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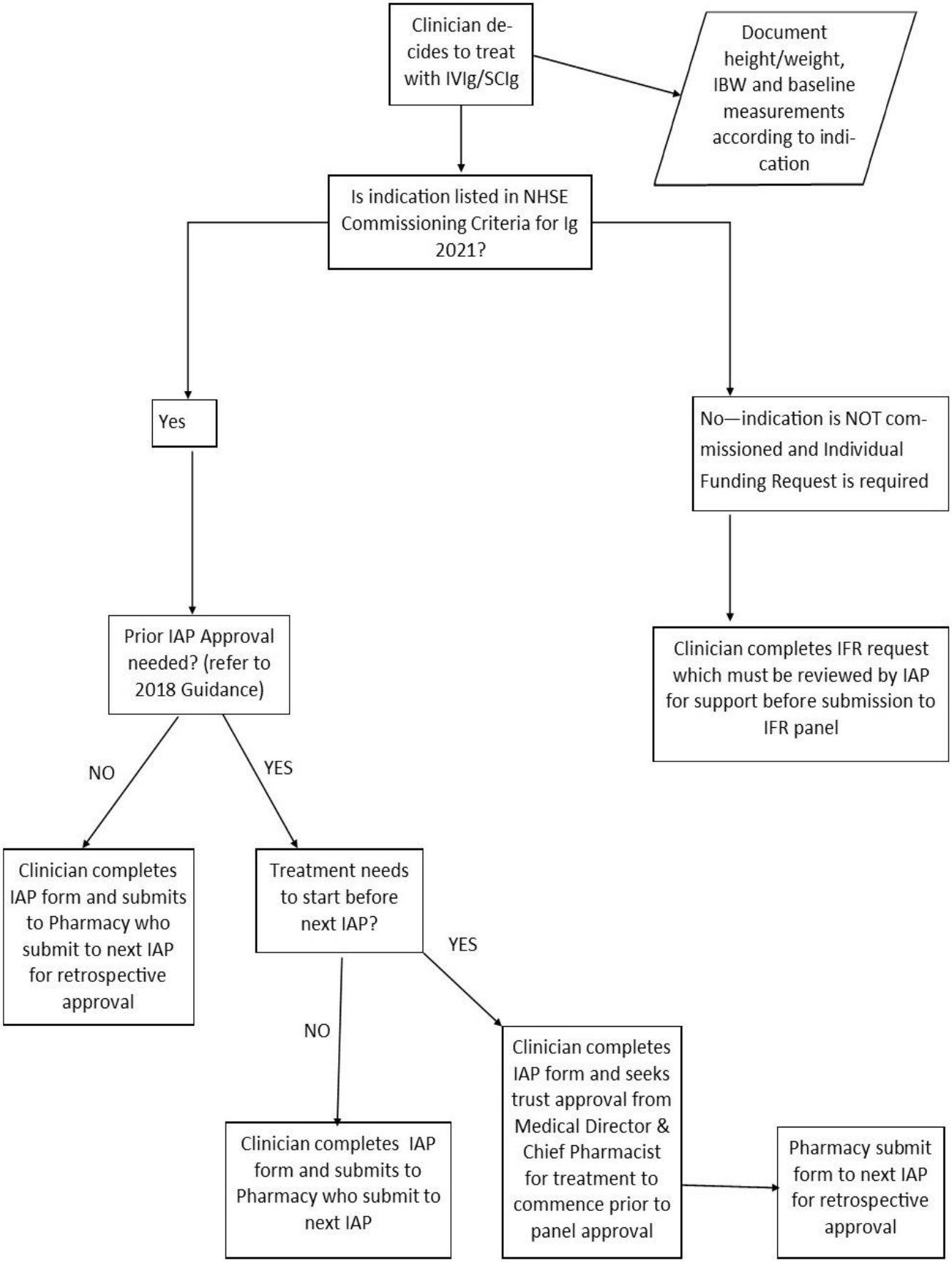
Royal Cornwall Hospitals NHS Trust

