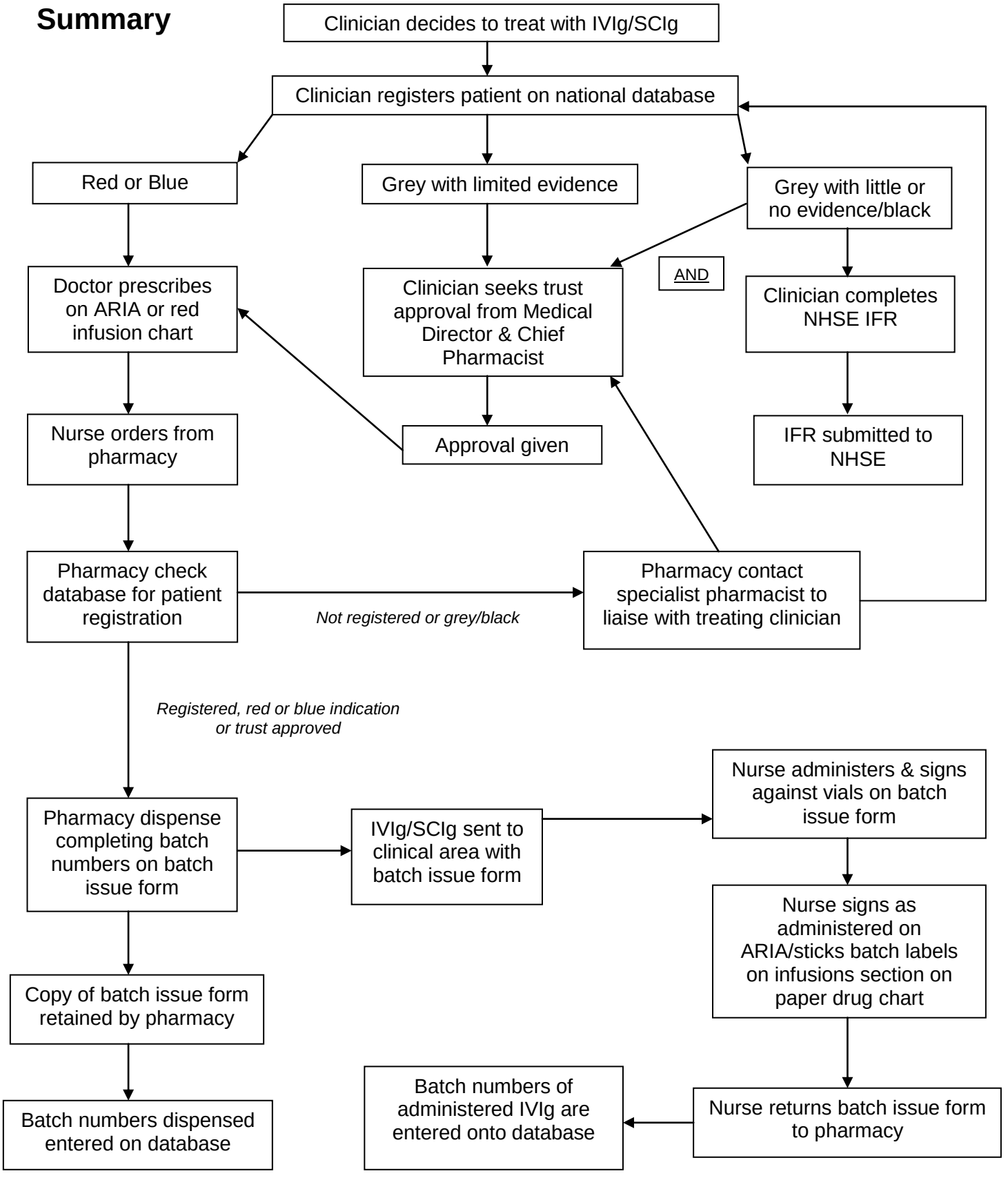
CLINICAL GUIDELINE FOR THE USE OF HUMAN NORMAL IMMUNOGLOBULIN (IVIg/SCIg)

Summary



1. Aim/Purpose of this Guideline

1.1. There have been global and in particular, UK supply issues with immunoglobulin preparations. There are also questions around cost effectiveness in some indications.

1.2. Intravenous Immunoglobulins (IVIg) are therefore subject to a national Demand Management Plan.

1.3. This consists of:

1.3.1. Guidance on which indications are considered appropriate for treatment with IVIg.

1.3.2. A national database with which all patients must be registered.

1.3.3. The collection of data on IVIg usage and patient outcomes.

1.4. This guideline applies to all staff who prescribe, dispense and administer human normal immunoglobulin. This may be for intravenous (IVIg) or subcutaneous (SCIg) use.

2. The Guidance

2.1. Indications for Treatment

2.1.1. In order to rationalize demand, the Department of Health Demand Management Plan describes a prioritization of treatment indications. Conditions for which IVIg are life-saving and/or the only treatment available are given the highest priority. Other indications are given a lower priority based on a weaker evidence base, or the availability of alternative treatments.

2.1.2. The table of indications, as described by the Demand Management Plan can be found in Appendix 3.

2.1.3. Each indication is assigned a priority as follows:

2.1.3.1. Red-high priority. Available at all times because of risk to life without treatment.

2.1.3.2. Blue-medium priority. Alternative treatments may be available. At times of shortage restrict use in this group.

2.1.3.3. Grey-low priority. Use to be considered on case-by-case basis.

2.1.3.4. Black-not recommended/not commissioned.

2.1.4. Conditions not listed in the table, for which immunoglobulin treatment may be considered, should be treated as grey indications.

