Improving Value in Specialised Services

New Model for Immunoglobulin Assessment Panels Implementation Pack

Insert Author Name: Leena Sevak & Rob Coster

Version: 0.1

10th October 2017

This pack provides information and guidance to support the local implementation of this Improving Value initiative. A local implementation project can use the guidance contained within this pack to guide successful implementation.

For regions/hubs to complete

This checklist can be used to check local readiness for implementation / identify gaps in readiness to implement.

Implementation Checklist	Y/N
Clear rationale of need to change	
Local Clinical engagement in project	
Measurable objectives	
Measurable success criteria	
Impact assumptions have been tested and are realistic	
Scale and timing of impact is clear	
Risks have been assessed	
Milestones for delivering change are clear	

Content

Scheme Details

Scheme Name	To ensure appropriate prescribing of immunoglobulin through expansion of regional panels (IAP) each serving a spoke hospital
Scheme Reference Number	F06181918 BI
Related Programme of Care	Blood & Infection
Related Clinical Reference Group	Specialist Immunology & Allergy
Scheme Lead	Rob Coster
Scheme Lead Contact	robcoster@nhs.net
Start Date for Implementation	December 2017
Other Details	

Key Updates – Summary of latest progress with this initiative

Date	Update	
March 2017	IVIG IAP Improving Value scheme proposed	
June 2017	IVIG IAP SOAP discussed at IV Workshop with regions & hubs	
September 2017	IVIG PWG agreed to fast track scheme for national implementation	
October 2017	IVIG IAP scheme implementation pack to IV Board for sign-off	

Project Team

The following team developed this national initiative:

Name	Title / Role	e-mail
Claire Bethune	Clinical Lead	claire.bethune@nhs.net
Rob Coster	Lead Commissioner for Immunology and Allergy	robcoster@nhs.net
Mandy Matthews	Specialist Medicines Pharmacist	miranda.matthews@nhs.net
Siraj Misbah	Specialist Immunology & Allergy CRG Chair	Siraj.Misbah@ouh.nhs.uk
Leena Sevak	Improving Value Manager	l.sevak@nhs.net

Summary of Scheme

What is the scheme trying to achieve?	This proposal is informed by the results of a survey conducted with 130 trusts in England. The results showed significant variation across England in terms of who was on the panel, how often the panel met, if they had agreed terms of reference and functions of the panel. The Department of Health guidelines for immunoglobulin use are designed to ensure that immunoglobulin is only used for evidence based indications. The guidance requires a panel of immunoglobulin users (with a non-immunoglobulin prescriber independent chair) to review requests for immunoglobulin use against the criteria set out in the guidelines. Generally individual hospitals have set up panels, but their effectiveness varies. In some areas a hub and spoke model has been set up with a central immunoglobulin panel providing approval and guidance to requestors from surrounding "spoke" hospitals. This model has the advantage of sharing best practice and experience across a region. It is anticipated that developing hub immunoglobulin panels in other areas would help spread best practice as well as providing an opportunity to review, audit and improve the advice given by each panel. This would reduce variations in prescribing and ensure the guidelines are being implemented appropriately across the country. To ensure appropriate prescribing of immunoglobulin through expansion of regional/hub immunoglobulin assessment panels (IAP) each serving a number of spoke hospitals.
How will we know change is an improvement?	Immunoglobulin prescribing will be more consistent across Trust/Regions especially for grey and blue indications from the management guidelines for immunoglobulin use, with decreased usage due to appropriate prescribing, dosages and review.
What changes will be made that will result in improvement?	IAPs are presently set up on a hospital or single trust basis. We would move this to a model of a central regional/hub immunoglobulin panel providing approval and guidance to requestors from surrounding spoke trusts. This model needs access to and input from an immunologist and with an independent non prescribing chair.

