University Hospitals of Derby and Burton
NHS Foundation Trust

Reference No.: CG-CLIN/905/23

Immunoglobulins (IV or SC) – Clinical Guideline

This guideline is for treating adults only if treating children please refer to Immunoglobulin in Neonates & Children - Paediatric Full Clinical Guideline – Joint Derby and Burton guideline. :
https://derby.koha-ptfs.co.uk/cgi-bin/koha/opac-detail.pl?biblionumber=635

Aim

To ensure immunoglobulin (Ig) prescribing in the Trust complies with NHS England Commissioning Criteria Policy and Demand Management Programme (DMP).

Purpose

To ensure that all medical staff in all clinical areas has easy access to guidelines and are informed of the procedure when prescribing immunoglobulin with the Trust. The guideline is to be used in conjunction with the NHS England clinical guidelines 2021 and demand management plan.

Introduction

Immunoglobulin (Human normal) is a blood product from human donors which is used to treat a wide range of conditions. Due to global shortages, there is concern regarding the availability of immunoglobulins to the NHS.

In May 2008, the Department of Health introduced a national Demand Management Programme (DMP) to provide guidance on appropriate use of immunoglobulin, to manage demand through more appropriate and consistent prescribing and to ensure that supply is maintained for patients for whom immunoglobulin is lifesaving, regardless of geographical location. In 2011, this guidance was updated with new dosing information and drug classification and updated again by NHS England in December 2021.

The national DMP incorporates a demand management plan and clinical guidelines for immunoglobulin use, as well as an immunoglobulin treatment database. All documents can be accessed via https://igd.mdsas.com . The programme also incorporates immunoglobulin

referral forms, requirements for a Trust Immunoglobulin Assessment Panel (IAP), and close liaison with commissioners.

Indications for treatment

Refer to the **clinical guidelines** (CCP2024): Clinical Commissioning Policy for the use of therapeutic immunoglobulin (Ig) England (2024) (mdsas.com)

Indications are now split into commissioned or non-commissioned (colour coded in previous guidelines) based on best available evidence. The table includes guidance for each commissioned indication including selection criteria, exclusion criteria, position of Ig, dose recommendation, outcome measures required for monitoring and, crucially, whether prior approval via immunoglobulin assessment panel is required.

For non-commissioned indications or indications not listed in the guidance, treatment is not recommended and requires an Individual Funding Request (IFR) submitted to NHS England.

Immunoglobulin Assessment Panel (IAP)

The Immunoglobulin Assessment Panel (IAP), a subgroup of the Drug and Therapeutics Committee, reviews all immunoglobulin use. The Panel's decision to approve immunoglobulin therapy will be based on the information provided on the Immunoglobulin Request form, the most up to date National Clinical Guidelines, expert knowledge of the condition, and a knowledge of locally available supplies of immunoglobulin products. The panel consists of consultants from relevant specialities, clinical pharmacists and commissioners or their representatives. The panel meets monthly.

Non prior approval indications will be reviewed retrospectively each month.

Prior approval indications will be reviewed virtually if the application is urgent and cannot wait for the monthly meeting.

All new immunoglobulin use will be reviewed and overseen by the Sub-Regional IAP (SRIAP), hosted in the East Midlands area by Nottingham University Hospitals NHS Trust.

All requests for immunoglobulin treatment should be sent to: uhdb.ivig@nhs.net

Patients who receive Ig should have outcomes measured and a follow-up form completed and returned to pharmacy or uhdb.ivig@nhs.net

For long term indications, follow-up assessment should be completed at least annually.

National Database

The national immunoglobulin database, run by MDSAS, exists to monitor the use of Ig throughout England. It is mandatory for all Trusts who use Ig to enter patient level data onto

the platform within 3 months of use. Compliance with the guidance is measured via a variety of Key Performance Indicators (KPI), depending on indication and length of treatment.

A referral service forms part of the database allowing users to refer cases to their SRIAP allowing for robust oversight of Ig use in the region.

Prescribing of Immunoglobulins (Ig)

- Before prescribing, the requesting clinician should complete the request form (Found here: https://derby.koha-ptfs.co.uk/cgi-bin/koha/opac-detail.pl?biblionumber=905 and give to the ward pharmacist (in hours) or the on-call pharmacist (out of hours).
- Pharmacy should review the request against the clinical criteria. Non prior approval indications may be supplied without delay, however prior approval indications must be reviewed by the IAP before supply is made.
- Ig should be prescribed using the relevant EPMA system (Lorenzo, Meditech, ChemoCare) within the clinical area. This is important as EPMA systems will be updated with administration notes or restrictions relating to infusion rates. At the time of publication it is noted and accepted that RDH ICU, ED & NICU remain on paper based medication charts.

Dosing of Immunoglobulins

For specific dosing information relating to indication, refer to the **clinical guidelines** (CCP2024): Clinical Commissioning Policy for the use of therapeutic immunoglobulin (Ig) England (2024) (mdsas.com)

In line with national guidance and to ensure cost effective use and minimisation of dose dependent adverse effects, doses should be calculated using Dose Determining Weight (DDW) available at: IVIG Dose Calculator with BMI and Speciality Recommendations (transfusionontario.org)

To minimise waste and the volume of Ig used, rounding down to the nearest whole vial is recommended.

In patients on long term therapy, reasonable attempts to use the minimum effective dose should be made by increasing the dose interval or reducing the daily dose or both.

Immunoglobulin preparations

IVIg preparations are supplied by allocation calculated by the regional commercial medicines unit (CMU) with oversight from NHS England, based on previous use. Subcutaneous (SCIg) products are more freely available.

For patients on long term Ig therapy, the same brand should be maintained where possible, however during times of shortage this may not be possible. Switching of products should be made with the approval of the treating clinician.

Patients transferred from other Trusts established on treatment should be maintained on that brand. Following consultation with the CMU, allocations may be transferred between Trusts to maintain continuity.

Administration of IVIg

- Prior to administration, ensure patient is fit to proceed and perform baseline observations:

Temperature, Pulse, Respiration Rate, BP, Weight

- Cannulate as per UHDB policy
- IVIg can be given peripherally or centrally, it should be infused via separate line and not mixed with other IV fluids, Medication or Blood products.
- Check the prescription against the patient and usual brand for the patient (unless a switch has been agreed)
- Check product, dose and expiry date of product. Record the batch number(s) administered. Ensure solution is homogeneous. Do not use if non-homogeneous or deposits can be seen. Commence a UHDB infusion checklist.
- Administer any pre-medication, if required.
- Ensure product is at room temperature. If stored in the 'fridge, remove 30 minutes before starting infusion.
- Follow UHDB Medicines Policy for 2-person checks to include prescription, products, and pump. Infuse from original container via a volumetric infusion pump. No further dilution is required.
- Administer as per the rate on the SmPC for the particular brand. In most cases this is a titration rate which is reviewed periodically and increased incrementally to the highest tolerated infusion rate (www.medicines.org.uk). All changes to infusion pumps require a check by two registered practitioners in accordance with UHDB Medicines Policy.
- Monitor patient for adverse reactions during infusion, prior to any titration and after infusion in accordance with the SmPC (www.medicines.org.uk).
- Flush the line with sodium chloride 0.9% or glucose 5% after use to ensure total dose administered.

References:

- Commissioning Criteria Policy for the use of therapeutic immunoglobulin (Ig) England 2024. Clinical Commissioning Policy for the use of therapeutic immunoglobulin (Ig) England (2024) (mdsas.com) last accessed April 2024.

- NHS England national database. igd – Home (mdsas.com) last accessed 29/11/23.

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