2.1.5. For further details on the indications and associated evidence base, please refer to the DH document, Clinical Guidelines for Immunoglobulin Use and the Second Edition Update Clinical Guidelines for Immunoglobulin Use.

2.1.6. Duration of treatment

2.1.6.1. Short term treatment is classed as up to three doses of up to 2g/kg at appropriate intervals, with a total treatment duration of no greater than three months.

2.1.6.2. Long term treatment is any treatment with a duration of longer than three months.

2.2. Immunoglobulin Database

2.2.1. Before treatment may be commenced all patients must be registered on the National Immunoglobulin Database.

2.2.2. This should be done by the requesting clinician. In the event that the requestor does not have access to the database, an alternative clinician may enter the patient details (within each specialty there should be at least one clinician who can access the database).

2.2.3. The database is found at www.igd.nhs.uk

2.2.4. Access to the database may be obtained by emailing support@mdsas.com to request an account. MDSAS will seek validation of the request from the trust Chief Pharmacist before issuing the account.

2.2.5. The database will assign a colour priority based on the clinical details which have been input.

2.2.6. Pharmacy will update the database with details and batch numbers of doses dispensed.

2.2.7. The database must also be updated when the dose is administered. The database will also need to be updated if a dose is not administered.

2.3. Immunoglobulin Panel

2.3.1. The function of the Trust Immunoglobulin Panel will be fulfilled by the Medicines Practice Committee, which meets on a bimonthly basis.

2.3.2. The Panel will review all new requests for IVIg as a standing agenda item.

2.3.3. Red and Blue indications will be reviewed retrospectively. Treatment may be commenced in advance of the Panel meeting. The Pharmacy Technician for IVIg will compile the list of new patients and indications for each Panel meeting.

2.3.4. Grey indications include two categories:

2.3.4.1. Conditions with limited evidence of efficacy-the Immunoglobulin Panel must approve the request before treatment is commenced. See appendix 4 for the application form. Final agreement for funding for these indications will also need to be sought from the Area Team at NHS England.

2.3.4.2. Conditions with little or no evidence of efficacy-an Individual Funding Request (IFR) to NHS England is required before treatment is commenced.

2.3.5. Black indications require an IFR to NHS England before treatment is commenced.

2.3.6. If treatment is required urgently before the Panel is due to meet, the application form must be sent by email for approval by both of:

2.3.6.1. The Chair of the Medicines Practice Committee or deputy.

2.3.6.2. The Chief Pharmacist or deputy.

2.4. IVIG Preparations

2.4.1. The preparations in use at RCHT are Flebogamma, Octagam, Kiovig, Privigen, Vigam, Gamunex and Gammaplex.

2.4.2. For patients on long term treatment, the same brand must be maintained throughout treatment.

2.4.3. For patients commencing new therapy the brand of IVIG will be dispensed by pharmacy according to stock availability and acquisition cost. Where possible the 10% strength will be issued. Once a patient has started treatment they will be maintained on that brand. Patients who are transferred from other hospitals established on a brand will be maintained on that brand.

2.4.4. Vigam should be avoided in patients receiving renal replacement therapy due to the sucrose content.

2.5. Dosing of IVIG

2.5.1. The standard immunomodulatory dose is 2g/kg.

2.5.2. This is usually divided into 5 daily infusions of 0.4g/kg.

2.5.3. Some physicians prefer to use two daily doses of 1g/kg each.

2.5.4. For specific dosing information for each indication, please refer to appendix 5 and the tables within the DH Second Edition Update Clinical Guidelines for Immunoglobulin Use.

2.5.5. For patients with BMI ≥30 kg/m2 or if actual weight >20% more than IBW, prescribers should consider using adjusted-bodyweight dosing of immunoglobulin.

2.5.6. In patients on long term immunomodulatory doses, reasonable attempts should be made to reduce the dose, by increasing the dose interval or by using a reduced dose, or both.

2.5.7. To minimize the amount of IVIg used in individual treatments, **rounding down** IVIg dose **to the nearest whole vial** (adults) is recommended. Where the dose would be less than one vial in children, IVIg dose should be rounded up to a whole vial of the most appropriate size.

2.6. Prescribing of IVIG

2.6.1. For inpatient areas using EPMA, IVIg should be prescribed on EPMA with a reference to 'see infusion protocol'. A 'note' should be added to the drug providing the treatment indication.

2.6.2. For inpatient areas not using EPMA, IVIg should be prescribed on the infusion section of the paper drug chart, again with a reference to the infusion protocol.

2.6.3. For outpatient/day case areas, IVIg will be prescribed using the usual outpatient paper drug charts.

2.6.4. For the Headland Unit/Lowen ward, IVIg should be prescribed using Aria.

2.7. Supply of IVIG

2.7.1 Human Normal Immunoglobulins are supplied by General Pharmacy, RCH.

2.7.2 The requesting ward/clinic must order from pharmacy using the EPMA ordering function if prescribed using this system. If the ward does not use EPMA they may order in the ward requisition book, providing patient details, the name of the consultant, treatment indication and the dose required.

