



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.

CONTINUED ON NEXT PAGE



STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

DEFERASIROX

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)

CONTINUED ON NEXT PAGE



STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

DEFERASIROX

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.

CONTINUED ON NEXT PAGE



STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

DEFERASIROX

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