DH Department of Health

SECOND EDITION

Demand Management Plan for Immunoglobulin Use

May 2008

DH INFORMATION READER BOX

Policy	Estates
HR / Workforce	Commissioning
Management	IM & T
Planning / Performance	Finance
Clinical	Social Care / Partnership Working

Document Purpose	Best Practice Guidance		
ROCR Ref:		**Gateway Ref:**	10013
Title	Demand Management Plan for Immunoglobulin Use		
Author	DH		
Publication Date	30 May 2008		
Target Audience	PCT CEs, NHS Trust CEs, SHA CEs, Foundation Trust CEs , Medical Directors, Directors of Finance, GPs, Communications Leads, Emergency Care Leads, Chief Pharmacists		
Circulation List			
Description	For some time, due to global supply shortages and UK specific issues, there has been concern about the availability of immunoglobulin to the NHS. In 2006, the DH initiated the 'National Demand Management Programme for Immunoglobulin' to provide guidance in appropriate use, to manage demand and to ensure supply for patients whom immunoglobulin is life-saving.		
Cross Ref	n/a		
Superseded Docs	Demand Management of Immunoglobulin' 2006		
Action Required	n/a		
Timing	**n/a**		
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Demand Management Plan for Immunoglobulin Use

BACKGROUND

Availability of immunoglobulin to the NHS

Therapeutic immunoglobulin, a blood product, is used effectively in the treatment of a wide range of diseases. For some time, there has been concern about the availability of immunoglobulin to the NHS, because of a global supply shortage and issues specific to the UK. Supply shortages have been compounded by an ever-increasing demand for immunoglobulin resulting from the emergence of new therapeutic indications and more wide-spread off-label usage, amongst others.

Issues related to immunoglobulin supply in the UK include:

- Plasma was previously sourced within the UK from voluntary blood donations. There is now a requirement for the major UK supplier of immunoglobulin, BPL, to buy plasma from the USA because of the risk of vCJD in the UK; this has significantly increased production costs
- Closure of a UK manufacturer, Scottish National Blood Transfusion Service, resulting in reduced local supply
- Decreased availability of therapeutic immunoglobulin because of reducing imports by commercial companies
- Very acute shortages caused by unexpected withdrawals of batches of immunoglobulin for safety reasons
- Prolonged immunoglobulin shortfall in the UK because of increasing costs world-wide, associated with reduced demand for factor VIII and albumin

Department of Health demand management initiative

In 2006, the Department of Health (DH) initiated a review to assess the opportunities available to secure the supply of immunoglobulin in the UK and to develop a more evidence-based approach to immunoglobulin use. The review identified the need to introduce:

1. New procurement arrangements for immunoglobulin products, with improved levels of commitment from purchasers and suppliers to ensure adequate supply.
2. A national Demand Management Programme to provide guidance in the appropriate use of immunoglobulin products, which would be expected

to manage demand through more consistent prescribing across the NHS and to ensure that supply is maintained to patients for whom immunoglobulin is life-saving.

3. Review of local arrangements for funding for immunoglobulin therapies by NHS agencies.

New procurement arrangements have been organised. Trusts have been asked to commit to volumes by signing a commitment *pro forma*. This provides suppliers with a greater level of commitment and helps increase availability of immunoglobulin products in future. New arrangements were in place on June 1, 2007.

The Demand Management Programme

The Demand Management Programme is a three-part initiative that consists of:

1. *The Demand Management Plan*. This Demand Management Plan outlines actions for Trusts and the procedures to be implemented in times of shortages.
2. *National Clinical Guidelines for Immunoglobulin Use.* The guidelines provide guidance on appropriate use of immunoglobulin and a framework for the promotion of evidence-based clinical practice.
3. *National Immunoglobulin Database.* (Reference No. ROCR/OR/0221). The database forms an integral part of demand management and will support long-term planning, predicting future use and improving consistency in standards of care. In conjunction with the Model Commissioning Policy, it also provides a means for consistent funding in all geographical areas.

