PRIOR AUTHORIZATION CRITERIA

BRAND NAME*
(generic)

RISPERDAL CONSTA
(risperidone long-acting injection)

Status: CVS Caremark Criteria
Type: Initial Prior Authorization ***Ref # 874-A***

** Drugs that are listed in the target drug box include both brand and generic and all dosage forms and strengths unless otherwise stated*

FDA-APPROVED INDICATIONS

Schizophrenia
Risperdal Consta is indicated for the treatment of schizophrenia.

Bipolar Disorder
Risperdal Consta is indicated as monotherapy or as adjunctive therapy to lithium or valproate for the maintenance treatment of Bipolar I Disorder.

COVERAGE CRITERIA

The requested drug will be covered with prior authorization when the following criteria are met:

- Tolerability with oral risperidone has been established
  AND
- The requested drug is being prescribed for any of the following: A) the treatment of schizophrenia, B) as monotherapy or as adjunctive therapy to lithium or valproate for the maintenance treatment of bipolar I disorder

RATIONALE

The intent of the criteria is to provide coverage consistent with product labeling, FDA guidance, standards of medical practice, evidence-based drug information, and/or published guidelines. Risperdal Consta is indicated for the treatment of schizophrenia. Risperdal Consta is also indicated as monotherapy or as adjunctive therapy to lithium or valproate for the maintenance treatment of Bipolar I Disorder.

For patients who have never taken oral risperidone, it is recommended to establish tolerability with oral risperidone prior to initiating treatment with Risperdal Consta.

REFERENCES

1. Risperdal Consta [package insert]. Titusville, NJ: Janssen Pharmaceuticals, Inc.; February 2017.
2. AHFS DI (Adult and Pediatric) [database online]. Hudson, OH: Lexi-Comp, Inc.; http://online.lexi.com/lco/action/index/dataset/complete_ashp [available with subscription]. Accessed September 2017.
3. Micromedex Solutions [database online]. Greenwood Village, CO: Truven Health Analytics Inc. Updated periodically. www.micromedexsolutions.com [available with subscription]. Accessed September 2017.

Written by:	UM Development (SE)
Date written:	12/2009
Revised:	(CT/SE) 09/2010 (CAS adapted), (SE) 11/2010 (CMS mandated change: removed exclusion criteria for torsade de pointes); (CY) 09/2011, 09/2012 (removed prescriber restriction); (PL) 10/2012 (extended duration); (CT) 09/2013, 09/2014; (MS) 09/2015, 09/2016 (removed safety question, aligned Q3 with other programs); (RP) 09/217 (removed noncompliance question)
Reviewed:	Medical Affairs (WF) 12/2009; (KP) 09/2010, 09/2011; (DC) 09/2012; (DNC) 09/2013; (LMS) 09/2014; (KC) 09/2015; (LS) 09/2016; (JG) 09/2017 External Review: 03/2010, 12/2010, 12/2011, 02/2013, 12/2013, 12/2014, 12/2015, 12/2016, 12/2017

CVS caremark™

CRITERIA FOR APPROVAL

1	Has tolerability with oral risperidone been established?	Yes	No
2	Is the requested drug being prescribed for any of the following: A) treatment of schizophrenia, B) as monotherapy or as adjunctive therapy to lithium or valproate for the maintenance treatment of bipolar I disorder?	Yes	No

Mapping Instructions			
	Yes	**No**	**DENIAL REASONS – DO NOT USE FOR MEDICARE PART D**
1.	Go to 2	Deny	Your plan covers this drug when you have taken risperidone by mouth. Your use of this drug does not meet the requirement. This is based on the information we have.
2.	Approve, 36 Months	Deny	Your plan covers this drug when you have any of these conditions: - schizophrenia - bipolar I disorder Your use of this drug does not meet the requirement. This is based on the information we have.