# Clinical Policy: Paliperidone (Invega)

Reference Number: CP.PMN.30
Effective Date: 08.15.15
Last Review Date: 02.18
Line of Business: Health Insurance Marketplace, Medicaid

Revision Log

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

## Description

Paliperidone (Invega®) is an atypical antipsychotic.

## FDA Approved Indication(s)

Invega is indicated for the treatment of:

- Schizophrenia in adults and adolescents age 12-17
- Schizoaffective disorder as monotherapy and as an adjunct to mood stabilizers and/or antidepressants in adults.

## Policy/Criteria

*Provider must submit documentation (including such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.*

It is the policy of health plans affiliated with Centene Corporation® that Invega is **medically necessary** when the following criteria are met:

**I. Initial Approval Criteria**

**A. Schizophrenia or Schizoaffective Disorder** (must meet all)**:**

1. Diagnosis of schizophrenia or schizoaffective disorder;
2. Age ≥ 12 years;
3. Failure of 2 preferred atypical antipsychotics (e.g., quetiapine, risperidone, ziprasidone, olanzapine) at up to maximally indicated doses, each trialed for ≥ 4 weeks unless contraindicated or clinically significant adverse effects are experienced
4. Dose does not exceed the following:
   a. Adults: 12 mg/day (1 tablet/day);
   b. Adolescents < 51 kg: 6 mg/day (1 tablet/day);
   c. Adolescents ≥ 51kg: 12 mg/day (1 tablet/day).

**Approval duration:** 12 months

**B. Other diagnoses/indications**

1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): HIM.PHAR.21 for health insurance marketplace, and CP.PMN.53 for Medicaid.

**II. Continued Therapy**

**A. Schizophrenia or Schizoaffective Disorder** (must meet all)**:**

1. Currently receiving medication via Centene benefit, or documentation supports that member is currently receiving Invega for schizophrenia or schizoaffective disorder 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 the following:
   a. Adults: 12 mg/day (1 tablet/day);
   b. Adolescents < 51 kg: 6 mg/day (1 tablet/day);
   c. Adolescents ≥ 51kg: 12 mg/day (1 tablet/day).

**Approval duration:** 12 months

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

1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.
   **Approval duration: Duration of request or 12 months (whichever is less)**; or
2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): HIM.PHAR.21 for health insurance marketplace and CP.PMN.53 for Medicaid.

## 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 policies – CP.CPA.09 for commercial, HIM.PHAR.21 for health insurance marketplace, and CP.PMN.53 for Medicaid or evidence of coverage documents.

## IV. Appendices/General Information

*Appendix A: Abbreviation/Acronym Key*
Not applicable

*Appendix B: Therapeutic Alternatives*
*This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.*

| Drug Name | Dosing Regimen | Dose Limit/ Maximum Dose |
|---|---|---|
| quetiapine (Seroquel®) | Adults: 150-750 mg/day<br>Adolescents: 400-800 mg/day | Adults: 750 mg/day<br>Adolescents: 800 mg/day |
| risperidone (Risperdal®) | Adults: 4 to 8mg<br>Adolescents: 3 mg | Adults: 16 mg<br>Adolescents: 6 mg |
| ziprasidone (Geodon®) | 20 mg to 100 mg twice daily | 800 mg/day |
| olanzapine (Zyprexa®) | 10 mg/day | 20 mg/day |
| aripiprazole (Abilify®) | 10-30 mg by mouth daily | 30 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.*

*Appendix C: General Information*
Invega has a black box warning for increased mortality in elderly patients with dementia-related psychosis. Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death. Invega is not approved for use in patients with dementia-related psychosis.

## V. Dosage and Administration

| Indication | | Dosing Regimen | Maximum Dose |
|---|---|---|---|
| Schizophrenia – adults | | 3-12 mg/day | 12 mg/day |
| Schizophrenia – adolescents | Weight < 51 kg | 3-6 mg/day | 6 mg/day |
| | Weight ≥ 51 kg | 3-12 mg/day | 12 mg/day |
| Schizoaffective disorder | | 3-12 mg/day | 12 mg/day |

## VI. Product Availability
Extended-release tablets: 1.5 mg, 3 mg, 6 mg, and 9 mg

## VII. References
1. Invega Prescribing Information. Titusville, NJ: Janssen Pharmaceuticals, Inc.; July 2017. Available at: http://www.invega.com. Accessed October 31, 2017.
2. Lehman AF, Lieberman JA, Dixon LB, et al. Practice guideline for the treatment of patients with schizophrenia, second edition. Arlington, VA: American Psychiatric Association; February 2004. Available online at https://www.psychiatry.org/psychiatrists/practice/clinical-practice-guidelines. Accessed October 31, 2017.
3. Dixon L, Perkins D, Calmes C. Guideline watch: practice guideline for the treatment of patients with schizophrenia. Arlington, VA: American Psychiatric Association; September 2009. Available online at https://www.psychiatry.org/psychiatrists/practice/clinical-practice-guidelines. Accessed November 16, 2016.

| Reviews, Revisions, and Approvals | Date | P&T Approval Date |
|---|---|---|
| 1Q18 annual review:<br>- Policy combined for HIM and Medicaid.<br>- No significant change from previously approved corporate policy<br>- Age added per safety guidance endorsed by Centene Medical Affairs.<br>- References reviewed and updated. | 11.14.17 | 02.18 |

**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.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. 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. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

**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.

**For Health Insurance Marketplace members**, when applicable, this policy applies only when the prescribed agent is on your health plan approved formulary. Request for non-formulary drugs must be reviewed using the formulary exception policy.