer for which the individual is currently seeking treatment) with breakthrough cancer pain (please document cancer type); **AND**
- II. Individual is 18 years of age or older (*16 years of age or older generic Fentanyl citrate lozenge or brand Actiq); **AND**
- III. Individual is already receiving opioids and is **TOLERANT** to opioid therapy as defined as receiving around the clock medicine consisting of one of the following:
 - A. At least 60 mg oral morphine daily **OR**

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This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.

WEB-PEC-0514-16

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- B. At least 25 mcg transdermal fentanyl/hour **OR**
- C. At least 30mg of oral oxycodone daily **OR**
- D. At least 8mg of oral hydromorphone daily **OR**
- E. At least 25mg of oral oxymorphone daily **OR**
- F. An equianalgesic dose of another opioid for a week or longer;

AND

- IV. Individual will be continuing around the clock opioids while utilizing TIRF agents for cancer related breakthrough pain.

Requests for Non-Preferred Transmucosal Immediate Release Fentanyl (TIRF) must also meet the following, in addition to Roman Numeral I.-IV. above:

- I. Individual has had a trial (medication samples/coupons/discount cards are excluded from consideration as a trial) of and inadequate response or intolerance to transmucosal fentanyl citrate lozenge (generic Actiq); **OR**
- II. Individual has completed titration and is maintained on a stable dose of the requested drug.

For approval of increased quantities of oral transmucosal immediate-release fentanyl (TIRF) agents, the following criteria must be met:

- I. Requests for increased quantity can be approved for the diagnosis of breakthrough cancer pain.

Note: It may be possible in some instances to use a higher strength of the requested medication and use fewer transmucosal delivery systems to achieve the same total daily dosage requested.

Requests for TIRF agents may not be approved for the following criteria:

- I. Individual is using for treatment of acute or postoperative pain; **OR**
- II. Individual is using for treatment of migraine headache pain; **OR**
- III. Individual is using for non-cancer related breakthrough pain.

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Note: TIRF agents have a black box warning that notes use in opioid non-tolerant individuals is contraindicated due to the risk for fatal respiratory depression. Also, use with a CYP3A4 inhibitor may cause fatal respiratory depression. In addition, TIRF agents are contraindicated for the management of acute or postoperative pain including migraine headaches. Because TIRF agents contain fentanyl, there is abuse liability similar to other opioids. TIRF cannot be converted on a mcg per mcg basis with other TIRF agents. TIRF agents are available only through a restricted TIRF REMS Access program.

State Specific Mandates		
State name	Date effective	Mandate details (including specific bill if applicable)
N/A	N/A	N/A

Key References:

Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2016. URL: <http://www.clinicalpharmacology.com>. Updated periodically.

DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>.

DrugPoints® System (electronic version). Truven Health Analytics, Greenwood Village, CO. Updated periodically.

Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2016; Updated periodically.

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