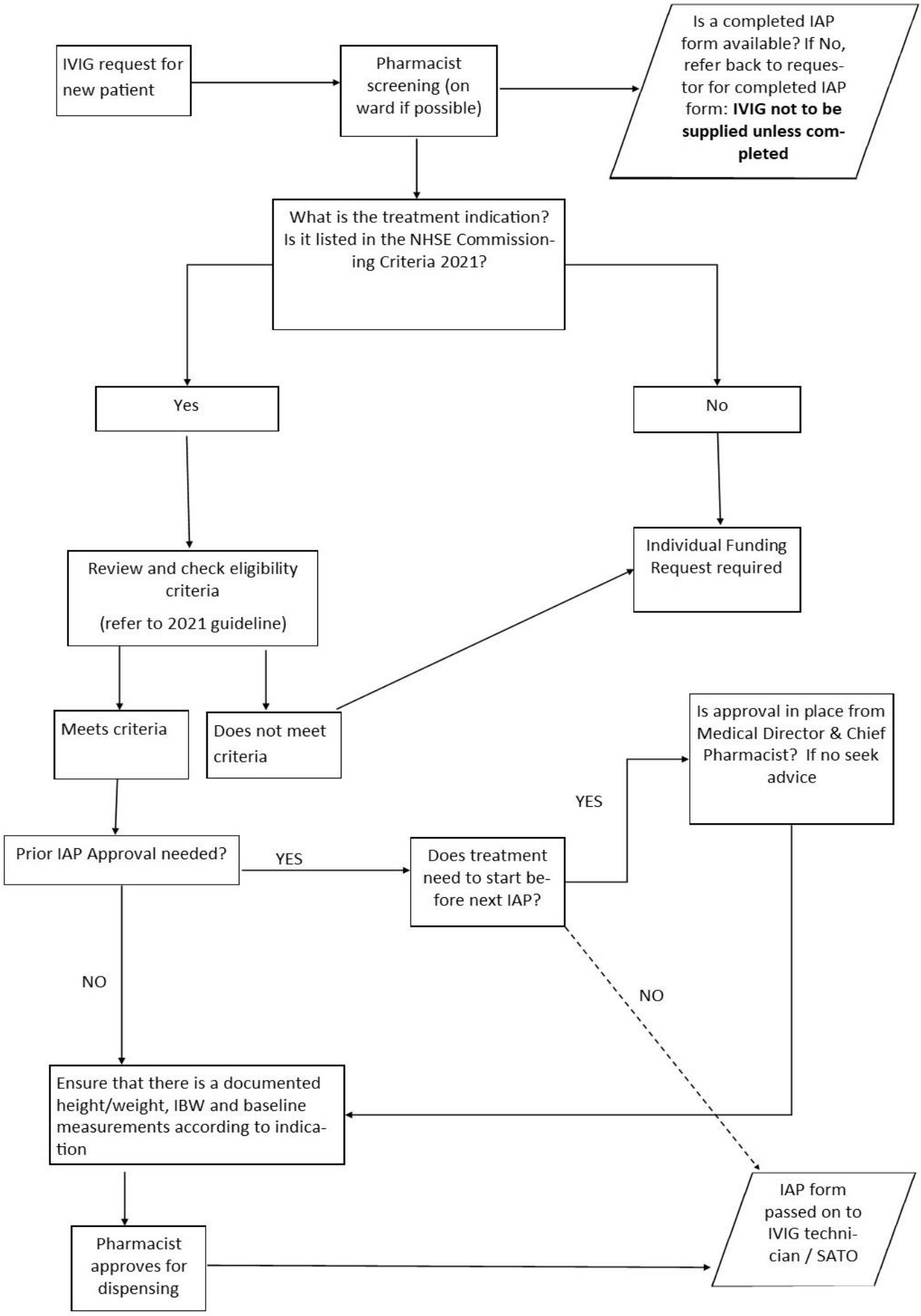
Use of Human Normal Immunoglobulin (IVIg/SCIg) Clinical Guideline

