Adasuve® (loxapine)

Last Review Date: April 4, 2020  Number: MG.MM.PH.208

Medical Guideline Disclaimer

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Definition

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

Package Insert

ADASUVE PRESCRIBING INFORMATION
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
   b. Member has confirmed diagnosis of schizophrenia or bipolar I disorder made by or in consultation with a psychiatrist
   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
   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:

1) Member is less than 18 years of age
2) Disease progression while on Adasuve® (loxapine).
3) Indications not supported by CMS recognized compendia or acceptable peer reviewed literature may be deemed as not approvable and therefore not reimbursable.
4) Current diagnosis or history of asthma, COPD, or other lung disease associated with bronchospasm
5) Acute respiratory symptoms or signs (e.g., wheezing)
6) Current use of medications to treat airways disease, such as asthma or COPD
7) History of bronchospasm following Adasuve treatment
8) Known hypersensitivity to loxapine or amoxapine. Serious skin reactions have occurred with oral loxapine and amoxapine.
9) 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.

Dosage/Administration

<table>
<thead>
<tr>
<th>Indication</th>
<th>Dose</th>
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<tbody>
<tr>
<td>1. Acute treatment of agitation associated with schizophrenia or bipolar I disorder</td>
<td>- 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,</td>
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using a single-use inhaler. Administer only a single dose within a 24-hour period.

Revision History

<table>
<thead>
<tr>
<th>Date</th>
<th>Description</th>
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<tbody>
<tr>
<td>04/06/2020</td>
<td>New Medical Policy created per FDA Label</td>
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Applicable Procedure Codes

<table>
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<th>Code</th>
<th>Description</th>
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<tr>
<td>J2062</td>
<td>Adasuve (loxapine) 10MG Aerosol Powder Breath Activated for inhalation, 1 mg</td>
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Applicable NDCs

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<th>Description</th>
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<tr>
<td>10885-0003-XX</td>
<td>ADASUVE 10MG Aerosol Powder Breath Activated</td>
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</table>

References


7. Product Information: ADASUVE(R) oral inhalation powder, loxapine oral inhalation powder. Teva Select Brands (per FDA), Horsham, PA, 2016.