2017 (v3.0) proposed changes to v2.1 of the Criteria for the Clinical use of Intravenous Immunoglobulin in Australia

v2.1 CONDITION NAME : **Feto-maternal/neonatal alloimmune thrombocytopenia (FMAIT/NAIT)**	
v3.0 CONDITION NAME: Fetal and neonatal alloimmune thrombocytopenia (FNAIT)	
In 2015 FNAIT was endorsed by NIGAC and JBC to retain in v3.0 as a condition for which Ig has an emerging therapeutic role. At the time, the need for further review was acknowledged by the SWG and had also been requested during the public consultation process. This review has now been completed as part of the current SWG work program. **PROPOSED APPROACH:** **To move Fetal and neonatal alloimmune thrombocytopenia (FNAIT) from *Emerging therapeutic role* to *Established therapeutic role* with the changes as outlined.**	**SUMMARY OF RATIONALE:** A number of contributing factors support the recommended changes: - The previous public consultation process in 2015 advised that IVIg is considered and used as standard therapy in FNAIT in Australia as it is internationally. A recent systematic review (Winkelhorst, 2017) recommends that first line antenatal management of FAIT is weekly IVIg administration. The established clinical practice to prescribe Ig for FNAIT is supported by published clinical guidelines and literature on which these criteria are based (Rayment et al, 2011; Pacheco et al, 2011 and Peterson et al, 2013). There are unlikely to be further RCTs conducted as this is now standard care and a RCT would present significant ethical challenges. - Multiple requests were received during the public consultation process requesting access to an increased dose for very high risk pregnancies and highlighting that Ig use in this setting is the established standard of care. - A stratified approach to treatment has been applied in accordance with the clinical risk and recommendations consistent with published international guidelines (Rayment et al, 2011 and Pacheco et al, 2011) which indicate that access to a higher dose in the later stages of very high risk pregnancies may result in improved clinical outcomes. - Given the relative rarity of this condition and reasonably stable Ig use over the last 5 years, the impact as a result of these changes is expected to be marginal, and only as a result of the increased dose for those instances where a previous pregnancy or neonate had FNAIT. - This condition is listed as a 'red' condition (high priority in times of shortage, not requiring approval by the local trust) in the UK NHS immunoglobulin Guidelines (UK Department of Health, 2011), and is also listed in the national Canadian IVIg Utilisation Management Guidelines (Ontario Regional Blood Coordinating Network, 2016) as recommended for funded use.

BLOODSTAR v2.1 CONDITION CATEGORY: Condition for which Ig has an Emerging therapeutic role (Chapter 6) **BLOODSTAR v3.0 CONDITION CATEGORY:** Condition for which Ig has an Established therapeutic role (Chapter 5)
Role of Ig therapy: IVIg plays a central role and is considered to be the standard of care in combination with steroid therapy in this condition, and as a result, randomised controlled trials are unlikely to ever be performed. The current criteria define the maternal dose to be 1 g/kg, however, where a previous pregnancy was affected in the context of demonstrated maternal antibodies, the subsequent pregnancy is likely to be more severely affected where the fetus is positive to the relevant paternal antigen and doses of up to 2 g/kg are now recommended. In 2011, Pacheco et al published a seminal article recommending a treatment algorithm applying a risk stratification approach where previous pregnancies have been variably affected by FNAIT and maternal alloantibodies are demonstrated against current paternal/fetal antigens. This approach is now applied internationally via clinical guidelines (Rayment et al, 2011 and Pacheco et al, 2011) with Ig and steroids being used concurrently during high risk pregnancies with more intense and earlier therapy being required if a previous untreated fetus experienced an early in- utero haemorrhage.

