NHS

VERSION TWO

Commissioning policy for all treating centres for the provision of intravenous and subcutaneous immunoglobulin to high priority patients

National Specialised Commissioning Group
Model Commissioning Policy

1st July 2008 –30th June 2009

[Insert Organisation; if commissioning under a collaborative arrangement, include 'on behalf of X, Y etc. PCT']

Commissioning policy for IMMUNOGLOBULIN USE

VERSION TWO

Red Indications

National Specialised Commissioning Group

Taken from Clinical Guidelines for the Use of Intravenous Immunoglobulin, Department of Health, May 2008 (2nd Edition)

2nd of 2 related documents

1. Introduction

1.1. This policy shall cover the period [date] to [date].

1.2. The policy provides the framework for the provision and supply of intravenous and subcutaneous immunoglobulin (IVIG/SCIG) to those patients with the highest priority.

1.3. It is recognised that immunoglobulin is provided to the patient as a result of a partnership between a number of organisations:

Organisation	Roles and responsibilities
Providers	Clinical management of patient, initiation of funding requests and prescribing of IVIG/SCIG
Commissioners	Commissioning IVIG/SCIG, home delivery services and community administration of IVIG/SCIG
Home Delivery Services	Providing IVIG/SCIG to patients on long-term treatment
Primary and Community services	Supervising infusions when necessary and providing clinical support under shared care protocols

2. The aim of this policy

The aim of this commissioning policy is to ensure that there is timely and uninterrupted provision of IVIG/SCIG to an agreed set of patients who have life-threatening conditions for whom IVIG/SCIG is either the only or the first-line option for treatment.

3. Designated IVIG/SCIG responsible person

Any hospital in which IVIG/SCIG is prescribed should have a designated responsible person whose role it is:

- To ensure that this commissioning policy is operated by all clinicians within the provider trust
- To sign off funding requests for IVIG/SCIG to confirm that they comply with this commissioning policy
- [Insert a list of designated responsible persons for local providers]

4. Key specifications

4.1 All applications for funding, even when retrospectively applied for, must be approved by the provider trust's designated IVIG/SCIG responsible person.

4.2 All new patients must be logged with the national IVIG/SCIG Database and their data provided as required. Existing patients must be logged during the next 12 months.

5. The commissioning policy

5.1 This commissioning policy only applies to Red indications which comprise conditions for which there is good evidence of benefit and where IVIG/SCIG is considered life saving. These are listed under 5.2. Other indications are covered by a separate commissioning policy.

5.2 Patients with the following conditions will be treated with IVIG/SCIG:

5.2.1 Short-term treatment

5.2.1.1 Patients with primary immunodeficiencies

5.2.1.2 Alloimmune thrombocytopenia – foetal therapy (treatment to the mother)

5.2.1.3 Alloimmune thrombocytopenia – neonatal therapy

5.2.1.4 Patients with autoimmune thrombocytopenia

5.2.1.5 Patients with low serum Ig levels (<4.0 g/L) following stem cell transplantation for malignancy

5.2.1.6 Patients with a probable or definite diagnosis of severe chronic inflammatory demyelinating polyneuropathy +/- IgA or IgG paraprotein and for whom other treatments are contraindicated

5.2.1.7 Patients with dermatomyositis whose disease is resistant to corticosteroids and immunosuppressants or those requiring hospitalisation with involvement of respiratory and bulbar musculature

5.2.1.8 Patients with severe Guillain-Barré syndrome

5.2.1.9 Patients with toxic epidermal necrolysis/Stevens-Johnson syndrome in whom other treatment is contraindicated

5.2.1.10 For adults with severe idiopathic thrombocytopenic purpura and who have a platelet count <30x10^9/L

5.2.1.11 As an emergency treatment for adults and children under the age of 16 with severe idiopathic thrombocytopenic purpura

5.2.1.12 As prophylaxis for children under the age of 16 who have idiopathic thrombocytopenic purpura and who are under going procedures likely to induce bleeding

5.2.1.13 Patients with Kawasaki disease

5.2.1.14 Juvenile dermatomyositis

5.2.1.15 Patients with CMV-induced pneumonitis following transplantation

5.2.2 Long-term treatment

5.2.2.1 Patients with primary immunodeficiencies

6. Quality

6.1 All decisions for short-term treatment will be undertaken by a consultant who has specialist knowledge of the use of IVIG/SCIG. This consultant will have ongoing responsibility for IVIG/SCIG prescribing until treatment is stopped.

6.2 All decisions relating to long-term treatment for primary immunodeficiencies will be undertaken by an immunologist. This consultant will have ongoing responsibility for IVIG/SCIG prescribing until treatment is stopped.

6.3 It is expected that all patients receiving long-term treatment will do so through one of the home care delivery schemes that are in operation unless there are clinical contraindications.

