Integrated Impact Assessment Report for Clinical Commissioning Policies	
Policy Reference Number	1864
Policy Title	Intravenous Immunoglobulin for the prevention of alloimmune neonatal and fetal haemochromatosis
Proposal	**for routine commissioning** (ref A3.1)

Integrated Impact Assessment – Index		
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A3 Comparator (next best alternative treatment) Patient Pathway	B3 Collaborative Commissioning	C3 Overall Cost Impact of this Policy to NHS England
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A5 Treatment Setting		C5 Funding
A6 Coding		C6 Financial Risks Associated with Implementing this Policy
		C7 Cost Profile

About this Impact Assessment: instructions for completion and explanatory notes
• Each section is divided into themes with each theme setting out a number of questions. • All figures should be provided up to 5 years only. • The cost per patient methodology is impact against Year 0 rather than incrementally against the previous year. • All questions are answered by selecting a drop-down option or including free text. • Free text boxes are provided to enable succinct relevant commentary to be added which explains the rationale for response or assumption. Please limit responses to 3 sentences of explanatory text.

- Data in this document is either drawn from one of the relevant policy documents or a source for the information is provided.
- Where assumptions are included where data is not available, this is specified.
- A bespoke financial model should be developed unless agreed otherwise. This will be worked up against a checklist of inputs/considerations. This will include the approach to regional allocations which will also be outlined in the Commissioning Plan.

Section A - Activity Impact	
A1 Activity	
A1.1 Provide the number of patients eligible for the treatment. If different, also provide the number of patients accessing treatment. Include OPCS codes where applicable.	10 *Source:* Policy Proposition
A2 Existing Patient Pathway (complete where additional information outside the policy proposition is likely to be beneficial)	
A2.1 **Existing pathway:** Describe the relevant currently routinely commissioned: • Treatment or intervention • Patient pathway • Eligibility and/or uptake estimates.	Not applicable
A2.2 What percentage of the total eligible population is expected to: a) Be clinically assessed for treatment b) Choose to initiate treatment c) Comply with treatment	Not applicable
A3 Comparator (next best alternative treatment) Patient Pathway **(NB: comparator/next best alternative does not refer to current pathway but to an alternative option)**	

A3.1 **Next best comparator**: Is there another 'next best' alternative treatment which is a relevant comparator? *If yes, describe relevant* • *Treatment or intervention* • *Patient pathway* • *Actual or estimated eligibility and uptake*	Not applicable
A3.2 What percentage of the total eligible population is estimated to: a) Be clinically assessed for treatment b) Be considered to meet an exclusion criteria following assessment c) Choose to initiate treatment d) Comply with treatment e) Complete treatment?	Not applicable
A4 New Patient Pathway	
A4.1 Specify the nature and duration of the proposed new treatment or intervention. For example, e.g patients receive a course of treatment over 6 cycles with the drug being administered via IV infusion on days 1 and 3 of each cycle. Include OPCS codes where applicable.	**<u>Time limited</u>** For time limited treatments, specify frequency and/or duration, as well as start and stop rates and mortality rates, as well as details of what happens if a patient does not start or stop. IVIg (1g/kg) (Dose capped at 60g) is given to the mother at 14, 16, weekly from 18 weeks until delivery between 37 and 38 weeks. *Source: Whitington, P., Kelly, S., Taylor, S., Nóbrega, S., Schreiber, R., Sokal, E., Hibbard, J. (2018). Antenatal Treatment with Intravenous Immunoglobulin to Prevent Gestational Alloimmune Liver Disease:*

	Comparative Effectiveness of 14-Week versus 18-Week Initiation. Fetal Diagnosis and Therapy, 43(3), pp.218-225 Click here to enter text.
A5 Treatment Setting	
A5.1 How is this treatment delivered to the patient?	Via intravenous infusion
A5.2 What is the current number of contracted providers for the eligible population by region?	The treatment can be delivered by any maternity centre with a consultant obstetrician and with input from a liver unit specialist
A5.3 Does the proposition require a change of delivery setting or capacity requirements?	No
A6 Coding	
A6.1 Specify the datasets used to record the new patient pathway activity. *expected to be populated for all commissioned activity	*Select all that apply:* Aggregate Contract Monitoring * ☒ Patient level contract monitoring ☒ Patient level drugs dataset ☒ Patient level devices dataset ☐

	<table><tr><td>Devices supply chain reconciliation dataset</td><td>☐</td></tr><tr><td>Secondary Usage Service (SUS+)</td><td>☒</td></tr><tr><td>Mental Health Services DataSet (MHSDS)</td><td>☐</td></tr><tr><td>National Return**</td><td>☐</td></tr><tr><td>Clinical Database**</td><td>☐</td></tr><tr><td>Other**</td><td>☐</td></tr></table>**If National Return, Clinical database or other selected, please specify: National MDSAS Immunoglobulin Database
A6.2 Specify how the activity related to the new patient pathway will be identified.	Through the patient level drugs data set and the prior approval system
A6.3 **Identification Rules for Devices:** How are device costs captured?	**Not applicable**
A6.4 **Identification Rules for Activity:** How are activity costs captured? (e.g., are there first and follow up outpatient appointments?)	**Not captured by an existing specialised service line** In line with many other drug and blood product policies, the associated day cases for the transfusion are usually contracted and paid for by CCGs
Section B - Service Impact	
B1 Service Organisation	

