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.293	**Effective Date: 10/17/2018** **Revision Date: 10/17/2018**
Policy Name: Risperidone Long-Acting Injection (Risperdal Consta)	**HC Approval Date:**

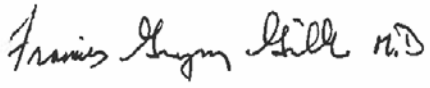
Type of Submission – Check all that apply:

- ✓ **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: Risperidone Long-Acting Injection (Risperdal Consta)

Reference Number: PA.CP.PHAR.293
Effective Date: 10.17.18
Last Review Date: 10.17.18

Revision Log

Description
Risperidone (Risperdal Consta®) is an atypical antipsychotic.

FDA Approved Indication(s)
Risperdal Consta is indicated:

- For the treatment of schizophrenia
- For the maintenance treatment of bipolar I disorder as monotherapy or as adjunctive therapy to lithium or valproate

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 Risperdal Consta is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Schizophrenia or Bipolar Disorder (must meet all)**:**

1. Diagnosis of schizophrenia or bipolar disorder;
2. Prescribed by or in consultation with a psychiatrist;
3. History of non-adherence to oral antipsychotic therapy (*see appendix D for examples*);
4. Established tolerability with oral risperidone;
5. Dose does not exceed 50 mg every two weeks.

Approval duration: 6 months

B. 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. Schizophrenia or Bipolar Disorder (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 50 mg every two weeks.

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
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 Bipolar Disorder Adults: initially, 2-3 mg PO QD Effective dose range: 1 to 6 mg/day	Schizophrenia: 16 mg/day Bipolar disorder: 6 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: 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®)	Aripiprazole (Abilify®)* Asenapine maleate (Saphris®) Brexpiprazole (Rexulti®)

Loxapine (Loxitane®) Perphenazine (Trilafon®) Pimozide (Orap®) Thioridazine (Mellaril®) Thiothixene (Navane®) Trifluoperazine (Stelazine®)	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

Indication	Dosing Regimen	Maximum Dose
Bipolar disorder Schizophrenia	The recommended dose is 25 mg IM every 2 weeks. Some patients not responding to 25 mg may benefit from a higher dose of 37.5 mg or 50 mg.	50 mg IM every 2 weeks

VI. Product Availability

Vial kits: 12.5 mg, 25 mg, 37.5 mg, and 50 mg

VII. References

1. Risperdal Consta Prescribing Information. Titusville, NJ: Janssen Pharmaceuticals, Inc.; March 2018. Available at http://www.janssencns.com/risperdal. Accessed May 4, 2018.
2. Kim B, Lee SH, Yang YK, et al. Review Article: Long-acting injectable antipsychotics for first-episode schizophrenia: The pros and cons. Schizophr Res Treatment. August 14, 2012; 2012: 560836. doi:10.1155/2012/560836
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	