2.7.3 If a prescription chart is available this must also be sent to pharmacy for screening.

2.7.4 For out of hours supply, the on call pharmacist must be contacted NOT blood bank.

2.7.5 Pharmacy staff will update the immunoglobulin database with dispensing details, recording all batch numbers of immunoglobulins issued.

2.7.6 Pharmacy staff will complete a pink Batch Issue Form which will be sent with the IVIg to the administering ward (see appendix 6). This pink form must be completed with appropriate information by the staff administering the IVIg and returned to pharmacy on the next working day.

2.8. Administration of IVIG

2.8.1 Prior to administration of IVIg, assess that the patient is fit to proceed with treatment and perform baseline observations of:

2.8.1.1 Temperature

2.8.1.2 Pulse

2.8.1.3 Respiration rate

2.8.1.4 Blood Pressure

2.8.1.5 Weight

2.8.2 If it is the first time the patient has had immunoglobulin, a sample must be sent to microbiology for the following tests: Hepatitis B Core Antibody, Hepatitis C, HIV, and request the sample to be stored.

2.8.3 Cannulate the patient as per RCHT policy.

2.8.4 IVIg can be administered peripherally or centrally. It should be infused via a separate line and should not be mixed with other IV fluids or medication.

2.8.5 Check that the named product to be used corresponds to that on the prescription and the bottle and is the correct brand for the patient.

2.8.6 Check the product, dose, batch number and expiry date of the product. Confirm these details against those provided on the pink form sent by pharmacy. Ensure the product is homogeneous. Do not use if a non-homogeneous solution, or a deposit can be seen.

2.8.7 Ensure that if pre-medication is required, it is prescribed and administered (only usually required if there has been a previous adverse reaction)

2.8.8 Ensure the product is at room temperature. Remove from the fridge at least 30 minutes prior to administration.

2.8.9 Infuse product from its container. No further reconstitution is required.

2.8.10 It is recommended that administration should begin immediately after piercing the cap.

2.8.11 Flush line with either sodium chloride 0.9% or glucose 5% after use.

2.8.12 Infusion protocols and documentation

2.8.12.1 Infusion rates for IVIg are calculated according to the patient's body weight.

2.8.12.2 For administration on the Headland Unit, the infusion protocols are found within the Questionnaires on the Aria prescribing system. Select the appropriate protocol for the product and complete the on-screen boxes as requested. Batch numbers of products used, dates and times are inputted and signed for using electronic signatures.

2.8.12.3 For other inpatient and outpatient areas within the hospital print out the appropriate infusion protocol found on the Forms page of the hospital intranet (within A-Z Services).

2.8.12.4 Using the patient's weight, calculate the infusion rates and enter into the boxes on the protocol.

2.8.12.5 The completed protocols must be filed in the patient's medical notes.

2.8.12.6 When the infusion has been given the batch number stickers from the bottles must be stuck onto the infusion section of the paper drug chart, if one is in use, or onto the pink Batch Issue form received from pharmacy.

2.8.12.7 The pink Batch Issue form should be initialled by the administering nurse to confirm that all bottles have been given and returned to pharmacy.

2.8.12.8 If treatment is cancelled for any reason, the pink Batch Issue Form must be marked as NOT GIVEN and returned to pharmacy.

2.8.12.9 Pink Batch Issue Forms must not be filed in the patient's notes.

2.8.13. Observation and monitoring

2.8.13.1 New patients – baseline observations prior to administration. Then 15 minutes after infusion has started and then every 30 minutes until treatment is completed. Observe the patient for 1 hour after completion of treatment.

2.8.13.2 On-going patients – take observations at the start and finish of treatment. Observe the patient for 20 minutes after completion of treatment.

2.8.13.3 Always ensure:

2.8.13.3.1 Adequate hydration prior to the initiation of the infusion

2.8.13.3.2 Monitoring of urine output

2.8.13.3.3 Monitoring of serum creatinine levels

2.8.13.3.4 Monitoring of blood pressure (reduce rate if BP falls)

2.8.14 Management of adverse reactions

2.8.14.1 Adverse reactions to IVIg are uncommon.

2.8.14.2 Acute reactions occur during the infusion or shortly after

2.8.14.3 Delayed reactions occur 24 – 48 hours after the infusion

2.8.14.4 Most common causes of adverse reactions are due to administering IVIg when there is an untreated bacterial infection and infusion at the incorrect rate

2.8.14.5 Risk of adverse reactions can be minimised by adhering to the prescribed rate

2.8.14.6 Rarely IVIg may cause a sudden fall in blood pressure and, in isolated cases, anaphylactic shock, even when the patient has shown no hypersensitivity to previous administration

2.8.14.7 If a reaction does occur, refer to the following advice:

Symptoms	Action
MILD reaction Headache Light headedness Fever, shivers or sweating Nausea, vomiting Generalised aches and pains Irritability	Slow or stop infusion Give paracetamol for fever/headaches Restart infusion as per protocol when symptoms have resolved If symptoms persist, stop the infusion and seek medical advice
MODERATE/SEVERE reaction Severe headache Nausea and vomiting Wheezing/difficulty breathing Chest/loin pain Itching, nettle rash, hives Loss of consciousness	Stop infusion Call for medical help Inform senior nurse If necessary, administer supportive drugs Hydrocortisone IV Chlorphenamine IV Salbutamol Anaphylaxis/Crash box should be available

2.8.15 On the Headland Unit – supportive drugs can be prescribed using the Standing Orders function on Aria.

2.8.16 In other areas of the hospital, supportive drugs should be prescribed on EPMA or the drug chart as appropriate.

2.9 Subcutaneous Immunoglobulin (SCIg)

2.9.1 Subcutaneous administration of immunoglobulin may offer a convenient alternative to intravenous therapy for some patients. Although SCIg involves more frequent infusions (weekly or biweekly) the advantages of using this method of administration include fewer side effects, reduced administration time and the ability for patients to self-administer their treatment at home. It also enables patients to have well controlled plasma IgG levels without the peaks and troughs associated with IVIg.

