SmartPA Criteria Proposal

Drug/Drug Class:	Transmucosal Immediate Release Fentanyl (TIRF) Clinical Edit
First Implementation Date:	July 14, 2016
Proposed Date:	December 17, 2020
Prepared for:	MO HealthNet
Prepared by:	MO HealthNet/Conduent
Criteria Status:	☐Existing Criteria ☒Revision of Existing Criteria ☐New Criteria

Executive Summary

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

Why Issue Selected: Transmucosal Immediate-Release Fentanyl (TIRF) products are FDA approved only 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 taking, for one week or longer, around-the-clock medicine consisting of at least 60 mg of oral morphine per day, at least 25 mcg of transdermal fentanyl per hour, at least 30 mg of oral oxycodone per day, at least 8 mg of oral hydromorphone per day, at least 25 mg oral oxymorphone per day, at least 60 mg oral hydrocodone per day, or an equianalgesic dose of another opioid daily for a week or longer. Fentanyl products must not be used in opioid non-tolerant patients because life-threatening hypoventilation could occur at any dose in patients not taking chronic opiates. For this reason, fentanyl containing agents are contraindicated in the management of acute or postoperative pain. Inappropriate use of fentanyl has resulted in life-threatening reactions and patient deaths, prompting FDA warnings on both transdermal and oral formulations. In 2011, the FDA established a Risk Evaluation and Mitigation Strategy (REMS) Access Program for the TIRF products to reduce the risk of adverse outcomes, misuse, abuse, addiction, and overdose. However, an assessment of the REMS program published in February 2019, found substantial inappropriate prescribing of TIRF agents despite the REMS program. In addition, according to a National Vital Statistics System report published in December 2018, fentanyl is now the drug most frequently involved in overdose deaths in the US. For these reasons, MO HealthNet will continue to edit these agents.

Program-Specific Information:

Date Range FFS 10-01-2019 to 9-30-2020		
Drug	**Claims**	**Spend**
All TIRF Agents	0	-

Type of Criteria:

☒ **Increased risk of ADE**
☒ **Appropriate Indications**
☐ **Preferred Drug List**
☒ **Clinical Edit**

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Data Sources: ☐ **Only Administrative Databases** ☒ **Databases + Prescriber-Supplied**

Setting & Population

- Drug class for review: Transmucosal Immediate Release Fentanyl (TIRF)
- Age range: All appropriate MO HealthNet participants aged 16 years and older

Approval Criteria

- Participant of appropriate age for agent:
  - 16 years and older: Actiq® **OR**
  - 18 years and older: Lazanda® and Fentora® **AND**
- Documented diagnosis ~~**or inferred diagnosis**~~ of cancer in the past 3 months **AND**
- Documented history of > 7 days of opioid therapy in the past 30 days **AND**
- Documented history of previous TIRF therapy in the past 90 days for:
  - Claims for Lazanda and Fentora for strengths > 100mcg **OR**
  - Claims for Actiq for strengths > 200mcg **AND**
- Claim is within approved dosage limitations (see Appendix A)

Denial Criteria

- Therapy will be denied if all approval criteria are not met
- Documented history of MAOI therapy in the past 30 days
- **Denial criteria contained within the High Risk Therapies Clinical Edit: Claim is for an opioid (excluding buprenorphine tablets and buprenorphine/naloxone combinations) and:**
  - **Participant has history of > 3 days of select oral benzodiazepine therapy (alprazolam, chlordiazepoxide, clonazepam, clorazepate, diazepam, lorazepam, and oxazepam) in the past 60 days AND**
  - **Participant lacks history of at least 1 claim for an opioid emergency reversal agent in the past 2 years**

Required Documentation

Laboratory Results:		Progress Notes:	
MedWatch Form:		Other:	**X**

Disposition of Edit

Denial: Exception code “0682” (Clinical Edit)
Rule Type: CE

Default Approval Period

3 months

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Appendix A

Drug Description	Generic Equivalent	Max Units Per Day
Actiq 200 mcg lozenge	Fentanyl Citrate Buccal	4 lozenges
Actiq 400 mcg lozenge	Fentanyl Citrate Buccal	4 lozenges
Actiq 600 mcg lozenge	Fentanyl Citrate Buccal	4 lozenges
Actiq 800 mcg lozenge	Fentanyl Citrate Buccal	4 lozenges
Actiq 1200 mcg lozenge	Fentanyl Citrate Buccal	4 lozenges
Actiq 1600 mcg lozenge	Fentanyl Citrate Buccal	4 lozenges
Fentora 100 mcg buccal tab	Fentanyl Citrate Buccal	4 tablets
Fentora 200 mcg buccal tab	Fentanyl Citrate Buccal	4 tablets
Fentora 400 mcg buccal tab	Fentanyl Citrate Buccal	4 tablets
Fentora 600 mcg buccal tab	Fentanyl Citrate Buccal	4 tablets
Fentora 800 mcg buccal tab	Fentanyl Citrate Buccal	4 tablets
Lazanda 100 mcg nasal spray	Fentanyl Citrate Nasal	4 sprays
Lazanda 300 mcg nasal spray	Fentanyl Citrate Nasal	4 sprays
Lazanda 400 mcg nasal spray	Fentanyl Citrate Nasal	4 sprays

References

- ACTIQ® (fentanyl citrate) oral transmucosal lozenge, [package insert]. North Wales, PA: Teva Pharmaceuticals USA, Inc.; October 2019.
- FENTORA® (fentanyl buccal tablet) [package insert]. North Wales, PA: Teva Pharmaceuticals USA, Inc.; October 2019.
- LAZANDA® (Fentanyl) Nasal Spray [package insert]. Northbrook, IL: West Therapeutic Development, LLC; August 2018
- Rollman, JE, et al. Assessment of the FDA Risk Evaluation and Mitigation Strategy for Transmucosal Immediate-Release Fentanyl Products. JAMA. 2019; 321(7):676-685. doi:10.1001/jama.2019.0235
- Hedegaard, H, et al. Drugs Most Frequently Involved in Drug Overdose Deaths: United States, 2011–2016. National Vital Statistics Reports, Vol. 67, No. 9, December 12, 2018

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