Clinical Edit Criteria Proposal

Drug/Drug Class:	**Transmucosal Immediate Release Fentanyl (TIRF) Clinical Edit**
Date:	**7/14/2016**
Prepared for:	**MO HealthNet**
Prepared by:	**Xerox-Heritage, LLC.**

☐ **New Criteria** ☒ **Revision of Existing Criteria**

Executive Summary

Purpose: Ensure appropriate utilization and control of Transmucosal Immediate Release Fentanyl (TIRF).

Why was this Issue Selected:

Transmucosal Immediate-Release Fentanyl products are Food and Drug Administration (FDA) approved for the management of breakthrough cancer pain. Moreover, these agents are specifically indicated for use in patients who are already receiving and who are tolerant to around-the-clock therapy for their underlying persistent cancer pain (opioid-tolerant). According to the FDA, patients considered opioid-tolerant are those who are regularly taking daily doses of at least 60 mg oral morphine, 30 mg oral oxycodone, 8 mg oral hydromorphone, 25 mg oral oxymorphone, 25 mcg transdermal fentanyl per hour, or an equianalgesic dose of another opioid for one week or longer. Six different dosage formulations of immediate-release fentanyl are currently available: a buccal film (Onsolis®), buccal tablet (Fentora®), nasal spray (Lazanda®), sublingual spray (Subsys®), sublingual tablet (Abstral®) and a transmucosal lozenge (Actiq®). Currently, only the fentanyl citrate transmucosal lozenge is available generically. Clinical trials have consistently demonstrated the well-established effectiveness of immediate-release fentanyl in the management of breakthrough pain in patients with cancer; however, there is limited evidence regarding head-to-head trials among the different formulations.

The FDA has established a Risk Evaluation and Mitigation Strategy (REMS) Access Program for the TIRF products.

	Drug	Claims	Expenses
Program-specific information:	• Actiq	15	*$15,516*
	• Subsys	85	*$1,387,309*
	• Abstral	6	*$28,934*

**FFS claims only for 2/1/15-1/31/16*

Setting & Population: Patients 16 years of age and older.

Type of Criteria: ☐ **Increased risk of ADE** ☐ **Non-Preferred Agent** ☒ **Appropriate Indications** ☐

Data Sources: ☐ **Only administrative databases** ☒ **Databases + Prescriber-supplied**

Setting and Population

- Drug for review: Transmucosal Immediate Release Fentanyl
- Age range: Patients 16 years of age and older
- Gender: Male and female

Approval Criteria

Approval Diagnoses		
Condition	**Inferred Drugs**	**Date Range**
Cancer	NA	2 years
	Antineoplastics	12 months
Opioid Tolerance	Opioids	> 7 days supply in the last 30 days

***For Approval, must meet BOTH Cancer and Opioid Tolerance Diagnoses**

Denial Criteria

Therapy will be denied if the patients meets any of the following criteria:

- MAOI history in the last 45 days
- < 16 years of age for Actiq and < 18 for Abstral, Fentora, Lazanda, Onsolis, or Subsys
- Actiq doses > 200mcg used for initial therapy. Initial therapy will be defined as patient not having Actiq therapy in the last 60 days.
- > 4 units per day
- Initial claim for > 100 mcg for Abstral, Fentora, Lazanda, Subsys or > 200 mcg for Actiq or Onsolis

Disposition of Edit

- **Denial:** Edit 682 "Clinical Edit"

Default Approval Period

- **Default Approval Period:** 90 Days

References

1. Actiq® Package Insert. Westchester, PA: Cephalon; 2002.
2. British National Formulary, March 2002. http://www.bnf.vhn.net/bnf/documents/bnf.941.html
3. Lippincott, Williams, Wilkins. PDR Electronic Library, Montvale NJ; 2016.
4. USPDI, Micromedex Online; 2016.
5. Drug Facts and Comparisons Online; 2016 by Clinical Drug Information. Opioid Analgesics – Fentanyl Citrate Transdermal; last accessed March 15, 2016.

Appendix A

GCNs used to identify claim for TIRF

Appendix B

Diagnosis Codes used to identify cancer

Appendix C

GCNs used to identify antineoplastic agents

Appendix D

GCNs used to identify MAOI's or Zyvox

Appendix E

GCNs to identify Actiq products

Appendix F

GCNs to identify Fentora, Lazanda, Abstral, and Subsys products

Appendix G

GCNs to identify 100 mcg strength

Appendix H

GCNs to identify Onsolis or Actiq 200 mcg

Appendix I

GCNs used to identify > 7 day supply of other opioid therapy in the last 30 days (Drug Subject 203218)