Case for Change

National / Strategic Context	Immunoglobulin is commissioned by NHS England in line with Department of Health "Clinical guidelines for immunoglobulin use". https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/216671/dh_131107.pdf The guidelines state which conditions immunoglobulin is recommended for and these are colour coded according to priority. A red classification indicates the highest priority as there could be a risk to life without treatment. A blue classification is for those indications where there is some evidence of benefit but for which there may be alternative treatments and for which treatment may be modified in times of supply shortages of immunoglobulin. Grey indications are those for which the evidence is weak. These include rare disorders. Patients from this group should be considered on a case-by-case basis and their need prioritised against other competing demands. The guidelines also state that Trusts establish immunoglobulin assessment panels to screen requests to use immunoglobulin and what controls are required for each classification. Immunoglobulin is a high cost drug, excluded from tariff. Expenditure across England is ~£120m per annum and increasing by ~10% per annum.
Evidence Base and notable case studies	There are two examples from Oxford University Hospitals and Southampton, Hampshire, Isle of Wight and Portsmouth (SHIP), Immunoglobulin Assessment Panels (IAP), which are constituted in line with the model described in the DH Demand Management Plan (May 2008) for a 'multi-trust Panel in conjunction with a representative of the lead Commissioner'.1 Oxford University Hospitals IAP is in the process of developing a case study about how the panel functions and the impact on prescribing immunoglobulins. 1 DH, Demand Management Plan (2008), p.7 .

Benefits

Benefit Type*	Description	Numerator	Denominator	Data Source	Service Line Detail (if applicable)	Comments
Patient	i. Correct and appropriate prescribing of immunoglobulin treatment reducing risk of harm to patient. ii. Regular review of condition iii. Outcomes monitored and recorded to improve patient care.	N/A	N/A	MO CQUIN data reporting on National Immunoglobulin Database (MDSAS)		See MO CQUIN trigger 4 in slide 10.
Commissioner	i. Reduced usage of immunoglobulin. ii. Improved recording of usage and out comes on national database. iii. Review of usage on a more consistent basis. iv. Standardisation of prescribing and ensure the guidelines are being implemented appropriately.	2018-19 spend	2017-18 spend	NCDR	Cost against immunoglobulin generic and branded products In High cost drug report	Ideally trusts should record activity under generic immunoglobulin rather than brand names.
Providers	i. Sharing best practice and experience across a region. ii. providing an opportunity to review, audit and improve the advice given by each panel. iii. Access to expert advice not normally available . iv. Reduce variations in prescribing and ensure the guidelines are being implemented appropriately.	2018-19 spend	2017-18 spend	High cost drug reporting & MO CQUIN reporting on National Immunoglobulin Database (MDSAS)	High cost drug report	

Activity / Cost Impact Assumptions –

- In the short term, until there is a shift from the present demand management model, to a policy based on clinical effectiveness; this model could reduce the variation in prescribing for grey indications and decrease dosage prescribing variation for blue and red indications. A 2-5% decrease in usage based on correct prescribing and dosage would result in £3-£8m/pa saving to specialised commissioning.
- Need to target areas with biggest variation e.g. Neurology blue conditions and long term use.
- Usage in black indications Approximately £100k should be £0.

Speciality	Indication	Financial Year	Total Grams	Average Gm/ Patient	ave £ per Gm	Est Cost 2017	3% Reduction	5% Reduction
Neurology	Blue	2015/16	1605359	645	32	£51,371,492.80	£1,541,144.78	£2,568,574.64
Immunology	Red	2015/16	1273789	368	32	£40,761,243.20	£1,222,837.30	£2,038,062.16
Other	Blue	2015/16	383685	195	32	£12,277,923.20	£368,337.70	£613,896.16
Haematology	Red	2015/16	320456	173	32	£10,254,576.00	£307,637.28	£512,728.80
Immunology	Blue	2015/16	307991	224	32	£9,855,720.00	£295,671.60	£492,786.00
Neurology	Red	2015/16	204642	189	32	£6,548,536.00	£196,456.08	£327,426.80
Other	Grey	2015/16	192961	253	32	£6,174,740.80	£185,242.22	£308,737.04
Neurology	Grey	2015/16	114340	338	32	£3,658,892.80	£109,766.78	£182,944.64
Haematology	Grey	2015/16	62779	250	32	£2,008,920.00	£60,267.60	£100,446.00
Haematology	Blue	2015/16	48348	167	32	£1,547,136.00	£46,414.08	£77,356.80
Other	Red	2015/16	25410	63	32	£813,120.00	£24,393.60	£40,656.00
Immunology	Grey	2015/16	25131	134	32	£804,177.60	£24,125.33	£40,208.88
						£146,076,478.40	£4,382,294.35	£7,303,823.92

