

Prior Authorization DRUG Guidelines

Invega Sustenna, Invega Trinza

Effective Date: 1/31/2023

Date Developed: 1/11/2023 by Dr. H. Taekman

Last Approval Date: 1/31/23, 2/13/24

Paliperidone (Invega Sustenna®, Invega Trinza®) is an atypical antipsychotic. It is the primary active metabolite of risperidone (Risperdal), available in oral and various injectable formulations: (Invega Sustenna®, Invega Trinza®, Invega Hayfera®).

Invega Sustenna is a monthly injection, Invega Trinza every three months and Invega Hayfera every six months. This publication considers the Sustenna and Trinza formulations.

FDA Approved Indication(s) Invega Sustenna is indicated:

- For the treatment of schizophrenia in adults
- For the treatment of schizoaffective disorder in adults as monotherapy and as an adjunct to mood stabilizers or antidepressants

Invega Trinza is indicated:

For the treatment of schizophrenia in patients after they have been adequately treated with Invega Sustenna for at least 4 months.

Pre-Authorization Criteria:

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

I. Initial Approval Criteria

A. Schizophrenia (must meet all):

1. Diagnosis of schizophrenia **AND**,
2. Prescribed by or in consultation with a psychiatrist **AND**,
3. Age \geq 18 years **AND**,
4. Failure of Risperdal Consta (risperidone q2wk injections) unless contraindicated or clinically significant adverse effects are experienced;
5. One of the following (a or b):
 - a. If Invega Sustenna is requested, meets (i or ii):
 - i. Established tolerability with long-acting risperidone injection (Risperdal Consta®) **OR**,
 - ii. Established tolerability with oral paliperidone or risperidone **AND** has a history of nonadherence to oral antipsychotic therapy (see Appendix for examples);
 - b. If Invega Trinza is requested, adequate treatment has been established with Invega Sustenna for \geq 4 months;
6. Dose does not exceed (a or b):
 - a. Invega Sustenna: 234 mg per month **OR**
 - b. Invega Trinza: 819 mg every 3 months

B. Schizoaffective Disorder (must meet all):

1. Diagnosis of schizoaffective disorder **AND**,
2. Request is for Invega Sustenna **AND**,
3. Prescribed by or in consultation with a psychiatrist **AND**,
4. Age \geq 18 years **AND**,
5. History of non-adherence to oral antipsychotic therapy **AND**,
6. Established tolerability with oral paliperidone or risperidone **AND**,
7. Dose does not exceed 234 mg per month.

II. Continued Therapy

D. All Indications in Section I (must meet all):

1. Documentation supports that member is currently receiving Invega Sustenna for schizophrenia or schizoaffective disorder, or Invega Trinza for schizophrenia, and has received this medication for at least 30 days **AND**,
2. Member is responding positively to therapy **AND**,
3. If request is for a dose increase, new dose does not exceed the following (a or b):
 - a. Invega Sustenna: 234 mg per month **OR**;
 - b. Invega Trinza: 819 mg every 3 months.

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

1. Documentation supports positive response to therapy **OR**,
2. 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:

- F. Non-FDA approved indications, which are not addressed in this policy
- G. Dementia-related psychosis.

Appendix

| Typical/First Generation Antipsychotics† | Atypical/Second Generation Antipsychotics |
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| <ul style="list-style-type: none">• Chlorpromazine (Thorazine)• Fluphenazine (Prolixin)• Haloperidol (Haldol)• Loxapine (Loxitane)• Perphenazine (Trilafon)• Pimozide (Orap)• Thioridazine (Mellaril)• Thiothixene (Navane)• Trifluoperazine (Stelazine) | <ul style="list-style-type: none">• 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

References

1. Invega Sustenna Prescribing Information. Titusville, NJ: Janssen Pharmaceuticals, Inc.; March 2018. Available at <https://www.invegasustennahcp.com/>. Accessed May 1,2018.
2. Invega Trinza Prescribing Information. Titusville, NJ: Janssen Pharmaceuticals, Inc.; March 2018. Available at <https://www.invegatrinzahcp.com/>. Accessed May 1, 2018.

Revision History:

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|---------------|--------------------------|--------------------------------------|-----------------------|
| 1/31/23 | New | Howard Taekman, MD; Robert Sterling, | New |

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| | | MD | |
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