Immune thrombocytopenic purpura (ITP) — in children 15 years and younger

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Condition for which IVIg has an emerging therapeutic role.

Specific Conditions	• ITP in children
Indication for IVIg Use	• Acute ITP • Chronic ITP
Level of Evidence	Clear evidence of benefit (Category 1)
Description and Diagnostic Criteria	ITP is a reduction in platelet count (thrombocytopenia) resulting from shortened platelet survival due to anti-platelet antibodies. When counts are very low (<30x10^9/L) bleeding into the skin (purpura) and mucous membranes can occur. Bone marrow morphology is normal. In some cases, there is additional impairment of platelet function, related to antibody binding to glycoproteins on the platelet surface. ITP is divided into chronic and acute forms. In children, the acute form is the most common. The disease tends to present abruptly, with dramatic evidence of bleeding into the skin (petechiae and purpura) and mucous membranes (gum bleeding, nose bleeds, blood blisters). **Occurrence** Girls and boys are affected equally. In 75% of patients, the episode follows vaccination or a viral infection, such as varicella or infectious mononucleosis. **Prognosis** At least 80–90% of children will have spontaneous remission of their disease within 6–12 months. In 5–10% of cases, the disease may become chronic (lasting >6 months). Morbidity and mortality from acute ITP is very low.
Justification for Evidence Category	Category 1 classification in the Biotext (2004) review was based on four low–moderate quality randomised controlled trials (RCTs). The Frommer and Madronio (2006) review identified a good-quality systematic review/meta-analysis of RCTs to support the Category 1 classification.
Qualifying Criteria for IVIg Therapy	Acute ITP • Life-threatening bleeding due to thrombocytopenia. OR • Platelet count <30x10^9 /L and moderate to severe mucosal and/or cutaneous bleeding.

	Chronic ITP • Life-threatening bleeding due to thrombocytopenia. OR • In responsive patients for treatment of thrombocytopenia (platelet count <$30x10^9$/L) with moderate to severe bleeding symptoms, where other therapeutic options have failed or are contraindicated. OR • Prior to surgery, to elevate the platelet count to haemostatically safe levels in responsive patients.
Exclusion Criteria	Platelet count greater than 30 x10^9/L in the absence of significant bleeding or the potential for significant bleeding.
Review Criteria for Assessing the Effectiveness of IVIg Use	Acute ITP Review is not mandated for this indication however the following criteria may be useful in assessing the effectiveness of therapy. Clinical effectiveness of Ig therapy may be demonstrated by: • An improvement in the platelet count and a reduction in evidence of any bleeding Chronic ITP Review must be undertaken by a Haematologist every six months. Documentation of clinical effectiveness is necessary for continuation of IVIg therapy. **On review of an authorisation request** Clinical effectiveness of Ig therapy may be demonstrated by: • An improvement in platelet count and a reduction in evidence of bleeding.

Dose	

Acute ITP

- **Life-threatening bleeding** - Up to 2 g/kg total dose, generally given as 2 doses of 1 g/kg.
- **Other indications** - 0.5 g/kg given as a single dose, repeated at 24-48 hours if the response is inadequate. A higher total dose of 2 g/kg may be required in 5-10% of cases.

The duration of response to the initial dose is typically two to four weeks. A repeat dose maybe considered if recurrent symptomatic thrombocytopenia occurs.

The aim should be to use the lowest dose possible that achieves the appropriate clinical outcome for each patient.

Dosing above 1 g/kg per day is contraindicated for some IVIg products.

Refer to the current product information sheet for further information.

Chronic ITP

- **Life-threatening bleeding** - Up to 2 g/kg total dose, generally given as 2 doses of 1 g/kg.
- **Other indications** - 0.5 - 1 g/kg at intervals generally three-weekly.

The aim should be to use the lowest dose possible that achieves the appropriate clinical outcome for each patient.

Dosing above 1 g/kg per day is contraindicated for some IVIg products.

Refer to the current product information sheet for further information.

Bibliography

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