Remestemcel-L (Prochymal) for steroid refractory acute graft versus host disease – second line

Record Status
This is a bibliographic record of a published health technology assessment. No evaluation of the quality of this assessment has been made for the HTA database.

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Authors' objectives
Remestemcel-L (Prochymal) is intended to be used as second line therapy for the treatment of steroid refractory acute graft versus host disease (GVHD). If licensed, it would offer a novel additional intravenous treatment option for this patient group, who currently have few effective therapies available. Remestemcel-L is a cell therapy product containing human mesenchymal stem cells that are involved in tissue repair through the coordinated release of tissue specific growth factors. Remestemcel-L does not currently have Marketing Authorisation in the EU for any indication. It is estimated that between 20% and 80% of patients undergoing an allogeneic haematopoietic stem cell transplant will develop some form of GVHD. The incidence of acute GVHD varies widely, ranging from 10-80% depending on risk factors such as mismatched donors and older age. Morbidity and mortality rates continue to rise above 70% in steroid refractory patients with acute GVHD. Management of GVHD is largely focused on prevention through immunosuppression of donor T-cells with immunomodulatory agents or through depletion of T-cells before or after transplant, using monoclonal or polyclonal antibodies. Generally, immunosuppression is initiated using methotrexate, followed by ciclosporin or tacrolimus post-transplant. Corticosteroid treatment is recommended in patients with acute GVHD, however this is effective in less than 50%. Remestemcel-L has completed two phase III clinical trials comparing its effect on complete response against treatment with placebo.

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