2.9.2 The products available at RCHT for subcutaneous use are Hizentra, Subcuvia, Gammanorm and Subgam. The choice of brand may be influenced by patient factors and tolerability.

2.9.3 The dose may need to be individualised for each patient dependent on the pharmacokinetic and clinical response and serum IgG trough levels. The following dose regimens are given as a guideline.

2.9.3.1 The dose regimen using the subcutaneous route should achieve a sustained level of IgG. A loading dose of at least 0.2 to 0.5 g/kg (1.0 to 2.5 ml/kg) body weight may be required. This may need to be divided over several days. After steady state IgG levels have been attained, maintenance doses are administered at repeated intervals to reach a cumulative monthly dose of the order of 0.4 to 0.8 g/kg (2.0 to 4.0 ml/kg) body weight.

2.9.3.2 For patients transferring from IVIg to SCIg the subcutaneous dose will initially be the same as the intravenous dose divided over several days. For example an intravenous dose of 30g every 3 weeks may be given subcutaneously as 10g every week. Subsequent dose adjustment may be required according to monitoring.

2.9.3.3 Trough levels should be measured and assessed in conjunction with the patient's clinical response. Depending on the clinical response (e.g. infection rate), adjustment of the dose and/or the dose interval may be considered in order to aim for higher trough levels.

2.9.4 SCIg may be injected into sites such as abdomen, thigh, upper arm, and lateral hip. If large doses are given (> 25 ml), it is advisable to administer them at multiple sites.

2.9.5 The recommended initial infusion rate depends on individual needs of the patient and should not exceed 15 ml/hour/site. If well-tolerated, the infusion rate can then gradually be increased to 25 ml/hour/site.

2.9.6 Infusion pumps appropriate for subcutaneous administration of immunoglobulins can be used. The most suitable and commonly used pumps for SCIg home therapy are the Cane Crono Super PID pump system and the Freedom 60 pump system.

2.9.7 Up to 4 injection sites can be used simultaneously, provided that the maximum infusion rate for all sites combined does not exceed 50 ml/hour. Injection sites should be at least 5 cm apart.

2.9.8 Subcutaneous administration of immunoglobulin can cause infusion related reactions as with intravenous administration. Potential complications can often be avoided by ensuring that patients:

2.9.8.1 are not sensitive to human normal immunoglobulin, by initially injecting the product slowly.

2.9.8.2 are carefully monitored for any symptoms throughout the infusion period. In particular, patients naive to human normal immunoglobulin, patients switched from an alternative product or when there has been a long interval since the previous infusion should be monitored during the first infusion and for the first hour after the first infusion, in order to detect potential adverse signs. All other patients should be observed for at least 20 minutes after administration.

2.9.9 When considering commencing patients on home treatment with subcutaneous immunoglobulin the following factors should be considered:

2.9.9.1 The patient or caregiver will need to receive full training in administration techniques, including the use of any pumps and troubleshooting. They will need to be advised on measures to be taken in case of severe adverse reactions.

2.9.9.2 The hospital clinician will be responsible for prescribing and monitoring of home treatment.

2.9.9.3 The use of a homecare provider company may be considered for some patients (for drug delivery, waste disposal and/or administration). If this service is required, it must be discussed with a Specialist Pharmacist first to consider whether it will be cost effective and appropriate.

2.10 Procedure for commencing patients on subcutaneous home therapy

2.10.1 Each patient must be entered onto the National Immunoglobulin Database prior to commencing home therapy. If funding approval is required, as described for IVIg (section 2.3), this must be completed before treatment is commenced.

2.10.2 The patient's GP and hospital Consultant must be informed and in agreement with their patient receiving SCIg Home Therapy.

2.10.3 The patient must consent to SCIg Home Therapy and meet the Eligibility Criteria for SCIg Home Therapy (Appendix 7).

2.10.4 The hospital Consultant will be responsible for prescribing SCIg Home Therapy and patients will need to continue with their regular outpatient Consultant review at least annually. Blood tests for monitoring purposes may be carried out at the GP surgery. The Consultant/hospital team will be responsible for reviewing and acting on these blood tests.

2.10.4.1 For Headland/Haematology patients the SCIg Home Therapy Nursing Team on the Headland Unit will monitor home treatment and the results of blood tests every three months via a telephone clinic.

2.10.4.2 For patients undergoing SCIg Home Therapy within other specialities arrangements must be made for monitoring by the hospital team responsible for their care.

2.10.5 The infusion pump that will be used within the Headland Unit for SCIg Home Therapy is the Cane Crono Super PID pump system.

2.10.6 Patients may require a home assessment prior to starting Home Therapy. Nursing Staff must have read and adhere to the RCHT Lone Working Policy if a home visit is required.

