Immunoglobulin Policy
<table>
<thead>
<tr>
<th>Policy Title:</th>
<th>East Cheshire NHS Trust Immunoglobulin Policy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Executive Summary:</td>
<td>This policy aims to govern the use of Immunoglobulin to ensure appropriate prescribing and supply to safeguard the future supplies of Immunoglobulins. This Policy follows Department of Health Guidelines.</td>
</tr>
<tr>
<td>Supersedes:</td>
<td>Version 4</td>
</tr>
</tbody>
</table>
| Description of Amendment(s): | Change of process – changes to National database submissions only  
                        | Change of documentation  
                        | Change of guidance  
                        | Change of Appendix 8 – Infusion guidance |
| This policy will impact on: | All Medical staff that treat patients with Immunoglobulin.  
                        | Pharmacy Staff |
| Financial Implications: | Ensure cost effective prescribing |
| Policy Area:       | Pharmacy                                      |
| Version Number:    | 4                                             |
| Issued By:         | Consultant Haematologist                      |
| Author:            | Pharmacy Operational Manager                  |
| Impact Assessment Date: | 17 Aug 2018                                    |
| APPROPVAL RECORD   |                                               |
| Committees / Group | Date                                          |
| Consultation:      | Medicines Management Group  
|                     | Specialist Advice  
| Approved by Director: | Medical Director  
                        | April 2016 |
| Received for information: | Trust SQS Committee  
                        | April 2016 |
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1 Introduction

1.1 Policy statement
This policy is to ensure the Trust follows the Department of Health guidance for prescribing and supplying Immunoglobulins. Full compliance with this policy will ensure the appropriate usage and safeguard the future availability of Immunoglobulins.

1.2 Audit
East Cheshire NHS Trust recognises its responsibility to assess practice in adherence to all trust policies. Compliance with this policy will be audited each year.

1.3 Training
Training will be provided to the Pharmacy Operational Manager to ensure the National Database is populated correctly.

1.4 Organisational Responsibilities
1.4.1 Chief Executive
Has ultimate responsibility for the implementation and monitoring of the policies in use in the Trust. This responsibility may be delegated to an appropriate colleague.

1.4.2 Medical Director
Has Trust Board responsibility for all aspects of medicines management. The Medical Director is responsible for reporting any medicines management issues identified to the Trust Board.

1.4.3 Chair of Medicines Management Group (MMG)
The Chair of the Medicines Management Group has responsibility for co-ordinating the activities of the Medicines Management Group to ensure that good practice relating to medicines becomes embedded in to everyday working practice across the Trust. The Chair will raise any medicines management issues at the SQS Committee.

1.4.4 Service Lines
It is the responsibility of the Heads of Service of all Departments within Service Lines to ensure that this policy is used appropriately and that appropriate staff are trained to carry out the tasks required of them in working under the guidance in this policy.

1.4.5 Consultant Medical Staff
Consultant medical staff have responsibility for initiating therapy in accordance with this policy, and must confirm the appropriateness of therapy with the consultant haematologist. They must also ensure the first section of the Immunoglobulin request form is completed and submitted to Pharmacy with the prescription.

1.4.6 Consultant Haematologist
The consultant haematologist must approve all usage of immunoglobulins in line with this policy. If the consultant haematologist wishes to initiate therapy, he must confirm the treatment is appropriate with a senior pharmacy manager first.
1.4.7 Pharmacy staff
The pharmacy staff must ensure appropriate approval has been given and paperwork completed before immunoglobulin is dispensed. The Pharmacy Operational Manager will ensure all issues are recorded on the National Database as well as completing the quarterly Dashboards for the National Database submissions.

1.5 Planning and Implementation
- This policy has been circulated to the members of the Medicines Management Group and the following for specialist advice.
  - Dr Monty Silverdale, Consultant Neurologist
  - Dr Guy Hayhurst, Consultant in Public Health
  - Dr Gail Whitehead, Consultant Paediatrician
  - Dr John Hudson, Consultant Haematologist
- The policy will be uploaded onto the Trust internet and an email containing a link to the policy will be sent to all staff. Awareness will be raised through discussion at OCF.

1.6 Measuring Performance
The Trust will be measured for its performance in Medicines Management, and may be measured for compliance with NHSLA standard C4d, and by the Care Quality Commission. The IGG database produces a quarterly dashboard for Trust performance on behalf of NHS England. The Dashboard submission must be completed by the Pharmacy Operational Manager to NHS England when requested to do so.