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Condition Name	Fetal and neonatal alloimmune thrombocytopenia (FNAIT)	Fetal and neonatal alloimmune thrombocytopenia (FNAIT)	No change
Specialty	Haematology	Haematology	
Category	*Emerging therapeutic role*	*Established therapeutic role*	See Summary of Rationale above.
Specific Conditions	Fetal alloimmune thrombocytopenia (FAIT) Neonatal alloimmune thrombocytopenia (NAIT) Neonate - mother with ITP	Fetal alloimmune thrombocytopenia (FAIT) Neonatal alloimmune thrombocytopenia (NAIT)	
Level of Evidence	Insufficient data (Category 4a).	Insufficient data (Category 4a)	
Justification	Evidence from randomised trials (Berkowitz et	Evidence from randomised trials (Berkowitz et	A paragraph was added to include

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for Evidence Category	al 2006, Bussel et al 1996), case series (Kiefel et al 2006, Yinon et al 2006) and a review (Spencer and Burrows 2001) shows that IVIg modulates the course of this condition. A 2004 Cochrane review (Rayment et al 2005) reported on one randomised controlled trial (RCT) comparing IVIg plus dexamethasone with IVIg alone. This RCT was methodologically sound, but too small to detect differences among comparison groups.	al, 2006 and Bussel et al, 1996), case series (Kiefel et al, 2006 and Yinon et al, 2006) and a review (Spencer and Burrows, 2001) shows that IVIg modulates the course of this condition. A 2004 Cochrane review (Rayment et al, 2005) reported on one randomised controlled trial (RCT) comparing IVIg plus dexamethasone with IVIg alone. This RCT was methodologically sound, but too small to detect differences among comparison groups. Pacheco et al (2011) recommended a management and treatment algorithm based on risk stratification where previous pregnancies have been variably affected by FNAIT and maternal alloantibodies are demonstrated against current paternal/fetal antigens. This approach was endorsed by Petersen et al (2013) through the publishing of the UK guideline.	references to the Pacheco risk-based algorithm and to reference the UK guidelines.
Indications	Prevention or treatment of fetal thrombocytopenia or haemorrhage. Prevention or treatment of neonatal	Prevention or treatment of fetal thrombocytopenia or haemorrhage where no previous pregnancy affected by FNAIT. Prevention or treatment of FAIT where unexplained previous fetal death or previous sibling affected by FNAIT Prevention or treatment of neonatal thrombocytopenia or haemorrhage.	A new indication for previously affected siblings has been included to limit access to the 2 g/kg dose for higher risk pregnancies as defined in the Pacheco risk based algorithm.

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	thrombocytopenia or haemorrhage.		
Description and Diagnostic Criteria	FAIT & NAIT develops because of maternal sensitisation to fetal platelets that possess a paternally inherited antigen. In Caucasians, the antigen is human platelet antigen (HPA) 1a in 80% of cases and HPA-5b in 15%, but other antigens are also implicated. The mother's antibodies cross the placenta and coat the baby's platelets, with accelerated platelet clearance leading to thrombocytopenia. This may result in serious and potentially life-threatening bleeding in the fetus or neonate. Pathogenesis is analogous to that of haemolytic disease of the newborn due to red cell antigen–antibody incompatibility. The aim of management of the thrombocytopenic fetus or neonate is to increase the platelet count. Instances of neonatal thrombocytopenia can occur in situations where the mother has idiopathic (autoimmune) thrombocytopenic purpura (ITP). If fetal blood sampling reveals thrombocytopenia, IVIg may be administered weekly to the mother, with or without steroids, until delivery. Recent studies using	FAIT &NAIT develops because of maternal sensitisation to fetal platelets that possess a paternally inherited antigen. In Caucasians, the antigen is human platelet antigen (HPA) 1a in 80% of cases and HPA-5b in 15%, but other antigens are also implicated. The mother's antibodies cross the placenta and coat the baby's platelets, with accelerated platelet clearance leading to thrombocytopenia. This may result in serious and potentially life-threatening bleeding in the fetus or neonate. Pathogenesis is analogous to that of haemolytic disease of the newborn due to red cell antigen–antibody incompatibility. The aim of management of the thrombocytopenic fetus or neonate is to treat or prevent severe bleeding by increasing the platelet count. Instances of neonatal thrombocytopenia can also occur in situations where the mother has	No changes