Contractual Levers

Contractual Lever	Used to Support this Scheme	Link to document / Guidance
CQUIN	Y	Medicines Optimisation CQUIN Guidance
Procurement	Y	Principle of switching to most cost effective products Circulars SSC1760, SSC 1802 & SSC1675 SSC1 Provider letter Immunoglobulin Availability 22/03/2018 **See Slide 22 for link to documents**
SDIP (service development improvement plan)	N	
DQIP (data quality improvement plan)	Y	Medicines Optimisation CQUIN: Trigger 4 focuses on improving data quality associated with outcome databases
Others		

Criteria for auditing effectiveness of Immunoglobulin assessment panels

Audit criterion	Evidence
Demonstrate that 100% of “grey” applications are reviewed by the panel Demonstrate that at least 50% of “blue” applications are reviewed by the panel	Minutes of meetings (*with a plan in place to increase to 100% in 2018/19)*
Demonstrate achievement of the MO CQUIN trigger 4 element quarterly, with at least 90% “blue” – short term and “grey” indications having outcomes reported in the database by end 2017/18 (for patients treated in quarters 1 &2)	Cross-check with MDSAS MO CQUIN reporting
Ensure Immunology and Neurology representation on panel	Confirmation from Trust Medical Director
Ensure use of appropriate dose of IVIg in ITP (1g/kg in first instance with repeat dosing only if a haemostatically safe platelet count was not achieved; timing of second dose at Day 7)	Dissemination of NHSE letter to haematologists and cross-check with MDSAS

IAP best practice recommendations:

- **Ensure IAP in place**
- **Terms of Reference (ToR) agreed and reviewed**
- **ToR to include purpose, membership, frequency, quoracy, accountability and functions**
- **Independent chair, i.e. ideally not a immunoglobulin prescriber haematologist, immunologist or neurologist**
- **Panel membership should include haematology, immunology, and neurology clinicans. Suggested representation; specialist nurse and/or pharmacist with knowledge of immunoglobulin therapy; minimum of two of these for quoracy**
- **Consider commissioner engagement (this may be more achievable in cross-trust IAPs)**
- **Ensure medical director support for the panel and process**

IAP best practice recommendations:

- **Consider mix of meetings to deliver functions, such as quarterly face to face meetings with virtual meetings for considering urgent requests; out of hours requests**
- **Review of dosing in long-term use of immunoglobulin**
- **Be prepared to challenge requests, dosing, on-going use**
- **Be familiar with the available evidence**
- **Reinforce process for consideration of grey indications**
- **Ensure efficacy outcome recording on the database; review and follow up as necessary**
- **Share best practice amongst trusts**

National Stakeholder Engagement

Stakeholder Group	National Engagement to Date	Ongoing Engagement?
IVIG Project Working Group		Updates at bimonthly meeting
MDSAS National Data Workshop	December 2016 & 2017	On going annually
IAP Project Sub-group	Quarterly meetings	Ongoing
Immunoglobulin Database Steering Group	Twice every year	Ongoing
National Immunology Database	Member of B&I PoC policy working group	Ongoing
Regional Immunoglobulin Events	2016-17 & 2017-18	5 out of 10 hub events have already taken place with engagement for local clinicians, pharmacists and commissioners
Neurology CRG	Member of PWG	Ongoing
Specialist Immunology & Allergy CRG	Member of PWG	Ongoing
Other associated PoC & CRGs		

Local Stakeholder Engagement

For regions/hubs to complete

Stakeholder Group	National Engagement to Date	Ongoing Engagement?
Existing IAPs in trusts/hospitals		
Immunologists		
Immunology Pharmacists		

National Project Milestones to Support Local Implementation

Milestone	Responsible Group or Lead	Completed?	Date for Completion
SOAP	Rob Coster & Leena Sevak	Completed	June 2017
Implementation Pack	Leena Sevak & Rob Coster	Completed	October 2017
Baseline Ig usage data for Grey indications by trusts and regions from MDSAS database	Leena Sevak & Rob Coster	Completed	October 2017
Case study from Oxford University Hospital on their IAP	Leena Sevak	Completed	November 2017
Regional implementation	IAP PWG	Implementation Pack posted on SharePoint	December 2017

