PRIOR AUTHORIZATION CRITERIA

BRAND NAME*
(generic)

INVEGA SUSTENNA
(paliperidone palmitate extended-release injectable suspension)

Status: CVS Caremark Criteria
Type: Initial Prior Authorization ***Ref # 869-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

Invega Sustenna is indicated for the treatment of:

- Schizophrenia in adults
- Schizoaffective disorder in adults as monotherapy and as an adjunct to mood stabilizers or antidepressants

COVERAGE CRITERIA

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

- Tolerability with oral paliperidone or oral risperidone has been established
  AND
- The requested drug is being prescribed for the treatment of one of the following:
  - Schizophrenia in adults
  - Schizoaffective disorder in adults as monotherapy or as an adjunct to mood stabilizers or antidepressants

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. Invega Sustenna is indicated for the treatment of schizophrenia in adults or for schizoaffective disorder in adults as monotherapy and as an adjunct to mood stabilizers or antidepressants. For patients who have never taken oral paliperidone or oral or injectable risperidone, it is recommended to establish tolerability with oral paliperidone or oral risperidone prior to initiating treatment with Invega Sustenna. While many patients prefer oral medication, patients with recurrent relapses related to partial or full non-adherence are candidates for a long-acting injectable antipsychotic medication, as are patients who prefer the injectable formulation.[4]

The American Psychiatric Association (APA) states, with the possible exception of clozapine for the management of treatment-resistant symptoms, there currently is no definitive evidence that one atypical antipsychotic agent will have superior efficacy compared with another agent in the class, although meaningful differences in response may be observed in individual patients. Patient response and tolerance to antipsychotic agents are variable, and patients who do not respond to or tolerate one drug may be successfully treated with an agent from a different class or with a different adverse effect profile. The choice of an antipsychotic agent should be individualized, considering past response to therapy, adverse effect profile (including the patient's experience of subjective effects such as dysphoria), and the patient's preference for a specific drug, including route of administration.[3,4]

REFERENCES

1. Invega Sustenna [package insert]. Titusville, NJ: Ortho-McNeil-Janssen Pharmaceuticals, Inc.; August 2018.
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.
4. American Psychiatric Association. Practice guideline for the treatment of patients with schizophrenia, 2nd edition. 2010. Available at: http://psychiatryonline.org/pb/assets/raw/sitewide/practice_guidelines/guidelines/schizophrenia.pdf. Accessed September 2018.

CVS caremark™

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CRITERIA FOR APPROVAL

1	Has tolerability with oral paliperidone or oral risperidone been established?	Yes	No
2	Is the requested drug being prescribed for one of the following: A) schizophrenia, B) schizoaffective disorder as monotherapy or as an adjunct to mood stabilizers or antidepressants?	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 paliperidone or oral risperidone. Your request has been denied based on the information we have. [Short Description: Not established on oral paliperidone or 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 - treatment of schizoaffective disorder as monotherapy or as an adjunct to mood stabilizers or antidepressants Your request has been denied based on the information we have. [Short Description: No approvable diagnosis]