Consultation Report

Topic details

Title of policy or policy statement:	Telotristat for treating carcinoid syndrome diarrhoea (adults)
Programme of Care:	Internal Medicine
Clinical Reference Group:	Specialised Endocrinology
URN:	1745

1. Summary

This report summarises the outcome of a public consultation that was undertaken to test the policy proposition for telotristat for treating carcinoid syndrome diarrhoea in adults.

2. Background

Carcinoid syndrome (CS) describes the symptoms that can sometimes occur from a rare cancer called neuroendocrine tumours (NET). NETs can increase the amount of hormones produced which can cause stomach pain and a disease of the heart known as carcinoid heart disease. Around 80% of people with CS will have diarrhoea, that cause further clinical problems and has a major impact on patient's quality of life. The policy proposition was put forward for routine commissioning but after the evidence review was considered NHS England requested a not for routine commissioning policy was developed.

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 60 days from 1 July to 31 August 2019. Consultation 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 policy might be recommended.

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 be made to this document, and why?

4. Results of consultation

There were 18 responses to the consultation; 14 from patients or a patient organisation, 2 from hospitals, 1 from a clinician and 1 from the pharmaceutical company.

The main themes were:

There was a repeated concern that the impact on patients' quality of life caused by carcinoid syndrome had not been considered when reaching a recommendation for telotristat to proceed with a not for routine commissioning position.

There was a concern that the evidence base had not been fully considered and some new evidence should be considered.

There was a concern that the decision was driven by consideration of costs of the treatment.

There were concerns that other countries within the UK do offer this to patients so there is inequality of access within the UK.

There was a concern about lack of research in this area.

5. How have consultation responses been considered?

Responses have been carefully considered and noted in line with the following categories:

- Level 1: Incorporated into draft document immediately to improve accuracy or clarity
- Level 2: Issue has already been considered by the CRG in its development and therefore draft document requires no further change
- Level 3: Could result in a more substantial change, requiring further consideration by the CRG in its work programme and as part of the next iteration of the document
- Level 4: Falls outside of the scope of the specification and NHS England's direct commissioning responsibility

Level 2: The comments about impact on patients were acknowledged but did not alter the quality of the evidence base which was the basis for the not routine commissioning proposition.
Level 3: The comments about evidence included concerns about the Evidence Review and that additional evidence should be considered. The Internal Medicine Board Public Health member reviewed both and advised the original Evidence

Review was satisfactory. A review of the new evidence concluded that although these was consistent with the evidence already considered the papers did not materially strengthen the evidence base.

Level 4: It was noted that the countries within UK have the authority to consider health policy individually so this may result in variation in health policy within the UK.

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

No changes have been made as responses focused on the evidence base and the additional evidence identified was considered and included within the additional evidence reports attached.

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

No.