1.7 Legislation
This policy follows the guidance issued by the Department of Health relating to the National Immunoglobulin Database, May 2008.

1.8 Review
This policy will be reviewed and up-dated every 3 years, and approved by the Medicines Management Group.

1.9 Dignity, Equality and Diversity
This policy has been impact assessed with regards to dignity, equality and diversity and there are no areas in the policy that contravene equality and diversity guidance – see appendix 1.
2 Background

The Department of Health issued the document ‘National Immunoglobulin Database’ in May 2008 to provide guidance and instruction to safeguard the future supply of Immunoglobulins. A National Database to monitor the usage of Immunoglobulins has been in place since June 2008. The Trust must have in place an expert panel, i.e. the Medicines Management Group, to govern the use of immunoglobulin. This Group will ensure the Trust has a system in place whereby the need to prescribe immunoglobulin is confirmed by an appropriate person such as the Consultant Haematologist, and the prescribing and supply of immunoglobulin is correctly recorded and reviewed.

3 Review of Immunoglobulin Therapy

3.1 A report on the usage of Immunoglobulins over the previous 12 months will be produced by the Dispensary Services Manager and submitted to the Medicines Management Group in April / May each year.

3.2 All long term patients who are receiving on-going therapy should be reviewed by the Consultant Haematologist to ensure this is still appropriate. This must be recorded on the database.

4 Approval to Prescribe Immunoglobulin

4.1 Immunoglobulin therapy should be initiated by consultants only (prescribing may be delegated to SPRs) via an MDT.

4.2 The ‘Summary of recommendations – National Clinical Guidelines for Immunoglobulin Use (Update to Second Edition), July 2011 (see Appendix 3) has a colour coded guide for the conditions treated with Immunoglobulin. Appendix 2 shows the approval process for the supply of Immunoglobulins, and Appendix 3 has a colour coded table illustrating the recommendations for Immunoglobulin use.

4.3 Prior to initiating therapy, the consultant who wishes to start therapy must discuss the use of Immunoglobulin with the Consultant Haematologist (IVIG/SCIG responsible person) and confirm it is an appropriate indication. If it is the Consultant Haematologist who wishes to initiate therapy – he / she must discuss the use with a senior pharmacy manager to confirm an appropriate indication. N.B. Prescribing for conditions classed as “Grey” or “Black” will also require an individual funding request to be approved from the commissioner (NHS England). This process will need approval via the Pharmacy Medicines Management team see Appendix 7 SSC 1539 (which describes the process in detail)

4.4 Approval for Initiation and review of immunoglobulin therapy for East Cheshire patients with neurological conditions will be undertaken by an expert panel at Hope Hospital.

4.5 The prescribing consultant must then complete the Clinical Request form (Appendix 4) electronically and send this electronically to the Pharmacy Operational Manager as well as attaching a hard copy to the prescription to facilitate the supply from Pharmacy.
4.6 The National IGG Database guidance for treating Red, Blue, Grey and Black indications are available by accessing the following link; http://www.ivig.nhs.uk and for the Summary indication table, see Appendix 3.

4.7 Follow up supplies will only be issued when a Follow up form is completed by the prescriber electronically and a hard copy printed and sent with the prescription to Pharmacy for supply.

4.8 The Pharmacy Department must not dispense the Immunoglobulin until the indication has been approved by a senior pharmacy manager and the Clinical request form or Follow up form (for further supplies) has been supplied.

4.9 The Infusion guidance for administration of Immunoglobulin is attached to this policy see Appendix 8.

4.10 The infusion detail must be recorded on the Infusion sheet see Appendix 6 electronically on the – Pharmacy shared drive – Office – Immunoglobulin infusions. This detail is then added to the IGG database by the Pharmacy Operational Manager at the end of each month.
5 Conditions where Treatment is considered to be of the Highest Priority

5.1 A supply of Immunoglobulin for the following clinical conditions, where it is identified there is an urgent need to start the therapy, may be made without prior discussion with the Consultant Haematologist (IVIG/SCIG responsible person):

