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

Reference Number: ERX.SPA.179
Effective Date: 12.01.17
Last Review Date: 08.22
Line of Business: Commercial, Medicaid

Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description
Risperidone (Perseris™, 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

Perseris is indicated for the treatment of schizophrenia in adults.

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.

Health plan approved formularies should be reviewed for all coverage determinations. Requirements to use preferred alternative agents apply only when such requirements align with the health plan approved formulary.

It is the policy of health plans affiliated with Envolve Pharmacy Solutions™ that Perseris and Risperdal Consta are **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 ≥ 18 years;
4. Member meets one of the following (a or b):
   a. History of non-adherence to oral antipsychotic therapy (*see Appendix D for examples*) and has established tolerability with oral risperidone;
   b. Therapy was initiated in an inpatient setting during a recent (within 60 days) hospital admission;
5. Request meets one of the following (a or b):
   a. For Perseris requests, dose does not exceed 120 mg every four weeks;
   b. For Risperdal Consta requests, dose does not exceed 50 mg every two weeks.

Approval duration:
Commercial – Length of Benefit
Medicaid – 6 months

B. Other diagnoses/indications

1. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

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

1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions, or documentation supports one of the following (a or b):
   a. Member is currently receiving the requested medication for a covered indication, and has received this medication for at least 30 days;
   b. Therapy was initiated in an inpatient setting, for a covered indication, during a recent (within 60 days) hospital admission;
2. Member is responding positively to therapy;
3. If request is for a dose increase, request meets one of the following (a or b):
   a. For Perseris requests, new dose does not exceed 120 mg every four weeks;
   b. For Risperdal Consta requests, new dose does not exceed 50 mg every two weeks.

Approval duration:
Commercial – Length of Benefit
Medicaid – 12 months

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

1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy.
   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to ERX.PA.01 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:

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 policy – ERX.PA.01 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 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/Boxed Warnings

- Contraindication(s): hypersensitivity to risperidone or paliperidone
- Boxed warning(s): increased mortality in elderly patients with dementia-related psychosis

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®) • Lumateperone (Caplyta®) • 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
Risperidone (Risperdal Consta)	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 every 2 weeks
Risperidone (Perseris)	Schizophrenia	90 mg or 120 mg SC once monthly	120 mg every 4 weeks

VI. Product Availability

Drug Name	Availability
Risperidone (Risperdal Consta)	Vial kits: 12.5 mg, 25 mg, 37.5 mg, and 50 mg
Risperidone (Perseris)	Extended-release injectable suspension: 90 mg, 120 mg

VII. References

1. Risperdal Consta Prescribing Information. Titusville, NJ: Janssen Pharmaceuticals, Inc.; February 2021. Available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/020272Orig1s083,020588Orig1s071,021444Orig1s057,021346Orig1s061lbl.pdf#page=60. Accessed May 12, 2022.
2. Perseris Prescribing Information. North Chesterfield, VA: Indivior, Inc.; December 2019. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/210655s004lbl.pdf. Accessed May 12, 2022.
3. 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
4. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2022. Available at: http://www.clinicalpharmacology-ip.com/. Accessed May 12, 2022.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
3Q 2018 annual review: no significant changes; references reviewed and updated.	05.04.18	08.18

Reviews, Revisions, and Approvals	Date	P&T Approval Date
3Q 2019 annual review: added Perseris to policy; initial and continued therapy criteria are revised to allow approval of Risperdal Consta for members who initiate therapy during a recent inpatient visit, without the requirement to step through oral agents; added Medicaid line of business with 6/12 month approval durations; references reviewed and updated.	06.03.19	08.19
3Q 2020 annual review: no significant changes; references reviewed and updated.	05.12.20	08.20
3Q 2021 annual review: no significant changes; references reviewed and updated.	03.22.21	08.21
3Q 2022 annual review: no significant changes; references reviewed and updated.	05.12.22	08.22

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.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. 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.

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