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PHARMACY COVERAGE GUIDELINES	**ORIGINAL EFFECTIVE DATE: 9/21/17**
SECTION: DRUGS	**LAST REVIEW DATE: 8/15/19**
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	ARCHIVE DATE:

TRANSMUCOSAL IMMEDIATE RELEASE FENTANYL FORMULATIONS:
ABSTRAL® (fentanyl citrate) sublingual tablet
ACTIQ® (fentanyl citrate) transmucosal lozenge
FENTORA® (fentanyl citrate) buccal tablet
LAZANDA® (fentanyl citrate) nasal spray
SUBSYS® (fentanyl) sublingual spray

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Pharmacy Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

This Pharmacy Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide BCBSAZ complete medical rationale when requesting any exceptions to these guidelines.

The section identified as "Description" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as "Criteria" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Pharmacy Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Pharmacy Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

This Pharmacy Coverage Guideline does not apply to FEP or other states' Blues Plans.

Information about medications that require precertification is available at www.azblue.com/pharmacy.

Some large (100+) benefit plan groups may customize certain benefits, including adding or deleting precertification requirements.

All applicable benefit plan provisions apply, e.g., waiting periods, limitations, exclusions, waivers and benefit maximums.

TRANSMUCOSAL IMMEDIATE RELEASE FENTANYL FORMULATIONS (cont.)

Precertification for medication(s) or product(s) indicated in this guideline requires completion of the request form in its entirety with the chart notes as documentation. All requested data must be provided. Once completed the form must be signed by the prescribing provider and faxed back to BCBSAZ Pharmacy Management at (602) 864-3126 or emailed to Pharmacyprecert@azblue.com. **Incomplete forms or forms without the chart notes will be returned.**

Criteria:

- **Criteria for initial therapy:** Abstral, Actiq, Fentora, Lazanda, or Subsys is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met:

1. Individual is
   - 18 years of age or older for Abstral, Fentora, Lazanda or Subsys
   - 16 years of age or older for Actiq
2. Documentation of a **current** confirmed diagnosis of cancer
3. Individual is experiencing **breakthrough** cancer-related pain
4. Member is currently on fentanyl transdermal patches with no side effects
5. For **Abstral, Fentora, Lazanda and Subsys** requests: Failure, contraindication, or intolerance to:
   - generic fentanyl citrate oral transmucosal lozenge **(Actiq)**
6. There is **NO** concomitant use with benzodiazepines-ex. clonazepam, lorazepam, diazepam etc. **OR** there is a plan to taper use and to coordinate care among all prescribers
7. There is documentation that coordination of care will be performed between different prescribers for **ALL** controlled substances
8. There are **NO** contraindications.
   - Contraindications include:
     - Use in the emergency department
     - Known or suspected gastrointestinal obstruction, including paralytic ileus
     - Hypersensitivity to Fentanyl or other component of the product
     - Acute or severe bronchial asthma in an unmonitored setting or in the absence of resuscitative equipment
     - Opioid non-tolerant patients
     - Management of acute or postoperative pain including headache/migraines dental pain
     - Significant respiratory depression

Initial approval duration:
- Abstral, Actiq (or generic), Fentora, Lazanda, or Subsys will be approved at the requested dosage for 12 months for pain related to cancer

TRANSMUCOSAL IMMEDIATE RELEASE FENTANYL FORMULATIONS (cont.)

- **Criteria for continuation of coverage (renewal request):** Abstral, Actiq, Fentora, Lazanda, or Subsys is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met:

  1. Individual's cancer related pain is controlled with these products

  2. There is documentation that coordination of care is being performed between different prescribers for **ALL** controlled substances

  3. The condition has not progressed or worsened while on therapy and no development of severe side effects like:
     - Apnea, dyspnea, epistaxis, hemoptysis, hyperventilation, hypoxia, upper respiratory infection etc.
     - Confusion/speech disturbance
     - Dehydration
     - Atrial fibrillation/arrhythmia/chest pain
     - Ascites

  4. There is **NO** concomitant use with benzodiazepines-ex. clonazepam, lorazepam, diazepam etc. **OR** there is a plan to taper use and to coordinate care among all prescribers

  Renewal duration:
  - Abstral, Actiq (or generic), Fentora, Lazanda, or Subsys will be approved at the requested dosage for 12 months for pain related to cancer

- **Patients should be tapered off or lower the dosage if any of the following apply: See "Definitions" section for Tapering guidelines**
  - The patient has committed serious or repeated drug seeking behavior
  - The patient makes no progress toward therapeutic goals

