NICE National Institute for Health and Care Excellence

HealthTech Programme

Digital self-help for eating disorders: early value assessment

Draft guidance comments

Theme 1: Population covered in the 'can be used with evidence generation' recommendation

Comment number	Consultee	Section number	Comment	Response
1	Consultee 3 Leeds and York Partnership NHS Foundation Trust	1.1 Can be used with evidence generation	Does this also include patients with non-underweight Atypical Anorexia who may also be binge eating? If not, will the primary care eating disorder assessment be able to distinguish between these patients? Will a standardised assessment be used if trialling in primary care?	Thank you for your comment, which the committee considered. An addition to the guidance has been made following the committee meeting, noting that self-help is not suitable for people with any form of anorexia nervosa. Please see the 'What this means in practice' section of the final draft guidance (section 1).

Theme 2: Evidence base for Digital CBTe

Comment number	Consultee	Section number	Comment	Response
2	Consultee 2 Credo Therapies	Not specified	Thank you for evaluating our programme and for considering our response. We very much appreciate the committee's thoughtful and detailed evaluation of the direct evidence. We recognise that this is a time-consuming process for everyone on the committee and are grateful for being included. 1. Question around the digital translation of CBT-E We wish to clarify how Early Value Assessment (EVA) considered the fact that Digital CBTe is a digital translation of an established printed programme, rather than a novel intervention built from scratch? In other words, Digital CBTe is the programme-led digital version of CBT-E, with both the printed programme and the digital version closely derived from the therapist-led CBT-E model. We have shared the underlying evidence base for the printed programme (Overcoming Binge Eating) with you (before the last meeting). For context, this body of indirect evidence, and the translation from therapist-led/printed to digital, formed an important component of the product's medical device clinical evaluation (see below). We fully respect the decision of the committee, but we would also like to share our opinion. Our position: We recognise the need for direct evidence on the digital programme itself. Indeed, we are keen to develop our evidence base further in line with your recommendations. At the same time, there is a relevant analogue evidence base from the printed programme (in particular) and the therapist-led CBT-E model which, in our opinion, should inform assessment of a digital	Thank you for your comment, which the committee considered. This comment refers to a stakeholder comment on the external assessment report. See comment 27 from Credo Therapies Ltd in committee papers for the first committee meeting for this topic (15 July 2025). The committee heard about the differences between the digital version of the programme and the printed version of the programme. The committee noted that Digital CBTe is not a direct translation of the printed programme, and so they concluded that the evidence on the printed programme is not generalisable

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			translation. The EVA interim methods (see quotations below) state that when direct evidence is limited, inclusion criteria may be broadened to a wider, relevant evidence base, and reviews may include studies that do not include the technology itself to inform decision-making and evidence gaps. Can you confirm to what extent you applied this principle to Digital CBTe? "It is expected that there will not be a comprehensive evidence base available for technologies included in early value assessment. The evidence considered by the committee should be relevant to the evaluation in terms of patient groups, comparators, perspective, outcomes and resource use as defined in the scope wherever possible. The aim of the evidence review is to identify the most relevant evidence relating to the decision question defined in the scope. If no evidence directly relevant to the evaluation is available, inclusion criteria should be expanded to look at a broader evidence base." 3.11 "In addition to reviewing the evidence on the technologies, additional reviews may be needed to look for studies that report on relevant information, but do not include the intervention technologies." Reference: https://www.nice.org.uk/process/pmg39/chapter/interim-process-and-methods-for-early-value-assessment [continues in comment 3]	to the digital version of the programme. Please see section 3.6 of the final draft guidance for further details.

