

Highly Specialised Technology

Setmelanotide for treating obesity and hyperphagia in Bardet-Biedl syndrome [ID3947]

Committee Papers

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

HIGHLY SPECIALISED TECHNOLOGY

Setmelanotide for treating obesity and hyperphagia in Bardet-Biedl syndrome [ID3947]

Contents:

The following documents are made available to stakeholders:

- 1. Consultee and commentator comments on the Draft Guidance**
from:
 - a. Bardet-Biedel Syndrome UK (BBS UK)
 - b. British Obesity and Metabolic Surgery Society

There were no comments received on the draft guidance from the company, Rhythm, or the NICE website.

Any information supplied to NICE which has been marked as confidential, has been redacted. All personal information has also been redacted.

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Draft guidance comments form

Consultation on the draft guidance document – deadline for comments 5pm on 14 March 2024. Please submit via NICE Docs.

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| | <p>Please read the checklist for submitting comments at the end of this form. We cannot accept forms that are not filled in correctly.</p> <p>The Appraisal Committee is interested in receiving comments on the following:</p> <ul style="list-style-type: none"> • has all of the relevant evidence been taken into account? • are the summaries of clinical and cost effectiveness reasonable interpretations of the evidence? • are the provisional recommendations sound and a suitable basis for guidance to the NHS? <p>NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others. Please let us know if you think that the preliminary recommendations may need changing in order to meet these aims. In particular, please tell us if the preliminary recommendations:</p> <ul style="list-style-type: none"> • could have a different impact on people protected by the equality legislation than on the wider population, for example by making it more difficult in practice for a specific group to access the technology; • could have any adverse impact on people with a particular disability or disabilities. <p>Please provide any relevant information or data you have regarding such impacts and how they could be avoided or reduced.</p> |
| <p>Organisation name – Stakeholder or respondent (if you are responding as an individual rather than a registered stakeholder please leave blank):</p> | <p>Bardet-Biedl Syndrome UK (BBS UK)</p> |

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| <p>Disclosure Please disclose any funding received from the company bringing the treatment to NICE for evaluation or from any of the comparator treatment companies in the last 12 months. [Relevant companies are listed in the appraisal stakeholder list.] Please state:</p> <ul style="list-style-type: none"> the name of the company the amount the purpose of funding including whether it related to a product mentioned in the stakeholder list whether it is ongoing or has ceased. | <p>August 2022: Rhythm Pharmaceuticals provided £7,000 sponsorship to the BBS UK conference in September 2022 to contribute to running costs of the meeting.</p> <p>June 2023: Rhythm Pharmaceuticals provided £10,000 sponsorship to the BBS UK conference (September 2023) to contribute to running costs of the meeting.</p> <p>Rhythm had no influence over the creation, development or content of the meeting.</p> |
| <p>Please disclose any past or current, direct or indirect links to, or funding from, the tobacco industry.</p> | <p>N/A</p> |
| <p>Name of commentator person completing form:</p> | <p>[REDACTED]</p> |
| <p>Comment number</p> | <p style="text-align: center;">Comments</p> <p style="text-align: center;">Insert each comment in a new row. Do not paste other tables into this table, because your comments could get lost – type directly into this table.</p> |
| <p>Example 1</p> | <p>We are concerned that this recommendation may imply that</p> |
| <p>1</p> | <p>Thank you for the opportunity to provide feedback on the consultation following the most recent Appraisal Committee Meeting.</p> |

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| | We are delighted that the Committee recommends setmelanotide as an option for treating obesity and hyperphagia in individuals aged 6-17 with BBS. We are supportive of this decision and grateful to all those involved for their thorough consideration of all the evidence. |
| 2 | Despite our disappointment, we understand why the Committee could not recommend setmelanotide to treat obesity and hyperphagia in adult patients, and remain fully committed to working with our clinicians, the Company, and NICE to gather the additional data that is required. |
| 3 | We recognise, and are grateful for the considerable input of all involved, including our expert patients and clinicians and ask that this appraisal process remains 'open' for a further review, so that we can return to NICE as soon as possible to seek a change in guidance to include the adult population. |
| 4 | Please accept our heartfelt thanks to all involved in this appraisal process. We understand that this has been a complex case and appreciate the efforts of all involved to date. |
| 5 | |
| 6 | |

Insert extra rows as needed

Checklist for submitting comments

- Use this comment form and submit it as a Word document (not a PDF).
- Complete the disclosure about links with, or funding from, the tobacco industry.
- Combine all comments from your organisation into 1 response. We cannot accept more than 1 set of comments from each organisation.
- Do not paste other tables into this table – type directly into the table.
- Please underline all confidential information, and separately highlight information that is [REDACTED] and information that is [REDACTED]. If confidential information is submitted, please submit a second version of your comments form with that information replaced with the following text: 'academic / commercial in confidence information removed'. See the [NICE Health Technology Evaluation Manual](#) (section 5.4) for more information.
- Do not include medical information about yourself or another person from which you or the person could be identified.
- Do not use abbreviations.
- Do not include attachments such as research articles, letters or leaflets. For copyright reasons, we will have to return comments forms that have attachments without reading them. You can resubmit your comments form without attachments, it must send it by the deadline.
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Note: We reserve the right to summarise and edit comments received during consultations, or not to publish them at all, if we consider the comments are too long, or publication would be unlawful or otherwise inappropriate.

Comments received during our consultations are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the comments we received, and are not endorsed by NICE, its officers or advisory committees.

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| <p>Name of commentator person completing form:</p> |  |
| <p>Comment number</p> | <p align="center">Comments</p> <p align="center">Insert each comment in a new row. Do not paste other tables into this table, because your comments could get lost – type directly into this table.</p> |
| <p>Example 1</p> | <p>We are concerned that this recommendation may imply that</p> |
| <p>1</p> | <p>As we stated in a previous round of stakeholder comments, it is stated that “Hunger generally increases after surgery” meaning bariatric surgery. There is clear evidence that there is appetite control with bariatric surgery with both hunger reduction and increase in satiety in patients without BBS. There are no studies examining formally hunger after bariatric surgery in patients with BBS.</p> |

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| 2 | We welcome the recommendation of setmelanotide for routine commissioning to treat obesity and hyperphagia only in people with Bardet-Biedl Syndrome who start treatment aged between 6 and 17 years (with continuation into adulthood if clinically indicated). |
| 3 | We acknowledge the current uncertainties regarding the cost effectiveness in the mixed population of adults and children. |
| 4 | |
| 5 | |
| 6 | |

Insert extra rows as needed

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