<table>
<thead>
<tr>
<th>Immunology</th>
<th>Kawasaki Disease</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Primary Immunodeficiencies</td>
</tr>
<tr>
<td>Haematology</td>
<td>Alloimmune Thrombocytopenia – fetal therapy (mother)</td>
</tr>
<tr>
<td></td>
<td>Alloimmune Thrombocytopenia – neonatal therapy</td>
</tr>
<tr>
<td></td>
<td>Autoimmune Thrombocytopenia</td>
</tr>
<tr>
<td></td>
<td>Idiopathic Thrombocytopenic Purpura</td>
</tr>
<tr>
<td>Haemato-oncology</td>
<td>Low serum IgG levels following HSCT for malignancy</td>
</tr>
<tr>
<td>Neurology</td>
<td>Chronic Inflammatory Demyelinating Polyradiculoneuropathy</td>
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<tr>
<td></td>
<td>Dermatomyositis</td>
</tr>
<tr>
<td></td>
<td>Guillain-Barre Syndrome</td>
</tr>
<tr>
<td></td>
<td>Paraprotein-associated Demyelinating Neuropathy (IgG or A)</td>
</tr>
<tr>
<td>Dermatology</td>
<td>Dermatomyositis</td>
</tr>
<tr>
<td></td>
<td>Toxic Epidermal Necrolysis, Steven’s Johnson Syndrome</td>
</tr>
<tr>
<td>Paediatrics</td>
<td>Alloimmune Thrombocytopenia – neonatal therapy</td>
</tr>
<tr>
<td></td>
<td>Idiopathic Thrombocytopenic Purpura (&lt;16 years old)</td>
</tr>
<tr>
<td></td>
<td>Neonatal Jaundice (to try &amp; stave off exchange transfusion whilst giving multiple phototherapy).</td>
</tr>
<tr>
<td>Paediatric Rheumatology</td>
<td>Juvenile Dermatomyositis</td>
</tr>
<tr>
<td></td>
<td>Kawasaki Disease</td>
</tr>
<tr>
<td>Adult rheumatology</td>
<td>Dermatomyositis</td>
</tr>
<tr>
<td>Transplantation</td>
<td>CMV induced Pneumonitis following transplantation</td>
</tr>
</tbody>
</table>

5.2 In these cases, therapy must be initiated by a consultant (prescribing responsibilities may be delegated).

5.3 The consultant must still provide a Clinical Request form however this may be completed retrospectively.
6 Dispensing of Immunoglobulin from Pharmacy

6.1 Prior to dispensing Immunoglobulin Pharmacy staff must ensure they have all the relevant information detailed above. When dispensing immunoglobulin, the dispenser should record the batch number and expiry date on the label so that this information can be recorded on the immunoglobulin database.

6.2 When issuing Immunoglobulin the Pharmacist must ensure clear guidance is provided for the nursing staff for the administration of the therapy – including details of the infusion rate see Appendix 8 of this policy.

6.3 If a request is made for Immunoglobulin ‘out of hours’ to the on-call pharmacist – the requesting consultant should be referred to this policy.

6.3.1 If the request for Immunoglobulin is to treat a condition listed in 5.1 above, a supply can be made. This request will be followed up the following day where the appropriate request form must be submitted.

6.3.2 If the request for Immunoglobulin is to treat a condition not listed in 5.1 above, a supply will not be made. This request will be followed up the following day when the appropriate approval can be provided.

6.3.3 The infusion detail must be recorded on the Infusion sheet see Appendix 6 electronically on the – Pharmacy shared drive – Office – Immunoglobulin infusions. This detail is then added to the IGG database by the Pharmacy Operational Manager at the end of each month.
Appendix 1 - Equality and Human Rights Policy Screening Tool

Equality Analysis (Impact assessment)

Please START this assessment BEFORE writing your policy, procedure, proposal, strategy or service so that you can identify any adverse impacts and include action to mitigate these in your finished policy, procedure, proposal, strategy or service. Use it to help you develop fair and equal services.

E.g. If there is an impact on Deaf people, then include in the policy how Deaf people will have equal access.

1. What is being assessed?

| East Cheshire NHS Trust Immunoglobulin Policy |

Details of person responsible for completing the assessment:

- Kashif Haque
- Chief Pharmacist and Clinical Director
- Service Line 2, M.D.G.H.

