

Specialty guides for patient management during the coronavirus pandemic

# Clinical guide for the management of patients requiring immunoglobulin treatment during the coronavirus pandemic and management of supply

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As doctors we all have general responsibilities in relation to coronavirus and for these we should seek and act upon national and local guidelines. We also have a specific responsibility to ensure that essential care continues with the minimum burden on the NHS. We must engage with those planning our local response. We may also need to work outside our specific areas of training and expertise and the [General Medical Council has already indicated its support for this](#) in the exceptional circumstances we may face.

## High-risk patient groups

Patients with primary immunodeficiencies (all ages and types), secondary antibody deficiency (adults) and patients who have previously undergone stem cell transplant for primary immunodeficiency (all ages), are likely to be at increased risk of complications from COVID-19.

It is recommended that immunology services and other services using immunoglobulin should still support the ongoing provision of immunoglobulin replacement therapy, especially for patients with immunodeficiency, unless they are advised by their trust or national body that this is no longer possible. [UK PIN](#) has produced [guidance for clinicians in respect of risk stratification](#).

## Leadership

- A consultant/senior pharmacist must be designated as lead for immunoglobulin within the trust and/or for sub-regional immunoglobulin assessment panels (SRIAPs).

- A team should support the lead and include relevant members of the sub-regional immunoglobulin assessment panel to review immunoglobulin requests as per the guidance below.
- Establish a daily rota to review immunoglobulin use to share across the workforce.
- It can be very stressful during a crisis. Support each other and share the workload. Do not expect the immunoglobulin lead to do all the reviews.

## Categories of patients receiving immunoglobulin treatment to consider

### Treatment of COVID-19

- The Immunology and Allergy Clinical Reference Group **does not recommend the use of intravenous immunoglobulin (IVIg) for the treatment of patients with COVID-19 infection.** The use of IVIg in patients with COVID-19 and a concurrent recognised commissioned indication is unaffected by this statement.
- IVIg is amongst the many treatments that have been used to treat patients infected with the newly emergent severe acute respiratory distress syndrome coronavirus 2 (SARS-CoV-2, also known as COVID-19). However, the published literature, to date, does not provide a rationale for the use of IVIg use and neither has there been a discussion of clinical outcomes in patients receiving IVIg. IVIg is not known to contain antibodies against COVID-19.

### Immunomodulatory maintenance

- For maintenance immunomodulatory use in neuropathies or inflammatory myositis, increasing/doubling the dose to half the frequency is not recommended for patients already at maximum interval. For some stable patients, it may be possible to increase the intervals between treatments, but this will need to be determined on an individual basis. If the maximum interval on a 2g/kg dose has already been established then increasing doses does not increase the interval any further, increases risk and increases catabolism and thus reduces efficacy.

### Secondary antibody deficiency

- For patients with secondary antibody deficiency, if they are already achieving satisfactory trough immunoglobulin G (IgG) levels then increasing it further will not provide added protection.

### Day case activity (intravenous immunoglobulin)

- On a case by case basis considering the balance of risk and benefit, continuing to provide IVIg as a day case is preferred.
- Where this is not appropriate, clinicians should consider how attendance can be minimised.

- Dependent on patient circumstances and trust capacity, possible options include considering short-term antibiotic prophylaxis (to replace immunoglobulin therapy) or changing immunoglobulin dosing (thereby increasing interval between attendances).
- For patients meeting the clinical criteria for safe use of subcutaneous immunoglobulin, it may be possible to consider a switch away from infusion-based treatments. However, the safety and viability of this option is dependent on NHS and/or homecare company capacity to deliver a training package to patients to self-administer the treatment and receive deliveries at home. Adequate lead-in time will be required to achieve attendance minimisation via this route.

