Medical Policy:
Adasuve® (loxapine)

POLICY NUMBER	LAST REVIEW	ORIGIN DATE
MG.MM.PH.208	February 14, 2025	April 6, 2020

Definitions

Adasuve, a typical antipsychotic, is an inhalation powder of loxapine supplied in a single-use, disposable inhaler containing 10 mg of loxapine base. ADASUVE is a drug-device combination product. The mechanism of action of loxapine in the treatment of agitation associated with schizophrenia is unknown. However, its efficacy could be mediated through a combination of antagonism of central dopamine D 2 and serotonin 5-HT 2A receptors. The mechanism of action of loxapine in the treatment of agitation associated with bipolar I disorder is unknown.

Length of Authorization

Coverage will be provided for 12 months and may be renewed.

Dosing Limits

Max Units (per dose and over time) [Medical Benefit]:

280 billable units per 28 days

Guideline

I. Initial Approval Criteria

Adasuve *may be considered medically necessary if one of the below conditions are met* ***AND*** *use is consistent with the medical necessity criteria that follows:*

1. **Acute treatment of agitation associated with schizophrenia or bipolar I disorder**
   A. Member is 18 years of age or older; **AND**
   B. Member has confirmed diagnosis of schizophrenia or bipolar I disorder made by or in consultation with a psychiatrist; **AND**
   C. Member suffers from "Psychomotor agitation" as defined in DSM-IV as "excessive motor activity associated with a feeling of inner tension." Members experiencing agitation often manifest behaviors that interfere with their care (e.g., threatening behaviors, escalating or urgently distressing behavior, self-exhausting behavior), leading clinicians to the use of rapidly absorbed antipsychotic medications to achieve immediate control of the agitation; **AND**
   D. Adasuve is part of the REMS Program to mitigate the risk of bronchospasm, Adasuve must be administered only in an enrolled healthcare facility

Limitations/Exclusions

Adasuve is not considered medically necessary for when any of the following selection criteria is met:

A. Member is less than 18 years of age
B. Disease progression while on Adasuve® (loxapine) .
C. Indications not supported by CMS recognized compendia or acceptable peer reviewed literature may be deemed as not approvable and therefore not reimbursable.
D. Current diagnosis or history of asthma, COPD, or other lung disease associated with bronchospasm
E. Acute respiratory symptoms or signs (e.g., wheezing)
F. Current use of medications to treat airways disease, such as asthma or COPD
G. History of bronchospasm following Adasuve treatment
H. Known hypersensitivity to loxapine or amoxapine. Serious skin reactions have occurred with oral loxapine and amoxapine.
I. Adasuve is part of the REMS Program to mitigate the risk of bronchospasm, Adasuve must be administered only in an enrolled healthcare facility

II. Renewal Criteria

- Patient continues to meet INITIAL APPROVAL CRITERIA.

Dosing/Administration

Indication	Dose
Acute treatment of agitation associated with schizophrenia or bipolar I disorder	Adasuve must be administered by a healthcare professional. Adasuve is administered by oral inhalation only. The recommended dose for acute agitation is 10 mg administered by oral inhalation, using a single-use inhaler. Administer only a single dose within a 24-hour period.

Applicable Procedure Codes

Code	Description
J2062	Adasuve (loxapine) 10MG Aerosol Powder Breath Activated for inhalation, 1 mg

Applicable NDCs

Code	Description
51097-0001-xx	Adasuve 10 mg single-use, disposable inhaler

ICD-10 Diagnoses

Code	Description
R45.1	Restlessness and Agitation

Revision History

Company(ies)	DATE	REVISION
EmblemHealth & ConnectiCare	2/14/2025	Annual Review: no criteria changes Removed: F25.0 Schizoaffective disorder, bipolar type
EmblemHealth & ConnectiCare	4/29/2024	Annual Review: removed PI link, no criteria changes
EmblemHealth & ConnectiCare	8/11/2023	Annual Review: removed NDC: 10885-0003-xx, added 51097-0001-xx, Added ICD-10 R45.1, F25.0
EmblemHealth & ConnectiCare	3/17/2022	Transferred policy to new template
EmblemHealth & ConnectiCare	4/6/2020	New Medical Policy created per FDA Label

References

1. Product Information: ADASUVE™ oral inhalation powder, loxapine oral inhalation powder. Alexza Pharmaceuticals, Inc. (per manufacturer), Mountain View, CA, 2012.
2. American Geriatrics Society Beers Criteria Update Expert Panel: American Geriatrics Society 2019 updated AGS Beers Criteria® for potentially inappropriate medication use in older adults. J Am Geriatr Soc 2019; 67(4):674-694.
   PubMed Abstract: http://www.ncbi.nlm.nih.gov/...
   PubMed Article: http://www.ncbi.nlm.nih.gov/...
3. Product Information: ADASUVE® oral inhalation powder, loxapine oral inhalation powder. Teva Select Brands (per DailyMed), Horsham, PA, 2015.
4. US Food and Drug Administration (FDA): Drug Safety Communications: FDA urges caution about withholding opioid addiction medications from patients taking benzodiazepines or CNS depressants: careful medication management can reduce risks. US Food and Drug Administration (FDA). Silver Spring, MD. 2017. Available from URL: https://www.fda.g... . As accessed 2017-09-20.
5. Product Information: ADASUVE® oral inhalation powder, loxapine oral inhalation powder. Alexza Pharmaceuticals Inc (per FDA), Mountain View, CA, 2017.
6. Dahl SG: Active metabolites of neuroleptic drugs: possible contribution to therapeutic and toxic effects. Ther Drug Monit 1982; 4:33-40.
7. Product Information: ADASUVE® oral inhalation powder, loxapine oral inhalation powder. Teva Select Brands (per FDA), Horsham, PA, 2016.