6.4 It is expected that, where clinically appropriate, subcutaneous delivery will be considered.

6.5 It is expected that, where clinically appropriate, cost minimisation will be applied.

6.6 Patients on long-term treatment will be required to have an annual review of their treatment.

6.7 For patients who receive treatment on a shared care basis:

- The specialist clinical team initiating treatment will retain overall clinical responsibility for the management of the patient including the prescribing of IVIG/SCIG and the annual review
- The specialist clinical team has the responsibility for ensuring that a satisfactory shared care arrangement is in place between itself and any local provider or community based service
- Providers should ensue that patients understand the precise nature of the shared care arrangements including which person to contact when problems arise

6.8 There will be no GP prescribing of these treatments.

6.9 The specialist clinical team responsible for prescribing will be expected to monitor communications from the Department of Health concerning any risks to supply and understand the mechanism for managing supplies of IVIG/SCIG at times of shortages.

6.10 Any failure to access stock due to interruption in the supply chain for patients with Red indications should be notified as a serious untoward incidence to both the Department of

Health and the commissioner.

6.11 Centres are expected, ***without exception***, to provide a complete dataset to the Department of Health IVIG/SCIG Database in line with information requests from the team overseeing the IVIG/SCIG Database. This will be monitored and ongoing failure to provide data may lead to penalty payments.

6.12 Developments in healthcare

The provider will notify the commissioner at an early stage of any change in the use of IVIG/SCIG that has resource implications.

All new indications for IVIG/SCIG will only be considered through a national process overseen by the National Specialised Commissioning Group (NSCG) on an annual basis.

In-year expansion to the list of Red indications will not normally be considered.

7.0 Decision-making protocol

7.1 No prior approval is required before commencing treatment for Red indications. However funding will not be released until all required information has been received and the application has been signed by the designated IVIG/SCIG responsible person. The information MUST include an IVIG/SCIG Database number.

7.2 [Insert local arrangements for dealing with funding requests and to whom they should be directed. Where funding has been put into contracts and does not occur on a case-by-case basis, the commissioner will have to agree locally how compliance and registration with the national IVIG/SCIG Database will be monitored.]

7.3 Requests for release of funding for new patients should be done by forwarding a photocopy of the front sheet of the national database form (Figure 1).

8.0 Mechanism of funding

8.1 The PCT responsible for funding of IVIG/SCID is identified by the General Practitioner's post code.

8.2 [It is recommended that the following monthly or quarterly monitoring requirements are required in order to track usage. A regular dataset might include:

- Database ID number
- Patient initials
- NHS Number
- PCT code
- Drug and dose
- Notification of changes to drugs and dosage
- Take-off date
- Reason for take off
- Monthly cost
- Annual cost

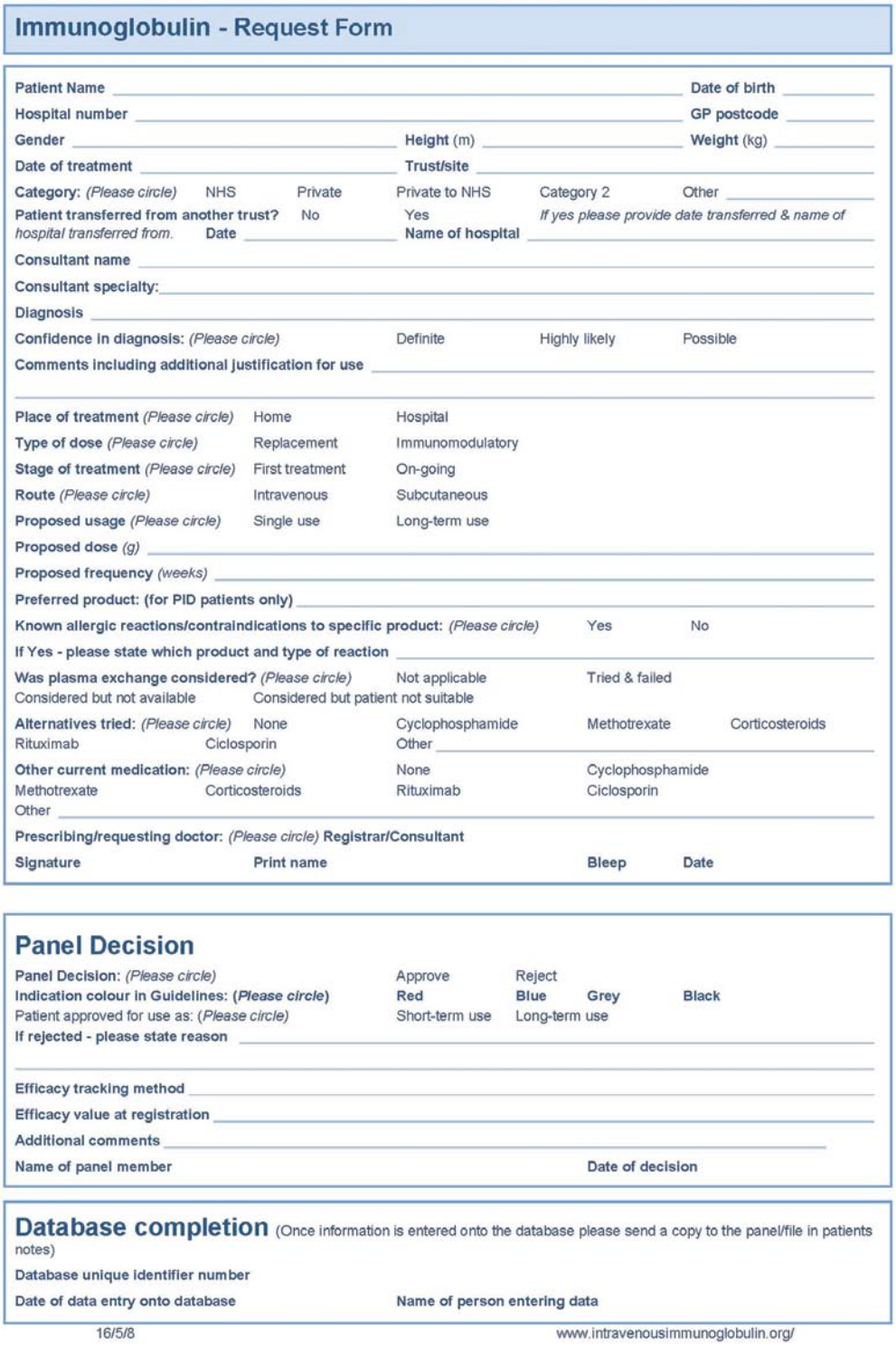
9. [Annual reporting]