ITEM	2015 JBC APPROVED WORDING	REVISIONS TO 2015 JBC APPROVED WORDING	SPECIALIST WORKING GROUP RATIONALE FOR ADDITIONS/CLARIFICATIONS
	intravenous immunoglobulin (IVIg) weekly from around 20 weeks gestation, without fetal blood sampling, have shown reduced fetal and neonatal morbidity. This approach may be used for current pregnancies where the condition in a previous pregnancy was not associated with a fetal death or severe haemorrhage. Where a previous pregnancy was affected in the context of demonstrated maternal antibodies, the subsequent pregnancy is likely to be more severely affected where the fetus is positive to the relevant paternal antigen. Testing on maternal blood for fetal DNA or early genetic testing of the fetus (for platelet genotype) by amniocentesis may predict the need to use IVIg. Management of this condition is a specialised area and may include administration of HPA-compatible intrauterine and/or neonatal platelet transfusions. Further information regarding specialised platelet support is available from the Blood Service. Random (non-HPA-matched) platelets may be of benefit in the neonatal setting when matched platelets are not available (Kiefel et al 2006).	idiopathic (autoimmune) thrombocytopenic purpura (ITP). If fetal blood sampling reveals thrombocytopenia, IVIg may be administered weekly to the mother, with or without steroids, until delivery. Recent studies using intravenous immunoglobulin (IVIg) weekly from around 20 weeks gestation, without fetal blood sampling, have shown reduced fetal and neonatal morbidity. This approach may be used for current pregnancies where the condition in a previous pregnancy was not associated with a fetal death or severe haemorrhage. Where a previous pregnancy was affected in the context of demonstrated maternal antibodies, the subsequent pregnancy is likely to be more severely affected where the fetus is positive to the relevant paternal antigen. Testing on maternal blood for fetal DNA or early genetic testing of the fetus (for platelet genotype) by amniocentesis may predict the need to use IVIg. Management of this condition is a specialised area and may include administration of HPA-compatible intrauterine and/or neonatal	

ITEM	2015 JBC APPROVED WORDING	REVISIONS TO 2015 JBC APPROVED WORDING		SPECIALIST WORKING GROUP RATIONALE FOR ADDITIONS/CLARIFICATIONS
		platelet transfusions. Further information regarding specialised platelet support is available from the Blood Service. Random (non-HPA-matched) platelets may be of benefit in the neonatal setting when matched platelets are not available (Kiefel et al, 2006).		
Diagnosis is required	No	No	By which specialty	No changes
Diagnosis must be verified		No	By which specialty	
Exclusion Criteria				No changes
Qualifying Criteria	**Prevention or treatment of fetal thrombocytopenia or haemorrhage.** Clinical suspicion of FAIT in the antenatal setting based on clinical and laboratory features: • Evidence of fetal thrombocytopenia OR • Evidence of spontaneous fetal haemorrhage OR • Unexplained previous fetal death or	**Prevention or treatment of fetal thrombocytopenia or haemorrhage where no previous pregnancy affected by FNAIT.** • Evidence of fetal thrombocytopenia OR • Evidence of spontaneous fetal haemorrhage **Prevention or treatment of FAIT where**		The wording of the criteria has been streamlined and a new indication to allow higher dosing (up to 2g/kg) for patients at greater risk of a poor outcome, as defined in Pacheco risk based algorithm.

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	previously affected sibling and maternal platelet-specific alloantibodies known or suspected to cause this condition and directed against current paternal antigens (most commonly HPA-1a or HPA-5b). **Note: Where fetal blood sampling demonstrates a failure to improve the platelet count, national guidelines recommend the consideration of intrauterine platelet transfusion rather than Ig therapy.** *Ref: Patient Blood Management Guidelines – Module 6 –Neonatal and paediatric (Section 4.2)* **Prevention or treatment of neonatal thrombocytopenia or haemorrhage.** • Evidence of thrombocytopenia <30 x 109/L in a neonate with NAIT or where a diagnosis of NAIT is highly suspected. OR • Evidence of thrombocytopenia <30 x 109/L in offspring of a mother with ITP.	**unexplained previous fetal death or previous sibling affected by FNAIT** • Unexplained previous fetal death or previous affected sibling AND • Maternal platelet-specific alloantibodies known or suspected to cause this condition (most commonly HPA-1a or HPA-5b) **Note: Where fetal blood sampling demonstrates a failure to improve the platelet count, national guidelines recommend the consideration of intrauterine platelet transfusion rather than Ig therapy.** *(Ref: Patient Blood Management Guidelines – Module 6 –Neonatal and paediatric (Section 4.2)* **Prevention or treatment of neonatal thrombocytopenia or haemorrhage.** • Evidence of thrombocytopenia <30 x 109/L in a neonate with NAIT or where a diagnosis of NAIT is highly	

