Medication Policy Manual

Policy No: dru261

Topic: Latuda®, lurasidone

Date of Origin: November 18, 2011

Committee Approval Date: May 8, 2015

Next Review Date: October 2015

Effective Date: June 1, 2015

IMPORTANT REMINDER

This Medical Policy has been developed through consideration of medical necessity, generally accepted standards of medical practice, and review of medical literature and government approval status.

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control.

The purpose of medical policy is to provide a guide to coverage. Medical Policy is not intended to dictate to providers how to practice medicine. Providers are expected to exercise their medical judgment in providing the most appropriate care.

Description

Lurasidone (Latuda) is an oral atypical antipsychotic used to treat schizophrenia.
Policy/Criteria

I. Most contracts require prior authorization approval of lurasidone prior to coverage. Lurasidone may be considered medically necessary when at least two best-value generic or preferred medications listed in Appendix 1 have been ineffective, are not tolerated or are contraindicated.

II. Administration and Authorization Period

A. Regence considers lurasidone to be a self-administered medication.

B. Authorization may be reviewed at least annually to confirm that current medical necessity criteria are met and that the medication is effective.

Position Statement

Overview

- There are many generic antipsychotic options available, of which generic olanzapine, quetiapine, risperidone, and ziprasidone provide the best value. Lurasidone (Latuda)) has not been established as superior in safety or efficacy to generic or preferred oral atypical antipsychotics but is more costly.

- There is a large body of evidence that indicates atypical antipsychotics are effective in certain conditions; however, because individual studies are unreliable, it cannot be determined if there is a clinically meaningful difference between individual medications.[13-17,19,20]

- No atypical antipsychotic has been shown to have an overall superior safety profile; however, individual medications differ in the incidence and severity of specific adverse events.[13-17,19,20]

Clinical Efficacy

SCHIZOPHRENIA

- Antipsychotics are recognized by guidelines as being effective for the treatment of schizophrenia. Atypical antipsychotics are generally preferred over first-generation (typical) antipsychotics due to the lower incidence of extrapyramidal side effects and tardive dyskinesia.[19,20,25,26]

- Guidelines recognize the superior efficacy of clozapine; however, due to risk of potentially serious blood dyscrasias, it is recommended only for treatment refractory disease.[19,20,25,26]
- With the exception of clozapine, there is no reliable evidence that one atypical antipsychotic is more effective than another. Guidelines recommend that treatment selection be guided by factors such as previous treatment response, adverse event profile, patient preference, route of administration, comorbid medical conditions and potential drug-drug interactions.\[13,19,20,25,26\]

- Multiple systematic reviews and meta-analyses have been published to describe the comparative efficacy between atypical antipsychotics; however, these analyses are all based on unreliable evidence. Overall, the evidence for atypical antipsychotics in all conditions is unreliable due to high attrition rates (up to 60%), small sample size, and lack of clinically meaningful endpoints.\[13-17\]

**BIPOLAR DISORDER**

Various atypical antipsychotics have been studied for the treatment of bipolar disorder; however, there is insufficient evidence to determine comparable efficacy between products.\[13,21,22,27-29\]

**Manic or mixed episodes**

- For manic or mixed episodes, guidelines recommend lithium carbonate or valproic acid with or without an antipsychotic as the preferred first line treatment.\[21,22,27-29\]

- Carbamazepine and oxcarbazepine are listed in guidelines as alternatives to lithium carbonate and valproic acid.\[21,22,27-29\]

**Depressive episodes**

- For depressive episodes, guidelines recommend lithium with or without an antidepressant or lamotrigine as the preferred first-line treatment.\[21,22,27-29\]

**MAJOR DEPRESSIVE DISORDER**

- Antidepressants such as selective serotonin reuptake inhibitors (SSRIs), serotonin norepinephrine reuptake inhibitors (SNRIs), mirtazapine and bupropion, are recommended by guidelines as first line treatment for patients with major depressive disorder.\[23\]

- Because all antidepressants generally have similar efficacy, guidelines indicate choice of therapy should be guided by other factors such as adverse event profiles, half-life, potential drug-drug interactions, prior response and patient preference.\[23\]

- Guidelines recommend optimizing the antidepressant dose for patients who show minimal or no response. If further improvement is required, patients may be transitioned to another antidepressant or the current antidepressant may be augmented with a second antidepressant, lithium carbonate, thyroid hormone or an atypical antipsychotic.\[23\]

- Two systematic reviews were identified and concluded that no atypical antipsychotic had evidence of providing a significant long-term benefit as an adjunct to antidepressants in treatment resistant depression.\[12,13\]
AUTISTIC DISORDER

There is limited evidence for the efficacy of pharmacotherapy in autistic disorder; however, SSRIs and atypical antipsychotics are used to alleviate some of the associated symptoms.[12,13,18,24]