### **Use of subcutaneous immunoglobulin and home therapy**

If the decision is taken to switch patients to subcutaneous immunoglobulin and self-care (self-administration) at home, trusts should follow these steps:

1. Identify any patients that meet the requirements for self-care at home.
2. Ensure that your hospital pharmacy homecare team and regional pharmacy homecare specialist are aware of this request to switch. Be mindful that your chosen homecare provider must hold a contract for this service with your hospital and/or regional procurement hub.
3. Liaise with your regional homecare specialist, chosen homecare provider and chosen subcutaneous immunoglobulin (SCIg) pharmaceutical company to ensure adequate supply is available across the system for ongoing SCIg therapy for the next 12 months for each patient identified.
4. Ensure that there is sufficient day case and nursing capacity to train and supervise switching to SCIg if the training is managed inhouse. It often takes four to six weeks for a patient/carer to be adequately trained to safely administer SCIg at home.
5. If you wish for the training to be managed by your chosen homecare provider, ensure they have sufficient nursing capacity to train these patients. Liaise with your chosen homecare provider to co-ordinate arrangements and dates for training.
6. Contact the relevant pharmaceutical company with details of dose and training dates.
7. Where homecare delivery services are not available, arrange alternative routes of supply such as via patient or carer pick-up, NHS volunteer delivery to homes or courier services.
8. Liaise with the commercial medicines unit (CMU) to ensure that trust level SCIg allocation volumes are increased going forward and IVIg allocated volumes are amended accordingly. This ensures there is adequate supply long term.

### **Outpatients:**

- Wherever possible patients should be offered telephone consultations.

## Immunoglobulin supply

Demand management arrangements for immunoglobulin remain in place and it is necessary to ensure current and future supply in general, and of subcutaneous immunoglobulin in particular, is not adversely affected by COVID-19.

Therefore, to protect supply, SRIAPs will continue to operate, maintaining stewardship to protect supplies of immunoglobulin for those that require it most. Oversight of immunoglobulin usage must be maintained. 'Light touch' arrangements are acceptable and greater use of systems for electronic/virtual review are encouraged. Ideally panels will continue to review new requests. However, if staffing capacity means this is not possible, it is expected that panels will follow these principles as a minimum:

1. All reviews of existing current long-term use and audits to be paused.
2. Where use is in line with the current commissioning criteria (prior approval not required), and at recommended dose and frequency, panel approval is not required.
3. Trust pharmacy should review and approve all prescribed usage which is within commissioning criteria.
4. Any use of immunoglobulin outside of current commissioning criteria (including in respect of dosage and frequency) must be reviewed by a panel clinician and either approved, amended in discussion with the clinician or declined.
5. All grey indications must receive review by a panel clinician.

An electronic referral system on the MDSAS Immunoglobulin Database is available to support SRIAPs and NHS England and NHS Improvement strongly recommends its use to facilitate virtual panel approval processes. Training has been provided to the majority of SRIAP co-ordinators. A training video will also be made available on the Immunoglobulin Future NHS site and on the MDSAS Immunoglobulin Database site or <https://youtu.be/YWWIRltq1vU>. If you have any questions about the use of the electronic referral system, please contact MDSAS Database [support@mdsas.com](mailto:support@mdsas.com).

It is expected that all immunoglobulin use continues to be recorded on the MDSAS Immunoglobulin Database within a timely manner. The electronic referral system will assist with this as it initiates the patient record on the database.

## Communication between patients and teams

Services may want to consider individual discussion with patients, particularly those at the highest risk of COVID-19 about the risks and benefits of attending for immunoglobulin replacement therapy.

Patients may request their treatment is switched to subcutaneous forms of immunoglobulin. This should be discussed on a case by case basis to take into account the clinical

presentation and the capacity of services to provide the necessary safety training and delivery.

Teams should consider if they have the resources to maintain regular contact via telephone with patients who are self-isolating. They should set up a generic email for patient queries with access to clinical staff to provide responses to patients.

Teams should consider setting up appropriate and secure mechanisms of communication between nearby trusts/networks so that they can provide clinical advice in the event of staff sickness, e.g. via WhatsApp or email groups.

## **What to say to patients**

Refer patients to up-to-date advice on:

- [The NHS.uk website](#)
- [NHS England and NHS Improvement's website](#)
- [The Gov.uk website](#)