

# Clinical Policy: Long-Acting Injectable Atypical Antipsychotics

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[Revision Log](#)  
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## Description

The intent of the criteria is to ensure that patients follow selection elements established by Centene<sup>®</sup> medical policy for the following long-acting injectable (LAI) atypical antipsychotics:

- Abilify<sup>®</sup> Maintena<sup>®</sup> (aripiprazole extended-release injectable suspension)
- Aristada<sup>™</sup> (aripiprazole extended-release injectable suspension)
- Invega<sup>®</sup> Trinza<sup>™</sup> (paliperidone palmitate extended-release injectable suspension)
- Zyprexa<sup>®</sup> Relprevv<sup>™</sup> (olanzapine extended-release injectable suspension)

## Preferred Formulary Products

NH Healthy Families has both Invega<sup>®</sup> Sustenna<sup>®</sup> (paliperidone palmitate extended-release injectable suspension) and Risperdal<sup>®</sup> Consta<sup>®</sup> (risperidone long-acting injection) as preferred formulary options (quantity limits apply).

## Policy/Criteria

It is the policy of health plans affiliated with Centene Corporation<sup>®</sup> that LAI atypical antipsychotics are **medically necessary** for members meeting the following criteria:

### I. Abilify Maintena

A. *Initiation* of Abilify Maintena therapy for 3 months (meets all):

1. Prescribed by a psychiatric specialist;
2. Age  $\geq 18$  years;
3. Documented trial and failure of Invega Sustenna OR Risperdal Consta for  $\geq 3$  months unless contraindicated;
4. Documented diagnosis of schizophrenia;
5. History of nonadherence to oral antipsychotic therapy;
6. Has established tolerability to oral antipsychotic therapy;
7. Therapeutic plan includes an initial 14 days of concomitantly administered oral antipsychotic therapy with Abilify Maintena;
8. No history of dementia-related psychosis.

B. *Continuation* of Abilify Maintena for 12 months (meets all):

1. Demonstrated a therapeutic response;
2. The treatment plan includes concomitant oral aripiprazole for 14 days with the next administered injection if one of the following:
  - a. The second or third doses are missed, and more than 5 weeks have elapsed since the last injection;
  - b. The fourth dose is missed, and more than 6 weeks have elapsed since the last injection;

3. No dementia-related psychosis.

## **II. Aristada**

- A. *Initiation* of Aristada therapy for 3 months (meets all):
  1. Prescribed by a psychiatric specialist;
  2. Age  $\geq 18$  years;
  3. Documented trial and failure of Invega Sustenna OR Risperdal Consta for  $\geq 3$  months unless contraindicated;
  4. Documented diagnosis of schizophrenia;
  5. History of nonadherence to oral antipsychotic therapy;
  6. Has established tolerability to oral antipsychotic therapy;
  7. Therapeutic plan includes an initial 21 days of concomitantly administered oral aripiprazole therapy with Aristada;
  8. No history of dementia-related psychosis.
- B. *Continuation* of Aristada for 12 months (meets all):
  1. Demonstrated a therapeutic response;
  2. The treatment includes concomitant oral aripiprazole if either of the following:
    - a. Currently taking 441 mg of Aristada and  $> 6$  weeks have elapsed since the last injection;
    - b. currently taking 662 mg or 882 mg of Aristada and  $> 8$  weeks have elapsed since the last injection;
  3. No dementia-related psychosis.

## **III. Invega Trinza**

- A. *Initiation* of Invega Trinza therapy for 3 months (meets all):
  1. Prescribed by a psychiatric specialist;
  2. Age  $\geq 18$  years;
  3. Documented diagnosis of schizophrenia;
  4. History of nonadherence to oral antipsychotic therapy;
  5. Has been adequately treated with Invega Sustenna for  $\geq 4$  months;
  6. No history of dementia-related psychosis.
- B. *Continuation* of Invega Trinza for 12 months (meets all):
  1. Demonstrated a therapeutic response;
  2. No dementia-related psychosis;
  3. If  $> 9$  months have elapsed since the last Invega Trinza injection, the patient should re-establish treatment with Invega Sustenna x four months before reinitiating Invega Trinza therapy.

## **IV. Zyprexa Relprevv**

- A. *Initiation* of Zyprexa Relprevv therapy for 3 months (meets all):
  1. Prescribed by a psychiatric specialist who is enrolled in the post-injection delirium/sedation syndrome (PDSS) REMS program;
  2. Age  $\geq 18$  years;

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3. Documented trial and failure of Invega Sustenna OR Risperdal Consta for  $\geq 3$  months unless contraindicated;
4. Documented diagnosis of schizophrenia;
5. History of nonadherence to oral antipsychotic therapy;
6. Has established tolerability to oral antipsychotic therapy;
7. No history of dementia-related psychosis.

