randomized to receive either IVIG 2 g/kg/week (group A) or IVIG 1 g/kg/week plus prednisone 0.5 mg/kg/day (group B), starting at about 20 weeks of gestation.[103] Fetal blood sampling was performed at about 32 weeks of gestation and, if the fetal platelet count was < 30,000 per mm^3 or cordocentesis could not be done, salvage therapy was given. Salvage therapy in patients in group A was addition of prednisone 0.5 mg/kg/day and in patients in group B was increasing IVIG to 2 g/kg/week in addition to the prednisone they were already taking. One neonate in each group suffered an ICH (primary outcome variable) during the neonatal period and neither was due to treatment failure. At the time of fetal blood sampling, the average platelet counts were 121,600 per mm^3 in group A and 116,100 per mm^3 in group B. The average birth platelet counts were 169,400 per mm^3 in group A and 134,000 per mm^3 in group B. In all, 27% of patients in group A and 17% of patients in group B received salvage therapy. Randomized controlled trials comparing IVIG or steroids vs. no treatment alone have not been done because of the known risk of ICH.[104]

According to guidelines from an expert panel of hematologists, there is no evidence to support use of IVIG in *newborns* with fetal/neonatal alloimmune thrombocytopenia; first-line therapy is antigen-negative compatible platelets and IVIG is adjunctive.[33]

Dosing in Antepartum Treatment of Fetal Alloimmune Thrombocytopenia. *Dosing must meet ONE of the following (A OR B):*

- **A)** IVIG 1 g per kg as an IV infusion every week;[33,102-103] OR
- **B)** IVIG 2 g per kg IV infusion every week or 1 g per kg twice weekly.[102-103]

Initial Approval/Extended Approval.

- **A)** *Initial Approval*. Approve for up to 6 months.
- **B)** *Extended Approval*. Not recommended.

Duration of Approval in Antepartum Treatment of Fetal Alloimmune Thrombocytopenia. Up to 6 months.

Antenatal therapy usually consists of IVIG and prednisone started between 12 and 20 weeks gestation, and then elective delivery at 37 to 38 weeks gestation.[105]

Lab/Diagnostics. None required.

Waste Management for All Indications. Vials of IVIG are available in many sizes and concentrations. The dose should be calculated and the number of vials needed assessed.

Conditions Not Recommended for Approval

IVIG has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. Rationale for non-coverage for these specific conditions is provided below. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval.)

the management of adolescents should follow the usual management for children. Children with no or mild bleeding are managed with observation alone regardless of platelet count.

In children and adolescents ≤ 17 years of age, use of IVIG is based on risk of bleeding and not on platelet counts. Most children do not require therapy with IVIG.[40,43] In emergency situations, platelet transfusions given with IV corticosteroids and IVIG should be given for intracranial hemorrhaging or other life-threatening or serious bleeding.[33]

Studies in children with ITP suggest the majority of children experience no bleeding or mild bleeding regardless of whether or not they initially receive drug therapy.[41] ASH notes the decision to manage with observation requires a detailed discussion between the healthcare provider, patient and family. Treatment may be appropriate if follow-up cannot be assured, if there are other societal concerns (e.g., travel, distance from hospital), if there are concerns attributed to activity level or risk of bleeding, or there is a need for upcoming procedures associated with a risk of bleeding. For pediatric patients requiring treatment, a single dose of IVIG or a short course of corticosteroids are recommended as first-line treatment (long-term use of corticosteroids should be avoided). IVIG can be used if a more rapid rise in platelet count is desired.[41,43]

ASH recommends pregnant patients requiring treatment for ITP receive either a corticosteroid or IVIG.[41] Newborns of mothers with ITP are hospitalized.

In pregnant women, corticosteroids and IVIG are considered safe with regard to teratogenicity but may have maternal side effects including exacerbation of gestational diabetes and post-partum psychiatric disorders.[41] The ASH guideline recommends IVIG or corticosteroids in pregnant patients requiring treatment with no recommendations for specific platelet counts at which patients should be treated. During labor and delivery, ITP management is based on assessment of maternal bleeding risks associated with delivery and epidural anesthesia, and the minimum platelet counts required to undergo these procedures.