[Insert performance management requirements]

10. Review of the Commissioning Policy

This commissioning policy will be reviewed annually by a National IVIG/SCIG Working Group set up under the auspices of the NSCG. Recommendations of changes will be put to primary care trusts through the NSCG. Any additional conditions will have to be considered as part of the annual commissioning round.

Commissioning contact for PCTs and SCTs: daphne.austin@wmsc.nhs.uk



Immunoglobulin - Request Form

Patient Name _____ **Date of birth** _____
Hospital number _____ **GP postcode** _____
Gender _____ **Height** (m) _____ **Weight** (kg) _____
Date of treatment _____ **Trust/site** _____
Category: *(Please circle)* NHS Private Private to NHS Category 2 Other _____
Patient transferred from another trust? No Yes *If yes please provide date transferred & name of hospital transferred from.* **Date** _____ **Name of hospital** _____
Consultant name _____
Consultant specialty: _____
Diagnosis _____
Confidence in diagnosis: *(Please circle)* Definite Highly likely Possible
Comments including additional justification for use _____

Place of treatment *(Please circle)* Home Hospital
Type of dose *(Please circle)* Replacement Immunomodulatory
Stage of treatment *(Please circle)* First treatment On-going
Route *(Please circle)* Intravenous Subcutaneous
Proposed usage *(Please circle)* Single use Long-term use
Proposed dose *(g)* _____
Proposed frequency *(weeks)* _____
Preferred product: (for PID patients only) _____
Known allergic reactions/contraindications to specific product: *(Please circle)* Yes No
If Yes - please state which product and type of reaction _____
Was plasma exchange considered? *(Please circle)* Not applicable Tried & failed Considered but not available Considered but patient not suitable
Alternatives tried: *(Please circle)* None Cyclophosphamide Methotrexate Corticosteroids Rituximab Ciclosporin Other _____
Other current medication: *(Please circle)* None Cyclophosphamide Methotrexate Corticosteroids Rituximab Ciclosporin Other _____
Prescribing/requesting doctor: *(Please circle)* **Registrar/Consultant**
Signature **Print name** **Bleep** **Date**

Panel Decision

Panel Decision: *(Please circle)* Approve Reject
Indication colour in Guidelines: (*Please circle*) **Red** **Blue** **Grey** **Black**
Patient approved for use as: *(Please circle)* Short-term use Long-term use
If rejected - please state reason _____
Efficacy tracking method _____
Efficacy value at registration _____
Additional comments _____
Name of panel member **Date of decision**

Database completion (Once information is entered onto the database please send a copy to the panel/file in patients notes)

Database unique identifier number
Date of data entry onto database **Name of person entering data**

16/5/8 www.intravenousimmunoglobulin.org/

Figure 1. Immunoglobulin Request Form

All entries should be complete, including the database number. The trust's designated IVIG/SCIG responsible person should sign the form.