State main purpose or aim of the policy, procedure, proposal, strategy or service:

(usually the first paragraph of what you are writing. Also include details of legislation, guidance, regulations etc which have shaped or informed the document)

The Department of Health issued the document ‘National Immunoglobulin Database’ in May 2008 to provide guidance and instruction to safeguard the future supply of Immunoglobulins. A National Database to monitor the usage of Immunoglobulins has been in place since June 2008. The Trust must have in place an expert panel, i.e. the Medicines Management Group, to govern the use of immunoglobulin. This Group will ensure the Trust has a system in place whereby the need to prescribe immunoglobulin is confirmed by an appropriate person such as the Consultant Haematologist, and the prescribing and supply of immunoglobulin is correctly recorded and reviewed.

2. Consideration of Data and Research

To carry out the equality analysis you will need to consider information about the people who use the service and the staff that provide it. Think about the information below – how does this apply to your policy, procedure, proposal, strategy or service

2.1 Give details of RELEVANT information available that gives you an understanding of who will be affected by this document

Cheshire East (CE) covers Eastern Cheshire CCG and South Cheshire CCG. Cheshire West & Chester (CWAC) covers Vale Royal CCG and Cheshire West CCG. In 2011, 370,100 people resided in CE and 329,608 people resided in CWAC.

**Age:** East Cheshire and South Cheshire CCG’s serve a predominantly older population than the national average, with 19.3% aged over 65 (71,400 people) and 2.6% aged over 85 (9,700 people).

Vale Royal CCGs registered population in general has a younger age profile compared to the CWAC average, with 14% aged over 65 (14,561 people) and 2% aged over 85 (2,111 people).

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Chief Pharmacist, Aug 2016
Since the 2001 census the number of over 65s has increased by 26% compared with 20% nationally. The number of over 85s has increased by 35% compared with 24% nationally.

Race:
- In 2011, 93.6% of CE residents, and 94.7% of CWAC residents were White British
- 5.1% of CE residents, and 4.9% of CWAC residents were born outside the UK – Poland and India being the most common
- 3% of CE households have members for whom English is not the main language (11,103 people) and 1.2% of CWAC households have no people for whom English is their main language.

Gender: In 2011, c. 49% of the population in both CE and CWAC were male and 51% female. For CE, the assumption from national figures is that 20 per 100,000 are likely to be transgender and for CWAC 1,500 transgender people will be living in the CWAC area.

Disability:
- In 2011, 7.9% of the population in CE and 8.7% in CWAC had a long term health problem or disability
- In CE, there are c.4500 people aged 65+ with dementia, and c.1430 aged 65+ with dementia in CWAC. 1 in 20 people over 65 has a form of dementia
- Over 10 million (c. 1 in 6) people in the UK have a degree of hearing impairment or deafness.
- C. 2 million people in the UK have visual impairment, of these around 365,000 are registered as blind or partially sighted.
- In CE, it is estimated that around 7000 people have learning disabilities and 6500 people in CWAC.
- Mental health – 1 in 4 will have mental health problems at some time in their lives.

Sexual Orientation:
- CE - In 2011, the lesbian, gay, bisexual and transgender (LGBT) population in CE was estimated at18,700, based on assumptions that 5-7% of the population are likely to be lesbian, gay or bisexual and 20 per 100,000 are likely to be transgender (The Lesbian & Gay Foundation).
- CWAC - In 2011, the LGBT population in CWAC is unknown, but in 2010 there were c. 20,000 LGB people in the area and as many as 1,500 transgender people residing in CWAC.

Religion/Belief:
The proportion of CE people classing themselves as Christian has fallen from 80.3% in 2001 to 68.9% in 2011 and in CWAC a similar picture from 80.7% to 70.1%, the proportion saying they had no religion doubled in both areas from around 11%-22%.
- Christian: 68.9% of Cheshire East and 70.1% of Cheshire West & Chester
- Sikh: 0.07% of Cheshire East and 0.1% of Cheshire West & Chester
- Buddhist: 0.24% of Cheshire East and 0.2% of Cheshire West & Chester
- Hindu: 0.36% of Cheshire East and 0.2% of Cheshire West & Chester
- Jewish: 0.16% of Cheshire East and 0.1% of Cheshire West & Chester
- Muslim: 0.66% of Cheshire East and 0.5% of Cheshire West & Chester
- Other: 0.29% of Cheshire East and 0.3% of Cheshire West & Chester
- None: 22.69%of Cheshire East and 22.0% of Cheshire West & Chester
- Not stated: 6.66% of Cheshire East and 6.5% of Cheshire West & Chester
Carers: In 2011, nearly 11% (40,000) of the population in CE are unpaid carers and just over 11% (37,000) of the population in CWAC.

