Normal immunoglobulin


### Normal immunoglobulin

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**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.

**Wikipedia:** Normal immunoglobulin

**DrugBank:** Normal immunoglobulin (Immune Globulin Human)

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**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 (SC Ig) was Study SCIG01 describing an open label study of SC Ig therapy in 50 patients (15 aged <12 years, 7 aged 12-20 years, 28 adults) previously stabilized on either SC Ig or IV Ig 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 SC Ig therapy; most patients preferred SC Ig to their previous therapy and there was no difference between patients previously treated with SC Ig and IV Ig. No clinically relevant changes in haematology or biochemistry related to SC Ig were reported. Several appendices to the application cited other observational studies and a review of SC Ig therapy, all of which supported the efficacy and safety of SC Ig therapy as an alternative to IV Ig therapy. Patient satisfaction and quality of life have also been assessed, with the majority of patients preferring SC Ig 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 IV Ig 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.