

UNIFORM PHARMACY PRIOR AUTHORIZATION REQUEST FORM

CONTAINS CONFIDENTIAL PATIENT INFORMATION

Complete this form in its entirety and send to Rocky Mountain Health Plans at 858-357-2538

<input type="checkbox"/> Initial Request		<input type="checkbox"/> Renewal		<input type="checkbox"/> Appeal/Redetermination¹	
<input type="checkbox"/> Urgent²		<input type="checkbox"/> Non-Urgent			
Requested Drug Name: Lazanda (fentanyl citrate nasal spray) – Medicare Part D					
Patient Information:			Prescribing Provider Information:		
Patient Name:			Prescriber Name:		
Member/Subscriber Number:			Prescriber Fax:		
Policy/Group Number:			Prescriber Phone:		
Patient Date of Birth (MM/DD/YYYY):			Prescriber Pager:		
Patient Address:			Prescriber Address:		
Patient Phone:			Prescriber Office Contact:		
Patient Email Address:			Prescriber NPI:		
			Prescriber DEA:		
Prescription Date:			Prescriber Tax ID:		
			Specialty/Facility Name (If applicable):		
			Prescriber Email Address:		
Prior Authorization Request for Drug Benefit					
Patient Diagnosis and ICD Diagnostic Code(s):					
Drug(s) Requested (with J-Code, if applicable):					
Strength/Route/Frequency:					
Unit/Volume of Named Drug(s):					
Start Date and Length of Therapy:					
Location of Treatment: (e.g. provider office, facility, home health, etc.) including name, Type 2 NPI (if applicable), address and tax ID:					
Clinical Criteria for Approval, Including other Pertinent Information to Support the Request, other Medications Tried, Their Name(s), Duration, and Patient Response:					
Lazanda (fentanyl citrate nasal spray)					
Underlying Diagnosis (documentation supportive of diagnosis is required for approval)					
<input type="checkbox"/> Breakthrough cancer pain					
<input type="checkbox"/> Other (please state): _____					
Clinical Consideration (for approval, please indicate and provide documentation of the following):					
<input type="checkbox"/> Patient is opioid tolerant (defined as morphine 60mg/day or equi-analgesic dose of another opioid)					
Please list current, chronic opioid therapy:					
Drug		Directions			
_____		_____			
_____		_____			

Patient has tried and failed fentanyl citrate lollipop (the generic form of Actiq). ***Trial of fentanyl citrate lollipop is required for approval.***

- Yes
 No

Oral administration is difficult/uncomfortable due to oral problems (e.g. xerostomia, mucositis). ***Documentation is required.***

My patient is not a candidate for oral transmucosal fentanyl (***Documentation Required***)

Not applicable

A pain contract is in place. Transmucosal fentanyl is only approvable for patients who have signed a pain/opioid contract with their physician. ***Please provide a copy of the contract.***

- Yes
 No

My patient is being evaluated for pain control every three months or more frequently. ***Documentation must be supplied showing physician visits for pain management no less often than every three months.***

- Yes
 No

REMS Program for Transmucosal Immediate Release Fentanyl COMPLETED (available at: www.tirfremssuccess.com)

*If all criteria are met, Lazanda will only be approved for 3 months at a time

*Each re-approval will only require documentation of office visits occurring no less often than every 3 months

Physician Specialty

- Oncologist
 Pain specialist

Other (please state): _____

For use in clinical trial? (If yes, provide trial name and registration number):

Drug Name (Brand Name and Scientific Name)/Strength:

Dose:	Route:	Frequency:
Quantity:	Number of Refills:	
Product will be delivered to:	<input type="checkbox"/> Patient's Home <input type="checkbox"/> Physician Office	Other:
Prescriber or Authorized Signature:		Date:
Dispensing Pharmacy Name and Phone Number:		

Approved

Denied

If denied, provide reason for denial, and include other potential alternative medications, if applicable, that are found in the formulary of the carrier:

1. Appeal/redetermination requests can be made for this medication within 60 calendar days from the date on the faxed/written denial notice you received at the time of the original request.

2. A request for prior authorization that if determined in the time allowed for non-urgent requests could seriously jeopardize the life or health of the covered person or the ability of the covered person to regain maximum function, or subject the person to severe pain that cannot be adequately managed without the drug benefit contained in the prior authorization request.

RMHP Formulary Coverage Policy

Lazanda® (fentanyl nasal spray)