2.2 Evidence of complaints on grounds of discrimination: (Are there any complaints or concerns raised either from patients or staff (grievance) relating to the policy, procedure, proposal, strategy or service or its effects on different groups?)

2.3 Does the information gathered from 2.1 – 2.3 indicate any negative impact as a result of this document?

3. Assessment of Impact

Now that you have looked at the purpose, etc. of the policy, procedure, proposal, strategy or service (part 1) and looked at the data and research you have (part 2), this section asks you to assess the impact of the policy, procedure, proposal, strategy or service on each of the strands listed below.

RACE:
From the evidence available does the policy, procedure, proposal, strategy or service affect, or have the potential to affect, racial groups differently? Yes ☐ No ☒

Explain your response:
Administration should normally be given in line with department of Health guidelines or occasionally based on individual clinical review.

GENDER (INCLUDING TRANSGENDER):
From the evidence available does the policy, procedure, proposal, strategy or service affect, or have the potential to affect, different gender groups differently? Yes ☐ No ☒

Explain your response:
Administration should normally be given in line with department of Health guidelines or occasionally based on individual clinical review

DISABILITY
From the evidence available does the policy, procedure, proposal, strategy or service affect, or have the potential to affect, disabled people differently? Yes ☐ No ☒

Explain your response:
Administration should normally be given in line with department of Health guidelines or occasionally based on individual clinical review

AGE:
From the evidence available does the policy, procedure, proposal, strategy or service, affect, or have the potential to affect, age groups differently? Yes ☐ No ☒
Explain your response:
Administration should normally be given in line with department of Health guidelines or occasionally based on individual clinical review

LESBIAN, GAY, BISEXUAL:
From the evidence available does the policy, procedure, proposal, strategy or service affect, or have the potential to affect, lesbian, gay or bisexual groups differently?  Yes  □  No  x

Explain your response:
Administration should normally be given in line with department of Health guidelines or occasionally based on individual clinical review

RELIGION/BELIEF:
From the evidence available does the policy, procedure, proposal, strategy or service affect, or have the potential to affect, religious belief groups differently?  Yes  x  No  □

Explain your response:
It is a human derived product and so there may be issues with Jehovah’s witnesses in a similar manner to the administration of blood products.

CARERS:
From the evidence available does the policy, procedure, proposal, strategy or service affect, or have the potential to affect, carers differently?  Yes  □  No  x

Explain your response:
Administration should normally be given in line with department of Health guidelines or occasionally based on individual clinical review

OTHER:  EG Pregnant women, people in civil partnerships, human rights issues.
From the evidence available does the policy, procedure, proposal, strategy or service affect, or have the potential to affect any other groups differently?  Yes  □  No  x

Explain your response:
Staff make sure medication appropriate for stage of pregnancy
4. Safeguarding Assessment - CHILDREN

<p>| | |</p>
<table>
<thead>
<tr>
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</thead>
<tbody>
<tr>
<td>a. Is there a direct or indirect impact upon children?</td>
<td>Yes x No □</td>
</tr>
</tbody>
</table>

b. If yes please describe the nature and level of the impact (consideration to be given to all children; children in a specific group or area, or individual children. As well as consideration of impact now or in the future; competing / conflicting impact between different groups of children and young people:

All prescriptions are clinically checked to ensure the appropriate dose and rate of administration. There are limited indications such as Alloimmune thrombocytopenia – neonatal therapy and Idiopathic thrombocytopenic purpura (<16 years old) applicable to paediatrics

c. If no please describe why there is considered to be no impact / significant impact on children

5. Relevant consultation

Having identified key groups, how have you consulted with them to find out their views and that the made sure that the policy, procedure, proposal, strategy or service will affect them in the way that you intend? Have you spoken to staff groups, charities, national organisations etc?

Consultants in paediatrics, neurology and haematology, Medicines Management group.

6. Date completed: 17/3/2015  
Review Date: February 2018

7. Any actions identified: Have you identified any work which you will need to do in the future to ensure that the document has no adverse impact?

<table>
<thead>
<tr>
<th>Action</th>
<th>Lead</th>
<th>Date to be Achieved</th>
</tr>
</thead>
</table>

8. Approval – At this point, you should forward the template to the Trust Equality and Diversity Lead lynbailey@nhs.net

Approved by Trust Equality and Diversity Lead: lynbailey

Date: 27.6.16

Immunoglobulin Policy, Version 5  
Chief Pharmacist, Aug 2016
Appendix 2 – Flow Chart Illustrating the Approval Process for the Supply of Immunoglobulins.