2.10.7 The patient or identified suitable infusion partner will need to receive full training in the following:

2.10.7.1 Product administration including aseptic non-touch technique training

2.10.7.2 Subcutaneous site selection and preparation as well as comfort measures and site care

2.10.7.3 Safe insertion, securing and removal of needles as well as checking correct needle placement.

2.10.7.4 Appropriate waste disposal.

2.10.7.5 Pump training.

2.10.7.6 Troubleshooting infusion problems.

2.10.7.7 Documentation and recording infusion details (e.g. Logging batch numbers and any side effects experienced from treatment)

2.10.7.8 Prevention and management of adverse effects.

2.10.7.9 Actions to take if the patient is unwell at home or a severe adverse reaction is experienced.

2.10.7.10 Safe storage and handling of medication.

2.10.7.11 Action to take if a patient is unwell or has pyrexia at home prior to SCIg administration.

2.10.7.12 Who to contact for advice if required.

2.10.8 Detailed training guidelines and documentation will be kept on the Headland Unit at RCHT.

2.10.9 At least six training sessions must be completed within the hospital environment before the patient commences home therapy and some patients may require further sessions before they feel comfortable and confident to administer their treatment at home.

2.10.10 Each patient must successfully complete a written assessment prior to commencing home therapy (example of written assessment will be kept on the Headland Unit at RCHT).

2.10.11 All training sessions, assessments and patient interactions (including telephone contact) must be documented. Headland Unit nursing staff may use the Aria system for this purpose.

2.10.12 Arrangements must be made with the patient to provide their administration records, including batch numbers, to hospital staff at regular intervals so that administration details can be updated on the National Database.

2.11 Ongoing monitoring

2.11.1 All patients on long term treatment must undergo an annual efficacy review.

2.11.2 All patients on short term treatment must be reviewed quarterly for outcome measures as defined in the DH documents, Clinical Guidelines for Immunoglobulin Use and the Second Edition Update Clinical Guidelines for Immunoglobulin Use

2.11.3 The outcome of the quarterly and annual reviews must be entered into the immunoglobulin database.

2.11.4 For Grey indications seeking Panel approval, the requesting clinician must specify how they plan to monitor efficacy (see form, appendix 4). The Panel will follow up all approved requests for IVIG to confirm that this monitoring has taken place.

3. Monitoring compliance and effectiveness

Element to be monitored	All
Lead	The IVIg Pharmacy Technician
Tool	JAC reports will be produced to monitor dispensing from pharmacy. The IVig Technician will follow up on dispensed doses to monitor administration. The IVIg Technician will follow up requests for new treatment using the immunoglobulins database to ensure that patients are registered and maintained correctly.

Frequency	Issues from pharmacy will be followed up on a daily or weekly basis as necessary. The IVIg Technician will compile a report of all new patients every 2 months including indication for treatment and 'colour'. Information on out-of-hours requests will be collected. Problems relating to patient registration with the database, or with updating the database will also be reported.
Reporting arrangements	The report will be reviewed by the Medicines Practice Committee as part of the immunoglobulins agenda item.
Acting on recommendations and Lead(s)	Recommendations made by the Medicines Practice Committee will be implemented by the various staff groups as identified by the Medicines Practice Committee.
Change in practice and lessons to be shared	Required changes to practice will be identified and actioned within 3 months. A lead member of the team will be identified to take each change forward where appropriate. Lessons will be shared with all the relevant stakeholders.

4. Equality and Diversity

4.1. This document complies with the Royal Cornwall Hospitals NHS Trust service Equality and Diversity statement which can be found in the 'Equality, Diversity & Human Rights Policy' or the Equality and Diversity website.

4.2. Equality Impact Assessment

The Initial Equality Impact Assessment Screening Form is at Appendix 2.

Appendix 1: Governance Information

Document Title	Clinical Guideline for the use of Human Normal Immunoglobulin (IVIg)			
Date Issued/Approved:	14th October 2016			
Date Valid From:	31st December 2016			
Date Valid To:	31st December 2019			
Directorate / Department responsible (author/owner):	Emma Nicholls, Lead Cancer Pharmacist			
Contact details:	01872 252984			
Brief summary of contents	Describes the process for treatment with immunoglobulins including patient approval/registration, dosing, administration and follow up.			
Suggested Keywords:	Human Normal Immunoglobulin, Flebogamma, Octagam, Kiovig, Privigen, Vigam			
Target Audience	RCHT	PCH	CFT	KCCG
	✓			
Executive Director responsible for Policy:	Medical Director			
Date revised:	October 2016			
This document replaces (exact title of previous version):	Clinical Guideline for the use of Human Normal Immunoglobulin (IVIg)			
Approval route (names of committees)/consultation:	Medicines Practice Committee			
Divisional Manager confirming approval processes				
Name and Post Title of additional signatories	Not Required			
Name and Signature of Divisional/Directorate Governance Lead confirming approval by specialty and divisional management meetings	{Original Copy Signed}			
	Name:			
Signature of Executive Director giving approval	{Original Copy Signed}			
Publication Location (refer to Policy on Policies – Approvals and Ratification):	Internet & Intranet	✓	Intranet Only	

Document Library Folder/Sub Folder	Clinical / Pharmacy
Links to key external standards	Department of Health Immunoglobulins Demand Management Plan
Related Documents:	Department of Health (2008) Clinical Guidelines for Immunoglobulin Use 2nd Edition. Department of Health (2011) 2nd Edition Update Clinical Guidelines for Immunoglobulin Use. Department of Health (2008) Demand Management Plan for Immunoglobulin Use.
Training Need Identified?	Yes. Pharmacy staff will be provided with training prior to taking over the dispensing of immunoglobulins. Headland nurse training for SCIg will be undertaken prior to commencing and patients on SCIg Home Therapy.

