



INLAND EMPIRE HEALTH PLAN

This policy has been developed through review of medical literature, consideration of medical necessity, generally accepted medical practice standards, and approved by the IEHP Pharmacy and Therapeutic Subcommittee.

Drug: Exjade (deferasirox)
Class: Heavy metal chelator
Formulary medication: N/A
Effective date: November 16, 2011

Policy/Criteria:

- I. Patient has chronic iron overload due to blood transfusions evidenced by baseline serum ferritin level > 1000 mcg/L (record of transfusions required); **AND**
- II. Prescribed by hematologist

Duration of Approval: Initial approval 3 months; may be approvable up to 6 months for chronic iron overload (serum ferritin not below 500 mcg/L) based upon response

Drug	Dosing	Cost (based avg. wt 70kg)/30 days
Exjade (deferasirox)	20mg/kg/day	\$6,480
Desferal (deferoxamine)	0.5—1 g IM daily, IV	\$1,103

Clinical Justification:

Deferasirox has been developed as an alternative to deferoxamine, the standard treatment of chronic iron overload, which is administered parenterally. Deferasirox is an orally active chelator that is selective for iron. It binds iron with high affinity in a 2:1 ratio. Iron excretion is predominantly fecal. Clinical trials designed to confirm a clinical benefit or increased survival have not been completed. Clinical trials have demonstrated that deferasirox was effective in reducing liver iron concentrations in patients with transfusional hemosiderosis secondary to betathalassemia and chronic anemias. The benefit of deferasirox over the alternative therapy (deferoxamine) is that the oral route of administration may increase compliance and improve the quality of life in patients with transfusion hemosiderosis. For continuation of therapy, serum ferritin levels should be monitored monthly.

References:

1. Package Insert: EXJADE(R). Novartis Pharmaceuticals Corporation, East Hanover, NJ, 2011.
2. A Randomized, Open-label, Multi-center, Phase II Study to Evaluate the Safety and Efficacy of Deferasirox (ICL670) 20 mg/kg/Day Relative to Subcutaneous Deferoxamine in Sickle Cell Disease Patients With Iron Overload From Repeated Blood Transfusions. Novartis Clinical Trials, 2008.
3. Kontoghiorghes GJ, Eracleous E, Economides C, et al. Advances in iron overload therapies. Prospects for effective use of deferiprone (L1), deferoxamine, the new experimental chelators ICL670, GT56-252, L1NAll and their combinations. *Curr Med Chem* 2005;12(23):2663-381.
4. Vichinsky et al. A randomised comparison of deferasirox versus deferoxamine for the treatment of transfusional iron overload in sickle cell disease. *Br J Haematol.* 2007 Feb;136(3):501-8.