Clinical Policy: Paliperidone (Invega) tablets

Reference Number: AZ.CP.PMN.30
Effective Date: 10.06.16
Last Review Date: 01.20
Line of Business: Arizona Medicaid

Revision Log

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

Description

Paliperidone (Invega®) is a second generation (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, as an adjunct to mood stabilizers, and/or antidepressants in adults.

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 Arizona Complete Health 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 3 preferred atypical antipsychotics, one of which must be risperidone (e.g., aripiprazole, clozapine, Latuda, 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 or lowest pill burden available);
   b. Adolescents < 51 kg: 6 mg/day (1 tablet/day);
   c. Adolescents ≥ 51kg: 12 mg/day (1 tablet/day or lowest pill burden available).

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): AZ.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 or lowest pill burden available);
   b. Adolescents < 51 kg: 6 mg/day (1 tablet/day);
   c. Adolescents ≥ 51kg: 12 mg/day (1 tablet/day or lowest pill burden available).

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): AZ.CP.PMN.53 for Arizona 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 policy AZ.CP.PMN.53 for Arizona Medicaid.

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®)	10-30 mg by mouth daily	30 mg/day
Clozapine	12.5 mg-450 mg in divided doses	900mg/day
ziprasidone (Geodon®)	40-80 mg by mouth twice daily	160 mg/day
Latuda® (lurasidone)	40 mg- 160 mg once daily with food.	160 mg/day
risperidone (Risperdal®)	1-4 mg by mouth daily to twice daily	16 mg/day
Quetiapine (Seroquel®)	400-800 mg/day by mouth twice daily to three times daily in divided doses	800 mg/day

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
olanzapine (Zyprexa®)	10-20 mg by mouth daily	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.

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 Initial dose: 6 mg PO QD Target dose: 3 to 12 mg PO QD Adolescents Initial dose: 3 mg PO QD Target dose: • Weight < 51 kg: 3 to 6 mg PO QD • Weight ≥ 51 kg 3 to 12 mg PO QD	Adults and adolescents weighing ≥ 51 kg: 12 mg/day 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, and 9 mg

VII. References
1. Invega Prescribing Information. Titusville, NJ: Janssen Pharmaceuticals, Inc.; October 2018. Available at: http://www.invega.com. Accessed December 30, 2019.
2. Stahl, Stephen. Stahl's Essential Psychopharmacology Prescriber's Guide Fifth Edition Cambridge University Press Published 2014
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 March 27, 2018.
4. Clinical Pharmacology [database online]. Tampa, FL Elsevier: Gold Standard, Inc.; 2018. Available http://www.clinicalpharmacology-ip.com/ Accessed March 2018

Reviews, Revisions, and Approvals	Date	P&T Approval Date

Reviews, Revisions, and Approvals	Date	P&T Approval Date
- Reformated to new template - References reviewed and updated.	03.18	04.18
- Reviewed, renumbered and rebranded.	09.18	
- Updated logo and once daily dosing for 12mg to lowest pill burden. - Renumbered to AZ.CP.PMN.30 to align with Corporate Medicaid criteria for Invega.	07.19	07.19
- Added clozapine and Latuda to examples of preferred atypical antipsychotics - Updated Appendix B for clozapine and Latuda	01.20	01.20

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.