Transmucosal Immediate Release Fentanyl (TIRF) Agents

Override(s)	Approval Duration
Prior Authorization Quantity Limit	1 year
Medications	**Quantity Limit**
*Fentanyl citrate lozenge - Generic	4 units per day
Fentora (fentanyl) buccal tablets	4 tablets per day
*Actiq (fentanyl citrate) lozenge-Brand	4 units per day
Abstral (fentanyl) sublingual 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. Documentation is provided that individual has a diagnosis of active cancer (such as, metastatic or locally invasive cancer for which the individual is currently seeking treatment) with breakthrough cancer pain (please provide diagnosis); **AND**

II. Individual is 18 years of age or older (*individual is 16 years of age or older for 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**
- 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. At least 60mg of oral hydrocodone daily; **OR**
- G. An equianalgesic dose of another opioid for a week or longer;

AND

IV. Documentation is provided that individual will be continuing around the clock opioids while utilizing TIRF agents for cancer related breakthrough pain.

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**
II. Individual is using for non-cancer related breakthrough pain; **OR**
IV. Individual has one of the following conditions:
    A. Significant respiratory depression; **OR**
    B. Acute or severe bronchial asthma or hypercarbia; **OR**
    C. Known or suspected paralytic ileus.

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.

Key References:

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2022. URL: http://www.clinicalpharmacology.com. Updated periodically.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed: July 12, 2022.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2022; Updated periodically.
5. Advanced Opioid Converter. GlobalRPh.com [Internet database]. URL: http://www.globalrph.com/opioidconverter2.htm.
6. American Society of Interventional Pain Physicians (07/2012). "American Society of Interventional Pain Physicians (ASIPP) guidelines for responsible opioid prescribing in chronic non-cancer pain: Part 2--guidance". Pain physician (1533-3159), 15 (3 suppl), p. S67.
7. Dowell D, Haegerich TM, Chou R. CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016. MMWR Recomm Rep 2016;65:1–49. DOI: http://dx.doi.org/10.15585/mmwr.rr6501e1.
8. The Effectiveness and Risks of Long-Term Opioid Treatment of Chronic Pain. October 2014. Agency for Healthcare Research and Quality, Rockville, MD. Available from: http://www.ahrq.gov/research/findings/evidence-based-reports/opioidstp.html.
9. FDA Drug Safety Communication: FDA restricts use of prescription codeine pain and cough medicines and tramadol pain medicines in children; recommends against use in breastfeeding women. U.S. Food and Drug Administration. 4-20-2017. Available from: https://www.fda.gov/drugs/drugsafety/ucm549679.htm. Accessed July 12, 2022.
10. VA/DOD Clinical Practice Guideline for Opioid Therapy for Chronic Pain. Department of Veterans Affairs/Department of Defense. Version 3.0 – 2017. Available from: https://www.healthquality.va.gov/guidelines/Pain/cot/VADoDOTCPG022717.pdf. Accessed July 12, 2022.

11. Washington State Agency Medical Directors' Group. Interagency guideline on opioid dosing for chronic non-cancer pain: an educational aid to improve care and safety with opioid treatment. Olympia (WA): Washington State Department of Labor and Industries; June 2015. Available from: http://www.agencymeddirectors.wa.gov/Files/2015AMDGOpioidGuideline.pdf

Federal and state laws or requirements, contract language, and Plan utilization management programs or polices may take precedence over the application of this clinical criteria.