Version Control Table

Date	Version No	Summary of Changes	Changes Made by *(Name and Job Title)*
Oct 2013	V1.0	Initial Issue	Emma Nicholls Lead Cancer Pharmacist
Oct 2016	V2.0	Additional information relating to subcutaneous administration added. Other procedural updates. Updated trust template. Appendix 3 indications 'acute disseminated encephalomyelitis' and 'autoimmune encephalitis' moved from Grey to Black following new NHSE guidance.	Emma Nicholls Lead Cancer Pharmacist; Caroline Ansell IVIg Technician

All or part of this document can be released under the Freedom of Information Act 2000

This document is to be retained for 10 years from the date of expiry.

This document is only valid on the day of printing

Controlled Document

This document has been created following the Royal Cornwall Hospitals NHS Trust Policy on Document Production. It should not be altered in any way without the express permission of the author or their Line Manager.

Appendix 2: Initial Equality Impact Assessment Form

Name of Name of the strategy / policy /proposal / service function to be assessed (hereafter referred to as *policy*) (Provide brief description): Clinical Guideline for the use of Human Normal Immunoglobulins	
Directorate and service area: Pharmacy/Clinical Areas	Is this a new or existing Policy? Existing
Name of individual completing assessment: Emma Nicholls	Telephone: 01872 252984
1. Policy Aim* Who is the strategy / policy / proposal / service function aimed at?	To describe the process within the trust for prescribing and administering immunoglobulins in order to comply with the national guidance.
2. Policy Objectives*	To ensure that patients are registered with the national immunoglobulins database prior to commencing treatment. To ensure that the approval process is followed according to treatment indication. To ensure that prescribing of immunoglobulins is clinically appropriate. To ensure that administration of immunoglobulins is safe and according to the product protocols. To ensure that the database is maintained with patient administration and follow up data.
3. Policy – intended Outcomes*	All patients are registered with the database and this is updated as described. Prescribing and administration of immunoglobulins is carried out appropriately
4. *How will you measure the outcome?	Through regular reports by the Pharmacy Technician for IVIG to the Medicines Practice Committee.
5. Who is intended to benefit from the policy?	Patients receiving treatment with immunoglobulins. The trust due to ensuring that all treatment is approved and funded. The wider health community due to reducing risks of global shortages by ensuring the national Demand Management Plan is adhered to.
6a) Is consultation required with the workforce, equality groups, local interest groups etc. around this policy? b) If yes, have these *groups been consulted? C). Please list any groups who have been consulted about this procedure.	No N/A

7. The Impact
Please complete the following table.

Are there concerns that the policy **could** have differential impact on:

Equality Strands:	Yes	No	Rationale for Assessment / Existing Evidence
Age		✓	The processes described in this guidance are focussed on the safe and effective provision of immunoglobulins to patients irrespective of their membership of any of the equality groups listed.
Sex (male, female, trans-gender / gender reassignment)		✓	
Race / Ethnic communities /groups		✓	
Disability - Learning disability, physical disability, sensory impairment and mental health problems		✓	
Religion / other beliefs		✓	
Marriage and civil partnership		✓	
Pregnancy and maternity		✓	
Sexual Orientation, Bisexual, Gay, heterosexual, Lesbian		✓	

You will need to continue to a full Equality Impact Assessment if the following have been highlighted:

- You have ticked "Yes" in any column above and
- No consultation or evidence of there being consultation- this excludes any *policies* which have been identified as not requiring consultation**. or**
- Major service redesign or development

8. Please indicate if a full equality analysis is recommended.	**Yes**	**No**

9. If you are not recommending a Full Impact assessment please explain why.

Signature of policy developer / lead manager / director	Date of completion and submission

Names and signatures of members carrying out the Screening Assessment	1. 2.	

Keep one copy and send a copy to the Human Rights, Equality and Inclusion Lead, c/o Royal Cornwall Hospitals NHS Trust, Human Resources Department, Knowledge Spa, Truro, Cornwall, TR1 3HD

A summary of the results will be published on the Trust's web site.

Signed _____

Date _____

Appendix 3: Indications for Treatment

Adapted from DH Second Edition Update Clinical Guidelines for Immunoglobulin Use

Red: High Priority		
INDICATION	SHORT TERM	LONG TERM
Alloimmune thrombocytopenia (foeto-maternal/neonatal)		
Chronic inflammatory demyelinating polyradiculoneuropathy (must be life-threatening to be classed as red)		
Guillain-Barré syndrome		
Haemolytic disease of the newborn		
HSCT in primary immunodeficiencies		
Immune thrombocytopenic purpura (acute and persistent, excluding chronic)		
Kawasaki disease		
Paraprotein-associated demyelinating neuropathy (IgM, IgG or IgA)		
Primary immunodeficiencies		
Specific antibody deficiency		
Thymoma with immunodeficiency		
Toxic epidermal necrolysis, Stevens Johnson syndrome		