B1.1 Describe how the service is currently organised? (i.e. tertiary centres, networked provision etc.)	Routine maternity unit
B1.2 Will the proposition change the way the commissioned service is organised?	**No** Please specify: NHS England commissions the drug *Source:* NHS England Drug List 14.1
B2 Geography & Access	
B2.1 How is the service currently accessed (e.g., self referral, referral from GP, secondary care, other)	Please specify: Accessed via secondary care following perinatal post mortem or previous child affected by confirmed alloimmune fetal haemochromatosis
B2.2 What impact will the new policy have on the sources of referral?	**No impact** Please specify: Still expected as above
B2.3 Is the new policy likely to improve equity[1] of access?	**Increase** Please specify: Treatment currently not available *Source: Equalities Impact Assessment (NB. this should be completed during Clinical Build/Impact Assessment phases)*
B2.4 Is the new policy likely to improve equality[1] of access and/or outcomes?	**Increase**

[1] https://www.england.nhs.uk/wp-content/uploads/2016/02/nhse-specific-duties-equality-act.pdf

	Please specify: Treatment currently not available *Source: Equalities Impact Assessment (NB. this should be completed during Clinical Build/Impact Assessment phases)*
B3 Commissioning Responsibility	
B3.1 Is this service currently subject to, or planned for, place-based commissioning arrangements? (e.g. new service (NHS England responsibiliy), future CCG lead, devolved commissioning arrangements, STPs)	**No change - NHSE**
Section C - Finance Impact	
C1 Tariff/Pricing	
C1.1 How is the service contracted and/or charged? Only specify for the relevant section of the patient pathway	*Select all that apply:*

Drugs	Not separately charged – part of local or national tariffs	☐
	Excluded from tariff – pass through	☒
	Excluded from tariff – other	☐
Devices	Not separately charged – part of local or national tariffs	☐
	Excluded from tariff (excluding HCTED programme) – pass through	☐
	Excluded from tariff (excluding HCTED) – other	☐

<table>
<tr><td></td><td>
<table>
<tr><td></td><td>Via HCTED model</td><td>☐</td></tr>
<tr><td rowspan="7">Activity</td><td>Paid entirely by National Tariffs</td><td>☒</td></tr>
<tr><td>Paid entirely by Local Tariffs</td><td>☐</td></tr>
<tr><td>Partially paid by National Tariffs</td><td>☐</td></tr>
<tr><td>Partially paid by Local Tariffs</td><td>☐</td></tr>
<tr><td>Part/fully paid under a Block arrangement</td><td>☐</td></tr>
<tr><td>Part/fully paid under Pass-Through arrangements</td><td>☐</td></tr>
<tr><td>Part/fully paid under Other arrangements</td><td>☐</td></tr>
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</td></tr>
<tr><td>C1.2 Drug Costs (to be completed by LC)
Where not included in national or local tariffs, list each drug or combination, dosage, quantity, list price including VAT if applicable and any other key information e.g. Chemotherapy Regime, homecare costs. Provide a basis for this assumption.
NB discounted prices or local prices must not be included as these are subject to commercial confidentiality and must not be disclosed.</td><td>Cost per gram of IVIG £41.44

No.of grams per infusion 60 (maximum)

Cost per infusion £2,486

No. of infusions per patient 22</td></tr>
<tr><td>C1.3 Device Costs(to be completed by LC)
Where not included in national or local tariff, list each element of the excluded device, quantity, list or expected price including VAT if applicable and any other key information.
NB: Discounted prices or local prices must not be included as these are subject to commercial confidentiality and must not be disclosed.</td><td>Not applicable</td></tr>
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C1.4 **Activity Costs covered by National Tariffs** *(to be completed by Finance)* List key HRG codes and descriptions, national tariffs (excluding MFF), volume and other key costs (e.g. specialist top up %). Include details of first and follow up outpatients appointment etc.	The associated activity groups to HRG SA44A Single Plasma Exchange or Other Intravenous Blood Transfusion, 19 years and over and which has a national tariff of £450 (paid by CCGs)
C1.5 **Activity Costs covered by Local Tariff** *(to be completed by Finance)* List all the HRGs (if applicable), HRG or local description, estimated average tariff, volume and any other key costs. Also indicate whether the Local Tariff(s) is/are newly proposed or established and if newly proposed how is has been derived, validated and tested.	Not applicable
C1.6 **Other Activity Costs not covered by National or Local Tariff** *(to be completed by Finance)* Include descriptions and estimates of all key costs.	Not applicable
C1.7 Are there any prior approval/notification mechanisms required either during implementation or permanently?	**Yes** Please specify: Sub regional Immunoglobulin Assessment panel (SRIAP)
C2 Average Cost per Patient	
C2.1 What is the average cost per patient per year for 5 years, including follow-up where required?	The average cost of the treatment for each patient is c£69.6k of which c79% relates to the cost of the Immunoglobulin and is paid by NHS England. The remaining 21% of costs relate to the transfusion episode and birth costs which are paid by CCGs.