Objective of the programme

The objective of the programme is to make immunoglobulin available for all essential infusions to patients, regardless of geographical location. Once implemented, the programme will ensure that:

- The most appropriate cases receive the supply in times of shortage
- An appropriate supply-demand balance is maintained so that the effect of shortages on patient health is minimised
- Immunoglobulin use is understood, which will improve Trust forecasting and patient care

Expert Working Group for the national Demand Management Programme

The DH appointed an immunoglobulin Expert Working Group in August 2006 to formulate the national Demand Management Programme. The group remains active

and includes hospital pharmacists, clinical experts and prescribers of therapeutic immunoglobulin, other stakeholders including patient groups and members of DH (see Clinical Guidelines for membership). The group consulted widely with additional stakeholders including commissioners, prescribers, patient groups and medical colleagues in the formulation of the Programme.

Update of the national Demand Management Programme

A commitment was made at the launch of the national Demand Management Programme to update the Demand Management Plan and the National Clinical Guidelines on an annual basis for 2 years and regularly thereafter. To ensure widespread, effective and transparent consultation, the decision was taken by the DH to formalise the review process in 2008. Interested bodies registered as Stakeholders (see Appendix 4 of the National Clinical Guidelines for list), and provided comments on the documents, which were reviewed by the Expert Working Group and appropriate changes made to the documents. Stakeholder comments and the Expert Working Group response were published (www.intravenousimmunoglobulin.org) in late-May 2008. This second edition of the Demand Management Plan was published by the DH on May 30th 2008.

Principles of demand management of immunoglobulin

Therapeutic immunoglobulins should always be used appropriately and alternatives considered. These recommendations should be followed even when there is ample supply of immunoglobulin.

For its successful implementation the policy depends upon some basic principles:

1. Immunoglobulin products must be available at all times.
2. Use must be safe and effective.
3. Arrangements apply mainly to intravenous immunoglobulin since subcutaneous products have only been shown to be effective as replacement therapy.
4. In view of the unknown risks of changing products, the current national policy for keeping maintenance patients on a single product will remain.
5. General Practitioners should not prescribe immunoglobulin; prescribing should be restricted to the specialist responsible for the patient's treatment.

DEMAND MANAGEMENT PLAN

This Demand Management Plan supersedes previous DH arrangements for managing immunoglobulin usage and shortages.

Objectives

- To categorise the indications for immunoglobulin treatment to simplify use on an evidence basis
- To identify priority patients to allow timely and uninterrupted supply
- To provide a process for Trusts to ensure availability for priority patients
- To provide a mechanism for supply continuity in times of shortages
- To simplify and standardise funding mechanisms by documenting all use of immunoglobulin for Trusts and Commissioners

Recommended actions before prescribing

Before prescribing immunoglobulin, clinicians should understand:

1. The colour coding of treatment indications presented in this document and in the National Clinical Guidelines.
2. The process by which their local Immunoglobulin Assessment Panel will approve treatment with immunoglobulin.

Colour coding of treatment indications

As part of demand management, a classification of immunoglobulin indications has been introduced. This provides the mechanism to be used for prioritisation and is clearly presented in the National Clinical Guidelines' recommendations. It also identifies the prescribing approval process that should be followed for every patient (see Table 1).

Red signifies a disease for which treatment is considered the highest priority because of a risk to life without treatment.

Blue indicates a disease for which there is a reasonable evidence base but where other treatment options are available. Since not all patients are responsive to immunoglobulin, proof of efficacy in a given patient is required for long-term therapy. The use of immunoglobulin in these indications should be modified in times of shortage.

