

## Engagement report

### Topic details

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|---|---|
| <b>Title of policy or policy statement:</b> | Human normal immunoglobulin for preventative treatment of Idiopathic Systemic Capillary Leak Syndrome following an acute episode (adults) |
| <b>Programme of Care:</b>                   | Blood and Infection   |
| <b>Clinical Reference Group:</b>            | Immunology and Allergy  |
| <b>URN:</b>                                 | 2270  |

### 1. Summary

This report summarises the feedback NHS England received from engagement during the development of this policy proposition, and how this feedback has been considered. The clinical commissioning policy proposition went out to stakeholder testing between 23<sup>rd</sup> June and 10<sup>th</sup> July 2023. There were 4 responses.

### 2. Background

Idiopathic Systemic Capillary Leak Syndrome (SCLS; also referred to as Clarkson's Syndrome) is an extremely rare condition characterised by episodes in which capillaries (small blood vessels) become leaky. This causes movement of fluid from inside the vessels to other spaces in the body, which can result in whole body swelling. Episodes are also associated with low blood pressure because of fluid shifts, which is life threatening and can cause complications such as organ failure and blood clots. Patients will often require hospital and intensive care admission during these acute episodes. The condition is diagnosed by ruling out other causes of this presentation. Most patients follow a relapsing course after diagnosis with acute episodes occurring up to monthly. The underlying cause for the condition is not fully understood, partly because it is so rare.

Standard care during acute episodes often involves admission, including to intensive care, to stabilise the fluid balance. Sometimes medication is required to increase the blood pressure in order for organs to function, and treatments to remove excess fluid may also be required. After an acute episode has resolved, preventative treatment is often started to try and stop future episodes.

Immunoglobulins are proteins found within plasma, which is the liquid component of blood. Human normal immunoglobulin (Ig) is a blood product prepared from donor plasma. It can be given to patients through an infusion into the veins or underneath the skin as treatment for certain conditions. In this policy proposition, Ig is being proposed

as preventative therapy, and the preventative effect lasts for several weeks between the treatment being delivered.

### 3. Engagement

NHS England has a duty under Section 13Q of the NHS Act 2006 (as amended) to 'make arrangements' to involve the public in commissioning. Full guidance is available in the Statement of Arrangements and Guidance on Patient and Public Participation in Commissioning. In addition, NHS England has a legal duty to promote equality under the Equality Act (2010) and reduce health inequalities under the Health and Social Care Act (2012).

The policy proposition was sent for stakeholder testing for 2 weeks between 23rd June and 10th July 2023. The comments have then been shared with the Policy Working Group to enable full consideration of feedback and to support a decision on whether any changes to the proposition might be recommended.

Respondents were asked the following questions:

- Do you believe that there is any additional information that we should have considered in the evidence review? If so, please give brief details.
- Do you support the Equality and Health Inequalities Impact Assessment?
- Does the Patient Impact Assessment present a true reflection of the patient and carers lived experience of this condition?
- Do you agree with the inclusion and exclusion criteria?
- Do you agree with the tapering and monitoring criteria?
- Do you have any further comments on the proposition? If so, please submit these in no more than 500 words.
- Please declare any conflict of interests relating to this document or service area.

A 13Q assessment has been completed following stakeholder testing.

The Programme of Care agreed that public consultation was not necessary. This has been assured by the Patient Public Voice Advisory Group.

### 4. Engagement Results

There were 4 respondents to the stakeholder testing: 4 clinicians.

All respondents supported the proposal.

#### How has feedback been considered?

Responses to engagement have been reviewed by the Policy Working Group and the Blood and Infection PoC. The following themes were raised during engagement with registered stakeholders:

| Keys themes in feedback                     | NHS England Response |
|---|----------------------|
| <b>Relevant Evidence</b>                    |                      |
| No further relevant evidence was identified |                      |
| <b>Impact Assessment</b>                    |                      |
| No comments                                 |                      |
| <b>Current Patient Pathway</b>              |                      |

|  |   |
|--|---|
| Two respondents questioned the exclusion criterion “Patients where SCLS is secondary to a documented cause as assessed by an MDT including the relevant specialties (for example, medication-induced capillary leak).”                                   | The evidence in this policy proposition has not considered the role of IVIg in induced CLS and so given the lack of evidence in this subgroup, this is out of scope of this proposition.  |
| One respondent highlighted that the local monitoring of patients with this condition would be difficult in hospitals that do not have specialists on site or easily available, without support and guidance from those organisations that have expertise | Wording has been added:<br><i>Ongoing care, including assessment of clinical response as below, should be undertaken by a team with relevant experienced specialists, for example, the team that agreed on treatment initiation. Where this is not feasible, local teams should liaise with an appropriate specialist team for advice and guidance.</i> |
| <b>Potential impact on equality and health inequalities</b>  |   |
| None   |   |
| <b>Changes/addition to policy</b>  |   |
| None   | Should additional evidence become available then NHS England will consider changes to the policy.   |

## 5. Has anything been changed in the policy proposition as a result of the stakeholder testing and consultation?

Yes - Wording has been added to monitoring section:

*Ongoing care, including assessment of clinical response as below, should be undertaken by a team with relevant experienced specialists, for example, the team that agreed on treatment initiation. Where this is not feasible, local teams should liaise with an appropriate specialist team for advice and guidance.*

## 6. Are there any remaining concerns outstanding following the consultation that have not been resolved in the final policy proposition?

No.