Engagement Report

Topic details

Title of policy or policy statement:	Human normal immunoglobulin for treatment of scleromyxedema
Programme of Care:	Internal medicine
Clinical Reference Group:	Specialised Rheumatology
URN:	2271

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 8th August 2023 and 23rd August 2023. There were 3 responses.

2. Background

Scleromyxedema is a very rare, severe skin disorder, the signs and symptoms of which include abnormal accumulation of mucin (naturally occurring proteins) under the skin. Mucins are usually associated with fighting infection and the buildup of mucin (mucinosis) causes abnormal lumps within the skin. The condition is also associated with an increased production of connective tissue cells which, whilst vital for maintaining the form and function of the body and its organs, when overproduced can lead to problems with organ function, for example, severe neurological involvement causing seizures and coma. The causes of scleromyxedema are not known.

Due to the extremely rare nature of the condition, there is a limited evidence base for treatment, and no standard therapies or treatment algorithms exist in England. Treatment options include phototherapy, and systemic immunosuppression. The proposed intervention is to prescribe human normal immunoglobulin which is a plasma derived blood product. It is proposed as either as an addition to current treatment, or as an alternative. The treatment is administered by infusion either intravenously or under the skin (subcutaneously) (IVIg/SCIg).

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 8th August 2023 and 23rd August 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 decided that public consultation was not required This decision has been assured by the Patient Public Voice Advisory Group.

4. Engagement Results

There were 3 respondents to the stakeholder testing: 2 individuals and 1 organisation.

All respondents supported the proposal.

How has feedback been considered?

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

Keys themes in feedback	NHS England Response
Relevant Evidence	
No further relevant evidence was identified	Noted
Inclusion criteria: diagnosis	
One respondent was concerned that while most centres will have access to joint dermatology-rheumatology assessment there may be centres that are expert and familiar that do not have this formal arrangement.	PWG have updated the inclusion criteria to state that: agreement from both specialties is sufficient in order for diagnosis, and for initiation of treatment
One respondent was concerned that a biopsy may not always be available or might be less classical in later stages.	PWG have amended the inclusion criteria around diagnosis such that: biopsy is “preferable” rather than mandatory.
Recommended dose and dose adjustment	
One respondent requested greater flexibility on frequency of infusion, drawing analogy with other indications for Ig such as dermatomyositis where intervals of up to 12 weeks may be considered in some cases,	PWG have amended policy wording has been amended to state that: [dose can be reduced by] gradually increasing the treatment interval to the maximum interval at which response is maintained.

especially in later stage disease of when other drugs have been extensively used.	

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

Yes - PWG have updated the inclusion criteria to state that: agreement from both rheumatology and dermatology specialties is sufficient in order for a diagnosis, and for initiation of treatment. PWG have amended the inclusion criteria around diagnosis such that: biopsy is “preferable” rather than mandatory. PWG have amended recommended dose and dose adjustment wording state that: [dose can be reduced by] gradually increasing the treatment interval to the maximum interval at which response is maintained.

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

No