- **For all patients receiving more than 200 mg morphine or equivalent per 24 hours: See "Definitions" section for Tapering guidelines**
  - Taper patient to a lower dosage
  - Provide a Naloxone prescription to avoid side effects
  - Initiate/augment non-opioid treatments
  - Provide BH/Case management support to help with the taper

Description:

Opioid therapy is the first-line approach for moderate or severe pain in populations with active cancer. However, the comprehensive management of pain in patients with cancer also requires expertise in the use of the nonopioid analgesics, such as acetaminophen (paracetamol), non-steroidal anti-inflammatory agents (NSAIDs), and a group of drugs referred to as "adjuvant" analgesics or coanalgesics. The term "adjuvant analgesics" has been used to describe drugs that are marketed for indications other than pain, but are potentially useful as analgesics when added to opioid therapy in patients with chronic pain syndromes. In more recent years, some of these drugs have acquired approved indications for pain.

TRANSMUCOSAL IMMEDIATE RELEASE FENTANYL FORMULATIONS (cont.)

Stepwise approach to management of cancer pain that includes both opioid and nonopioid drugs has been codified in the World Health Organization's (WHO) "analgesic ladder" approach to cancer pain management (figure 1) [1]:

World Health Organization (WHO) analgesic ladder:

- Step 1, which represents mild to moderate cancer-related pain, suggests the use of acetaminophen or an NSAID, possibly combined with an adjuvant drug to provide additional analgesia, treat a side effect, or manage a coexisting symptom.

- For patients with moderate or severe pain, and those who do not achieve adequate relief with acetaminophen or an NSAID alone, treatment with a step 2 opioid (conventionally used for moderate pain) or a step 3 opioid (conventionally used for severe pain) is appropriate. On both steps 2 and 3, the use of an acetaminophen or an NSAID should be considered, as well as other drugs (adjuvants) to enhance analgesia or treat side effects.

Therapeutic dose ranges for commonly used adjuvant analgesics:

Category based on conventional use	Class	Drugs	Usual starting dose	Usual effective dose range*
Multipurpose analgesics	Corticosteroids	Dexamethasone	Varies	1-2 mg twice daily, orally or IV
		Prednisone	Varies	5-10 mg twice daily
	Antidepressants	Desipramine	10-25 mg at bedtime	50-150 mg at bedtime
		Duloxetine	20-30 mg daily	60-120 mg daily¶
		Bupropion	75 mg twice daily	300-450 mg daily$^{\Delta}$
		Venlafaxine, sustained release	75 mg once daily	150-225 mg daily
		Nortriptyline	10 to 25 mg at bedtime	50 to 150 mg at bedtime
	Alpha-2 adrenergic agonists	Tizanidine	1-2 mg at bedtime	2-8 mg twice daily
Used for neuropathic pain	Anticonvulsants	Gabapentin	100-300 mg twice daily	300-1200 mg three times daily
		Pregabalin	25-75 mg twice daily	150-300 mg twice daily
	GABA agonists	Clonazepam	0.5 mg at bedtime	0.5-3 mg daily
Used for bone pain	Osteoclast inhibitors	Pamidronate	–	60-90 mg monthly, IV
		Zoledronic acid	–	4 mg monthly, IV
		Denosumab	–	120 mg monthly, subcutaneously
Used for bowel obstruction	Anticholinergic drugs	Glycopyrrolate	0.1 mg daily	0.1-0.2 mg three times daily, subcutaneously
	Somatostatin analogue	Octreotide	Varies	0.1-0.3 mg twice daily, subcutaneously

TRANSMUCOSAL IMMEDIATE RELEASE FENTANYL FORMULATIONS (cont.)

GABA: gamma amino butyric acid.

* All dosages shown are for adult patients, oral administration, unless otherwise noted.

¶ Randomized trials conducted in patients with diabetic peripheral neuropathy suggest no additional efficacy from

120 mg daily versus 60 mg daily.

Δ Bupropion doses ≥150 mg should be sustained release.

Transmucosal immediate release (oral and nasal) formulations of the opioid analgesic fentanyl are indicated only for the management of breakthrough cancer pain in individuals, who are already receiving around-the-clock opioid pain medication for cancer pain and who are tolerant to opioid therapy for their persistent cancer pain.

Substantial differences exist in the pharmacokinetic profiles of each product formulation that result in clinically important differences in extent of absorption of fentanyl. The formulations are not interchangeable on a mcg for mcg basis. There are no dose conversion directions available on any other fentanyl product; this includes oral, transdermal, or parenteral formulations.

