Effective Date: 10/2022
Last P&T Approval/Version: 10/2022
Next Review Due By: 10/2023
Policy Number: C23973-A

Invega Hafyera (paliperidone palmitate) extended-release injectable suspension, for gluteal intramuscular use IL Medicaid Only

PRODUCTS AFFECTED

Invega Hafyera (paliperidone palmitate)

COVERAGE POLICY

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.
This Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide Molina Healthcare complete medical rationale when requesting any exceptions to these guidelines

Documentation Requirements:
Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive

DIAGNOSIS:
Schizophrenia [per package label]

REQUIRED MEDICAL INFORMATION:
This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. If a drug within this policy receives an updated FDA label within the last 180 days, medical necessity for the member will be reviewed using the updated FDA label information along with state and federal requirements, benefit being administered and formulary preferencing. Coverage will be determined on a case-by case basis until the criteria can be updated through Molina Healthcare, Inc. clinical governance. Additional information may be required on a case-by-case basis to allow for adequate review

A. FOR ALL INDICATIONS:
   1. Pharmacy claims or medical records documenting the use of Invega Sustenna (1-month paliperidone palmitate extended-release injectable suspension) once monthly for at least 4 months or Invega Trinza (3-month paliperidone palmitate extended-release injectable suspension) for at least one three-month cycle.

CONTINUATION OF THERAPY:

Drug and Biologic Coverage Criteria

A. FOR ALL INDICATIONS:
   1. Documentation that member meets initial criteria.

NOTE: If more than 6 months and 3 weeks but less than 11 months have elapsed since the last dose of Invega Hafyera, then reinitiate with the once-a-month paliperidone palmitate extended-release injectable suspension as described in the prescribing information for INVEGA HAFYERA. If more than 11 months have elapsed since the last dose of INVEGA HAFYERA, re-initiate treatment with a once-a-month paliperidone palmitate extended-release injectable suspension as described in the prescribing information for that product.

DURATION OF APPROVAL:
Initial authorization: 12 months. Continuation of Therapy: 12 months

PRESCRIBER REQUIREMENTS:
None

AGE RESTRICTIONS:
18 years of age and older

QUANTITY:
Quantity limit of one injection (one package) every 6 months.

PLACE OF ADMINISTRATION:
The recommendation is that injectable medications in this policy will be for pharmacy or medical benefit coverage and the intramuscular injectable products be administered in a place of service that is a non-hospital facility-based location.

DRUG INFORMATION

ROUTE OF ADMINISTRATION:
Intramuscular

DRUG CLASS:
Antipsychotics/Antimanic Agents, benzisoxazole

FDA-APPROVED USES:
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.
- INVEGA TRINZA® (3-month paliperidone palmitate extended-release injectable suspension) for at least one three-month cycle

COMPENDIAL APPROVED OFF-LABELED USES:
None

APPENDIX

APPENDIX:
None

BACKGROUND AND OTHER CONSIDERATIONS

BACKGROUND:
After an intramuscular (IM) injection, paliperidone palmitate dissolves slowly due to its extremely low water solubility. Paliperidone palmitate is then hydrolyzed to paliperidone and absorbed into the systemic

circulation. INVEGA HAFYERA delivers paliperidone over a 6-month period, compared to the 1-month or 3-month products which are administered every month or every three months, respectively. INVEGA HAFYERA doses of 1,092 mg and 1,560 mg result in paliperidone total exposure ranges that are encompassed within the exposure range for corresponding doses of 1-month paliperidone palmitate injections (PP1M) (156 mg and 234 mg) or corresponding doses of 3-month paliperidone palmitate (PP3M) injections (546 mg and 819 mg, respectively) or to corresponding once daily doses of paliperidone extended-release tablets. However, mean trough concentrations (Ctrough) at the end of the dosing interval were approximately 20 - 25% lower for INVEGA HAFYERA as compared to corresponding doses of 3-month paliperidone palmitate. The mean peak concentration (Cmax) was higher (1.4 to 1.5-fold) for INVEGA HAFYERA as compared to corresponding doses of 3-month paliperidone palmitate.

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:
Known hypersensitivity to paliperidone, risperidone, or to any excipients in Invega Hafyera.