BCP: Bespoke Care Panel
Cons Haem: Consultant Haematologist
## Appendix 3 - Summary of recommendations - National Clinical Guidelines for Immunoglobulin Use (Second Edition), 2011

### Red - High priority
- Alloimmune Thrombocytopenia (Feto-Maternal/Neonatal)
- Chronic inflammatory demyelinating polyradiculoneuropathy
- Guillain-Barré Syndrome
- Haemolytic disease for the newborn
- HSCT in primary immunodeficiencies
- Immune thrombocytopenic purpura (acute and persistent, excluding chronic)
- Kawasaki disease
- Paraprotein - associated demyelinating neuropathy (IgM, IgE or IgA)
- Primary immunodeficiencies
- Specific antibody deficiency
- Thymoma with immunodeficiency
- Toxic epidermal necrolysis, Stevens-Johnson syndrome

*Updated February 2016*

### Blue - Medium priority
- Acquired red cell aplasia
- Autoimmune congenital heart block
- Autoimmune haemolytic anaemia
- Autoimmune uveitis
- Congenital factor deficiencies (coagulation and autonomic)
- Haemophagocytic syndrome
- Hemophagocytic lymphohistiocytosis
- Inflammatory myopathies
- Malignant motor neuropathy
- Myasthenia gravis (including Lambert-Eaton myasthenic syndrome)
- Necrotising (PV - associated) staphylococcal spondylitis
- Post-transplant purpura
- Rasmussen syndrome
- Secondary antibody deficiency (any cause)
- Severe or recurrent Clostridium difficile colitis
- Staphylococcal abscess

### Grey - Low Priority
- Immune-mediated disorders with limited evidence of immunoglobulin efficacy
- Acute disseminated encephalomyelitis (if high dose steroids have failed)
- Autoimmune encephalitis (including NMDA and VGKC antibodies, among others)
- Catastrophic antiphospholipid syndrome
- Cerebral infection with antiphospholipid antibodies
- Chronic idiopathic thrombocytopenia purpura
- CNS Vasculitis
- Complex regional pain syndrome
- Neumonitera
- Intactable childhood epilepsy
- Intestinal malabsorption
- Osseous Myelodysplasia
- Post-exposure prophylaxis for viral or pathogenic infection if intramuscular infections is contraindicated, or treatment when hyper-immune
- Immunoglobulins are unavailable
- Myoclonus

### Black
- Immunodeficiency secondary to pediatric HIV infection
- Autologous BMT
- Adrenoleukodystrophy
- Alzheimer’s disease
- Amyotrophic lateral sclerosis
- Critical illness neuropathy
- Multiple sclerosis
- Rheumatoid arthritis
- Neonatal sepsis (prevention or treatment)
- Sepsis in the intensive care unit not related to specific toxins or C. difficile
- Asthma
- Graves ophthalmopathy/IVF failure
- Recurrent spontaneous pregnancy loss

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**Immunoglobulin Policy, Version 5**  
**Chief Pharmacist, Aug 2016**
### Immunoglobulin Request Form

**Has this patient met the Selection Criteria as prescribed in the Clinical Guidelines Second Edition Update:**

* Fields marked with an asterisk are mandatory for the upload feature  
** Fields marked with a double asterisk are mandatory for a subsequent panel review  
*** For Scottish Centres the CHI number is required and the Trust Id is not mandatory

#### Registration Details:

<table>
<thead>
<tr>
<th>Field</th>
<th>Requirement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient Name</td>
<td></td>
</tr>
<tr>
<td>Trust Id (Hospital Number)</td>
<td>*</td>
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<tr>
<td>Date First Seen (dd/mm/yyyy)</td>
<td></td>
</tr>
<tr>
<td>Date of Birth (dd/mm/yyyy)</td>
<td>*</td>
</tr>
<tr>
<td>Gender</td>
<td>*</td>
</tr>
<tr>
<td>NHS / CHI Number</td>
<td>***</td>
</tr>
<tr>
<td>GP Postcode</td>
<td>or GP Practice Code</td>
</tr>
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<td>Height (m)</td>
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<tr>
<td>Weight (kg)</td>
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</tr>
<tr>
<td>Patient Transferred from other trust</td>
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#### Panel Details:

