Consultation Report

Topic details

Title of policy or policy statement:	Clinical Commissioning Policy Proposition: Ustekinumab for refractory Crohn's disease in pre-pubescent children
Programme of Care:	Women and children
Clinical Reference Group:	Paediatric medicine
URN:	1861

1. Summary

This report summarises the outcome of a public consultation that was undertaken to test the policy proposition.

2. Background

Crohn's disease (CD) is a long-term condition that mainly affects the bowel. Some people may develop symptoms that affect other body parts as well. There are currently at least 115,000 people in the UK with CD. Up to a third of people with CD are diagnosed before the age of 21 years. Common symptoms of CD in children include bloody diarrhoea, weight loss, abdominal (tummy) pain and delayed puberty.

Treatment is largely to relieve symptoms rather than cure. For mild disease, two types of therapies are generally used: enteral nutrition or steroids. For severe disease, add on therapy with stronger immunosuppressive medications such as azathioprine and methotrexate are used. Infliximab, a tumour necrosis factor (TNF) alpha inhibitor can be used in severe, active CD. For children who have failed all the treatment as stated above, there is no alternative licensed therapy. These patients may be dependent on steroids to control the disease. Patients are at risk of complications and repeated surgical interventions if the disease is poorly controlled.

Ustekinumab is a biological medicine which inhibits molecules involved in the immune system functions and reduces disease activity. It is licensed for the treatment of adults with moderate to severely active CD as the fourth line treatment. Ustekinumab is not licensed for this indication in pre-pubescent children).

This policy proposition is not routinely commissioned, as there is not enough evidence to make the treatment available at this time. It has been subject to stakeholder testing and public consultation in line with the standard methods.

3. Publication of consultation

The policy proposition was published and sign-posted on NHS England's website and was open to consultation feedback for a period of 30 days from 2nd October until 1st November 2019.

Respondents were asked the following consultation questions:

- Has all the relevant evidence been taken into account?
- Does the impact assessment fairly reflect the likely activity, budget and service impact? If not, what is inaccurate?
- Does the policy proposition accurately describe the current patient pathway that patients experience? If not, what is different?
- Please provide any comments that you may have about the potential impact on equality and health inequalities which might arise as a result of the proposed changes that have been described?
- Are there any changes or additions you think need to made to this document, and why?

4. Results of consultation

All stakeholders (including CRG members and registered stakeholders) were notified when the draft policy proposition went out to public consultation. Despite this, there were no responses received to the public consultation.

5. How have consultation responses been considered?

Not applicable, as no responses received.

6. Has anything been changed in the policy as a result of the consultation?

No.

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

No.