Pharmacy Policy Bulletin

Title: Deferasirox (Exjade®)
Policy #: Rx.01.22

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 restrictions. 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. This Pharmacy Policy will be regularly updated as scientific and medical literature becomes available. 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.

Intent:
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 (i.e. clinical pharmacy and/or Medical Director review).

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:
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

Guidelines:
Refer to the specific manufacturer's prescribing information for administration and dosage details and any applicable Black Box warnings.
BENEFIT APPLICATION

Subject to the terms and conditions of the applicable benefit contract, the applicable drug(s) identified in this policy is (are) covered under the pharmacy benefits of the Company’s products when the medical necessity criteria listed in this pharmacy policy are met. Any services that are experimental/investigational or cosmetic are benefit contract exclusions for all products of the Company.

References:


Applicable Drugs:

<table>
<thead>
<tr>
<th>Brand Name</th>
<th>Generic Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exjade</td>
<td>deferasirox</td>
</tr>
</tbody>
</table>

Cross References:

Policy Version Number: 1.00
P&T Approval Date: July 12, 2012
Policy Effective Date: October 01, 2012
Next Required Review Date: July 12, 2013

The Policy Bulletins on this web site were developed to assist Independence Blue Cross (“IBC”) in administering the provisions of the respective benefit programs, and do not constitute a contract. If you are an IBC member, please refer to your specific benefit program for the terms, conditions, limitations and exclusions of your coverage. IBC does not provide health care services, medical advice or treatment, or guarantee the outcome or results of any medical services/treatments. The facility and professional providers are responsible for providing medical advice and treatment. Facility and professional providers are independent contractors and are not employees or agents of IBC. If you have a specific medical condition, please consult with your doctor. IBC reserves the right at any time to change or update its Policy Bulletins. ©2012 Independence Blue Cross. All Rights Reserved.

Independence Blue Cross is an independent licensee of the Blue Cross and Blue Shield Association