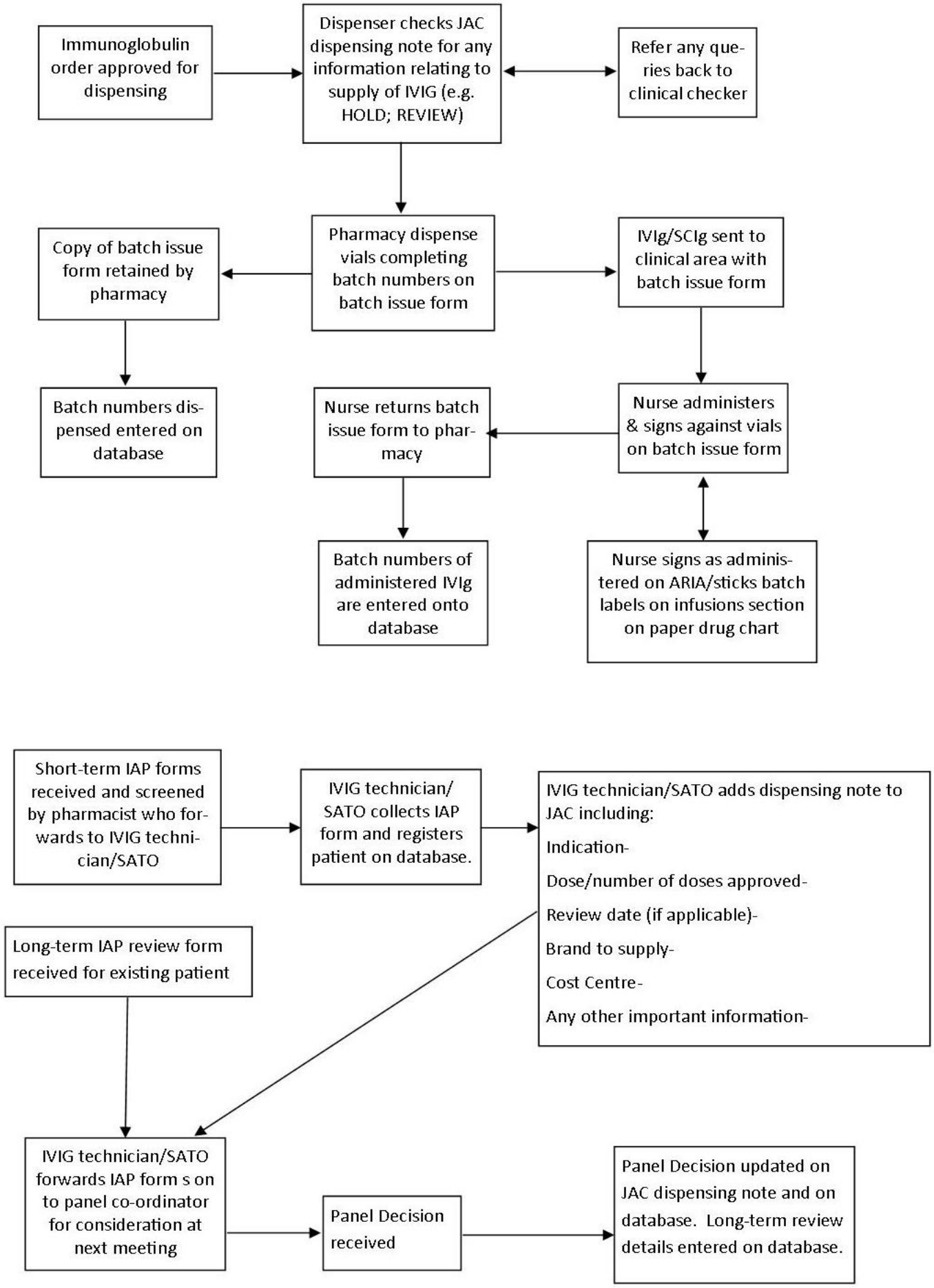
V4.0

January 2023

Summary


Clinician decides to treat with IVIg/SCIg
Document height/weight, IBW and baseline measurements according to indication
Is indication listed in NHSE Commissioning Criteria for Ig 2021?
Yes
No—indication is NOT commissioned and Individual Funding Request is required
Prior IAP Approval needed? (refer to 2018 Guidance)
Clinician completes IFR request which must be reviewed by IAP for support before submission to IFR panel
NO
YES
Clinician completes IAP form and submits to Pharmacy who submit to next IAP for retrospective approval
Treatment needs to start before next IAP?
YES
NO
Clinician completes IAP form and seeks trust approval from Medical Director & Chief Pharmacist for treatment to commence prior to panel approval
Clinician completes IAP form and submits to Pharmacy who submit to next IAP
Pharmacy submit form to next IAP for retrospective approval


IVIG request for new patient
Pharmacist screening (on ward if possible)
Is a completed IAP form available? If No, refer back to requestor for completed IAP form: IVIG not to be supplied unless completed
What is the treatment indication? Is it listed in the NHSE Commissioning Criteria 2021?
Yes
No
Review and check eligibility criteria
(refer to 2021 guideline)
Individual Funding Request required
Meets criteria
Does not meet criteria
Is approval in place from Medical Director & Chief Pharmacist? If no seek advice
YES
Prior IAP Approval needed?
YES
Does treatment need to start before next IAP?
NO
NO
Ensure that there is a documented height/weight, IBW and baseline measurements according to indication
IAP form passed on to IVIG technician / SATO
Pharmacist approves for dispensing


Immunoglobulin order approved for dispensing
Dispenser checks JAC dispensing note for any information relating to supply of IVIG (e.g. HOLD; REVIEW)
Refer any queries back to clinical checker
Pharmacy dispense vials completing batch numbers on batch issue form
Copy of batch issue form retained by pharmacy
IVIg/SCIg sent to clinical area with batch issue form
Batch numbers dispensed entered on database
Nurse returns batch issue form to pharmacy
Nurse administers & signs against vials on batch issue form
Batch numbers of administered IVIg are entered onto database
Nurse signs as administered on ARIA/sticks batch labels on infusions section on paper drug chart
Short-term IAP forms received and screened by pharmacist who forwards to IVIG technician/SATO
IVIG technician/ SATO collects IAP form and registers patient on database.
IVIG technician/SATO adds dispensing note to JAC including:
Indication-
Dose/number of doses approved-
Review date (if applicable)-
Brand to supply-
Cost Centre-
Any other important information-
Long-term IAP review form received for existing patient
IVIG technician/SATO forwards IAP form s on to panel co-ordinator for consideration at next meeting
Panel Decision received
Panel Decision updated on JAC dispensing note and on database. Long-term review details entered on database.

