Clinical Policy: Olanzapine Long-Acting Injection (Zyprexa Relprevv)

Reference Number: ERX.SPA.180
Effective Date: 12.01.17
Last Review Date: 11.17 Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description
Olanzapine (Zyprexa Relprevv®) is a long-acting atypical antipsychotic.

FDA Approved Indication(s)
Zyprexa Relprevv is indicated for the treatment of schizophrenia.

Zyprexa Relprevv is available only through a restricted distribution program called Zyprexa Relprevv Patient Care Program and requires prescriber, healthcare facility, patient, and pharmacy enrollment.

Policy/Criteria
Provider must submit documentation (which may include office chart notes and lab results) supporting that member has met all approval criteria

It is the policy of health plans affiliated with Envolve Pharmacy Solutions™ that Zyprexa Relprevv is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Schizophrenia (must meet all)**:**

1. Diagnosis of schizophrenia;
2. Prescribed by or in consultation with a psychiatrist;
3. Age ≥ 18 years;
4. History of non-adherence to oral antipsychotic therapy (see Appendix B);
5. Established tolerability with oral olanzapine;
6. Failure of Risperdal Consta unless contraindicated or clinically significant adverse effects are experienced;
7. Dose does not exceed 405 mg every 4 weeks or 300 mg every 2 weeks.

Approval duration: Length of Benefit

B. Other diagnoses/indications

1. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

A. Schizophrenia (must meet all)**:**

1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions, or documentation supports that member is currently receiving Zyprexa Relprevv for schizophrenia, and has received this medication for at least 30 days;
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed 405 mg every 4 weeks or 300 mg every 2 weeks.

Approval duration: Length of Benefit

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

1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy.
   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off-label use policy – ERX.PA.01 or evidence of coverage documents;
B. Dementia-related psychosis;
C. Alzheimer's disease.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
FDA: Food and Drug Administration

Appendix B: Examples of Oral Antipsychotics – Generic (Brand)

Typical/First Generation Antipsychotics†	Atypical/Second Generation Antipsychotics
• Chlorpromazine (Thorazine) • Fluphenazine (Prolixin) • Haloperidol (Haldol) • Loxapine (Loxitane) • Perphenazine (Trilafon) • Pimozide (Orap) • Thioridazine (Mellaril) • Thiothixene (Navane) • Trifluoperazine (Stelazine)	• Aripiprazole (Abilify)* • Asenapine maleate (Saphris) • Brexpiprazole (Rexulti) • Cariprazine (Vraylar) • Clozapine (Clozaril) • Iloperidone (Fanapt) • Lurasidone (Latuda) • Olanzapine (Zyprexa)* • Olanzapine/Fluoxetine (Symbyax) • Paliperidone (Invega)* • Quetiapine (Seroquel) • Risperidone (Risperdal)* • Ziprasidone (Geodon)

†Most typical/first generation antipsychotics are available only as generics in the U.S.
**Long-acting injectable formulation available*

Appendix C: Therapeutic Alternatives

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
olanzapine (Zyprexa®)	Schizophrenia 5 to 10 mg PO QD	20 mg/day

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Schizophrenia	IM: 150 mg/2 weeks, 300 mg/4 weeks, 210 mg/2 weeks, 405 mg/4 weeks, or 300 mg/2 weeks	405 mg every 4 weeks or 300 mg every 2 weeks

VI. Product Availability

Powder for suspension: 210 mg/vial, 300 mg/vial, and 405 mg/vial

VII. References

1. Zyprexa Relprevv Prescribing Information. Indianapolis, IN: Lilly USA, LLC; January 2017. Available at https://www.zyprexarelprevvprogram.com/public/prescribing_Info.aspx. Accessed October 2, 2017.
2. Olanzapine: Drug information. In: UpToDate (Lexicomp), Waltham, MA: Walters Kluwer Health; 2017. Available at UpToDate.com. Accessed August 1, 2017.
3. Schizophrenia spectrum and other psychotic disorders. Diagnostic and Statistical Manual of Mental Health Disorders (DSM-5), Fifth Edition. May 2013. American Psychiatric Association. Washington, DC: American Psychiatric Publishing. Available at http://dsm.psychiatryonline.org/doi/abs/10.1176/appi.books.9780890425596.dsm02. Accessed October 2, 2017.

4. Kim B, Lee SH, Yang YK, et al. Review Article: Long-acting injectable antipsychotics for first-episode schizophrenia: The pros and cons. *Schizophr Res Treatment*. August 14, 2012; 2012: 560836. doi:10.1155/2012/560836

Reviews, Revisions, and Approvals	Date	P&T Approval Date
4Q17 Annual Review Policy split from ERX.SPMN.192 Long-acting injectable antipsychotics. Converted to new template. Added age restriction as safety and effectiveness have not been established in patients < 18 years. Added max dose. Increased all approval durations to length of benefit. Added dementia-related psychosis and Alzheimer's disease as indications/diagnoses for which coverage is not authorized per PI.	10.02.17	11.17

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.