# Thames Valley Priorities Committees
## Buckinghamshire/Milton Keynes Priorities Committee

### Policy Statement 56: Deferasirox in the management of iron overload
*TV Ref: 95*

**Date of Issue: October 2007**

Deferasirox is an oral iron chelator licensed for treatment of chronic iron overload due to frequent blood transfusions (> or = 7ml/kg/month of packed red blood cells) in patients with beta thalassaemia major aged 6 years and older.

It is also licensed for the treatment of chronic iron overload due to blood transfusions when desferrioxamine therapy is contraindicated or inadequate in patients other than those mentioned above (see Summary of Product Characteristics).

***The Thames Valley Priorities Committees recommend that Deferasirox may be an option for the management of iron overload in patients with beta-thalassaemia major.***

***Its use in patients with myelodysplastic syndromes should be considered a LOW PRIORITY treatment. Patients with myelodysplastic syndromes, the commonest cause of transfusion-dependent anaemia, were poorly represented in the clinical trial population and the economic case was not demonstrated in this group.***

**Summary**
The pivotal open label phase III study showed that deferasirox is probably as efficacious as desferrioxamine and the added benefits in terms of quality of life and compliance could be significant. It cannot be assumed that deferasirox is effective in the management of iron overload associated with all transfusion-dependent anaemias other than ß thalassaemia, as the evidence is weak.

Data on safety is limited. Pooled safety data showed that serum creatinine increases of 30% to >90% occurred early, in general within the first month of treatment with deferasirox, and were dose dependent. In 50% of patients, the serum creatinine values only stabilised after dose reduction. The long-term consequences of the renal toxicity of deferasirox are unknown. Changes have recently been made to the product labelling for deferasirox in the USA, advising of additional safety concerns that have arisen from post-marketing experience. This is as a result of case reports of acute renal failure and cytopenias, which have in some cases been fatal following post marketing use.

*NOTES:*

1. *Exceptional circumstances may be considered where there is evidence of significant health impairment and there is also evidence of the intervention improving health status.*
2. *This policy will be reviewed in light of new evidence or guidance from NICE.*
3. *Buckinghamshire/Milton Keynes Priorities Committee policy statements can be viewed at http://www.mkpct.org.uk/content.asp?ContentID=548*