

Medical Policy: ADASUVE® (loxapine)

POLICY NUMBER	LAST REVIEW	ORIGIN DATE
MG.MM.PH.208	August 11, 2023	April 6, 2020

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The treating physician or primary care provider must submit to EmblemHealth, or ConnectiCare, as applicable (hereinafter jointly referred to as “EmblemHealth”), the clinical evidence that the member meets the criteria for the treatment or surgical procedure. Without this documentation and information, EmblemHealth will not be able to properly review the request preauthorization or post-payment review. The clinical review criteria expressed below reflects how EmblemHealth determines whether certain services or supplies are medically necessary. This clinical policy is not intended to pre-empt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. Health care providers are expected to exercise their medical judgment in rendering appropriate care.

EmblemHealth established the clinical review criteria based upon a review of currently available clinical information (including clinical outcome studies in the peer reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). EmblemHealth expressly reserves the right to revise these conclusions as clinical information changes and welcomes further relevant information. Each benefit program defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered and/or paid for by EmblemHealth, as some programs exclude coverage for services or supplies that EmblemHealth considers medically necessary.

If there is a discrepancy between this guideline and a member's benefits program, the benefits program will govern. Identification of selected brand names of devices, tests and procedures in a medical coverage policy is for reference only and is not an endorsement of any one device, test or procedure over another. In addition, coverage may be mandated by applicable legal requirements of a state, the Federal Government or the Centers for Medicare & Medicaid Services (CMS) for Medicare and Medicaid members. All coding and web site links are accurate at time of publication.

EmblemHealth may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice. EmblemHealth Services Company, LLC, has adopted this policy in providing management, administrative and other services to EmblemHealth Plan, Inc., EmblemHealth Insurance Company, EmblemHealth Services Company, LLC, and Health Insurance Plan of Greater New York (HIP) related to health benefit plans offered by these entities. ConnectiCare, an EmblemHealth company, has also adopted this policy. All of the aforementioned entities are affiliated companies under common control of EmblemHealth Inc.

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

[ADASUVE PRESCRIBING INFORMATION](#)

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
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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.
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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
F25.0	Schizoaffective disorder, bipolar type

Revision History

Company(ies)	DATE	REVISION
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.