SSRIs

- Fluoxetine, fluvoxamine and citalopram have been used for patients with high anxiety or obsessive symptoms.[18,24]
- One systematic review was identified and concluded that there is no evidence of effect for SSRIs in autistic disorder.[18]

Atypical antipsychotics

- Aripiprazole and risperidone have an FDA indication for irritability associated with autistic disorder.[1,7]
- Two systematic reviews were identified and found that there is insufficient evidence to draw a conclusion regarding the efficacy of atypical antipsychotics for the treatment of autistic disorder.[12,13]

Safety

- There is a general lack of useful data on the relative overall safety and tolerability of the atypical antipsychotics.
- Individual products vary in variety and severity of adverse events.[1-10]
- The most common adverse events to this class of medications are:[1-24]
  * Movement disorders and restlessness
  * Anticholinergic effects including sedation, blurry vision and dry mouth
  * Metabolic complications including weight gain, increased lipids and increased blood glucose
- Generally, treatments are selected based on side effect profiles and the impact on the patient’s existing health status.[19-24]
- Use of atypical antipsychotics for dementia-related psychosis is associated with an increased risk of death and all medications in this class carry a Black Box warning with regard to use in this indication.[1-10]
# Appendix 1: Best-Value Generic and Preferred Brand Medication Alternatives

<table>
<thead>
<tr>
<th>Class</th>
<th>Generic and Preferred Brand Alternatives</th>
</tr>
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<tbody>
<tr>
<td><strong>Atypical antipsychotics</strong></td>
<td>Best-Value Generics</td>
</tr>
<tr>
<td></td>
<td>- clozapine (generic Clozaril®)</td>
</tr>
<tr>
<td></td>
<td>- olanzapine (generic Zyprexa®)</td>
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<tr>
<td></td>
<td>- quetiapine (generic Seroquel®)</td>
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<tr>
<td></td>
<td>- risperidone (generic Risperdal®)</td>
</tr>
<tr>
<td></td>
<td>- ziprasidone (generic Geodon®)</td>
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<tr>
<td></td>
<td>Preferred Brand Alternatives</td>
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<tr>
<td></td>
<td>- quetiapine XR (Seroquel XR®)</td>
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<tr>
<td><strong>Mood stabilizers, antiepileptics</strong></td>
<td>- carbamazepine (generic Tegretol®)</td>
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<tr>
<td></td>
<td>- divalproex sodium, valproic acid (generic Depakote®, Depakote ER®, Depakene®)</td>
</tr>
<tr>
<td></td>
<td>- lamotrigine (generic Lamictal®)</td>
</tr>
<tr>
<td></td>
<td>- oxcarbazepine (generic Trileptal®)</td>
</tr>
<tr>
<td><strong>Mood stabilizers, other</strong></td>
<td>- lithium carbonate (generic Lithobid®)</td>
</tr>
<tr>
<td></td>
<td>- olanzapine (generic Zyprexa®)</td>
</tr>
<tr>
<td></td>
<td>- quetiapine (generic Seroquel®)</td>
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<td></td>
<td>- risperidone (generic Risperdal)</td>
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<tr>
<td><strong>Antidepressants</strong></td>
<td>- citalopram (generic Celexa®)</td>
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<tr>
<td></td>
<td>- escitalopram (generic Lexapro®)</td>
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<tr>
<td></td>
<td>- fluoxetine (generic Prozac®)</td>
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<tr>
<td></td>
<td>- paroxetine (generic Paxil®)</td>
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<td></td>
<td>- sertraline (generic Zoloft®)</td>
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<tr>
<td></td>
<td>- bupropion SR/XL (generic Wellbutrin SR®, Wellbutrin XL®)</td>
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<tr>
<td></td>
<td>- fluvoxamine (generic Luvox®)</td>
</tr>
<tr>
<td></td>
<td>- mirtazapine (generic Remeron®)</td>
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<tr>
<td></td>
<td>- venlafaxine (generic Effexor®)</td>
</tr>
<tr>
<td></td>
<td>- venlafaxine SR tablets (generic Effexor XR®)</td>
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</tbody>
</table>

1 Based on FDA-approval or guidelines. [19-30]
### Cross References

<table>
<thead>
<tr>
<th>Cross References</th>
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<tbody>
<tr>
<td>aripiprazole-containing medications (oral), Abilify®, dru257.</td>
</tr>
<tr>
<td>Fanapt®, iloperidone, dru258.</td>
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<tr>
<td>paliperidone-containing medications (oral), Invega®, dru260.</td>
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<td>Saphris®, asenapine, dru262.</td>
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### Codes

<table>
<thead>
<tr>
<th>Codes</th>
<th>Number</th>
<th>Description</th>
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<tr>
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### References


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