

Clinical Policy: Risperidone Long-Acting Injection (Risperdal Consta)

Reference Number: CP.PHAR.293

Effective Date: 12.01.16

Last Review Date: 08.18

Line of Business: HIM, Medicaid

[Revision Log](#)

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

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 Centene Corporation[®] 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. Age \geq 18 years;
4. History of non-adherence to oral antipsychotic therapy (*see appendix D for examples*);
5. Established tolerability with oral risperidone;
6. 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 for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): HIM.PHAR.21 for health insurance marketplace and CP.PMN.53 for Medicaid.

II. Continued Therapy

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

1. Currently receiving medication via Centene benefit, or documentation supports that member is currently receiving Risperdal Consta for schizophrenia or bipolar 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 50 mg every two weeks.

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 6 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): HIM.PHAR.21 for health insurance marketplace and CP.PMN.53 for 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 policies – HIM.PHAR.21 for health insurance marketplace and CP.PMN.53 for Medicaid or evidence of coverage documents;
- 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 [®])	<p style="text-align: center;">Schizophrenia</p> 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 <p style="text-align: center;">Bipolar Disorder</p> 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 [®])	Aripiprazole (Abilify [®])*
Fluphenazine (Prolixin [®])	Asenapine maleate (Saphris [®])
Haloperidol (Haldol [®])	Brexpiprazole (Rexulti [®])
Loxapine (Loxitane [®])	Cariprazine (Vraylar [®])
Perphenazine (Trilafon [®])	Clozapine (Clozaril [®])
Pimozide (Orap [®])	Iloperidone (Fanapt [®])
Thioridazine (Mellaril [®])	Lurasidone (Latuda [®])
Thiothixene (Navane [®])	Olanzapine (Zyprexa [®])*
Trifluoperazine (Stelazine [®])	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	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
Schizophrenia		

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 split from CP.PHARM.122.LAI Antipsychotics and converted to new template. Age removed and max dose added. Hypersensitivity contraindication added per PI. Appendix B: Oral Antipsychotics – reviewed, edited and updated per UptoDate and FDA websites (5-7). Specialist review by psychiatrist.	11.16	12.16
Converted to new template. Added age restriction per PI. Removed requirements related to hypersensitivity to either risperidone or paliperidone and history of dementia-related psychosis per safety approach. Increased initial approval duration from 3 to 6 months. Re-auth: updated to allow continuation of therapy for schizophrenia and bipolar disorder. Added dementia-related psychosis under section III.	07.17	11.17
3Q 2018 annual review: policies combined for Medicaid and HIM lines of business; Medicaid: removed requirement related to therapeutic plan since specialist is involved in care; HIM: removed “no history of dementia-related psychosis” as a requirement and added it to section III Diagnoses/Indications for which coverage is NOT authorized; extended initial approval duration from 3 to 6 months; references reviewed and updated.	05.04.18	08.18

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.

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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.

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