

Reference number(s) 3257-D

#### This document applies to the following:

Formulary	Applies	
Standard Control (SF)	$\checkmark$	
Standard Control – Choice (SCCF)	V	
Preferred Drug Plan Design (PDPD)		
Advanced Control Specialty (ACSF)	$\checkmark$	
Advanced Control Specialty – Choice (ACSCF)	$\checkmark$	
Managed Medicaid Template (MMT)		
Marketplace (MF)		
Aetna Small Group Affordable Care Act (SG ACA) Aetna Health		
Exchange (AHE)		
Aetna Individual Lives (IVL)		
Value (VF)	$\checkmark$	

Formulary	Applies
New to Market (NTM)	
Standard Formulary Chart (SFC)	A
Basic Control Chart Preferred Drug Plan Design (BCC PDPD)	
Advanced Control Specialty Formulary Chart (ACSFC)	V
Value Formulary Chart (VFC)	V
Medical Benefit	
Medical Benefit: Advanced Biosimilars First	
Medical Benefit: Managed Medicaid (MMMB)	
Medicare Part B	
Medicare Part B: Advanced Biosimilars First	

### Exceptions Criteria Iron Chelators

This document informs prescribers of preferred products and provides an exception process for targeted products through prior authorization.

These criteria were developed to align with the following: Standard Control Formulary (SF), Standard Control Choice Formulary (SCCF), Advanced Control Specialty Formulary (ACSF), Advanced Control Specialty – Choice Formulary (ACSCF), Value Formulary (VF), Standard Control Formulary Chart (SFC), Advanced Control Specialty Formulary Chart (ACSFC), and Value Formulary Chart (VFC).

#### **Plan Design Summary**

This program applies to the iron chelating agents specified in this document. Coverage for the targeted products is provided based on clinical circumstances that would exclude the use of the preferred products and may be based on previous use of a product. The coverage review process will ascertain situations where a clinical exception can be made. This program applies to all members requesting treatment with the targeted product.

Each referral is reviewed based on all utilization management (UM) programs implemented for the client.

#### Table. Iron Chelators

Medications considered formulary or preferred on your plan may still require a clinical prior authorization review.

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	Product(s)
Preferred	<ul> <li>deferasirox (generic)</li> <li>deferiprone (generic)</li> <li>deferoxamine (generic)</li> </ul>
Target	<ul> <li>Desferal (deferoxamine)</li> <li>Exjade (deferasirox)</li> <li>Ferriprox (deferiprone)</li> <li>Jadenu (deferasirox)</li> </ul>

#### **Exception Criteria**

This program applies to members requesting treatment for an indication that is FDA-approved for the preferred products.

#### Desferal

Coverage for Desferal is provided when all of the following criteria are met:

- Member has a documented intolerable adverse event to the preferred product generic deferoxamine, and the adverse event was not an expected adverse event attributed to the active ingredient as described in the prescribing information.
- Member has a documented inadequate response or intolerable adverse event with the preferred product deferasirox, or member has a documented clinical reason to avoid treatment with deferasirox products (see Appendix I).
- Member has a documented inadequate response or intolerable adverse event with the preferred product deferiprone, or member has a documented clinical reason to avoid treatment with deferiprone products (see Appendix II).

#### Exjade and Jadenu

Coverage for Exjade or Jadenu is provided when all of the following criteria are met:

- Member has a documented intolerable adverse event to the preferred product generic deferasirox, and the
  adverse event was not an expected adverse event attributed to the active ingredient as described in the
  prescribing information.
- Member has a documented inadequate response or intolerable adverse event with the preferred product deferiprone, or member has a documented clinical reason to avoid treatment with deferiprone products (see Appendix II).
- Member has a documented inadequate response or intolerable adverse event with the preferred product deferoxamine, or member has a documented clinical reason to avoid treatment with deferoxamine products (see Appendix III).

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#### Ferriprox

Coverage for Ferriprox is provided when all of the following criteria are met:

- Member has a documented intolerable adverse event to the preferred product generic deferiprone, and the adverse event was not an expected adverse event attributed to the active ingredient as described in the prescribing information.
- Member has a documented inadequate response or intolerable adverse event with the preferred product deferasirox, or member has a documented clinical reason to avoid treatment with deferasirox products (see Appendix I).
- Member has a documented inadequate response or intolerable adverse event with the preferred product deferoxamine, or member has a documented clinical reason to avoid treatment with deferoxamine products (see Appendix III).

### Appendix

## Appendix I: Clinical Reasons to Avoid Treatment with Deferasirox Products (deferasirox, Exjade, Jadenu)

- Estimated glomerular filtration rate (GFR) less than 40 mL/min/1.73 m<sup>2</sup>
- Poor performance status
- High-risk myelodysplastic syndrome
- Advanced malignancy
- Platelet count less than 50 x 10<sup>9</sup>/L
- Known hypersensitivity to deferasirox or any component of drug formulation
- Severe (Child-Pugh C) hepatic impairment

# Appendix II: Clinical Reasons to Avoid Treatment with Deferiprone Products (deferiprone, Ferriprox)

• Known hypersensitivity to deferiprone or to any of the excipients in the formulation

## Appendix III: Clinical Reasons to Avoid Treatment with Deferoxamine Products (deferoxamine, Desferal)

- Severe renal disease
- Anuria
- Known hypersensitivity to deferoxamine

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### References

- 1. Deferasirox oral granule [package insert]. Laurelton, NY: Epic Pharma, LLC; December 2023.
- 2. Deferasirox tablet [package insert]. Warren, NJ: Cipla USA, Inc.; November 2021.
- 3. Deferasirox tablet for suspension [package insert]. Parsippany, NJ: Teva Pharmaceuticals; August 2021.
- 4. Deferiprone tablet [package insert]. Hawthorne, NY: Taro Pharmaceuticals U.S.A., Inc.; January 2024.
- 5. Deferoxamine mesylate [package insert]. Lake Forest, IL: Hospira, Inc.; November 2023.
- 6. Desferal [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; September 2022.
- 7. Exjade [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; July 2020.
- 8. Ferriprox solution [package insert]. Cary, NC: Chiesi USA, Inc.; November 2021.
- 9. Ferriprox tablet [package insert]. Cary, NC: Chiesi USA, Inc.; July 2023.
- 10. Jadenu [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; July 2020.

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