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 and NHS England (NHSE) commissioning criteria.

1.3. This consists of

1.3.1. Guidance on which indications are considered appropriate for treatment with IVIg. In 2021 NHSE released Updated Commissioning Criteria for the use of immunoglobulin in specific indications. This has been carried out after further review of the evidence base, since the original Department of Health (DH) guidelines, and provides greater detail around the role, dose and place of immunoglobulin in the treatment pathway for the specified indications.

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

1.3.3. The creation of a Sub-Regional Immunoglobulin Assessment Panel (SRIAP) who are tasked with reviewing and approving the use of immunoglobulin in all patients who require immunoglobulin (both newly starting patients and long-term patients).

1.3.4. 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.

1.5. This version supersedes any previous versions of this document.

Data Protection Act 2018 (General Data Protection Regulation – GDPR) Legislation

The Trust has a duty under the Data Protection Act 2018 and General Data Protection Regulations 2016/679 to ensure that there is a valid legal basis to process personal and sensitive data. The legal basis for processing must be identified and documented before the processing begins. In many cases we may need consent; this must be explicit, informed, and documented. We cannot rely on opt out, it must be opt in.

Data Protection Act 2018 and General Data Protection Regulations 2016/679 is applicable to all staff; this includes those working as contractors and providers of services.

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Royal Cornwall Hospital Trust rch-tr.infogov@nhs.net

2. The Guidance

2.1. Indications for Treatment

2.1.1. The NHS England Commissioning Criteria for the use of therapeutic immunoglobulin 2021 describes all conditions for which immunoglobulin is commissioned.

2.1.2. This guideline includes, for each indication:

- Eligibility criteria – these should be reviewed prior to commencing treatment to ensure the patient meets the criteria
- Exclusion criteria
- Position of immunoglobulin, taking into account alternative therapies – where available it is usually preferred that other alternatives have been tried before requesting immunoglobulin
- Recommended dose including number of permitted doses – this should be followed carefully, as doses outside of the recommendations will not be approved or commissioned. Dosing should be based on Ideal Body Weight and use of the calculator is recommended http://ivig.transfusionontario.org/dose/
- For ideal body weight calculation in paediatrics see appendix 5.
- Outcome measures to be recorded on the national database – measurement of these will be required at baseline and at subsequent review if ongoing treatment is to be requested
- Prior panel approval required – if 'no' treatment can proceed without prior SRIAP approval but a completed application form must still be completed and retrospectively reviewed by the panel. If this is subsequently declined (for example if eligibility criteria are not met, or dosing outside of the recommendations), the cost of the immunoglobulin will not be reimbursed by NHSE. If 'yes' an application form to the SRIAP should be made before commencing treatment.

2.1.3. Any indications not covered by the 2021 Commissioning Criteria are not commissioned and an individual funding request (IFR) will be required. This must be submitted to the SRIAP to obtain support before submitting to the IFR panel.

2.1.4. All guidelines can be found at http://igd.mdsas.com/clinical-info/

2.2. The Sub-Regional Immunoglobulin Assessment Panel (SRIAP)

2.2.1. The SRIAPs have been set up in order to provide effective overall clinical stewardship of the limited immunoglobulin supplies.

2.2.2. The SRIAP for the South West meets at least monthly and consists of clinicians, pharmacy representatives and commissioners.

2.2.3. The SRIAP will review requests for new patients, and ongoing patients, to ensure that the indication for treatment is appropriate, that the appropriate dose and frequency of treatment is used and that outcomes/evidence of efficacy are being reviewed. Where necessary the panel will allow prioritization of the patients most in need of treatment in times of product shortage.

2.2.4. Prescribers who wish to initiate immunoglobulin in a new patient will need to compete an immunoglobulin request form (available from pharmacy or at https://www.plymouthhospitals.nhs.uk/sriap) and submit to the SRIAP regardless of whether the condition requires prior panel approval as per the NHSE guidelines.

2.2.5. Conditions that do not require prior SRIAP approval will automatically be funded by NHSE (provided eligibility and dose recommendations are followed) but a request form will still need to be submitted to SRIAP for review. Treatment can begin before the panel review the application.

2.2.6. Conditions that do require prior SRIAP approval will need to be approved in order to secure a NHSE funded supply of immunoglobulin. In clinically urgent situations (e.g when the clinical team feel that they are unable to wait for SRIAP approval) the request form should be completed and the prescriber must obtain local approval from the Medical Director (or Deputy) and Chief Pharmacist (or Deputy). The request form will be submitted to the SRIAP and considered retrospectively. In the event that the SRIAP declines the application, the supply of immunoglobulin will not be funded by NHSE for that patient and this will result in a cost pressure for the relevant Care Group.

