Normal immunoglobulin

Section: 11. Blood products, coagulation factors, and plasma substitutes > 11.2. Human immunoglobulins

EMLc | ATC codes: J06BA02

Indication	Primary immunodeficiencies ICD11 code: 4A0Z
Medicine type	Biological agent
List type	Complementary
Additional notes	All human plasma-derived medicines should comply with the WHO requirements
Formulations	**Parenteral > General injections > IV:** 5% protein solution ; 10% protein solution **Parenteral > General injections > IM:** 16% protein solution **Parenteral > General injections > SC:** 15% protein solution ; 16% protein solution
EML status history	First added in 1977 (TRS 615) Changed in 1979 (TRS 641) Changed in 1993 (TRS 850) Removed in 2003 (TRS 920) Added in 2007 (TRS 946) Changed in 2007 (TRS 950)
Sex	All
Age	Also recommended for children
Therapeutic alternatives	The recommendation is for this specific medicine
Patent information	Read more about patents.
Tags	Biological
Wikipedia	Normal immunoglobulin
DrugBank	Normal immunoglobulin (Immune Globulin Human)

Summary of evidence and Expert Committee recommendations

The EMLc Subcommittee endorsed the inclusion of normal human immunoglobulin on the complementary list of the EMLc. The EMLc Subcommittee considered the application to list a subcutaneous formulation of polyvalent human normal immunoglobulin. The specific evidence relating to subcutaneous administration was assessed alongside the detailed application for the listing of the intramuscular and intravenous forms of human normal immunoglobulin considered at the Expert Committee meeting in March 2007. The Subcommittee accepted that while the burden of disease in children was likely to be low, data supported the benefits of treatment of primary immunodeficiency disorders with human normal immunoglobulin on morbidity and survival. The main trial evidence provided in support of listing of the subcutaneous human normal immunoglobulin (SCIg) was Study SCIG01 describing an open label study of SCIg therapy in 50 patients (15 aged <12 years, 7 aged 12-20 years, 28 adults) previously stabilized on either SCIg or IVIg therapy. Efficacy and safety short-term was assessed as well as long-term effectiveness, tolerability and patient acceptability. Mean IgG levels increased and were maintained above pre-treatment levels for at least 36 months of therapy. There was no marked increase in frequency, severity or seriousness of bacterial infections prior to and during SCIg therapy; most patients preferred SCIg to their previous therapy and there was no difference between patients previously treated with SCIg and IVIg. No clinically

relevant changes in haematology or biochemistry related to SCIg were reported. Several appendices to the application cited other observational studies and a review of SCIg therapy, all of which supported the efficacy and safety of SCIg therapy as an alternative to IVIg therapy. Patient satisfaction and quality of life have also been assessed, with the majority of patients preferring SCIg home-based therapy. The Subcommittee accepted that the evidence presented in the application supports the claims of efficacy and safety of polyvalent human immunoglobulin for subcutaneous administration and it appears to offer some advantages in patient/carer convenience over IVIg therapy and where there are venous access problems. The Subcommittee therefore endorsed the inclusion of human normal immunoglobulin for subcutaneous use (subcutaneous administration of 15%, 16% protein solution) for the treatment of primary immunodeficiency disorders in the EMLc.

