



STANDARD COMMERCIAL DRUG FORMULARY  
PRIOR AUTHORIZATION GUIDELINES

DEFERASIROX

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
DEFERASIROX	EXJADE, JADENU, JADENU SPRINKLE, DEFERASIROX	33337		GPI-10 (9310002500)	

**GUIDELINES FOR USE**

**INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)**

1. Is the request prescribed by or given in consultation with a hematologist or hematologist-oncologist?

If yes, continue to #2.

If no, do not approve.

**DENIAL TEXT:** See the initial denial text at the end of the guideline.

2. Does the patient have a diagnosis of chronic iron overload due to blood transfusions?

If yes, continue to #3.

If no, continue to #4.

3. Does the patient meet **ALL** of the following criteria?

- The patient is 2 years of age or older
- The patient's serum ferritin levels are consistently greater than 1000mcg/L (at least 2 lab values in the previous 3 months)

If yes, continue to #6.

If no, do not approve.

**DENIAL TEXT:** See the initial denial text at the end of the guideline.

4. Does the patient have a diagnosis of chronic iron overload resulting from non-transfusion dependent thalassemia (NTDT)?

If yes, continue to #5.

If no, do not approve.

**DENIAL TEXT:** See the initial denial text at the end of the guideline.

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INITIAL CRITERIA (CONTINUED)

5. Does the patient meet **ALL** of the following criteria?

- The patient is 10 years of age or older
- The patient's serum ferritin levels are consistently greater than 300mcg/L (at least 2 lab values in the previous 3 months)
- The patient's liver iron concentration (LIC) is at least 5mg Fe/g dry weight

If yes, continue to #6.

If no, do not approve.

**DENIAL TEXT:** See the initial denial text at the end of the guideline.

6. Is the request for Exjade or Jadenu tablets?

If yes, **approve Exjade or Jadenu tablets for all strengths of the requested drug for 6 months by GPID or GPI-14.**

If no, continue to #7.

7. Is the request for Jadenu sprinkle packets **AND** the patient has tried a generic equivalent of Exjade or Jadenu tablets?

If yes, **approve Jadenu Sprinkle for all strengths for 6 months by GPID or GPI-14.**

If no, do not approve.

**INITIAL DENIAL TEXT: \*Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.**

Our guideline named **DEFERASIROX (EXJADE, JADENU, JADENU SPRINKLE, DEFERASIROX)** requires the following rule(s) be met for approval:

- A. You have chronic iron overload due to blood transfusions (you have too much iron from blood transfers) or non-transfusion dependent thalassemia (a blood disorder involving less than normal amounts of an oxygen-carrying protein)
- B. The medication is prescribed by or given in consultation with a hematologist (blood specialty doctor) or hematologist/oncologist (tumor/cancer doctor)
- C. **If you have chronic iron overload due to blood transfusions, approval also requires:**
  1. You are 2 years of age or older
  2. Your serum ferritin levels (amount of iron-containing blood cell proteins) are regularly greater than 1000mcg/L (we need at least 2 lab values taken within the previous 3 months)

***(Initial denial text continued on next page)***

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INITIAL CRITERIA (CONTINUED)

- D. If you have chronic iron overload resulting from non-transfusion dependent thalassemia (NTDT), approval also requires:
1. You are 10 years of age or older
  2. Your serum ferritin levels (amount of iron-containing blood cell proteins) are regularly greater than 300mcg/L (we need at least 2 lab values taken within the previous 3 months)
  3. Your liver iron concentration (LIC) is at least 5mg Fe/g dry weight or greater
- E. Requests for Jadenu sprinkle packets require a trial of equivalent generic Exjade or Jadenu tablets

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

1. Does the patient have a diagnosis of chronic iron overload due to blood transfusions **AND** meet the following criterion?
  - The patient's serum ferritin levels are consistently greater than 500mcg/L (at least 2 lab values in the previous 3 months)

If yes, **approve for 12 months by HICL or GPI-10.**

If no, continue to #2.

2. Does the patient have a diagnosis of chronic iron overload resulting from non-transfusion dependent thalassemia (NTDT) and meet **ONE** of the following criteria?
  - The patient's serum ferritin levels are consistently greater than 300mcg/L (at least 2 lab values in the previous 3 months)
  - The patient's liver iron concentration (LIC) is at least 3mg Fe/g dry weight (*Liver iron concentration supersedes serum ferritin level when both measurements are available*)

If yes, **approve for 12 months by HICL or GPI-10.**

If no, do not approve.

**DENIAL TEXT:** See the renewal denial text at the end of the guideline.

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RENEWAL CRITERIA (CONTINUED)

**RENEWAL DENIAL TEXT:** \*Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **DEFERASIROX (EXJADE, JADENU, JADENU SPRINKLE, DEFERASIROX)** requires the following rule(s) be met for renewal:

- A. You have chronic iron overload due to blood transfusions (you have too much iron from blood transfers) or non-transfusion dependent thalassemia (a blood disorder involving less than normal amounts of an oxygen-carrying protein)
- B. **If you have chronic Iron overload due to blood transfusions, renewal also requires:**
  - 1. Your serum ferritin levels (amount of iron-containing blood cell proteins) are regularly greater than 500 mcg/L (we need at least 2 lab values taken within the previous 3 months)
- C. **If you have chronic iron overload resulting from non-transfusion dependent thalassemia (NTDT), renewal also requires ONE of the following:**
  - 1. Your serum ferritin levels (amount of iron-containing blood cell proteins) are regularly greater than 300mcg/L (we need at least 2 lab values taken within the previous 3 months)
  - 2. Your liver iron concentration (LIC) is at least 3mg Fe/g dry weight or greater

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

**RATIONALE**

For further information, please refer to the Prescribing Information and/or Drug Monograph for Exjade and Jadenu.

**REFERENCES**

- Jadenu [Package Insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; July 2017.
- Exjade [Package Insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; August 2016.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 09/07/20

Created: 08/17

Client Approval: 08/20

P&T Approval: 01/20