

## **Clinical Policy: Paliperidone (Invega)**

Reference Number: CP.PMN.30

Effective Date: 08.15.15

Last Review Date: 02.19

Line of Business: Medicaid

[Revision Log](#)

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

### **Description**

Paliperidone (Invega<sup>®</sup>) is an atypical antipsychotic.

### **FDA Approved Indication(s)**

Invega is indicated for the treatment of:

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

### **Policy/Criteria**

*Provider must submit documentation (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<sup>®</sup> 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  $\geq$  12 years;
3. Failure of two preferred atypical antipsychotics (e.g., aripiprazole, ziprasidone, quetiapine, risperidone, or olanzapine) at up to maximally indicated doses, each used for  $\geq$  4 weeks, unless contraindicated or clinically significant adverse effects are experienced
4. Dose does not exceed the following:
  - a. Adults and adolescents weighing  $\geq$  51 kg: 12 mg (1 tablet) per day;
  - b. Adolescents weighing  $<$  51 kg: 6 mg (1 tablet) per 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): 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 and adolescents weighing  $\geq 51$  kg: 12 mg (1 tablet) per day;
  - b. Adolescents weighing  $< 51$  kg: 6 mg (1 tablet) per 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): 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.PMN.53 for Medicaid or evidence of coverage documents.

**IV. Appendices/General Information**

*Appendix A: Abbreviation/Acronym Key*

FDA: Food and Drug Administration

*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
aripiprazole (Abilify <sup>®</sup> )	10 to 15 mg PO QD	30 mg/day
olanzapine (Zyprexa <sup>®</sup> )	Initial: 5 to 10 mg PO QD; target: 10 mg PO QD	20 mg/day
quetiapine (Seroquel <sup>®</sup> )	Initial: 25 mg PO BID; target: 400 to 800 mg/day	800 mg/day
risperidone (Risperdal <sup>®</sup> )	Initial: 1 mg PO BID or 2 mg PO QD; target: 4 to 8 mg PO QD	Adults: 16 mg/day Adolescents: 6 mg/day
ziprasidone (Geodon <sup>®</sup> )	20 mg PO BID	160 mg/day

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

*Appendix C: Contraindications/Boxed Warnings*

- Contraindication(s): Known hypersensitivity to paliperidone, risperidone, or to any excipients in Invega
- Boxed warning(s): 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	<u>Adults</u> Initial dose: 6 mg PO QD Target dose: 3 to 12 mg PO QD	Adults and adolescents weighing $\geq$ 51 kg: 12 mg/day
	<u>Adolescents</u> Initial dose: 3 mg PO QD Target dose: <ul style="list-style-type: none"> <li>• Weight &lt; 51 kg: 3 to 6 mg PO QD</li> <li>• Weight <math>\geq</math> 51 kg 3 to 12 mg PO QD</li> </ul>	Adolescents weighing < 51 kg: 6 mg/day
Schizoaffective disorder	Initial dose: 6 mg PO QD Target dose: 3 to 12 mg PO QD	12 mg/day

**VI. Product Availability**

Extended-release tablets: 1.5 mg, 3 mg, 6 mg, 9 mg

**VII. References**

1. Invega Prescribing Information. Titusville, NJ: Janssen Pharmaceuticals, Inc.; July 2018. Available at: <http://www.invega.com>. Accessed October 30, 2018.
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 30, 2018.
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 October 30, 2018.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
1Q18 annual review: Policy combined for HIM and Medicaid; No significant change from previously approved corporate policy; Age added per safety guidance endorsed by Centene Medical Affairs; References reviewed and updated.	11.14.17	02.18
1Q 2019 annual review: removed HIM line of business; no significant changes; references reviewed and updated.	10.30.18	02.19

**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.

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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.

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