CLINICAL PRIORITIES ADVISORY GROUP
6 October 2021

Agenda Item No	2.1
National Programme	Blood and Infection
Clinical Reference Group	Immunology and Allergy
URN	

Title
Commissioning criteria policy for the use of therapeutic immunoglobulin (Ig) England, 2021

Actions Requested	1. Support its approval as an IYSD

Proposition
For routine commissioning. The purpose of this paper is to provide CPAG with the assurance and governance required for the "Commissioning Criteria policy for the use of therapeutic Immunoglobulin in England, 2021", to be formally ratified and published. This will support clinical teams to manage the ongoing issues related to supply and demand of immunoglobulin products. The clinical commissioning criteria for the use of therapeutic Immunoglobulin in England were reviewed by the Clinical Panel in June 2021 and then again in August 2021 following a stakeholder testing exercise. PPVAG were asked to review the finding from the above and supported the approach undertaken by NHSE&I, they recommended that no further consultation process was required for either document. The 2021 commissioning criteria were developed by the Immunoglobulin expert working group (IG EWG) and were developed from the review of the previous 2018 commissioning clinical criteria. This was based on the previous review of the literature (2011) which was updated/supported with subsequently published evidence, expert opinion and stakeholder input from specialty experts, relevant

scientific societies, alongside input from the respective Clinical Reference Groups such as; immunology, neurology and infectious diseases.
The criteria apply to the use of Ig for both adults and children.

Clinical Panel recommendation
The Clinical Panel recommended that the commissioning clinical criteria progresses as a routine commissioned clinical criteria.

The committee is asked to receive the following assurance:	
1.	The Head of Clinical Effectiveness confirms the proposition has completed the appropriate sequence of governance steps and includes an: Evidence Review; Clinical Panel Report.
2.	The Head of Acute Programmes confirms the proposition is supported by an: Impact Assessment; Engagement Report; Equality and Health Inequalities Impact Assessment; Clinical Policy Proposition.
3.	The Director of Finance (Specialised Commissioning) confirms that the impact assessment has reasonably estimated a) the incremental cost and b) the budget impact of the proposal.
4.	The Clinical Programmes Director (Specialised Commissioning) confirms that the service and operational impacts have been completed.

The following documents are included (others available on request):	
1.	Clinical Policy Proposition
2.	Engagement Report
3.	Evidence Summary
4.	Equality and Health Inequalities Impact Assessment

Patient Impact Summary
The condition has the following impacts on the patient's everyday life: • **Mobility:** Patients have **moderate, occasional problems** in walking about or are unable to walk about • **Ability to provide self-care:** Patients have **moderate, occasional problems** in washing or dressing or are unable to wash or dress • **Undertaking usual activities:** Patients have **moderate, occasional problems** in doing their usual activities or are unable to do their daily activities • **Experience of pain/discomfort:** Patients have **moderate, occasionally severe** pain or discomfort

- **Experience of anxiety/depression:** Patients are **moderately** anxious or depressed

Further details of impact upon patients:

The impact of therapeutic immunoglobulin (Ig) as a treatment regimen for a range of conditions in the specialties of Neurology, Immunology, Haematology, Infectious Diseases, to name but a few, would be to improve the condition status and care for all patients. For some conditions there is a risk to life if the treatment is not provided. The delivery of this treatment is either through intravenous or subcutaneous methods either in a hospital setting or at home.

Whilst the treatment can be invasive patients do respond well and are generally supportive of Ig treatments and can have a positive impact on the lives of patients.

Further details of impact upon carers:

The impact on carers would be to ensure that patients had access to treatment in either the home and delivered through 'Homecare' mechanisms or in a hospital setting. This would add to the overall burden of care relating to the patient's condition but would be perceived in the main as a supportive to the overall treatment package.

Considerations from review by Rare Disease Advisory Group

Not applicable.

Pharmaceutical considerations

The Commissioning criteria policy for the use of therapeutic immunoglobulin (Ig) England, 2021 covers a range of indications some of which are licensed indications for immunoglobulin and others which are off label but where expert opinion and clinical evidence suggest clinical benefit. Immunoglobulins are excluded from tariff.

Considerations from review by National Programme of Care

Due to the time critical nature of the commissioning criteria the documentation was been reviewed and supported by the Clinical Panel in August 2021, and received scrutiny, oversight and sign off senior management team scrutiny.

The Programme of Care have been fully informed on the progress of the work throughout the exercise by the POC Chair (also clinical lead for the IG expert working group).