Formulary Exception
Opioids Transmucosal – Lazanda® (fentanyl nasal spray)

Table of Contents

National Formulary Medical Necessity 1
Conditions Not Covered.....2
References 2
Revision History.....2

Product Identifier(s)

13692

INSTRUCTIONS FOR USE
The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

National Formulary Medical Necessity

Cigna covers fentanyl (Lazanda®) nasal spray as medically necessary when the following criteria are met:

Approval Duration: All approvals are provided for the duration noted below.

1. **Breakthrough Pain in Individuals with Cancer:** Approve for 1 year if the individual meets the following criteria (A, B, and C):
   - **A)** Individual meets ONE of the following conditions (i or ii):
     - **i.** Individual is unable to swallow, has dysphagia, esophagitis, mucositis, or uncontrollable nausea/vomiting; OR
     - **ii.** Individual is unable to take two other short-acting narcotics secondary to allergy or severe adverse events; AND
       Note: Examples of short-acting narcotics include immediate-release formulations of oxycodone, morphine sulfate, hydromorphone, etc.
   - **B)** Individual is on or will be on an oral or transdermal long-acting narcotic, or the individual is on intravenous, subcutaneous, or spinal (intrathecal, epidural) narcotics; AND

Note: Examples of long-acting narcotics include Duragesic, OxyContin, and morphine extended-release. Examples of intravenous, subcutaneous, or spinal narcotics include morphine sulfate, hydromorphone, and fentanyl citrate.

C) Individual meets ONE of the following conditions (i, ii, or iii):

- **i.** The individual has tried two of the following, if two are formulary (or one if only one is formulary or none if none are formulary): fentanyl citrate oral transmucosal lozenge (Actiq,generics), Abstral, Fentora, Subsys [verification of therapies required]; OR
- **ii.** In individuals who cannot tolerate the sugar content of fentanyl citrate oral transmucosal lozenge (Actiq, generics) [e.g., individuals who are glucose intolerant, diabetic, at high risk of dental caries], the individual has tried two of the following, if two are formulary (or one if only one is formulary or none if none are formulary): Abstral, Fentora, or Subsys [verification of therapies required]; OR
- **iii.** The individual has cancer and mucositis.

Verification of Therapies Required: Previous trials of other fentanyl transmucosal therapies are required to be verified by a clinician in the Cigna Coverage Review Department when noted in the criteria as [verification of therapies required].

Conditions Not Covered

Any other exception is considered not medically necessary.

References

1. U.S. Food and Drug Administration. Drugs@FDA. U.S. Department of Health & Human Services: http://www.accessdata.fda.gov/scripts/cder/drugsatfda/

Revision History

Type of Revision	Summary of Changes	Approval Date
Annual Revision	**Breakthrough Pain in Patients with Cancer:** Removed the statement "In the professional opinion of specialist physicians reviewing the data, we have adopted this criterion" from criteria. Changed examples of narcotics to notes.	09/21/2021

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