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5.99.002

Section:	Prescription Drugs	**Effective Date:**	April 1, 2025
Subsection:	Miscellaneous Products	**Original Policy Date:**	December 7, 2011
Subject:	Exjade Jadenu	**Page:**	1 of 7

Last Review Date: March 7, 2025

Exjade Jadenu

Description

Exjade (**deferasirox**) tablets, for oral suspension
Jadenu (**deferasirox**) tablets, for oral use
Jadenu Sprinkle (**deferasirox**) granules, for oral use

Preferred product: generic deferasirox

Background
Exjade (deferasirox) and Jadenu (deferasirox) are iron chelating agents indicated for the treatment of chronic iron overload. Exjade and Jadenu are used for the treatment of patients who have too much iron in their blood due to repeated blood transfusions or for patients with an inherited disorder called non-transfusion-dependent thalassemia (NTDT). Too much iron in the blood results in the formation of insoluble ferritin which over time can lead to organ damage. Although NTDT usually does not require individuals to get frequent red blood cell transfusions, some patients with NTDT are still at risk for iron overload that can lead to organ damage (1-2).

Regulatory Status
FDA-approved indications: Exjade and Jadenu are iron chelators indicated for:

1. Treatment of chronic iron overload due to blood transfusions in patients 2 years of age and older. This indication is based on reduction in serum ferritin and liver iron concentration (LIC).
2. Treatment of chronic iron overload in patients 10 years of age and older with non-transfusion-dependent thalassemia (NTDT) syndromes and with a liver iron (Fe) concentration (LIC) of at least 5 mg Fe per gram of dry weight and a serum ferritin greater than 300 mcg/L (1-2).

Limitations of Use: The safety and effectiveness of Exjade and Jadenu when administered with other iron chelation therapy have not been established (1-2).

Exjade and Jadenu have a boxed warning regarding the development of renal failure, hepatic failure, and gastrointestinal hemorrhage, which can be fatal in some patients. Creatinine clearance (estimated by the Cockcroft-Gault method) must be determined before initiating therapy in all patients in order to establish a reliable pretreatment baseline. Monitor serum creatinine weekly during the first month after initiation or modification of therapy and at least monthly thereafter (1-2).

Exjade and Jadenu are contraindicated in patients with creatinine clearance less than 40 mL/min or serum creatinine greater than 2 times the age-appropriate upper limit of normal. Baseline serum transaminases and bilirubin should also be obtained in all patients before the initiation of treatment and every 2 weeks during the first month and at least monthly thereafter (1-2).

Avoid the use of Exjade and Jadenu in patients with severe (Child-Pugh C) hepatic impairment. Patients with mild (Child-Pugh A) or moderate (Child-Pugh B) hepatic impairment may be at higher risk for hepatic toxicity. Closely monitor patients with mild (Child-Pugh A) or moderate (Child-Pugh B) hepatic impairment for efficacy and adverse reactions that may require dose titration (1-2).

GI hemorrhage, including deaths, has been reported, especially in elderly patients who had advanced hematologic malignancies and/or low platelet counts. Non-fatal upper GI irritation, ulceration and hemorrhage have been reported in patients, including children and adolescents, receiving Exjade or Jadenu. Patients should be monitored for suspected GI ulceration or hemorrhage during Exjade or Jadenu therapy and promptly initiate additional evaluation and treatment if a serious GI adverse event is suspected. The risk of gastrointestinal hemorrhage may be increased when administering Exjade or Jadenu in combination with drugs that have ulcerogenic or hemorrhagic potential, such as non-steroidal anti-inflammatory drugs (NSAIDs), corticosteroids, oral bisphosphonates, or anticoagulants (1,2).

Exjade and Jadenu are contraindicated in patients with any of the following: serum creatinine greater than 2 times the age-appropriate upper limit of normal, creatinine clearance less than 40 mL/min, high-risk myelodysplastic syndromes (MDS), advanced malignancies and platelet counts below 50,000 per microliters (1-2).

Related policies
Ferriprox, Zynteglo

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Exjade and Jadenu may be considered **medically necessary** if the conditions indicated below are met.

Exjade and Jadenu may be considered **investigational** for all other indications.