2.2.7. Ensure that the forms are completed fully (including the patient's height and weight) otherwise the application will be rejected. The panel require clear description of the clinical condition of the patient (e.g. what is the impact of the specified condition on the patient's clinical condition and why is immunoglobulin being requested for them now?) and whether alternatives have been tried and why they are not suitable.

2.2.8. If an indication is commissioned for a short course to assess response, a further request form for long term treatment will need to be submitted if the clinician wishes to continue treatment beyond the initial course. Demonstration of improvement in outcome measures will be required.

2.2.9. The SRIAP will also require existing patients to show evidence of benefit at regular reviews, (yearly unless otherwise specified at SRIAP) by reporting pre and post treatment outcomes relevant to the condition. These outcomes can be found on the aforementioned NHSE document. Long term review forms for existing patients will be distributed to clinicians by pharmacy. Failure to submit long-term patients for review by the SRIAP will result in cessation of funding by NHSE.

2.3. National Immunoglobulin Database

2.3.1. There is a national database to record the details of all administration of immunoglobulin. This is to ensure appropriate tracking of immunoglobulin usage and batch numbers in the case of infected batches.

2.3.2. All new patients must be registered on the National database – this will be done by pharmacy upon completion of a fully completed SRIAP form by the clinician.

2.3.3. The database is found at www.igd.nhs.uk and access may be requested by emailing support@mdsas.com MDSAS will seek validation of the request from the trust Chief Pharmacist before issuing the account.

2.3.4. Pharmacy staff will update the database with details and batch numbers of each dose dispensed. Upon receipt of confirmation of administering they will also update the administration (or non-administration if applicable) of doses.

2.3.5. Upon completion of annual review forms, pharmacy staff will update the database with the patient outcome measures as provided in the form by the clinician.

2.4. Immunoglobulin preparations

2.4.1. The preparations stocked by RCHT pharmacy are: Flebogamma 5%, Privigen, Octagam, Gamunex, Intratect, Iqymune, Panzyga, Kiovig and Gammaplex 10%. This is subject to change depending on product availability.

2.4.2. For patients on long-term treatment the same brand will usually be maintained throughout treatment.

2.4.3. In situations of shortage of certain products it may be necessary to switch patients to an alternative brand. This will be discussed with the patient(s) clinician(s).

2.4.4. For patients commencing new therapy the brand of IVIG will be dispensed by pharmacy according to stock availability. 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.

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

2.5. Dosing of Immunoglobulin

2.5.1. Information on dosage for each indication can be found by referring to the NHSE guidelines described above.

2.5.2. Dosing should be calculated according to Ideal Body Weight and using the calculator at http://ivig.transfusionontario.org/dose/ . See appendix 5 for IBW calculation in paediatrics.

2.5.3. Doses higher than the guidelines or the ideal body weight calculation are unlikely to be approved by the SRIAP and will be questioned by pharmacy.

2.5.4. Doses should be rounded down to the nearest vial size (5g vials stocked at RCHT). Specific rounded doses will be indicated by the calculator above.

2.5.5. 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.

2.6. Prescribing of Immunoglobulin

2.6.1. Informed consent should be discussed with the patient. Consent form should be completed by an appropriately trained individual and to be filed in patient notes. Consent discussion should include as a minimum:

- Potential side effects/adverse events
- Increased risk of thromboembolic disease (particularly IVIG)
- Risk of renal impairment (especially if pre-existing renal disease)
- Immunoglobulin is a blood product
- Risk of blood borne virus/other infection transmission

2.6.2. Ensure a baseline height and weight is recorded to enable correct dosing calculations.

2.6.3. Ensure baseline measurements are recorded to enable provision of 'outcome measures' as described in the NHSE guideline for the specific indication being treated.

2.6.4. Send baseline virology: Hepatitis Core Antibody, Hepatitis C, HIV and request the sample to be stored. This is in case of concern over virus transmission at a later date.

2.6.5. Premedication is recommended for the first two (or more as indicated) infusions: cetirizine 10mg PO and hydrocortisone 100mg IV. See appendix 5 for suggested pre-medication in paediatrics.

2.6.6. 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.

2.6.7. 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.

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

2.6.9. For the Headland Unit/Lowen ward, IVIg may be prescribed using Aria.

2.7. Supply of Immunoglobulin

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 Pharmacy Ordering Portal (POP). If the ward does not use POP they may order in the ward requisition book or specific Order Sheet, 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. The pharmacist will screen the request before authorizing the supply, which may then be made by Blood Bank staff.