Grey indications are those for which the evidence base is weak, in many cases because the disease is rare; IVIg treatment should be considered on a case-by-case basis, prioritised against other competing demands

Table 1: ***Colour coding of immunoglobulin treatment indications***

Indication colour	Prescribing of immunoglobulin	Approval process
Red	Available at all times because of risk to life	Automatic approval
Blue	Treatment for patients in whom alternative therapies have been used where appropriate. Proven efficacy for long-term therapy. Reduced use in times of shortage	Panel approval required
Grey	To be considered on a case-by-case basis only	Panel and PCT funding approval required
Black	Not recommended	Automatic rejection

for immunoglobulin, especially in times of shortage. Rare diseases or clinical scenarios not listed in the guidelines will be considered as grey indications.

Black indications are those for which there is evidence to suggest immunoglobulin is not an appropriate treatment and treatment is not recommended; these are listed separately in the clinical guidelines.

Prescribing approval process

The prescribing approval process is outlined in Figure 1.

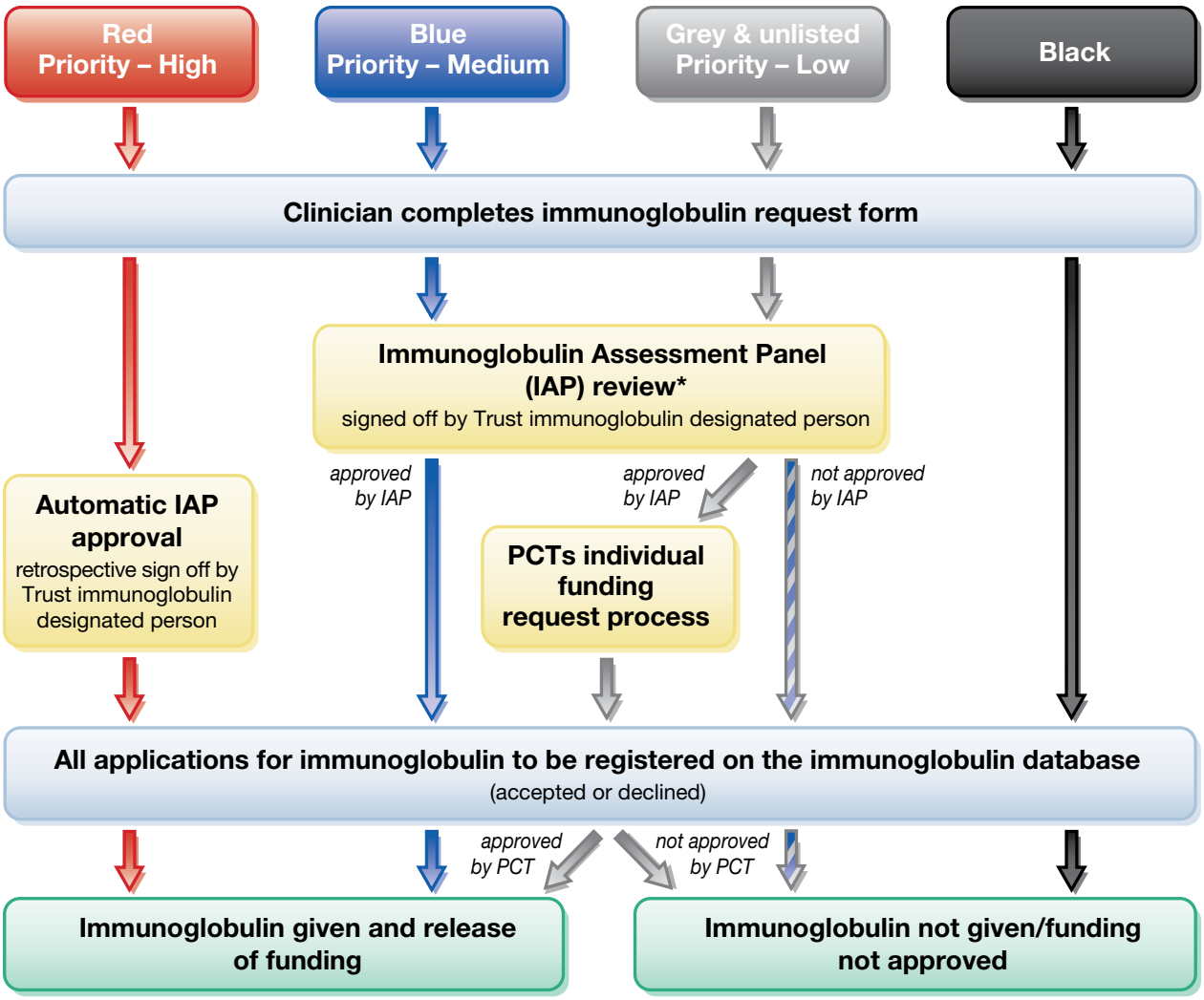
Red: Immunoglobulin Assessment Panel approval is automatic for acute treatment. Access is guaranteed in times of shortage.