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<tr><td colspan="2">C3 Overall Cost Impact of this Policy to NHS England</td></tr>
<tr><td>C3.1 Specify the budget impact of the proposal on NHS England in relation to the relevant pathway. Use list prices where drugs and devices are included. Commercial in confidence discounts are not included therefore the actual cost pressure may be lower than stated.</td><td>Choose an item.<table><tr><td>Year 1</td><td>£291.8k</td></tr><tr><td>Year 2</td><td>£291.8k</td></tr><tr><td>Year 3</td><td>£291.8k</td></tr><tr><td>Year 4</td><td>£291.8k</td></tr><tr><td>Year 5</td><td>£291.8k</td></tr></table></td></tr>
<tr><td>C3.2 If the budget impact on NHS England cannot be identified set out the reasons why this cannot be measured.</td><td>N/A</td></tr>
<tr><td>C3.3 If the activity is subject to a change of commissioning responsibility, from CCG to NHS England, has a methodology for the transfer of funds been identified, and calculated?</td><td>N/A</td></tr>
<tr><td colspan="2">C4 Overall cost impact of this policy to the NHS as a whole</td></tr>
<tr><td>C4.1 Specify the budget impact of the proposal on other parts of the NHS.</td><td>Budget impact for CCGs:
<u>Cost pressure</u></td></tr>
</table>

Year 1	£116.2k
Year 2	£116.2k
Year 3	£116.2k
Year 4	£116.2k
Year 5	£116.2k

Budget impact for providers:

Cost neutral

Year 1	£0k
Year 2	£0k
Year 3	£0k
Year 4	£0k
Year 5	£0k

C4.2 Taking into account responses to C3.1 and C4.1, specify the budget impact to the NHS as a whole.

Cost pressure

Year 1	£408.0k
Year 2	£408.0k
Year 3	£408.0k
Year 4	£408.0k
Year 5	£408.0k

C4.3 Are there likely to be any costs or savings for non-NHS commissioners and/or public sector funders?	**No** Please specify: N/A
C5 Funding	
C5.1 Where a cost pressure is indicated, state known source of funds for investment, where identified, e.g. decommissioning less clinically or cost-effective services.	CPAG Prioritisation
C6 Financial Risks Associated with Implementing this Policy	
C6.1 Describe the parameters used to generate the low, mid and high case scenarios for patient numbers and activity. Specify the range.	The annual numbers of patients is very small (10) so no scenario planning has been undertaken.
C6.2 What scenario has been recommended and why? What would be the impact of a discounted scenario?	N/A
C7 Cost Profile	
C7.1 Factors which impact on costs	**No** If yes, specify type and range: N/A

The full integrated impact assessment should be used for all clinical commissioning policies and for policy statements which are proposing a for routine commissioning position. The rapid impact assessment template should be used for urgent policy statements and for policy statements which are proposing not for routine commissioning

Appendix A – Current Patient Population & Demography / Growth (for Public Health Lead to complete)

		Source	*Please specify any further detail*
Number of patients who meet the proposed commissioning criteria and who would be treated if the proposal is approved per year.	*[10]*	Feldman et al, 2013	*Based on 646,794 live births in England in 2017 (incidence 15/million live births). Please nteo overall peak birthsin late Septemeber early October.*
Age group for which the treatment is proposed according to the proposed criteria	*Adults: [female-childbearing age]*	*Policy*	
Age distribution of the patient population eligible according to the proposed criteria	*[30.5 Standardised mean age of mother at childbirth]*	*ONS 2017(released Jan 2019)*	*Mothers age distribution;* *3% under 20 years old* *14.4% age 20-25* *28% age 25-29* *31.9% age 30-34* *18.4% age 35-39* *4% age 40-44* *0.3% age over 45*

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<tr><td>How is the population currently geographically distributed</td><td>Evenly
<table><tr><td>North</td><td>20%</td></tr><tr><td>Midlands & East</td><td>30%</td></tr><tr><td>London</td><td>20%</td></tr><tr><td>South</td><td>20%</td></tr></table></td><td>Policy proposition (section 6)

ONS live births 2017</td><td></td></tr>
<tr><td>What are the growth assumptions for the disease / condition?</td><td>15 addtional live births at risk</td><td>Policy proposition (section 6)</td><td>Unknown based on current disease awareness but based on population projections mid-2016 and mid-2041 estimated 12.1% growth at 1.6 million resulting in growth of 15 addtional live briths at risk</td></tr>
<tr><td>Is there evidence of current inequalities in access to service or outcomes?</td><td>Not applicable</td><td></td><td></td></tr>
<tr><td>Is there evidence that implementing the service specification will improve current inequities of access or outcomes?</td><td>Not applicable</td><td></td><td></td></tr>
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