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<th>Field</th>
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<tbody>
<tr>
<td>Panel Decision</td>
<td>**</td>
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<tr>
<td>Panel Date (dd/mm/yyyy)</td>
<td>**</td>
</tr>
<tr>
<td>If rejected give details</td>
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<tr>
<td>Panel Colour</td>
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<td>Efficacy Tracking Method</td>
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<tr>
<td>Name of Panel Member</td>
<td>**</td>
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<tr>
<td>Next Panel Review Date (dd/mm/yyyy)</td>
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#### Clinical Details:

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<th>Field</th>
<th>Requirement</th>
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<tr>
<td>Consultant Speciality</td>
<td>*</td>
</tr>
<tr>
<td>Consultant/Registrar Name</td>
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</tr>
<tr>
<td>Diagnosis</td>
<td>*</td>
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<tr>
<td>if Other please specify</td>
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<tr>
<td>Confidence in diagnosis</td>
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<tr>
<td>Comments, including additional justification for use:</td>
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<tr>
<td>Secondary Diagnosis</td>
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<td>Secondary Diagnosis Speciality</td>
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<tr>
<td>Was Plasma Exchange Considered?</td>
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<tr>
<td>Alternative Tried Before Ig</td>
<td></td>
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<tr>
<td>if Other please specify</td>
<td></td>
</tr>
<tr>
<td>Current Treatment</td>
<td></td>
</tr>
<tr>
<td>if Other please specify</td>
<td></td>
</tr>
<tr>
<td>Place of Treatment</td>
<td></td>
</tr>
<tr>
<td>Stage of Treatment</td>
<td></td>
</tr>
<tr>
<td>Has the Patient Been Offered Home Care</td>
<td>**</td>
</tr>
<tr>
<td>Has the Patient Been Given Training</td>
<td>**</td>
</tr>
<tr>
<td>Treatment Route</td>
<td></td>
</tr>
<tr>
<td>Proposed Treatment Regime</td>
<td>*</td>
</tr>
<tr>
<td>Dosage Type</td>
<td></td>
</tr>
<tr>
<td>Proposed Dose</td>
<td></td>
</tr>
<tr>
<td>grams every Day(s) for Day(s)</td>
<td></td>
</tr>
<tr>
<td>Proposed Treatment Date</td>
<td></td>
</tr>
<tr>
<td>Preferred Product</td>
<td></td>
</tr>
<tr>
<td>Additional Comments</td>
<td></td>
</tr>
<tr>
<td>Completed By</td>
<td></td>
</tr>
<tr>
<td>Date (dd/mm/yyyy)</td>
<td></td>
</tr>
</tbody>
</table>

** This question is only for Primary Immunodeficiency Conditions

---

**Immunoglobulin Policy, Version 5**

**Chief Pharmacist, Aug 2016**
# Immunoglobulin Database - Follow up Form

## Patients Details:
- **Patient Name:** 
- **Trust Id (Hospital Number):** 
- **NHS/ CHI Number:** 
- **Date of Birth:** 
- **Consultant Name:** 

**Please make sure the Trust ID or CHI Number is completed to locate patient**

## Follow Up Details:
- **Follow up date:** 
- **Treatment state?:** 
- **Has the patient’s GP been notified of any annual review / follow-up:** 
- **Improvement since last follow up?:** 
- **Follow-up outcome?:**

## Follow-up Comments:

## Next Follow up date:

## Signature:

## Print Name:

## Date Completed:

## Database Completion:
(Once information is entered onto the database please send a copy to the panel/file in patients notes)
- **Database patient Identifier:** 
- **Date of data entry onto database:**
  - **Name of person entering data:**
### Immunoglobulin - Infusion / Issue Form

<table>
<thead>
<tr>
<th>Trust ID</th>
<th>NHS / CHI no</th>
<th>Infusion Date</th>
<th>Product</th>
<th>Batch No.</th>
<th>Grams per Vial</th>
<th>Vial Count</th>
<th>Total Grams</th>
<th>Comments</th>
<th>Method</th>
</tr>
</thead>
<tbody>
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</table>
Specialised Services Circular

<table>
<thead>
<tr>
<th>Issue date:</th>
<th>21 September 2015</th>
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</thead>
<tbody>
<tr>
<td>ID</td>
<td>SSC 1539</td>
</tr>
<tr>
<td>Category:</td>
<td>Commissioning</td>
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<tr>
<td>Status:</td>
<td>For action</td>
</tr>
<tr>
<td>Public &amp; Press:</td>
<td>Not applicable</td>
</tr>
</tbody>
</table>

Title: Access to normal human immunoglobulin products

Circulation

For action
- Local Team Assistant Directors of Specialised Commissioning
- Regional Team IFR Leads
- Finance Leads
- Local Team Pharmacists

Local Teams to circulate to:
- Acute Trust Chief Executives
- Acute Trust Medical Directors
- Acute Trust Chief Pharmacists

Clinical Reference Group Chairs: onward circulation relevant CRG members.

