Policies Repository

Independence Blue Cross

Policy Title	Deferasirox (Exjade®)
Policy Number	FS.CLIN.26

Application of Pharmacy Policy is determined by benefits and contracts. Benefits may vary based on product line, group or contract. Some medications may be subject to precertification, age, gender or quantity edits. Individual member benefits must be verified.

This Pharmacy Policy document describes the status of pharmaceutical information and/or technology at the time the document was developed. Since that time, new information relating to drug efficacy, interactions, contraindications, dosage, administration routes, safety or FDA approval may have changed. If the Medical/Pharmacy Reviewer is aware of any new information on the subject of this document, please provide it promptly to the Medical/Pharmacy Policy Department. This information may include new FDA approved indications, withdrawals or other FDA alerts. This type of information is relevant not only when considering whether this Policy should be updated, but also when applying it to current requests for coverage.

Members are advised to use participating pharmacies in order to receive the highest level of benefits.

Policy

Deferasirox (Exjade®) is indicated for the treatment of transfusional hemosiderosis (chronic iron overload due to blood transfusions) in individuals who are 2 years of age or older.

The use of deferasirox (Exjade®) requires prior authorization (ie, clinical pharmacy and/or Medical Director review).

Policy Description

Deferasirox (Exjade®) is an orally active chelator that is selective for iron (as Fe3+). It is a tridentate ligand that binds iron with high affinity in a 2:1 ratio. Although deferasirox (Exjade®) has very low affinity for zinc and copper, there are variable decreases in the serum concentration of these trace metals after the administration of deferasirox (Exjade®). The clinical significance of these decreases is uncertain.

Policy Guideline Inclusion

Initial approval for the use of deferasirox (Exjade®) is valid for three months. Approval can be extended in three-month increments if a benefit is demonstrated.

Initial approval criteria
Deferasirox (Exjade®) is approved when **all** of the following inclusion criteria are met:

- Documentation that the individual is 2 years of age or older
- Documentation of a diagnosis of chronic iron overload due to blood transfusions
- Documentation that the serum ferritin levels are consistently greater than 1000 mcg/L (as demonstrated with at least two lab values within two months prior to treatment)

Continuation criterion
Deferasirox (Exjade®) is approved when the following inclusion criterion is met:

- Documentation of a decreased serum ferritin level compared with the baseline level

Policy Guideline Exclusion

Initial denial criteria
Deferasirox (Exjade®) is denied when **any** of the following exclusion criteria are found:

- No documentation that the individual is 2 years of age or older
- No documentation of a diagnosis of chronic iron overload due to blood transfusions
- No documentation that the serum ferritin levels are consistently greater than 1000 mcg/L (as demonstrated with at least two lab values within two months prior to treatment)

Continuation criterion
Deferasirox (Exjade®) is denied when the following exclusion criterion is found:

- No documentation of a decreased serum ferritin level compared with the baseline level

Policy List of Applicable Drugs

Brand Name	Generic Name
Exjade	deferasirox

Dosing and Administration

Refer to the specific manufacturer's prescribing information for administration and dosage details for each specific agent.

Policy References

Exjade® (deferasirox) [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; April 2009. Also available online at: http://www.pharma.us.novartis.com/product/pi/pdf/exjade.pdf. Accessed May 12, 2009.

Novartis AG. Exjade® (deferasirox). [Exjade Web site]. Available at: http://www.exjade.com. Accessed May 11, 2009.

Wolters Kluwer Health, Inc. Exjade® (deferasirox). [Facts and Comparisons Web site]. Available at: http://www.factsandcomparisons.com [via subscription only]. Accessed May 11, 2009.

Policy Link to Related Policies

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