Prior Authorization Review Panel

CHC-MCO Policy Submission

A separate copy of this form must accompany each policy submitted for review.
Policies submitted without this form will not be considered for review.

Plan: PA Health & Wellness	**Submission Date: 11/1/2018**
Policy Number: PA.CP.PHAR.291	**Effective Date: 10/17/2018** **Revision Date: 10/17/2018**
Policy Name: Paliperidone Long-Acting Injections (Invega Sustenna, Invega Trinza)	**HC Approval Date:**

Type of Submission – Check all that apply:

- ✓ **New Policy**
- ☐ **Revised Policy***
- ☐ **Annual Review – No Revisions**
- ☐ **Attestation of HC PARP Policy –** *This option should only be used during Readiness Review for Community HealthChoices. The policy must be identical to the PARP approved policy for the HealthChoices Program, with the exception of revisions/clarifications adding the term "Community HealthChoices" to the policy.*

***All revisions to the policy must be highlighted using track changes throughout the document.**

Please provide any changes or clarifying information for the policy below:

New Policy created.

Name of Authorized Individual (Please type or print): **Francis G. Grillo, MD**	**Signature of Authorized Individual:**

Clinical Policy: Paliperidone Long-Acting Injections (Invega Sustenna, Invega Trinza)

Reference Number: PA.CP.PHAR.291
Effective Date: 10.17.18
Last Review Date: 10.17.18 Revision Log

Description
Paliperidone (Invega Sustenna®, Invega Trinza®) is an atypical antipsychotic.

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 (1-month paliperidone palmitate extended-release injectable suspension) for at least four months.

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 PA Health & Wellness® that Invega Sustenna and Invega Trinza are **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Schizophrenia (must meet all)**:**

1. Diagnosis of schizophrenia;
2. Prescribed by or in consultation with a psychiatrist;
3. 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®);
      ii. Established tolerability with oral paliperidone or risperidone (preferred agent) AND has a history of non-adherence to oral antipsychotic therapy (*see Appendix D for examples*);
   b. If Invega Trinza is requested, adequate treatment has been established with Invega Sustenna for ≥ 4 months;
4. Dose does not exceed (a or b):
   a. Invega Sustenna: 234 mg per month;
   b. Invega Trinza: 819 mg every 3 months.

Approval duration: 6 months

B. Schizoaffective Disorder (must meet all)**:**

1. Diagnosis of schizoaffective disorder;
2. Request is for Invega Sustenna;
3. Prescribed by or in consultation with a psychiatrist;
4. History of non-adherence to oral antipsychotic therapy (*see Appendix D for examples*);
5. Established tolerability with oral paliperidone or risperidone (preferred agent);
6. Dose does not exceed 234 mg per month.

Approval duration: 6 months

C. Other diagnoses/indications

1. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53.

II. Continued Therapy

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

1. Currently receiving medication via Pennsylvania Health and Wellness benefit or member has previously met all initial approval criteria or the Continuity of Care Policy (PA.LTSS.PHAR.01) applies;
2. Member is responding positively to therapy;
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;
   b. Invega Trinza: 819 mg every 3 months.

Approval duration: 12 months

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

1. Currently receiving medication via Pennsylvania Health and Wellness benefit or member has previously met all initial approval criteria or the Continuity of Care Policy (PA.LTSS.PHAR.01) applies.
   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53.

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 – PA.CP.PMN.53;

B. Dementia-related psychosis.

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
paliperidone (Invega®)	Schizophrenia and schizoaffective Adults: initially, 6 mg PO QD Recommended dose: 3-12 mg/day	12 mg/day
risperidone (Risperdal®)	Schizophrenia Adults: initially, 2 mg/day PO (as a single dose) or 1 mg PO BID; adjust as tolerated to the recommended target dose of 4 to 8 mg/day Effective dose range: 4 to 16 mg/day	16 mg/day
Risperdal Consta (risperidone)	Schizophrenia Adults: 25 mg IM (deep gluteal or deltoid injection) once every 2 weeks; some adult patients not responding to the 25 mg dose may benefit from 37.5 mg or 50 mg IM once every 2 weeks	50 mg every 2 weeks
Invega Sustenna (paliperidone)	See Section V Dosage and Administration	See Section V Dosage and Administration

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: Contraindications
Not applicable

Appendix D: Examples of Oral Antipsychotics – Generic (Brand)

Typical/First Generation Antipsychotics†	Atypical/Second Generation Antipsychotics
Chlorpromazine (Thorazine®) Fluphenazine (Prolixin®) Haloperidol (Haldol®) Loxapine (Loxitane®) Perphenazine (Trilafon®) Pimozide (Orap®) Thioridazine (Mellaril®) Thiothixene (Navane®) Trifluoperazine (Stelazine®)	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*

V. Dosage and Administration

Drug Name	Indication	Dosing Regimen	Maximum Dose
Paliperidone (Invega Sustenna)	Schizophrenia	Initial: 234 mg IM on day 1 and 156 mg one week later (day 8), both administered in the deltoid muscle Maintenance*: 39-234 mg IM monthly in either the deltoid or gluteal muscle	234 mg/month
	Schizoaffective disorder	Initial: 234 mg IM on day 1 and 156 mg one week later (day 8), both administered in the deltoid muscle Maintenance*: 78-234 mg IM monthly in either the deltoid or gluteal muscle	234 mg/month
Paliperidone (Invega Trinza)	Schizophrenia	Invega Trinza is to be used only after Invega Sustenna® (1-month paliperidone palmitate extended-release injectable suspension) has been established as adequate treatment for at least four months. Initiate Invega Trinza when the next 1-month paliperidone palmitate dose is scheduled with an Invega Trinza dose based on the previous 1-month injection dose, using the equivalent 3.5-fold higher dose as shown: If the Last Dose of Invega Sustenna is: → Initiate Invega Trinza at the Following Dose: 78 mg → 273 mg 117 mg → 410 mg 156 mg → 546 mg 234 mg → 819 mg Following the initial Invega dose, Invega Trinza should be administered IM every 3 months. Invega Trinza may be administered up to 7 days before or after the monthly time point of the next scheduled paliperidone palmitate 1-month dose.	819 mg every 3 months

*****Administered 5 weeks after the first injection*

VI. Product Availability

Drug Name	Availability
Paliperidone (Invega Sustenna)	Extended-release injectable suspension: 39 mg, 78 mg, 117 mg, 156 mg, or 234 mg
Paliperidone (Invega Trinza)	Extended-release injectable suspension: 273 mg, 410 mg, 546 mg, or 819 mg

VII. References

1. Invega Sustenna Prescribing Information. Titusville, NJ: Janssen Pharmaceuticals, Inc.; March 2018. Available at https://www.invegasustennahPA.CP.com/. Accessed May 1, 2018.
2. Invega Trinza Prescribing Information. Titusville, NJ: Janssen Pharmaceuticals, Inc.; March 2018. Available at https://www.invegatrinzahPA.CP.com/. Accessed May 1, 2018.
3. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2018. Available at: http://www.clinicalpharmacology-ip.com/.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy Created	10/18	