

Clinical Policy: Long-acting injectable atypical antipsychotics

Reference Number: ERX.SPMN.192

Effective Date: 01/17

Last Review Date:

[Revision Log](#)
[Coding Implications](#)

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

Policy/Criteria

It is the policy of health plans affiliated with Envolve Pharmacy Solutions™ that the following long-acting injectable (LAI) atypical antipsychotics:

- Abilify® Maintena® (aripiprazole extended-release injectable suspension)
- Aristada™ (aripiprazole extended-release injectable suspension)
- Invega® Sustenna® (paliperidone palmitate extended-release injectable suspension)
- Invega® Trinza™ (paliperidone palmitate extended-release injectable suspension)
- Risperdal® Consta® (risperidone long acting injection)
- Zyprexa® Relprevv™ (olanzapine extended-release injectable suspension)

are **medically necessary** for members meeting the following criteria:

I. Initial Approval Criteria

A. Schizophrenia (must meet all):

1. Prescribed by a psychiatrist;
2. Documented diagnosis of schizophrenia;
3. History of nonadherence to oral antipsychotic therapy;
4. Has established tolerability to oral antipsychotic therapy;
5. If request is not for Risperdal Consta, member has tried and failed, or is intolerant or contraindicated to, Risperdal Consta;
6. Member meets one of the following drug-specific criteria if applicable:
 - a. For Abilify Maintena, therapeutic plan includes an initial 14 days of concomitantly administered oral antipsychotic therapy with Abilify Maintena;
 - b. For Aristada, therapeutic plan includes an initial 21 days of concomitantly administered oral aripiprazole therapy with Aristada;
 - c. For Invega Trinza, age ≥ 18 years and member has been adequately treated with Invega Sustenna for ≥ 4 months;
 - d. For Risperdal Consta, treatment plan includes initial 3 weeks of concomitantly administered oral antipsychotic therapy and Risperdal Consta.

Approval duration: 3 months

B. Schizoaffective Disorder (must meet all):

1. Prescribed by a psychiatrist;
2. Documented diagnosis of schizoaffective disorder;
3. Request is for Invega Sustenna;
4. Invega Sustenna is prescribed as monotherapy or as an adjunct to mood stabilizers or antidepressants;
5. History of nonadherence to oral antipsychotic therapy;
6. Has established tolerability to oral antipsychotic therapy.

Approval duration: 3 months

C. Bipolar I Disorder (must meet all):

1. Prescribed by a psychiatrist;
2. Documented diagnosis of bipolar I disorder;
3. Request is for Risperdal Consta;
4. Risperdal Consta is prescribed as monotherapy or as adjunctive therapy to lithium or valproate;
5. History of nonadherence to oral antipsychotic therapy;
6. Has established tolerability to oral antipsychotic therapy;
7. Treatment plan includes initial 3 weeks of concomitantly administered oral antipsychotic therapy.

Approval duration: 3 months

D. Other diagnoses/indications: Refer to ERX.SPMN.16 - Global Biopharm Policy

II. Continued Approval

A. All Indications (must meet all):

1. Currently receiving medication via health plan benefit or documentation supports that member is currently on this medication for schizophrenia, schizoaffective disorder, or bipolar disorder, has received this medication for at least 30 days, and is responding positively to therapy;
2. Demonstrated a therapeutic response;
3. Member meets one of the following drug-specific criteria if applicable:
 - a. For Abilify Maintena, the treatment plan includes concomitant oral aripiprazole for 14 days with the next administered injection if one of the following applies:
 - i. The second or third doses are missed, and more than 5 weeks have elapsed since the last injection;
 - ii. The fourth dose is missed, and more than 6 weeks have elapsed since the last injection;
 - b. For Aristada, the treatment includes concomitant oral aripiprazole if either of the following applies:
 - i. Currently taking 441 mg of Aristada and > 6 weeks have elapsed since the last injection;
 - ii. Currently taking 662 mg or 882 mg of Aristada and > 8 weeks have elapsed since the last injection;
 - c. For Invega Trinza if > 9 months have elapsed since the last Invega Trinza injection, member should re-establish treatment with Invega Sustenna for 4 months before reinitiating Invega Trinza therapy.

Approval duration: 12 months

CLINICAL POLICY

Long-acting injectable atypical antipsychotics

B. Other diagnoses/indications (must meet 1 or 2):

1. Currently receiving medication via health plan benefit and documentation supports positive response to therapy; or
2. Refer to ERX.SPMN.16 - Global Biopharm Policy.

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.⁷ Schizophrenia also is characterized by a decreased ability to care for one's self, or function socially or occupationally.⁷ For a diagnosis, symptoms must be present for six months and include at least one month of active symptoms.⁷ Diagnosis also involves ruling out potential causes such as other medical conditions or medications.⁷

Antipsychotic medications are considered first-line treatment for schizophrenia.⁷ The primary treatment goal is to prevent relapse and restore functioning.⁸ 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.⁸ 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.⁸ 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.⁸ If transitioning to LAI therapy, patients should first establish tolerability to an oral antipsychotic agent.¹⁻⁶ Evidence points to similar efficacy across the atypical LAIs.⁸

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.⁷ Risperdal Consta is FDA approved as monotherapy, or as adjunctive therapy to lithium or valproate, for maintenance treatment of Bipolar I Disorder.⁵ Schizoaffective Disorder includes a combination of schizophrenia symptoms, such as hallucinations or delusions, and mood disorder symptoms, such as mania or depression.⁷ Invega Sustenna is FDA approved for treatment of Schizoaffective Disorder.³

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"> • Haldol (haloperidol) • Prolixin (fluphenazine) 	<ul style="list-style-type: none"> • Risperdal (risperidone)* • Invega (paliperidone)*

CLINICAL POLICY

Long-acting injectable atypical antipsychotics

Typical Antipsychotics	Atypical Antipsychotics
<ul style="list-style-type: none"> • Navane (thiothixene) • Stelazine (trifluoperazine) • Trilafon (perphenazine) • Loxitane (loxapine) • Mellaril (thioridazine) • Thorazine (chlorpromazine) • Orap (pimozide) 	<ul style="list-style-type: none"> • Saphris (asenapine) • Zyprexa (olanzapine)* • Fanapt (iloperidone) • Abilify (aripiprazole)* • Latuda (lurasidone) • Geodon (ziprasidone) • Clozaril (clozapine) • Seroquel (quetiapine)

*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

Reviews, Revisions, and Approvals	Date	Approval Date
Policy created.	12/16	01/17

References

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3. Invega Sustenna [package insert]. Titusville, NJ: Janssen Pharmaceuticals, Inc.; June 2015. <http://www.janssencns.com/shared/product/invegasustenna/prescribing-information.pdf>
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7. American Psychiatric Association, (2013). Diagnostic and statistical manual of mental health disorders: DSM-5 (5th ed.). Washington, DC: American Psychiatric Publishing.

CLINICAL POLICY

Long-acting injectable atypical antipsychotics

8. Kim B, Lee SH, Yang YK, et al. Review Article: Long-Acting Injectable Antipsychotics for First-Episode Schizophrenia: The Pros and Cons. *Hindawi Publishing Corporation, Schizophrenia Research and Treatment*. 2012;(2012):1-8. doi:10.1155/2012/560386

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.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members.

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