Effective Date: 6/2017
Last Reviewed: 2/2020, 2/2021, 1/2022, 2/2023, 3/2024, 2/2025 Scope: Medicaid

Paliperidone palmitate extended-release injectable products: Invega Hafyera, Invega Trinza, Invega Sustenna

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met, and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications:

Invega Hafyera

- Invega Hafyera is an every-six-month injection, is indicated for the treatment of schizophrenia in adults after they have been adequately treated with:
  - A once-a-month paliperidone palmitate extended-release injectable suspension (e.g., Invega Sustenna) for at least four months, or
  - An every-three-month paliperidone palmitate extended-release injectable suspension (e.g., Invega Trinza) for at least one three-month cycle.

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

Invega Trinza

- Invega Trinza, a 3-month injection, is indicated for the treatment of schizophrenia in patients after they have been adequately treated with Invega Sustenna (1-month paliperidone palmitate extended-release injectable suspension) for at least four months.

All other indications are considered experimental/investigational and are not a covered benefit.

II. CRITERIA FOR APPROVAL

Invega Hafyera

An authorization of 12 months may be granted when all the following criteria are met:

A. The requested drug is being prescribed for the treatment of schizophrenia
B. The patient has been adequately treated with Invega Sustenna for at least four months or Invega Trinza for at least one three-month cycle

Invega Sustenna

An authorization may be granted for 12 months when all the following criteria are met:

A. Tolerability with oral paliperidone or oral risperidone has been established
B. 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

Invega Trinza

An authorization may be granted for 12 months when all the following criteria are met:

C. The requested drug is being prescribed for the treatment of schizophrenia
D. The patient has been adequately treated with Invega Sustenna for at least four months

III. QUANTITY LIMIT

Invega Hafyera 1092mg & 1560mg: 1 syringe per 180 days

IV. REFERENCES

1. Invega Sustenna [package insert]. Titusville, NJ: Janssen Pharmaceuticals, Inc.; February 2025.
2. Invega Hafyera package insert]. Titusville, NJ: Janssen Pharmaceuticals, Inc.; February 2025.
3. Invega Trinza [package insert]. Titusville, NJ: Janssen Pharmaceuticals, Inc.; January 2025.
4. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Hudson, OH: Wolters Kluwer Clinical Drug Information, Inc. http://online.lexi.com/. Accessed February 2020.
5. Micromedex (electronic version). Truven Health Analytics, Greenwood Village, Colorado, USA. http://www.micromedexsolutions.com/. Accessed February 2020.
6. 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 2019.