Blue: Medium priority		
	SHORT TERM	LONG TERM
Acquired red cell aplasia		
Autoimmune congenital heart block		
Autoimmune haemolytic anaemia		
Autoimmune uveitis		
Coagulation factor inhibitors (alloantibodies and autoantibodies)		
Haemophagocytic syndrome		
Immunobullous diseases		
Inflammatory myopathies		
Multifocal motor neuropathy		
Myasthenia gravis (including Lambert-Eaton myasthenic syndrome)		
Necrotising (PVL associated) staphylococcal sepsis		
Post-transfusion purpura		
Rasmussen syndrome		
Secondary antibody deficiency (any cause)		
Severe or recurrent Clostridium difficile colitis		
Staphylococcal or streptococcal toxic shock syndrome		
Stiff person syndrome		
Transplantation (solid organ)		

Grey: Low priority	
Immune-mediated disorders with limited evidence of immunoglobulin efficacy	Presumed immune-mediated disorders with little or no evidence of efficacy
Catastrophic antiphospholipid syndrome Cerebral infarction with antiphospholipid antibodies Chronic ITP CNS vasculitis	Acquired red cell aplasia NOT due to parvovirus B19 Acute idiopathic dysautonomia Aplastic anaemia/pancytopenia Atopic dermatitis/eczema

Complex regional pain syndrome Neuromyotonia Intractable childhood epilepsy Neuromyotonia Opsoclonus Myoclonus Post-exposure prophylaxis for viral or pathogenic infection if intramuscular injection is contraindicated, or treatment when hyper-immune immunoglobulins are unavailable Pyoderma gangrenosum Systemic juvenile idiopathic arthritis Systemic vasculitides and ANCA disorders Urticaria (severe, intractable)	Autoimmune neutropenia Chronic facial pain Diabetic proximal neuropathy Haemolytic uraemic syndrome PANDAS Paraneoplastic disorders that are known not to be B- or T-cell mediated POEMS SLE without secondary immunocytopenias (including juvenile)

Black: not permitted

Acute disseminated encephalomyelitis (if high dose steroids have failed)

Autoimmune encephalitis (including NMDA and VGKC antibodies, among others)

Immunodeficiency secondary to HIV infection

Autologous BMT

Adrenoleukodystrophy

Alzheimer's disease

Amyotrophic lateral sclerosis

Chronic fatigue syndrome

Critical illness neuropathy

Multiple sclerosis

Rheumatoid arthritis

Neonatal sepsis (prevention or treatment)

Sepsis in the intensive care unit not related to specific toxins or C. difficile

Asthma

Graves opthalmopathy

IVF failure

Recurrent spontaneous pregnancy loss

Appendix 4: Application to Immunoglobulins Panel for Grey Indications

Patient Name	
Hospital/NHS number	
Date of Birth	
Indication for Treatment	
Intended dose and schedule	
Intended duration of treatment	
Reason for request (why alternative treatment is not appropriate)	
Intended monitoring process (NB annual efficacy monitoring must be entered into the immunoglobulin database)	
Requesting Consultant	
Urgency of request	

Request to be submitted to the Trust Immunoglobulins Panel (via Medicines Practice Committee- send to Tracey Nicholas, PA to the Chief Pharmacist).

If request is urgent please email to Iain Davidson, Chief Pharmacist **AND** the Medical Director.

Approved by Immunoglobulins Panel Yes/No Date…….

Approved by Area Team Yes/No Date……..

Appendix 5: Dosing Guidelines

Adapted from DH Second Edition Update Clinical Guidelines for Immunoglobulin Use

Condition	Short/Long term therapy	Dosing
PRIMARY AND SECONDARY ANTIBODY DEFICIENCY STATES		
Primary immunodeficiencies (associated with significant antibody defects)	LONG	Initiate at 0.4-0.6g/kg/month; dose requirements may increase and should be based on clinical outcome
Thymoma with immunodeficiency	LONG	Initiate at 0.4-0.6g/kg/month; dose requirements may increase and should be based on clinical outcome
HSCT in primary immunodeficiencies	LONG	Initiate at 0.4-0.6g/kg/month; dose requirements may increase and should be based on clinical outcome
Specific antibody deficiency	LONG	Initiate at 0.4-0.6g/kg/month; dose requirements may increase and should be based on clinical outcome
Secondary antibody deficiencies (any cause)	LONG	0.4g/kg/month modified to achieve an IgG trough level of at least the lower limit of the age specific serum IgG reference range
HAEMATOLOGY		
Acquired red cell aplasia	SHORT	2g/kg in two to five divided doses; repeated on relapse and for a second relapse
Alloimmune thrombocytopenia (foeto-maternal/neonatal)	LONG	Maternal: 1g/kg weekly throughout pregnancy Neonatal: 1g/kg; occasionally >1 dose required if thrombocytopenia persists
Autoimmune haemolytic anaemia (including Evans syndrome and post-transfusion hyper-haemolysis)	SHORT	Up to 2g/kg as a single or divided dose
Coagulation factor inhibitors (alloantibodies and autoantibodies)	SHORT	Initial therapy: either 0.4g/kg for 5 days or 1g/kg for 2 days
Haemolytic disease of the newborn	SHORT	0.5g/kg over 4 hours
Haemophagocytic syndrome	SHORT	Up to 2g/kg as a single or divided dose
Immune thrombocytopenic purpura-acute	SHORT	Use 1g/kg (0.8-1 for children) as a single infusion, to be repeated at a later date if platelet count has not responded
Immune thrombocytopenic purpura-persistent	SHORT	Use 1g/kg (0.8-1 for children) as a single infusion, to be repeated at a later date if platelet count has not responded
Post-transfusion purpura	SHORT	2g/kg in divided doses over 2-5 consecutive days
NEUROLOGY		
Chronic Inflammatory Demyelinating Polyradiculoneuropathy (CIDP)	SHORT LONG	2 doses of IVIg (2g/kg given over several days) 6 weeks apart; restarted at relapse and repeated using the 'time to relapse' as the interval between courses (i.e. if a patient relapses after 6 weeks, 2g/kg is given over several days every 6 weeks)
Guillain-Barré syndrome (included Bickerstaff's brain stem encephalitis)	SHORT	2g/kg usually given over 5 days (shorter time frame not recommended because of potential fluid overload and autonomic problems); second dose may be considered at 14 days for non-responsive or late deteriorating patients