Use of transmucosal immediate release (oral and nasal) formulations of fentanyl is subject to a Risk Evaluation and Mitigation Strategies (REMS) program that requires provider, patient, and dispensing pharmacy be enrolled into the program. Only providers and Pharmacies enrolled into the REMS may prescribe and dispense the drug, respectively, to individuals who are also in the program. A REMS program attempts to manage known or potentially serious risks associated with a drug product and is required by the Food and Drug Administration (FDA) for some drugs to ensure that the benefits of a drug outweigh its risks.

Providers, pharmacies, and individual patients must be enrolled in the shared Transmucosal Immediate-release Fentanyl (TIRF) Risk Evaluation and Mitigation Strategy (REMS) Access Program in order to prescribe, dispense, and receive TIRF products. The TIRF REMS web site can be accessed at: www.TIRFREMSaccess.com.

Definitions:

CDC Recommendations for Opioid Prescribing for Chronic Pain:

A. Determining when to initiate or continue opioids for chronic pain

1. Opioids are not first-line or routine therapy for chronic pain
2. Establish and measure goals for pain and function
3. Discuss benefits and risks and availability of non-opioid therapies with patient

B. Opioid selection, dosage, duration, follow-up, and discontinuation

1. Use immediate-release opioids when starting
2. Start low and go slow-Use caution at any dose and avoid increasing to high dosages
3. When opioids are needed for acute pain, prescribe no more than needed
    - Do NOT prescribe ER/LA opioids for acute pain

TRANSMUCOSAL IMMEDIATE RELEASE FENTANYL FORMULATIONS (cont.)

4. Follow-up and re-evaluate risk of harm; reduce dose or taper and discontinue if opioids cause harm or are not helping

C. Assessing risk and addressing harms of opioid use

1. Evaluate risk factors for opioid-related harms
2. Check CSPMP for high dosages and prescriptions from other providers at the beginning of the treatment and at least quarterly while on the opioid treatment
3. Use urine drug testing to identify prescribed substances and undisclosed use
4. Avoid concurrent benzodiazepine and opioid prescribing
5. Arrange treatment for opioid use disorder if needed

Prescriber Education:

- Guidelines for Prescribing Opioids for Chronic Pain
  https://www.cdc.gov/drugoverdose/pdf/TurnTheTide_PocketGuide-a.pdf
  http://www.agencymeddirectors.wa.gov/Files/FY16-288SummaryAMDGOpioidGuideline_FINAL.pdf
  https://www.cdc.gov/drugoverdose/pdf/Guidelines_Factsheet-a.pdf

- Checklist for prescribing opioids for chronic pain
  https://www.cdc.gov/drugoverdose/pdf/PDO_Checklist-a.pdf

- Tapering Opioids for Chronic Pain
  https://www.cdc.gov/drugoverdose/pdf/Clinical_Pocket_Guide_Tapering-a.pdf

- Non-Opioid Treatments
  https://www.cdc.gov/drugoverdose/pdf/nonopioid_treatments-a.pdf

- Assessing Benefits and Harms of Opioid
  https://www.cdc.gov/drugoverdose/pdf/Assessing_Benefits_Harms_of_Opioid_Therapy-a.pdf

- Calculating Total Daily Dose of Opioids for Safer Dosage
  https://www.cdc.gov/drugoverdose/pdf/calculating_total_daily_dose-a.pdf

- Checking Controlled Substances Prescription Monitoring Program (CSPMP)
  https://arizona.pmpaware.net/login
  https://pharmacypmp.az.gov/

- Educational Webinar Series for Prescribers
  https://www.cdc.gov/drugoverdose/pdf/COCA-webinar-series-allslides-a.pdf
  https://www.cdc.gov/drugoverdose/prescribing/trainings.html
  http://www.coperems.org/

- CDC Guideline for Prescribing Opioids for Chronic Pain
  https://www.cdc.gov/drugoverdose/prescribing/clinical-tools.html

- Washington State Opioid Taper Plan Calculator

TRANSMUCOSAL IMMEDIATE RELEASE FENTANYL FORMULATIONS (cont.)

www.agencymeddirectors.wa.gov/Files/2015AMDGOpioidGuideline.pdf

- Tapering Long-Term Opioid Therapy in Chronic Non-cancer Pain
  www.mayoclinicproceedings.org/article/S0025-6196(15)00303-1/fulltext

- UpToDate
  https://www-uptodate-com.mwu.idm.oclc.org/contents/overview-of-the-treatment-of-chronic-non-cancer-pain?source=search_result&search=non-cancer%20pain&selectedTitle=1~150