CLASSIFICATION

- Opioid analgesic

DESCRIPTION

- Lazanda is indicated ONLY for the management of breakthrough cancer pain (BTCP) in patients 18 years of age and younger who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain.
- Patients considered opioid tolerant are those who are taking around-the-clock opioid consisting of at least 60 mg of oral morphine daily, at least 25 mcg of transdermal fentanyl/hour, at least 30 mg of oral oxycodone daily, at least 8 mg oral hydromorphone daily or an equianalgesic dose of another opioid for a week or longer.
- Life-threatening respiratory depression could occur at any dose in opioid non-tolerant patients. Deaths have occurred in opioid non-tolerant patients. For that reason, these products are contraindicated in the management of acute or postoperative pain including headache/migraine.
- Lazanda is intended to be used only in the care of cancer patients and only by oncologists and pain specialists who are knowledgeable of and skilled in the use of Schedule II opioids to treat cancer pain.
- Lazanda in individuals with known allergic (seasonal) rhinitis showed no clinically meaningful differences in rate or extent of exposure to fentanyl, or in local tolerability of Lazanda when compared to asymptomatic state. However, the titration of a patient while they are experiencing an acute episode of rhinitis could lead to incorrect dose identification. Avoid titration under these circumstances.
- Different oral/buccal/nasal transmucosal preparations of fentanyl citrate cannot be converted on a mcg per mcg basis one to another and are not substitutable. Substantial differences exist in the pharmacokinetic profiles of each product that results in clinically important differences in the extent of absorption of fentanyl. As a result of these differences, the substitution of one fentanyl product with any other fentanyl product may result in fatal overdose.
- Actiq is available as a cost-saving generic. There exists a huge cost disparity between this generic formulation and brand name counterparts.

FORMULARY COVERAGE

Prior authorization:	Required
Good Health Formulary:	Tier 4
Legacy Commercial Formulary:	Tier 4
Medicare Part D coverage:	Tier 5

COVERAGE CRITERIA

Lazanda® (fentanyl) nasal spray meets the definition of **medical necessity** for any FDA approved indication, not otherwise excluded from Part D, including:

- Management of breakthrough pain in patients 18 years of age and younger with cancer who are already receiving and who are tolerant to around-the-clock opioid therapy
- Approval will be given in 3 month increments. Re-approval requires documentation showing physician visits for pain management no less often than every three months.
- A trial of fentanyl citrate lollipop is required for approval unless documentation is provided that indicates oral administration is difficult/uncomfortable due to oral problems (e.g. xerostomia, mucositis).

Lazanda® (fentanyl) nasal spray is considered **experimental** for the following (requests will be individually reviewed for medical necessity):

- Treatment of other types of pain that are not breakthrough cancer pain
- Treatment of breakthrough cancer pain in patient 18 years of age and younger

For members previously established or maintained on fentanyl citrate for non-cancer breakthrough pain:

- A review of clinical documentation provided will be conducted.
- Consideration will be given to allow a 6 month period of coverage. This is to provide adequate time for the member to transition over to a different pain medication.
- After a period of 6 months, this medication will no longer be covered by RMHP for this indication.

Required Provider Specialty:

- Approval is limited to oncology or a pain specialist
- Transmucosal Immediate Release Fentanyl (TIRF) Risk Evaluation and Mitigation Strategy (REMS) program is an FDA-required program effective March 2012.
- To complete the TIRF REMS, access: <https://www.tirfremssaccess.com/TirfUI/remss/home.action>
- For the FDA News Release, access: <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm285345.htm>

DOSAGE/ADMINISTRATION:

Adult Dosing (safety and efficacy in pediatric patients has not been established)

- Dosing should be individualized
- Dosing varies by preparation used (refer to corresponding prescribing information)
- Limit consumption to treat ≤ 4 episodes of breakthrough cancer pain per day once successful dose is found.

Dosing adjustments:

- Refer to corresponding prescribing information

PRECAUTIONS:

- **Contraindicated in opioid non-tolerant patients, or in the management of acute or postoperative pain including headache/migraines**
- Clinically significant respiratory and CNS depression can occur. Monitor patients accordingly.
- Ensure proper storage and disposal - keep in child-resistant container between uses and empty any unused solution into the carbon-lined pouch to bind the drug before disposal. Deaths due to accidental ingestion have been reported in children.

- Use with other CNS depressants and potent cytochrome P450 3A4 inhibitors may increase depressant effects including respiratory depression, hypotension, and profound sedation. Consider dosage adjustments if warranted.
- Titrate cautiously in patients with chronic obstructive pulmonary disease or preexisting medical conditions predisposing them to respiratory depression.
- Administer with extreme caution in patients susceptible to intracranial effects of CO₂ retention.
- Abuse potential, high risk of addiction, misuse, or diversion (transmucosal) - classified as a schedule II controlled substance.
- Due to different bioavailabilities among products and manufacturers, do not convert patients from one fentanyl product to another on a mcg to mcg basis. This includes Actiq®, Fentora®, Abstral®, Lazanda®, and Onsolis®.

Billing/Coding information:

- n/a

COST:

- AWP (May 2012):
 - Lazanda® (1 - 5ml bottle): \$336.00 – \$480.00 (dosed up to 4 times daily)
 - One month of therapy averages \$5,040 - \$7,200
 - Fentanyl citrate oral transmucosal lollipop (generic Actiq): \$11.02 - \$19.33 per lollipop (based on estimated “maximum allowable cost”)

COMMITTEE APPROVAL:

May 2012

GUIDELINE UPDATE INFORMATION:

May 2012	Prior Authorization and Coverage Policy created

REFERENCES:

- DRUGDEX®, accessed 05/22/2012.
- Product Information: Lazanda® (fentanyl) Nasal Spray. Archimedes Pharma US Inc, Bedminster, NJ, 2011.