OTHER SPECIAL CONSIDERATIONS:
WARNINGS AND PRECAUTIONS

1. Black Box Warning: Increased mortality in elderly patients with dementia-related psychosis: Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death. Paliperidone is not approved for use in patients with dementia-related psychosis.
2. *Cerebrovascular Adverse Reactions, Including Stroke, in Elderly Patients with Dementia-Related Psychosis*: Increased incidence of cerebrovascular adverse reactions (e.g. stroke, transient ischemic attack, including fatalities). INVEGA HAFYERA® is not approved for use in patients with dementia-related psychosis
3. *Neuroleptic Malignant Syndrome*: Manage with immediate discontinuation of drug and close monitoring
4. *QT Prolongation*: Avoid use with drugs that also increase QT interval and in patients with risk factors for prolonged QT interval
5. *Tardive Dyskinesia*: Discontinue drug if clinically appropriate
6. *Metabolic Changes*: Atypical antipsychotic drugs have been associated with metabolic changes that may increase cardiovascular/cerebrovascular risk. These metabolic changes include:
    a. *Hyperglycemia and Diabetes Mellitus*: Monitor for symptoms of hyperglycemia including polydipsia, polyuria, polyphagia, and weakness. Monitor glucose regularly in patients with diabetes or at risk for diabetes.
    b. *Dyslipidemia*: Undesirable alterations have been observed.
    c. *Change in Body Weight*: Significant weight gain has been reported. Monitor weight gain.
7. *Orthostatic Hypotension and Syncope*: Use with caution in patients with known cardiovascular or cerebrovascular disease and patients predisposed to hypotension
8. *Falls*: Assess the risk of falls when initiating antipsychotic treatment
9. *Leukopenia, Neutropenia, and Agranulocytosis*: Monitor complete blood count in patients with a history of a clinically significant low white blood cell count (WBC) or a drug-induced leukopenia/neutropenia. Consider discontinuation if clinically significant decline in WBC in the absence of other causative factors
10. *Hyperprolactinemia*: Prolactin elevations occur and persist during chronic administration
11. *Potential for Cognitive and Motor Impairment*: Use caution when operating machinery
12. *Seizures*: Use cautiously in patients with a history of seizures or with conditions that lower the seizure threshold

13. *Seizures:* Conditions that lower the seizure threshold may be more prevalent in patients 65 years or older.
14. *Dysphagia:* Use cautiously in patients at risk for aspiration pneumonia
15. *Priapism*
16. *Disruption of Body Temperature Regulation:* Disruption of the body's ability to reduce core body temperature has been attributed to antipsychotic agents

DOSAGE:
Use Invega Hafyear only after the patient has been adequately treated with the 1-month paliperidone palmitate extended-release injectable suspension for at least four months or the 3-month paliperidone palmitate extended-release injectable suspension for at least one three-month cycle. Invega Hafyera should be administered once every 6 months. See the package insert for recommended starting doses based on previous therapy.

Renal Impairment
Use of Invega Hafyera is not recommended for use in patients with mild, moderate, or severe renal impairment (creatinine clearance <90 ml/min) because necessary dosage adjustment is not possible with available strengths of Invega Hafyera.

CODING/BILLING INFORMATION

Note: 1) This list of codes may not be all-inclusive. 2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement

HCPCS CODE	DESCRIPTION
NA	

AVAILABLE DOSAGE FORMS:

PRODUCT NAME
Invega Hafyera SUSY 1092MG/3.5ML
Invega Hafyera SUSY 1560MG/5ML

REFERENCES

1. Illinois Medicaid Preferred Drug List, Effective October 1, 2022
2. Illinois HFS Drugs with Stipulated PA Language per Contract for MCOs 10.1.22, revised
3. Invega Hafyera™ (paliperidone palmitate) [package insert]. Titusville, NJ: Janssen Pharmaceuticals, Inc.; August 2021.
4. Paliperidone. Clinical Pharmacology [Internet]. Elsevier. c2020- [cited March 2020]. Available from: http://www.clinicalpharmacology.com

SUMMARY OF REVIEW/REVISIONS	DATE
New	Q4 2022