Blue: Immunoglobulin Assessment Panel approval is required for all treatment. In emergency cases, prescribing must be sanctioned by at least two panel members independent of the request. Evidence of efficacy in a given patient will be needed for long-term therapy. In times of shortage, prescribing must be reduced with emphasis on alternative treatments.

Grey: Immunoglobulin treatment will be considered by the Immunoglobulin Assessment Panel on a case-by-case basis. Treatment requests agreed by the panel require further approval by the PCT funding request panel. These indications have the lowest priority in times of shortage.

Black: Immunoglobulin treatment is automatically declined. However, exceptionality

Figure 1. ***Immunoglobulin prescribing approval process***



*Number of panel members required to approve indications depends on urgency and local policy

can be applied and a form must be completed for panel consideration.

Exceptionality: For treatment requests that fall outside these definitions, a funding request sanctioned by the local Immunoglobulin Assessment Panel can be made to the local Commissioner for consideration before treatment.

Patients who are already self-infusing therapeutic immunoglobulin at home are excluded from limitation in times of shortages. These patients have been trained to treat

themselves at home and will have already had a thorough risk assessment. However, they should be reviewed at least annually in line with good clinical practice and clinical guidelines for home therapy patients.

Likewise, this Demand Management Plan and the National Clinical Guidelines will be reviewed regularly. If new evidence becomes available that supports or refutes the efficacy of immunoglobulin for a given indication, the guidelines will be updated appropriately.

Recommended actions for Trusts/ Strategic Health Authorities (as appropriate):

Establish a local immunoglobulin assessment panel

Trusts or Strategic Health Authorities (SHAs) should establish a local Immunoglobulin Assessment Panel in conjunction with local Commissioners and pharmaceutical advisors, to agree a local policy based on the National Clinical Guidelines, to approve applications and monitor use of immunoglobulin, either at the Trust level or the SHA level.

All prescribing staff should be aware of the Immunoglobulin Assessment Panel's existence and be willing to accept that the decision-making process, however difficult, is necessary to ensure those patients for whom there are no alternative therapies continue to be supplied in times of shortage.

The most appropriate type of Immunoglobulin Assessment Panel should be established, dependent on local needs. Some SHAs already have a local Panel to ensure that immunoglobulin usage is appropriate; such arrangements are likely to remain. Trusts may wish to use existing committees, such as the Drugs and Therapeutics Committee or the Area Prescribing/Medicine Management Committee, to reduce the amount of work necessary, to establish additional structures and to prevent an increase in unnecessary bureaucracy.

Examples of types of Immunoglobulin Assessment Panel, which have been successful, are:

- Single Trust Panel in conjunction with a representative of the lead PCT (e.g. PCT pharmaceutical advisor) may utilise current panels
- Multi-trust Panel in conjunction with a representative of the lead PCT or lead Commissioner (e.g. PCT pharmaceutical advisor); may be helpful where there is one teaching hospital with nearby DGHs

Panel membership

Regardless of the panel type, membership should be agreed by key medical staff and Commissioners. Local policies should have input from:

- PCTs
- Specialised services Commissioner
- Medical Director or representative
- Lead clinicians in specialties prescribing immunoglobulin
- Consultants in Public Health

It is recommended that Panels include:

- PCT/specialised services Commissioner representatives (e.g. pharmaceutical advisors)
- Independent chairman e.g. consultant in Public Health
- Clinicians from specialties using immunoglobulin, usually clinical immunology, intensive care, transplantation, haematology, neurology, obstetric medicine, infectious disease, rheumatology and paediatrics
- Pharmacist
- Appropriate specialty nurse

Specialist Commissioners within the Trust/SHA area may wish to be part of the Immunoglobulin Assessment Panel. With a Model Commissioning Policy in place for immunoglobulin, Commissioners may not wish to attend all Immunoglobulin Assessment Panel meetings but oversee the process through review of meeting minutes.

Recommended panel actions

1. Elect a Chairperson.
2. Establish a local policy to implement the Demand Management Plan and manage the appropriate use of immunoglobulin.
3. The Chairperson should oversee all immunoglobulin requests and report decisions to Commissioners.
4. Review and approve applications for initial immunoglobulin therapy for individual patients according to this Demand Management Plan and The National Clinical Guidelines.
5. Respond to shortage situations. The Immunoglobulin Assessment Panel should be in communication with the DH concerning supply risks and the national mechanism for managing supplies of immunoglobulin at times of shortage. Any interruption to the supply chain for patients with Red indications should be notified as a serious untoward incident to both the DH and the local Commissioner. All shortages will be advertised on the National Immunoglobulin

Database and the website. The Chairperson should register the panel with Medical Data Solutions and Services (MDSAS), who will inform panels of emergency shortages.

6. Monitor and review Trust usage. Immunoglobulin Assessment Panels should ensure that complete datasets are provided to the National Immunoglobulin Database and review the reports provided annually by DH.
7. The Immunoglobulin Assessment Panel should undertake local audit of their decisions.
8. Local policies should be reviewed to reflect updates to the National Clinical Guidelines and in the light of the annual audit of immunoglobulin usage within Trusts.

Commissioning and funding

Development of a national Commissioning Policy Framework has been in progress since 2007. In March 2008, the National Specialised Commissioning Group (NSCG) approved two Model Commissioning Policies on the provision of immunoglobulin to (i) high and (ii) medium and low priority patients for use by all SCGs procuring immunoglobulin therapy services.

In addition, the March 2008 NSCG meeting agreed that:

- SCGs should make plans during 2008/09 to commission immunoglobulin services, commencing in 2009/10 wherever possible
- SCGs should work with their PCTs during 2008/09 to implement the Demand Management Plan, including monitoring the Immunoglobulin Assessment Panels, and to utilise the two Model Commissioning Policies on immunoglobulin

SCGs should work with the immunoglobulin assessment panels to ensure transparency and mutual understanding of any local problems.

Research on alternatives to immunoglobulin

The use of effective alternatives to immunoglobulin is an important consideration. One alternative to immunomodulatory doses of immunoglobulin in some situations is plasma exchange. At present, these services are under-developed in many areas. Actions are being taken to achieve greater access and availability, throughout the UK, initially with a new model in London.

There is an urgent need for more planned research to define the precise indications for immunomodulatory immunoglobulin therapy in some diseases. Due to the

