



Prior Authorization Approval Criteria

Invega (paliperidone)

Generic name: paliperidone

Brand name: Invega

Medication class: atypical antipsychotics

FDA Approved Uses: treatment of schizophrenia

Available dosage forms: extended release tablets; 3 mg, 6 mg, and 9 mg

Usual dose: Recommended dose is 6 mg daily. Dose range 3 mg-12 mg daily. At least 6 days should elapse between dosage increases. The dose should be increased no more than 3 mg at a time.

Duration of therapy: Indefinite

Approximate monthly cost (based on AWP 2007): 6 mg daily is \$366.00/month

Criteria for use: (bullet points below are all inclusive unless otherwise noted)

- The indicated diagnosis (including any applicable labs and /or tests) and medication usage must be supported by documentation from the patient's medical records.

Schizophrenia:

- Clinically diagnosed schizophrenia.
- Must be 18 years of age or older
- Failed/intolerant to Risperdal (risperidone)
- Failed/intolerant to **one** of the following:
 - Zyprexa (olanzapine)**OR**
 - Geodon (ziprasidone)

Schizoaffective disorder:

- Clinically diagnosed with schizoaffective disorder
- Must be 18 years of age or older.

Cautions:

- Extrapyramidal symptoms.
- QTc prolongation
- Tachycardia
- Rarely associated with obstructive gastrointestinal symptoms.
- Should not be used with other drugs that prolong QTc interval (view QT drug lists at www.arizonacert.org)
- High fat meals can increase absorption by 50% or more.
- Max dose should be 6mg/day in mild renal impairment (CrCl 50-80mL/min)
- Max dose should be 3mg/day in severe renal impairment (CrCl 10-50 mL/min)

Contraindications:

- Hypersensitivity to any components in Invega or to risperidone.

Not approved if:

- Elderly patients that have dementia with psychosis, since increased mortality has been reported.
- Patient does not meet the above-stated criteria
- Patient has any contraindications to the use of Invega.

Special considerations:

- Paliperidone is the active metabolite of the atypical antipsychotic risperidone.
- Utilizes the OROS osmotic delivery technology.
- No head-to-head comparisons with risperidone.
- One study compared Invega to one other antipsychotic, olanzapine, and it showed that Invega appeared similar in efficacy.
- Side effects similar to risperidone.
- No specific advantages of the new formulation have been demonstrated other than being dosed once a day.
- Longer studies and adequate comparisons with other antipsychotics are needed.
- Serum concentrations peak in 24 hours and it takes 4-5 days to achieve steady state.

Cost comparisons:

Paliperidone Extended-release Invega/Janssen					
3 mg tablets	1 tablet PO QD	\$ 351.36			
6 mg tablets	1 tablet PO QD	\$ 351.36			
Aripiprazole Abilify/Bristol-Myers Squibb			Olanzapine Zyprexa/Eli Lilly		
5 mg tablets	1 tablet PO QD	\$ 369.00	5 mg tablets	1 tablet PO QD	\$ 234.29
10 mg tablets	1 tablet PO QD	\$ 369.00	10 mg tablets	1 tablet PO QD	\$ 352.80
15 mg tablets	1 tablet PO QD	\$ 369.00	15 mg tablets	1 tablet PO QD	\$ 529.20
Risperidone Risperdal/Janssen			Ziprasidone Geodon/Pfizer		
1 mg tablets	1 tablet PO BID	\$ 254.92	20 mg capsules	1 capsule PO BID	\$ 314.99
2 mg tablets	1 tablet PO BID	\$ 426.01	40 mg capsules	1 capsule PO BID	\$ 314.99
3 mg tablets	1 tablet PO BID	\$ 500.38	60 mg capsules	1 capsule PO BID	\$ 343.02
<i>The Average Wholesale Price (AWP) as published by Thomson Healthcare may be the manufacturer's suggested AWP, may be calculated based on a markup specified by the manufacturer or may be an amount calculated by Thomson Healthcare applying a standard markup. The AWP does not necessarily reflect the actual AWP charged by a wholesaler. Please refer to the AWP Policy, available at http://www.micromedex.com/products/redbook/awp for more information on the published AWP information.</i>					

P&T Approval: _____ Date: _____

Adopted: 6/13/07