2.7.5. Pharmacy staff will complete a pink Batch Issue Form which will be sent with the IVIg to the administering ward (see appendix 1). This pink form must be completed with appropriate information by the staff administering the IVIg and returned to pharmacy on the next working day. If the pink form is not returned, pharmacy staff will contact the administering ward to chase this up, as it is required in order to update the National Database with administration details.

2.8. Administration of Immunoglobulin

2.8.1. Before each Infusion ensure that baseline temperature, pulse, respiratory rate, oxygen saturations and blood pressure are recorded. If the patient has signs or symptoms of acute infection or is otherwise unwell, delay the infusion and consider requesting a medical review.

2.8.2. There is a risk of infusion related reactions with immunoglobulins. For this reason the following precautions should be taken during (at least) the first two infusions: slow rate (using infusion protocols described below) and pretreatment with cetirizine 10mg PO and hydrocortisone 100mg IV (see appendix 5 for paediatric dosing).

2.8.3. Subsequent infusions must be started at a slow rate and gradually increased to the maximum infusion rate for the individual patient. Once the maximum tolerable rate is known, it is important to document this rate and inform the patient of the value for future reference.

2.8.4. Check that the samples have been requested/sent for the baseline virology listed in point 2.41.

2.8.5. Cannulate the patient as per policy.

2.8.6. 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.

2.8.7. 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.

2.8.8. 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.

2.8.9. Ensure that if pre-medication is required (as above), it is prescribed and administered. After the first two courses premedication may not be required if there have been no previous adverse reactions.

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

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

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

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

2.9. Infusion Protocols and Documentation

2.9.1. All infusion protocols may be found on the Forms to Print section of the Documents Library. For patients being treated on the Headland Unit or Lowen Ward, the protocols can also be found as questionnaires on Aria.

2.9.2. Infusion rates for IVIg are calculated using the patient's body weight. Using the patient's weight, calculate the infusion rates for each step and enter into the boxes on the protocol.

2.9.3. The completed protocols should be filed in the patient's medical notes (or if an Aria questionnaire, retained within the Aria patient record).

2.9.4. 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.

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

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

2.9.7. Pink Batch Issue Forms must NOT be filed in the patient's notes.

2.10. Observation and Monitoring

2.10.1. 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.

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

2.10.3. Always ensure:

- Adequate hydration prior to the initiation of the infusion
- Monitoring of urine output
- Monitoring of serum creatinine levels
- Monitoring of blood pressure (reduce rate if BP falls)

2.11. Management of adverse reactions

2.11.1. Adverse reactions to IVIg are uncommon.

2.11.2. Acute reactions occur during the infusion or shortly after

2.11.3. Delayed reactions occur 24 – 48 hours after the infusion

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

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

2.11.6. 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

2.11.7. If a reaction does occur, refer to advice below.

2.11.8. Adverse reactions should be documented on the pink Batch Issue Form so that this information can be entered onto the National Database.

Symptoms	**Action**
MILD reaction Headache Light headedness	Slow or stop infusion Give paracetamol for fever/headaches Restart infusion as per protocol when symptoms have resolved

Symptoms	Action
Fever, shivers or sweating Nausea, vomiting Generalised aches and pains Irritability	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

2.12. Subcutaneous Immunoglobulin (SCIg)

2.12.1. 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.

2.12.2. Product shortages have particularly impacted supplies of SCIg. Before any patients may commence SCIg approval will need to be sought from the SRIAP. Consideration will need to be made around product availability at that time, commissioning status and acquisition cost.

2.12.3. The dose given will 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.

2.12.4. 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 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 to 4 ml/kg) body weight.

2.12.5. 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.

2.12.6. 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.

2.12.7. 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.

2.12.8. 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.

2.12.9. 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.

2.12.10. 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.

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

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

- 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.

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

- 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.

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

- 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.

- In the event that the patient is unable to administer their treatment at home, it may be appropriate for their treatment to be delivered on a Daycase Unit. See Appendix 6 for considerations that must be undertaken for this to be put in place.

2.13. Procedure for Commencing Patients on Subcutaneous Home Therapy

2.13.1. A request form must be submitted to and approved by the SRIAP. Patients must also be entered onto the National Database (done by pharmacy upon receipt of the SRIAP form).

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

2.13.3. The patient must consent to SCIg Home Therapy and meet the Eligibility Criteria for SCIg Home Therapy (Appendix 2).

2.13.4. 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. Prior to commencing Home Therapy, specific arrangements must be made for monitoring by the hospital team responsible for their care.

2.13.5. 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.

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

- Product administration including aseptic non-touch technique training

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

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

- Appropriate waste disposal.

- Pump training.