ITEM	2015 JBC APPROVED WORDING	REVISIONS TO 2015 JBC APPROVED WORDING	SPECIALIST WORKING GROUP RATIONALE FOR ADDITIONS/CLARIFICATIONS
		suspected OR • Evidence of thrombocytopenia <30 x 109/L in offspring of a mother with ITP	
Review Criteria	**Prevention or treatment of fetal thrombocytopenia or haemorrhage.** Review is not mandated for this indication however the following criteria may be useful in assessing the effectiveness of therapy. **Outcome data to be measured** • Fetal/neonatal morbidity and/or mortality in the context of maternal alloantibodies. • Occurrence and severity of thrombocytopenia in the neonate. Neonates with NAIT are eligible under the indication for prevention or treatment of neonatal thrombocytopenia or haemorrhage. **Prevention or treatment of neonatal thrombocytopenia or haemorrhage.**	**Prevention or treatment of fetal thrombocytopenia or haemorrhage where no previous pregnancy affected by FNAIT.** 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: • Fetal or neonatal morbidity or mortality in the context of maternal alloantibodies • Occurrence and severity of thrombocytopenia in the neonate Neonates with NAIT are eligible under the indication for prevention or treatment of neonatal thrombocytopenia or haemorrhage.	While standard outcome measures have been defined, prescribers will also be given an opportunity to describe the clinical outcome as a result of Ig therapy as text entry. This will support the assessment and continuous improvement of suitable measures to assess the benefit of Ig therapy.

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	Review is not mandated for this indication however the following criteria may be useful in assessing the effectiveness of therapy. **Outcome data to be measured** • Occurrence and severity of thrombocytopenia in the neonate. • Maximum platelet count achieved within 7 days of Ig treatment.	**Prevention or treatment of FAIT where unexplained previous fetal death or previous sibling affected by FNAIT** 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: • Fetal or neonatal morbidity or mortality in the context of maternal alloantibodies • Occurrence and severity of thrombocytopenia in the neonate Neonates with NAIT are eligible under the indication for prevention or treatment of neonatal thrombocytopenia or haemorrhage. **Prevention or treatment of neonatal thrombocytopenia or haemorrhage.** 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	

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		demonstrated by: • Occurrence and severity of thrombocytopenia in the neonate • Maximum platelet count achieved within 7 days of Ig treatment	
Dose	**Prevention or treatment of fetal thrombocytopenia or haemorrhage.** **Maternal dose:** 1 g/kg (up to a maximum weight of 100 kg) weekly throughout pregnancy, with starting time tailored to individual risk profile and history if relevant. Other doses and schedules have been used and some studies have used IVIg in conjunction with steroids. The aim should be to use the lowest dose possible that achieves the appropriate clinical outcome for each patient. **Refer to the current product information sheet for further information.** **Prevention or treatment of neonatal**	**Prevention or treatment of fetal thrombocytopenia or haemorrhage where no previous pregnancy affected by FNAIT.** **Dose during pregnancy**: 1 g/kg (up to a maximum weight of 100 kg) weekly throughout pregnancy. Other doses and schedules have been used and some studies have used IVIg in conjunction with steroids. The aim should be to use the lowest dose possible that achieves the appropriate clinical outcome for each patient. **Refer to the current product information sheet for further information on dose, administration and contraindications.**	