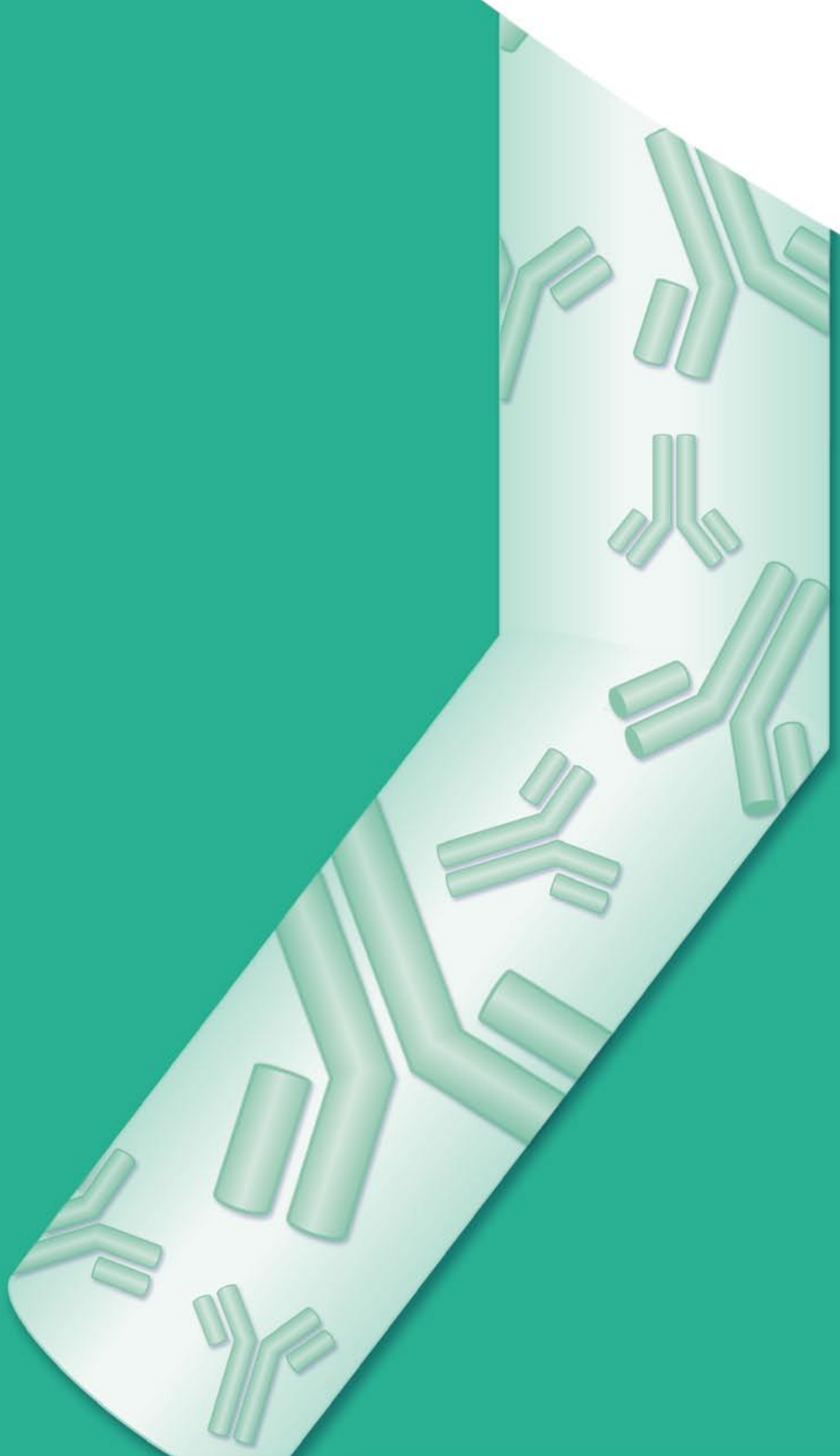
large number of indications with a lack of evidence for immunoglobulin use, rare indications are not included in the National Clinical Guidelines. However, use of immunoglobulin for rare or new indications is at the panel's discretion and commissioner agreement. Trials to enable better prediction of response and persistence of response are a priority for the DH.

Patient communications

Given that immunoglobulin is life saving for certain patients, particularly those with PID diseases, we acknowledge that there may be some concern among patients and their clinicians about the demand management process. Patient leaflets, highlighting the need to control immunoglobulin usage, the value of considering alternative therapies to immunoglobulin because of some of the risks associated with immunoglobulin and the value of the Demand Management Plan in securing provision to those most at need, have been prepared.

These can be accessed at:

www.intravenousimmunoglobulin.org
or
www.dh.gov.uk/prod_consum_dh/idcplg?IdcService=GET_FILE&dID=156655&Rendition=Web



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