- Troubleshooting infusion problems.
- Documentation and recording infusion details (e.g. Logging batch numbers and any side effects experienced from treatment)
- Prevention and management of adverse effects.
- Actions to take if the patient is unwell at home or a severe adverse reaction is experienced.
- Safe storage and handling of medication.
- Action to take if a patient is unwell or has pyrexia at home prior to SCIg administration.
- Who to contact for advice if required.

2.13.7. An appropriate number of 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.

2.13.8. 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.

2.13.9. 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.

3. Monitoring compliance and effectiveness

Information Category	Detail of process and methodology for monitoring compliance
Element to be monitored	All
Lead	Pharmacy
Tool	Reports from National Database will allow monitoring of patient registration and outcome recording. SRIAP request forms - distribution and completion of these to be monitored and escalated if lack of engagement with completion
Frequency	As required
Reporting arrangements	Immunglobulins is a standing agenda item on the Medicines Practice Committee and issues identified will be escalated as necessary

Information Category	Detail of process and methodology for monitoring compliance
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, Inclusion and 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

Information Category	Detailed Information
Document Title:	Use of Human Normal Immunoglobulin (IVIg/SCIg) Clinical Guideline V4.0
This document replaces (exact title of previous version):	Clinical Guideline for the use of Human Normal Immunoglobulin (IVIg/SCIg) V3.2
Date Issued/Approved:	November 2022
Date Valid From:	January 2023
Date Valid To:	January 2026
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, Gamunex, Panel, SRIAP
Target Audience:	RCHT: Yes CFT: No CIOS ICB: No
Executive Director responsible for Policy:	Chief Medical Officer
Approval route for consultation and ratification:	Medicines Practice Committee
General Manager confirming approval processes:	Richard Andrzejuk
Name of Governance Lead confirming approval by specialty and care group management meetings:	Kevin Wright
Links to key external standards:	Department of Health Immunoglobulins Demand Management Plan NHSE Commissioning Requirements

Information Category	Detailed Information
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. Commissioning Criteria Policy for the use of therapeutic immunoglobulin (Ig) England, 2021
Training Need Identified?	Training has been completed in relevant areas upon introduction of SRIAP
Publication Location (refer to Policy on Policies – Approvals and Ratification):	Internet and Intranet
Document Library Folder/Sub Folder:	Clinical / Pharmacy

Version Control Table

Date	Version Number	Summary of Changes	Changes Made by
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
May 2018	V2.1	Appendix 3 indications 'acute disseminated encephalomyelitis' and 'autoimmune encephalitis' moved from Black to Grey following amendment to NHSE guidance. Updates to brands stocked within the trust.	Emma Nicholls Lead Cancer Pharmacist
Dec 2019	V3.0	Review in light of changes in NHSE commissioning process and introduction of SRIAP.	Emma Nicholls Lead Cancer Pharmacist

Date	Version Number	Summary of Changes	Changes Made by
Aug 2021	V3.1	Addition of paediatric-specific information/appendix 5. Minor amendments in products stocked.	Emma Nicholls Lead Cancer Pharmacist, Sabrina Tierney Lead Pharmacist for Women & Children
Feb 2022	V3.2	Updated to reflect availability of updated 2021 NHSE guidance and removal of previous DoH guidance. Flow charts updated.	Emma Nicholls, Lead Cancer Pharmacist
Nov 2022	V4.0	Addition of Appendix 6	Emma Nicholls, Lead Cancer Pharmacist

Appendix 2. Equality Impact Assessment

Section 1: Equality Impact Assessment (EIA) Form

The EIA process allows the Trust to identify where a policy or service may have a negative impact on an individual or particular group of people.

For guidance please refer to the Equality Impact Assessment Policy (available from the document library) or contact the Equality, Diversity and Inclusion Team rcht.inclusion@nhs.net

Information Category	Detailed Information
Name of the strategy / policy / proposal / service function to be assessed:	Use of Human Normal Immunoglobulin (IVIg/SCIg) Clinical Guideline V4.0
Directorate and service area:	Pharmacy, Clinical Areas
Is this a new or existing Policy?	Existing
Name of individual completing EIA (Should be completed by an individual with a good understanding of the Service/Policy):	Emma Nicholls, Lead Cancer Pharmacist
Contact details:	01872 252984

Information Category	Detailed Information
1. Policy Aim - Who is the Policy aimed at? (The Policy is the Strategy, Policy, Proposal or Service Change to be assessed)	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 the SRIAP approval process is followed according to treatment indication. To ensure that patients are registered with the national immunoglobulins database prior to commencing treatment. 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 reviewed and approved by SRIAP upon commencement and at appropriate follow-up points All patients are registered with the database and this is updated as described. Prescribing and administration of immunoglobulins is carried out appropriately

Information Category	Detailed Information
4. How will you measure each outcome?	Through regular reporting 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 commissioning guidelines and national Demand Management Plan are adhered to.
6a. Who did you consult with? (Please select Yes or No for each category)	• Workforce: Yes • Patients/ visitors: No • Local groups/ system partners: No • External organisations: No • Other: No
6b. Please list the individuals/groups who have been consulted about this policy.	**Please record specific names of individuals/ groups:** Consultant groups in Haematology, Neurology and Paediatrics Medicines Practice Committee
6c. What was the outcome of the consultation?	Accepted
6d. Have you used any of the following to assist your assessment?	**National or local statistics, audits, activity reports, process maps, complaints, staff or patient surveys:** No

7. The Impact

Following consultation with key groups, has a negative impact been identified for any protected characteristic? Please note that a rationale is required for each one.