Opioid Risk Assessment Tool:

Score each that applies	Female	Male
Family history of substance abuse		
Alcohol	1	3
Illegal drugs	2	3
Rx drugs	4	4
Personal history of substance abuse		
Alcohol	3	3
Illegal drugs	4	4
Rx drugs	5	5
Age between 16-45 years	1	1
History of preadolescent sexual abuse	3	0
Psychological disorders		
ADD,OCD, Bipolar, Schizophrenia	2	2
Depression	1	1
Total score		
Assessment of risk		
Low risk for abuse	≤ 3	
Moderate risk for abuse	4-7	
High risk for abuse	≥ 8	
Definitions of risk		
Low = unlikely to abuse Moderate = as likely will as will not abuse High = likely to abuse		

Resources:

Abstral. Package Insert. Revised 5/2017 by manufacturer. Reviewed 07-19-2018.

Abstral. Package Insert. Revised 12-2016 by manufacturer Reviewed 02-25-2017.

Abstral. Package Insert. Revised July 2013 by manufacturer Reviewed 05-08-2014.

TRANSMUCOSAL IMMEDIATE RELEASE FENTANYL FORMULATIONS (cont.)

Actiq. Package Insert. Revised 7/2018 by manufacturer. Reviewed 07-19-2018.

Actiq. Packet Insert. Revised 12-2016 by manufacturer. Reviewed 02-25-2017.

Actiq. Packet Insert. Revised December 2011 by manufacturer. Reviewed 05-08-2014.

Fentora. Package Insert. Revised 7/2018 by manufacturer. Reviewed 07-19-2018.

Fentora. Packet Insert. Revised 02-2017 by manufacturer. Reviewed 02-25-2017.

Fentora. Packet Insert. Revised February 2013 by manufacturer. Reviewed 05-08-2014.

Lazanda. Package Insert. Revised 3/2017 by manufacturer. Reviewed 07-19-2018.

Lazanda. Packet Insert. Revised 03-2015 by manufacturer. Reviewed 02-27-2017.

Lazanda. Packet Insert. Revised November 2013 by manufacturer. Reviewed 05-08-2014, 02-25-2017.

Subsys. Packet Insert. Revised 12-2016 by manufacturer. Reviewed 02-25-2017, 07-19-2018.

Subsys. Packet Insert. Revised July 2013 by manufacturer. Reviewed 05-08-2014.

Transmucosal immediate release fentanyl (TIRF) Risk Evaluation and Mitigation Strategy 12-2014.

Off Label Use of Cancer Medications: A.R.S. §§ 20-826(R) & (S). Subscription contracts; definitions.

Off Label Use of Cancer Medications: A.R.S. §§ 20-1057(V) & (W). Evidence of coverage by health care service organizations; renewability; definitions.

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Fax completed prior authorization request form to 602-864-3126 or email to pharmacyprecert@azblue.com.
Call 866-325-1794 to check the status of a request.
All requested data must be provided. **Incomplete forms or forms without the chart notes will be returned.**
Pharmacy Coverage Guidelines are available at www.azblue.com/pharmacy.

Opioid Prior Authorization Request Form

Do not copy for future use. Forms are updated frequently.
REQUIRED: Office notes, labs, and medical testing relevant to the request that show medical justification are required.

Member Information			
Member Name (first & last):	Date of Birth:	Gender:	BCBSAZ ID#:
Address:	City:	State:	Zip Code:
Prescribing Provider Information			
Provider Name (first & last):	Specialty:	NPI#:	DEA#:
Office Address:	City:	State:	Zip Code:
Office Contact:	Office Phone:		Office Fax:
Dispensing Pharmacy Information			
Pharmacy Name:	Pharmacy Phone:		Pharmacy Fax:
Requested Medication Information			
Medication Name:	Strength:		Dosage Form:
Directions for Use:	Quantity:	Refills:	Duration of Therapy/Use:

☐ Check if requesting **brand** only ☐ Check if requesting **generic**

☐ Check if requesting continuation of therapy (prior authorization approved by BCBSAZ expired)

Turn-Around Time For Review

☐ Standard ☐ Urgent. Sign here: _____ ☐ Exigent (requires prescriber to include a written statement)

Clinical Information

1. Select all applicable diagnoses below.

☐ Confirmed diagnosis of pain severe enough that is not controlled by the current dosage
☐ Confirmed diagnosis of Migraines
☐ Confirmed diagnosis of Neuropathic Pain
☐ Confirmed diagnosis of Osteoarthritis
☐ Confirmed diagnosis of Fibromyalgia
☐ Other diagnosis: _____ ICD-10 Code(s): _____

