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
- Schizoaffective disorder 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
- Invega Sustenna is being prescribed for the treatment of one of the following:
  - Schizophrenia
  - Schizoaffective disorder 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 or for schizoaffective disorder as monotherapy and as an adjunct to mood stabilizers or antidepressants. 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]

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.

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.; July 2017.
2. Micromedex Solutions [database online]. Greenwood Village, CO: Truven Health Analytics Inc. Updated periodically. www.micromedexsolutions.com [available with subscription]. Accessed July 2017.
3. 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 July 2017.
4. American Psychiatric Association. Practice guideline for the treatment of patients with schizophrenia. Available at: http://psychiatryonline.org/pb/assets/raw/sitewide/practice_guidelines/guidelines/schizophrenia.pdf. Accessed July 2017.

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CRITERIA FOR APPROVAL

1	Has tolerability with oral paliperidone or oral risperidone been established?	Yes	No
2	Is Invega Sustenna being prescribed for one of the following: A) treatment of schizophrenia, B) treatment of 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	Your plan covers this drug when you can tolerate oral paliperidone or oral risperidone. Your use of this drug does not meet the requirements. This is based on the information we have.
2.	Approve, 36 months	Deny	Your plan covers this drug when you have one of these conditions: - treatment of schizophrenia - treatment of schizoaffective disorder as monotherapy or as an adjunct to mood stabilizers or antidepressants Your use of this drug does not meet the requirements. This is based on the information we have.

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