For information
- Regional Directors of Specialised Commissioning
- Regional Medical Directors
- Regional Clinical Directors of Specialised Commissioning

Background

Therapeutic immunoglobulin is a blood product that can be effective in the treatment of a wide variety of conditions.

In August 2006, the Department of Health set a programme of action to enable the management of demand for immunoglobulin and to ensure supplies for high risk...
Appendix 8 – Infusion of Normal Human Immunoglobulin

**Infusion of Normal Human Immunoglobulin**

**Privigen 100mg/ml Dosage** This can range from 0.4g - 1g/ kg body weight depending on the condition. Consult the product literature available via www.medicines.org.uk.

**Prescribing** This should be prescribed as dose / Kg body weight AND the total dose to be administered. The weight of the patient should be stated on the prescription.

**Administration**

This should be administered in a gradually increasing dose. The initial rate should be 0.3mls/kg/hour for 30mins and gradually increasing the rate up to a rate of 4.8mls/kg/hour.

Suggested regimen

- 0.3ml/kg/hour for 30mins
- 0.6mls/kg/hour for 30mins
- 1.2mls/kg/hour for 30mins
- 2.4mls/kg/hour for 30mins
- 4.8mls/kg/hour for the rest of the infusion

<table>
<thead>
<tr>
<th>Rate of infusion in mls/hour</th>
<th>Body weight</th>
<th>55kg</th>
<th>60kg</th>
<th>65kg</th>
<th>70kg</th>
<th>75kg</th>
<th>80kg</th>
<th>85kg</th>
<th>90kg</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.3ml/kg/hr</td>
<td></td>
<td>16.5</td>
<td>18</td>
<td>19.5</td>
<td>21</td>
<td>22.5</td>
<td>24</td>
<td>25.5</td>
<td>27</td>
</tr>
<tr>
<td>0.6ml/kg/hr</td>
<td></td>
<td>33</td>
<td>36</td>
<td>39</td>
<td>42</td>
<td>45</td>
<td>48</td>
<td>51</td>
<td>54</td>
</tr>
<tr>
<td>1.2ml/kg/hr</td>
<td></td>
<td>66</td>
<td>72</td>
<td>78</td>
<td>84</td>
<td>90</td>
<td>96</td>
<td>102</td>
<td>108</td>
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<tr>
<td>2.4ml/kg/hr</td>
<td></td>
<td>132</td>
<td>144</td>
<td>156</td>
<td>168</td>
<td>180</td>
<td>192</td>
<td>204</td>
<td>216</td>
</tr>
<tr>
<td>4.8ml/kg/hr</td>
<td></td>
<td>264</td>
<td>288</td>
<td>312</td>
<td>336</td>
<td>360</td>
<td>384</td>
<td>408</td>
<td>432</td>
</tr>
</tbody>
</table>

Patients must be closely monitored and carefully observed throughout the infusion period for any symptoms and for one hour post infusion. Certain adverse reactions may occur more frequently:

- in case of high rate of infusion
- in patients with hypogammaglobulinaemia or agammaglobulinaemia, with or without IgA deficiency
- in patients who receive human normal immunoglobulin for the first time or, in rare cases, when the human normal immunoglobulin product is switched or when there has been a long interval since the previous infusion.

Potential complications can be avoided by ensuring that patients are not sensitive to human immunoglobulin by initially infusing slowly (0.3ml/kg bw/hr) and that patients are carefully monitored throughout the infusion period and for the first hour afterwards.

Adverse reactions such as chills, headache, dizziness, fever, vomiting, allergic reactions, nausea, arthralgia, low blood pressure and moderate low back pain may occur.

Rarely human normal immunoglobulins 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. If adverse reactions occur the infusion should be stopped and medical advice sought.

Consult the product literature available at www.medicines.org.uk for further information.