2. What is the quantity requested per day? _____

3. What is the reason for exceeding the plan limitations? Please specify below (if applicable).

_____

4. For Migraines: Check all applicable non-opioid therapies failed, intolerated, or contraindicated.

PREVENTATIVE TREATMENTS

☐ Anticonvulsants (Topiramate)
☐ Beta-Blockers (Propranolol, Atenolol)
☐ TCAs (Amitriptyline, Imipramine)
☐ Calcium Channel Blockers (Amlodipine, Verapamil)
☐ Non pharmacological treatments (Cognitive behavioral therapy, Relaxation, Biofeedback, Exercise therapy)

ACUTE TREATMENTS

☐ Aspirin, Acetaminophen, NSAIDS (Naproxen, Ibuprofen, Meloxicam, Diclofenac) may be combined with caffeine
☐ Anti-nausea medication (Ondansetron, Promethazine)
☐ Triptans - migraine-specific (Rizatriptan, Sumatriptan)

5. For Neuropathic Pain: Check all applicable non-opioid therapies failed, intolerated, or contraindicated.

☐ TCAs (Amitriptyline, Imipramine)
☐ SNRIs (Duloxetine, Venlafaxine)
☐ Gabapentin/Lyrica
☐ Topical Aspercreme 4% cream or Patches
☐ Non pharmacological treatments (Exercise, Weight loss, patient education)

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Opioid Prior Authorization Request Form

6. For Osteoarthritis: Check all applicable non-opioid therapies failed, intolerated, or contraindicated.

FIRST LINE

- ☐ Acetaminophen
- ☐ Oral NSAIDs (Naproxen, Ibuprofen, Meloxicam, Diclofenac)
- ☐ Topical NSAIDs (Diclofenac Gel)

SECOND LINE

- ☐ Intra-articular hyaluronic acid (OA of the knee only)
- ☐ Capsaicin

7. For Fibromyalgia: Check all applicable non-opioid therapies failed, intolerated, or contraindicated.

- ☐ Duloxetine
- ☐ Lyrica
- ☐ Gabapentin
- ☐ TCAs (Amitriptyline, Imipramine)
- ☐ Non pharmacological treatments (Low impact aerobic exercise such as brisk walking, swimming, water aerobics or bicycling. Cognitive behavioral therapy, biofeedback, interdisciplinary rehabilitation)

8. ☐ Yes ☐ No **A treatment plan must be submitted with this request form that includes ALL of the following:**

- Pain intensity (scales or ratings)
- Functional status (physical and psychosocial)
- Patient's goal of therapy (level of pain acceptable and/or functional status)
- Current non-pharmacological treatment

9. ☐ Yes ☐ No **A physician-patient pain management contract must be submitted with this request form.**

10. ☐ Yes ☐ No **Individual must not be actively using illicit substances or NOT have a drug seeking behavior.**

11. ☐ Yes ☐ No **Results from random urine or blood test twice a year must be submitted with this request form.**

12. ☐ Yes ☐ No **Has the state's Prescription Drug Monitoring Program (PDMP) been reviewed for this individual every time a prescription for controlled substance is provided?**

13. What other controlled substances is the patient currently receiving? Please specify below.

_____

14. One pharmacy (plus one closest 24 hour pharmacy) must be selected for all the controlled substances prescription services. Please specify:

_____

15. ☐ Yes ☐ No **There is NO concomitant use with benzodiazepines-ex. clonazepam, lorazepam, diazepam etc.**

16. ☐ Yes ☐ No **There is absence of ALL contraindications.**

17. What medication(s) has the individual tried and failed for this diagnosis? Please specify below.

Important note: Samples provided by the provider are not accepted as continuation of therapy or as an adequate trial and failure.

Medication Name, Strength, Frequency	Dates started and stopped or Approximate Duration	Describe response, reason for failure, or allergy

18. Are there any supporting labs or test results? Please specify below.

Date	Test	Value

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Opioid Prior Authorization Request Form

19. Is there any additional information the prescribing provider feels is important to this review? Please specify below.

Signature affirms that information given on this form is true and accurate and reflects office notes

Prescribing Provider's Signature: Date:

Please note: Some medications may require completion of a drug-specific request form.

Incomplete forms or forms without the chart notes will be returned.

Office notes, labs, and medical testing relevant to the request that show medical justification are required.