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. OTC products are not included 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. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Hudson, OH: Wolters Kluwer Clinical Drug Information, Inc. http://online.lexi.com/. Accessed September 2018.
3. Micromedex (electronic version). Truven Health Analytics, Greenwood Village, Colorado, USA. http://www.micromedexsolutions.com/. Accessed September 2018.

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) 09/2017 (removed noncompliance question), (ME) 09/2018 (no clinical changes)
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, 12/2018

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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	You do not meet the requirements of your plan. Your plan covers this drug when you can tolerate oral risperidone. Your request has been denied based on the information we have. [Short Description: Not established on oral risperidone]
2.	Approve, 36 Months	Deny	You do not meet the requirements of your plan. Your plan covers this drug when you are using it for one of the following: - treatment of schizophrenia - maintenance treatment of bipolar I disorder as monotherapy or as adjunctive therapy to lithium or valproate Your request has been denied based on the information we have. [Short Description: No approvable diagnosis]