Prior - Approval Requirements

Diagnoses

Patient must have **ONE** of the following:

1. Chronic iron overload due to blood transfusions
    a. 2 years of age and older
    b. Serum ferritin >1000 mcg/L

2. Non-transfusion-dependent thalassemia (NTDT)
    a. 10 years of age and older
    b. Liver iron concentration (LIC) of at least 5 milligrams of iron per gram of dry liver tissue weight
    c. Serum ferritin >300 mcg/L

AND ALL of the following:

1. Platelet counts >50,000 per microliters
2. Obtain baseline transaminases (AST and ALT) and bilirubin before initiation of therapy and every 2 weeks during the first month and at least monthly thereafter
3. **Brand Exjade ONLY:** Patient **MUST** have tried the preferred product (generic Exjade: deferasirox) unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)
4. **Brand Jadenu ONLY:** Patient **MUST** have tried the preferred product (generic Jadenu: deferasirox) unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)

AND NONE of the following:

1. High-risk myelodysplastic syndromes (MDS)
2. Advanced malignancies
3. Severe (Child-Pugh C) hepatic impairment
4. Serum creatinine greater than 2 times the age-appropriate upper limit of normal
5. Creatinine clearance less than 40 mL/min
6. Concurrent therapy with another iron chelating agent (see Appendix 1)

Prior – Approval *Renewal* Requirements

Diagnoses

Patient must have **ONE** of the following:

1. Chronic iron overload due to blood transfusions
    a. 2 years of age and older
    b. Serum ferritin >500 mcg/L
2. Non-transfusion-dependent thalassemia (NTDT)
    a. 10 years of age and older
    b. Liver iron concentration (LIC) of at least 5 milligrams of iron per gram of dry liver tissue weight
    c. Serum ferritin >300 mcg/L

AND ALL of the following:

1. Platelet count >50,000 per microliters
2. Transaminases (AST and ALT) and bilirubin monitored monthly
3. **Brand Exjade ONLY:** Patient **MUST** have tried the preferred product (generic Exjade: deferasirox) unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)
4. **Brand Jadenu ONLY:** Patient **MUST** have tried the preferred product (generic Jadenu: deferasirox) unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)

AND NONE of the following:

1. High-risk myelodysplastic syndromes (MDS)
2. Advanced malignancies
3. Severe (Child-Pugh C) hepatic impairment
4. Serum creatinine greater than 2 times the age-appropriate upper limit of normal
5. Creatinine clearance less than 40 mL/min

6. Concurrent therapy with another iron chelating agent (see Appendix 1)

Policy Guidelines

Pre – PA Allowance

None

Prior - Approval Limits

Duration 12 months

Prior – Approval *Renewal* Limits

Same as above

Rationale

Summary

Exjade (deferasirox) and Jadenu (deferasirox) are iron chelating agents indicated for the treatment of chronic iron overload. Exjade and Jadenu are FDA approved for treating chronic iron overload due to blood transfusions in patients 2 years of age and older. This orally active iron chelator is most commonly used in patients with b-thalassemia, who, with repeated red blood cell transfusions, accumulate iron. Exjade and Jadenu is also approved to treat patients 10 years of age and older who have chronic iron overload resulting from a genetic blood disorder called non-transfusion-dependent thalassemia (NTDT) (1-2).

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of Exjade and Jadenu while maintaining optimal therapeutic outcomes.

References

1. Exjade [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; July 2020.
2. Jadenu [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; July 2020.

Policy History

Date	Action
December 2011	New Policy
December 2012	Annual editorial review
March 2013	Annual review and reference update

	Addition of non-transfusion-dependent thalassemia (NTDT) to criteria
December 2014	Annual editorial review and reference update
April 2015	Addition of Jadenu
June 2015	Annual editorial review and reference update
September 2015	Annual review and reference update
December 2016	Annual review and reference update Policy number change from 5.11.02 to 5.99.02
June 2017	Annual editorial review and reference update, separation of MDS and advanced malignancies in renewal section
June 2018	Annual review and reference update
June 2019	Annual editorial review and reference update. Addition of requirement of no concurrent therapy with another iron chelating agent and addition of Appendix 1
June 2020	Annual editorial review and reference update
December 2020	Annual editorial review and reference update. Added requirement that brand Exjade has to t/f the preferred product deferasirox
March 2021	Annual review
December 2021	Annual review. Added requirement that brand Jadenu has to t/f the preferred product deferasirox
March 2022	Annual review
December 2022	Annual review. Changed policy number to 5.99.002
March 2023	Annual review
March 2024	Annual review
March 2025	Annual review

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 7, 2025 and is effective on April 1, 2025.

Appendix 1 - List of Iron Chelating Agents

Generic Name	Brand Name
deferiprone	Ferriprox
deferasirox	Exjade
deferasirox	Jadenu