Local Implementation Milestones

For regions/hubs to complete

Milestone	Responsible Group or Lead	Completed?	Date for Completion

Overall Risks and Issues

Risk	L	I	Overall Risk Level	Mitigation	L	I	Residual Risk
Lack of uptake from hubs	3	3	Medium risk	Engagement with hub pharmacists and local hub events	2	3	Medium risk
Lack of engagement from trusts	4	4	High risk	Engagement with trusts especially large specialist trusts with required clinical expertise to support surrounding hospitals	3	2	Low risk
Set up costs of IAPs	4	4	High risk	Implementing shared-funding model such as in Oxford UH	2	3	Low risk
Access to required clinicians for panel within IAP footprint	2	4	Medium risk	Engagement and planning with regional trusts to include required clinical disciplines	2	2	Low risk

Issues	L	I	Overall Risk Level	Mitigation	L	I	Residual Risk

	Risk Matrix		Likelihood / Probability				
			Rare	Unlikely	Possible	Likely	Almost Certain
		SCORES	1	2	3	4	5
Impact	Major	5					
	Significant	4					
	Moderate	3					
	Minor	2					
	Negligible	1					

Very High Risk
High Risk
Medium Risk
Low Risk
Very Low Risk

Quality Impact Assessment

Describe the Impact on Clinical Effectiveness:
The hub & spoke model of IAPs has the potential to be more effective as it would facilitate access to clinicians with expertise for spoke trusts/hospitals.
Prescribing decisions for immunoglobulins will be standardised in line with DH guidelines & improve governance for Ig usage.

Risk	L	I	Overall Risk Level	Mitigation	L	I	Residual Risk
The system needs sufficient flexibility so that trust/s have the most appropriate model for them.	2	3	Medium risk	Provide evidence and tools to support measurement of the positive impact of IAP hub & spoke model on clinical decisions	1	3	Low risk
Specialist centres with large number of patients and a robust panel will not see advantage in changing the model.	3	3	Medium risk	Invite DGHs that specialist centres draws patients from to join the panel.	1	3	Low risk

Describe the Impact on Patient Safety:

- Having a standardised process, governance and data recording will ensure that prescribing decisions are compliant with clinical guidelines.

Risk	L	I	Overall Risk Level	Mitigation	L	I	Residual Risk
Risk that the project will be seen as a way of saving money .	3	3	Medium risk	Ensure that aims of project are communicated effectively to patients with emphasis on improving patient benefit.	1	3	Low risk

Quality Impact Assessment

Describe the Impact on Patient Experience:
This project will seek to improve patient experience by ensuring a robust process is in place for timely prescribing decision for immunoglobulins.

Risk	L	I	Overall Risk Level	Mitigation	L	I	Residual Risk
Risk that the project will be seen as a way of saving money.	3	3	Moderate	Ensure that aims of project are communicated effectively to clinical teams with emphasis on improving patient benefit.	2	2	Low risk

Describe the Impact on Equality and Diversity:
The IAP will be available to all patients for whom treatment by immunoglobulin is considered clinically appropriate. Therefore it should not differentially impact on any group of people.

Risk	L	I	Overall Risk Level	Mitigation	L	I	Residual Risk

Key Documents & Guidance

Document Name	Reference in attached Zip Folder
Circulars for ITP dosage change, switching circulars and Provider letter	Principle of switching to most cost effective products Circulars SSC1760, SSC1802 & SSC1675 SSC1 Provider letter Immunoglobulin Availability 22/03/2018 Zip folder on SharePoint
Oxford University Hospital ToR for IAP	Zip folder on SharePoint
Oxford University Hospital submission form for request to fund	Zip folder on SharePoint
IVIG IAP - SOAP	Zip folder on SharePoint
IAP Survey Results	Zip folder on SharePoint

Further Guidance	Web Link
Clinical guidelines for immunoglobulin use Department of Health 2011	https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/216671/dh_131107.pdf
Prescribed Specialised Services (PSS) CQUIN Guide – 2017-19	https://www.england.nhs.uk/wp-content/uploads/2016/11/pss-cquin-guide-nov16.pdf