B. *Continuation of Zyprexa Relprevv therapy for 12 months (meets all):*

1. Demonstrated a therapeutic response;
2. No dementia-related psychosis.

### Background

#### *Schizophrenia*

Schizophrenia is characterized by delusions, hallucinations, disorganized speech and behavior, and negative symptoms (diminished emotional expression or avolition). These symptoms are known as active-phase symptoms.<sup>7</sup> Schizophrenia also is characterized by a decreased ability to care for one's self, or function socially or occupationally.<sup>7</sup> For a diagnosis, symptoms must be present for six months and include at least one month of active symptoms.<sup>7</sup> Diagnosis also involves ruling out potential causes such as other medical conditions or medications.<sup>7</sup>

Antipsychotic medications are considered first-line treatment for schizophrenia.<sup>7</sup> The primary treatment goal is to prevent relapse and restore functioning.<sup>8</sup> The relapse rate in patients with first-episode schizophrenia is relatively low during the first year but rises to over 50% after two years and over 80% after five years.<sup>8</sup> Lack of adherence to oral medication is the most common cause of relapse and has been associated with a five-fold increased relapse risk in first-episode schizophrenia.<sup>8</sup> LAI atypical antipsychotics have been associated with a decreased relapse rate compared to oral antipsychotic drugs in first-episode schizophrenia and have been shown to improve non-adherence.<sup>8</sup> If transitioning to LAI therapy, patients should first establish tolerability to an oral antipsychotic agent.<sup>1-6</sup> Evidence points to similar efficacy across the atypical LAIs.<sup>8</sup>

#### *Bipolar I Disorder and Schizoaffective Disorder*

Bipolar I Disorder is defined by manic or mixed episodes lasting for at least one week (or less if hospitalization is required) with or without subsequent depressive episodes lasting for at least two weeks.<sup>7</sup> Risperdal Consta is FDA approved as monotherapy, or as adjunctive therapy to lithium or valproate, for maintenance treatment of Bipolar I Disorder.<sup>5</sup> Schizoaffective Disorder includes a combination of schizophrenia symptoms, such as hallucinations or delusions, and mood disorder symptoms, such as mania or depression.<sup>7</sup> Invega Sustenna is FDA approved for treatment of Schizoaffective Disorder.<sup>3</sup>

### Appendices

#### **Appendix A: Abbreviation Key**

CrCl: creatinine clearance

LAI: long acting injectable

PDSS: post-injection delirium/sedation syndrome

WBC: white blood cells

**Appendix B: Oral Antipsychotics**

Typical Antipsychotics	Atypical Antipsychotics
<ul style="list-style-type: none"> <li>• Haldol (Haloperidol)</li> <li>• Prolixin (Fluphenazine)</li> <li>• Navane (Thiothixene)</li> <li>• Stelazine (Trifluoperazine)</li> <li>• Trilafon (Perphenazine)</li> <li>• Loxitane (Loxapine)</li> <li>• Mellaril (Thioridazine)</li> <li>• Thorazine (Chlorpromazine)</li> <li>• Orap (Pimozide)</li> </ul>	<ul style="list-style-type: none"> <li>• Risperdal (Risperidone)*</li> <li>• Invega (Paliperidone)*</li> <li>• Saphris (Asenapine)</li> <li>• Zyprexa (Olanzapine)*</li> <li>• Fanapt (Iloperidone)</li> <li>• Abilify (Aripiprazole)*</li> <li>• Latuda (Lurasidone)</li> <li>• Geodon (Ziprasidone)</li> <li>• Clozaril (Clozapine)</li> <li>• Seroquel (Quetiapine)</li> </ul>

\*LAI atypical antipsychotic formulation available

**Coding Implications**

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
J0401	Injection, aripiprazole, extended release, 1 mg
J2426	Injection, paliperidone palmitate extended release, 1 mg
J2794	Injection, risperidone, long acting, 0.5 mg
J2358	Injection, olanzapine, long-acting, 1 mg

**References**

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Reviews, Revisions, and Approvals	Date	Approval Date
Policy developed.	01/18	01/18

**Important Reminder**

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

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**Note: For Medicaid members,** when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

**Note: For Medicare members,** to ensure consistency with the Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), all applicable NCDs and LCDs should be reviewed prior to applying the criteria set forth in this clinical policy. Refer to the CMS website at <http://www.cms.gov> for additional information.

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