Where a negative impact is identified without rationale, the key groups will need to be consulted again.

Protected Characteristic	(Yes or No)	Rationale
Age	No	The processes described in this guidance are focussed on the safe and effective provision of immunoglobulins to patients irrespective of their age.
Sex (male or female)	No	The processes described in this guidance are focussed on the safe and effective provision of immunoglobulins to patients irrespective of their sex.

Protected Characteristic	(Yes or No)	Rationale
Gender reassignment (Transgender, non-binary, gender fluid etc.)	No	
Race	No	The processes described in this guidance are focussed on the safe and effective provision of immunoglobulins to patients irrespective of their race/ethnic origin.
Disability (e.g. physical or cognitive impairment, mental health, long term conditions etc.)	No	The processes described in this guidance are focussed on the safe and effective provision of immunoglobulins to patients irrespective of disability.
Religion or belief	No	The processes described in this guidance are focussed on the safe and effective provision of immunoglobulins to patients irrespective of their beliefs.
Marriage and civil partnership	No	The processes described in this guidance are focussed on the safe and effective provision of immunoglobulins to patients irrespective of marital status.
Pregnancy and maternity	No	The processes described in this guidance are focussed on the safe and effective provision of immunoglobulins to patients irrespective of maternal status.
Sexual orientation (e.g. gay, straight, bisexual, lesbian etc.)	No	The processes described in this guidance are focussed on the safe and effective provision of immunoglobulins to patients irrespective of their sexual orientation.

A robust rationale must be in place for all protected characteristics. If a negative impact has been identified, please complete section 2. If no negative impact has been identified and if this is not a major service change, you can end the assessment here.

I am confident that section 2 of this EIA does not need completing as there are no highlighted risks of negative impact occurring because of this policy.

Name of person confirming result of initial impact assessment: Emma Nicholls, Lead Cancer Pharmacist

If a negative impact has been identified above OR this is a major service change, you will need to complete section 2 of the EIA form available here:
Section 2. Full Equality Analysis

Appendix 3. 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	
Patient weight as of	…./…./….. ……Kg
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 4. 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 approved by SRIAP and 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.

11. 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

Appendix 5. Paediatric Considerations

Ideal Body Weight

Dosing should be based on ideal body weight in all children over 2 years of age with a BMI above the 98th centile. At RCHT we use the reverse BMI method, which can be calculated using the formula below. BMI growth charts can be found at the RCPCH website, https://www.rcpch.ac.uk/resources/body-mass-index-bmi-chart or in the "Dosing in Extremes of Body Weight" folders available on the paediatric wards.

$$IBW = BMI_{50} \times height^2$$

(BMI_{50} is the BMI at the 50th centile for the child using their height, age and gender)

Premedication

IVIG is a blood product and can cause sensitivity reactions. Premedication may be considered for the first two (or more as indicated) infusions.

Hydrocortisone sodium succinate IV 30 mins before infusion:

2mg/kg (max 100mg)

AND

Chlorphenamine PO 30-60 minutes before infusion:

1month – 5 years 1 mg

6–11 years 2 mg

12–17 years 4 mg

Appendix 6. Administration of SCIg within Daycase Units

There may be occasions where patients are suitable for treatment with SCIg but are unable to manage the self-administration of this at home. In these cases it may be suitable for them to attend a daycase unit for administration via nursing staff.

In order for this to be provided safely the following considerations must be made:

1. Consideration should be given of whether provision by a homecare nursing service or Acute Care at Home can be provided. If this is not possible then treatment in the day unit could be considered.

2. The nursing staff on the unit must receive full training on use of the infusion pump (usually the Crono pump), troubleshooting and who to contact in the event of queries (usually the immunology team on the Eden Unit, Derriford Hospital).

3. If the pump has been provided by a homecare provider, this must undergo annual servicing and maintenance to ensure it is safe for use.

4. The pump must be cleaned when it is brought onto the unit, and upon discharge, using trust-approved standard equipment cleaning processes.

5. A suitable drug supply must be co-ordinated via the relevant hospital pharmacy. If it is necessary to utilise patient's own stock from home, this must be risk assessed by pharmacy for its suitability to use. Where possible stock should be procured directly into the hospital pharmacy.