Inflammatory myopathies • Dermatomyositis (DM) • Polymyositis (PM) • Inclusion body myositis (IBM)	LONG	2 doses of IVIg (2g/kg given over several days) 6 weeks apart; restarted at relapse and repeated using the 'time to relapse' as the interval between courses
Myasthenia gravis (includes Lambert-Eaton myasthenic syndrome LEMS)	SHORT	2g/kg given over 2-5 days
Multifocal motor neuropathy	LONG	2 doses of IVIg (2g/kg given over several days) 6 weeks apart; restarted at relapse and repeated using the 'time to relapse' as the interval between courses (often may be 4 weeks, but doses required may be less than CIDP)
Paraprotein-associated demyelinating neuropathy (IgM, IgG or IgA)	SHORT LONG	2 doses of IVIg (2g/kg given over several days) 6 weeks apart; restarted at relapse and repeated using 'time to relapse' as the interval between courses
Rasmussen syndrome	LONG	2 doses of IVIg (2g/kg given over several days) 6 weeks apart; restarted at relapse and repeated using 'time to relapse' as the interval between courses
Stiff person syndrome	LONG	2 doses of IVIg (2g/kg given over several days) 6 weeks apart; restarted at relapse and repeated using 'time to relapse' as the interval between courses
OTHER		
Autoimmune congenital heart block (anti-Ro) OR Paediatric myocarditis	SHORT	0.4g/kg every 3 weeks for a total of 5 treatments from weeks 12 through 24 of gestation
Autoimmune uveitis	SHORT	1.5g/kg/month for 3 months
Immunobullous diseases	LONG	2g/kg over 2-5 days
Kawasaki disease	SHORT	2g/kg single dose, given over 10-12 hours, in conjunction with high-dose aspirin; a second dose may be given if no response, or if relapse within 48h
Necrotising (PVL-associated) staphylococcal sepsis	SHORT	2g/kg as a single dose
Severe or recurrent *Clostridium difficile* colitis	SHORT	0.4g/kg, one dose, and consider repeating
Staphylococcal or streptococcal toxic shock syndrome	SHORT	2g/kg as a single dose
Toxic epidermal necrolysis, Stevens Johnson syndrome	SHORT	2g/kg, preferably as a single dose, or divided over 3 consecutive days
Transplantation (solid organ) • Antibody Incompatible Transplant (AIT) • Antibody Mediated Rejection (AMR) • Viral Pneumonitis	SHORT	AIT: up to 2g/kg to be repeated as per DSA, in renal desensitisation at 0.1g/kg for 8-12 doses AMR: up to 2g/kg to be repeated for 2-3 doses Viral pneumonitis: 0.5g/kg for 5 days

Appendix 6: Immunoglobulins Batch Issue Form

This form must NOT be filed in the patients notes. Please RETURN to Pharmacy SIGNED and DATED after treatment has been given or if cancelled.

Immunoglobulins Batch Issue Form:

Patient Name	
Hospital Number	
NHS Number	
Date of Birth	
Date of supply	
Area supplied to	

If this is the first time this patient has had immunoglobulin, a sample must be sent to microbiology for the following tests: Hepatitis B Core Antibody, Hepatitis C, HIV and request a sample to be stored.

Product Issued and Batch Numbers (completed by pharmacy)	Nurse to initial and date when administered

DISPENSED BY (PHARMACY ONLY)	CHECKED BY (PHARMACY ONLY)

Did the patient react to Immunoglobulins- Please tick where appropriate

Yes ☐ **No** ☐

If yes please indicate what type of reaction occurred

Mild ☐ **Moderate** ☐ **Severe** ☐

Appendix 7: Eligibility Criteria for Home Therapy

1. Consultant and GP and patient must agree that this method of delivery is suitable and beneficial.

2. Patient must be correctly entered onto the National Immunoglobulin Database.

3. The patient may be trained to infuse but training could also be offered to one suitable infusion partner.

4. The patient must consent to therapy and be motivated and committed to attending the training sessions until deemed competent to infuse alone at home.

5. The patient must have telephone access where the home infusion will take place.

6. A home visit is desirable to assess the first patient administration of SCIg in the patient home environment.

7. Agreement from the patient to maintain an infusion/symptom diary with a record of product batch numbers.

8. The patient must be able to successfully complete a written assessment on the completion of their training programme.

9. Agreement from the patient to attend an outpatient clinic at least annually for consultant review-SCIg therapy will be withheld if the patient does not comply with this after nurse contact has been made with them.

10. Agreement from the patient to receive telephone calls from the SCIg Home Therapy team so that 3 monthly assessments can be made and any concerns be addressed.

Agreement from the patient that hospital infusions may need to be reintroduced if any of the above criteria fails to be met or if deemed necessary by their consult