ITEM	2015 JBC APPROVED WORDING	REVISIONS TO 2015 JBC APPROVED WORDING	SPECIALIST WORKING GROUP RATIONALE FOR ADDITIONS/CLARIFICATIONS
	thrombocytopenia or haemorrhage. **Treatment of the neonate -** 1 g/kg. Occasionally more than one dose is required if thrombocytopenia persists. The aim should be to use the lowest dose possible that achieves the appropriate clinical outcome for each patient **Refer to the current product information sheet for further information.**	**Prevention or treatment of FAIT where unexplained previous fetal death or previous sibling affected by FNAIT.** **Dose during pregnancy**: 1 to 2 g/kg (up to a maximum weight of 100 kg) weekly throughout pregnancy, with starting time and dose tailored to individual risk profile and history. Pacheco et al (2011) recommends Ig treatment (at times in conjunction with steroids): Previous infant with thrombocytopenia but no intracranial haemorrhage –from 20 weeks at 1 to 2 g/kg, increasing to 2 g/kg at 32 weeks until birth; Previous fetus or neonate with intracranial haemorrhage diagnosed at 28 or more weeks gestation –from 12 weeks at 1g/kg; 1 to 2 g/kg from 20 weeks, increasing to 2 g/kg from 28 weeks until birth; Previous fetus or neonate with intracranial haemorrhage diagnosed at less than 28 weeks gestation - from 12 weeks at 2 g/kg until birth; The aim should be to use the lowest dose possible that achieves the appropriate clinical outcome for each patient. **Refer to the current product information sheet for further information on dose,**	For the indication supporting higher risk pregnancies, scripts have been added to provide guidance regarding the recommended dosing throughout the pregnancy.

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		administration and contraindication. **Prevention or treatment of neonatal thrombocytopenia or haemorrhage.** **Treatment of the neonate - 1 g/kg. Occasionally more than one dose is required if thrombocytopenia persists.** The aim should be to use the lowest dose possible that achieves the appropriate clinical outcome for each patient. **Refer to the current product information sheet for further information on dose, administration and contraindications.**	

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(most recent update: August 2016)

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POTENTIAL OPERATIONAL IMPACT

It is not anticipated that clinical practice will change as a result of the recommended changes. The current criteria (v2.1) are very vague and leave decision making as to when to start treatment up to the clinician. The management of patients identified with FNAIT for the first time will be unchanged. The recommended changes are in line with the UK and other international guidelines that are likely to already be being applied in Australia, however the changes will allow patients with very high risk pregnancies to be treated at a higher dose during the later stages of pregnancy than are provided under the current criteria.

POTENTIAL IMPACT ON PATIENTS, DEMAND AND EXPENDITURE

Description of impact on patients:	The use of Ig therapy in this condition is largely unchanged as it plays an important role in treatment of FNAIT and this will continue. . The proposed changes mainly allow access to an increased dose in very high risk pregnancies. This will provide consistency with recommendations in international treatment guidelines and practice, given that access to a higher dose has not previously been available in Australia.
Impact on demand	There will be no change in management of patients diagnosed with FNAIT for the first time. For those patients with subsequent pregnancies, who are identified as being at higher risk of fetal haemorrhage, a higher dose is recommended for the later stages of pregnancy than is supported in the current Criteria. The higher dose is recommended slightly earlier when the risks are determined to be greater, and Ig is given in combinations with steroids. Given that this condition is relatively rare, the impact on demand is expected to be marginal.

	2011-12	2012-13	2013-14	2014-15	2015-16	The Specialist Working Group's estimated magnitude of effect: Marginal: <$500K increase against projected demand
Patient number	**42**	**48**	**39**	**38**	**44**	
Total Grams issued	**11,854**	**14,414**	**10,854**	**13,914**	**16,334**	
% Total Grams issued	**0.36%**	**0.4%**	**0.27%**	**0.31%**	**0.33%**	

Specialist Working Group knowledge development opportunities and recommendations

None identified at this stage

END OF PUBLIC CONSULTATION DOCUMENT

Next review: Twelve to eighteen months after BloodSTAR v3.0 implemented