Theme 3: Regulatory status of Digital CBTe

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3	Consultee 2 Credo Therapies	Not specified	2. Question around Medical Device Status and EVA We would also like to enquire what impact Digital CBTe's medical device status had on the EVA? We fully respect the decision of the committee, but we would also like to share our opinion. Our position: In our opinion, Digital CBTe's medical device status is relevant to EVA for two reasons: Firstly, it was our understanding that achieving medical device status represents a minimum threshold for eligibility under NICE's medical technologies guidance. As outlined on the NICE website, technologies must have, or be expected to get within 12 months, UKCA/CE (or equivalent) approval (https://www.nice.org.uk/what-nice-does/our-guidance/about-medical-technologies-guidance/get-a-medical-technology-evaluated) and EVA refers to this explicitly within its scope https://www.nice.org.uk/what-nice-does/our-guidance/about-medical-technologies-guidance/early-value-assessment-eva-for-medtech. We ensured Digital CBTe obtained medical device status to establish it firmly as a regulated technology, and not within the category of unregulated technologies offering psychoeducation materials or similar. Secondly, we believe it is relevant because it establishes a lawful intended purpose as mental health/function therapeutic software". In particular, we have defined Digital CBTe's purpose as a psychological treatment for the clinical eating disorders of bulimia nervosa and binge eating disorder. Device status also requires a documented clinical evaluation demonstrating that the content	Thank you for your comment, which the committee considered. The committee was advised that NICE considers the regulatory status in the assessment as part of the eligibility criteria. It was clarified that the technologies in the assessment have appropriate medical device regulation, where needed, based on information provided by the companies in relation to the MHRA guidance on digital mental health technology qualification and classification. The committee does not assess the documentation

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			faithfully implements the manualised CBT-E/CBT-ED approach (structure, techniques, dose), and it places the product under a statutory post-market surveillance duty (planned monitoring, vigilance, periodic reporting). These obligations go well beyond what is expected of unregulated "self-help materials" and provide assurance on fidelity, safety and lawful claims, which are important foundations for any assessment of clinical and cost-effectiveness. While medical device status does not replace the need for direct digital evidence, it materially strengthens confidence in the programme's clinical evaluation, legitimacy, safety governance and suitability for EVA's "use while evidence is generated" framework. Importantly, it also enables a clear and specific indication: Digital CBTe can be used as a psychological treatment for clinical eating disorders.	submitted for regulation. All relevant information was reported in the assessment report overview.

Theme 4: What evidence generation and research is needed

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4	Consultee 1 Surrey and Borders Partnership NHS Foundation Trust	1	Clinical concerns that this digital alternative to AEDimhs with very little research/outcomes of its efficacy. AEDimhs is an early intervention ED service which intervenes quickly and begins treatment for those who would previously have had unmet needs or potentially been deemed low risk and on the AEDS wait list.	Thank you for your comment, which the committee considered. The committee noted that digital self-help technologies are not intended to replace existing care or services for eating disorders, and would only be used after an initial eating disorder assessment.

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5	Consultee 1 Surrey and Borders Partnership NHS Foundation Trust	1.4 More research is needed	Without pilot studies it would be difficult to ascertain if indeed these treatments did halt further deterioration or have a positive impact on moderate to severe services. Whilst cheaper in the short term would there be a longer-term benefit? Or would this postpone patients accessing help and making the duration of illness lengthen? 40+% of referrals to our service are 18-25 in the first 3 years of illness – would this possibly unsuccessful treatment hinder further engagement – be seen as not taken seriously or rejected if not carefully introduced. From our experience accessing technology can be a challenge and requires support for some and care is required to make treatments accessible for all. Completion of online forms can be challenging and wonder what steps have been taken to make these interventions accessible to all.	Thank you for your comment, which the committee considered. The guidance recommends use with evidence generation and more research on these technologies, with short- and long-term clinical outcomes noted. Potential equality and accessibility issues are discussed in sections 3.9 of the final draft guidance. This includes conditions that may make it more difficult to use or complete digital self-help.
6	Consultee 1 Surrey and Borders Partnership NHS Foundation Trust	2.1 Reasons for high attrition and barriers to engagement	We would like to see the outcomes of these digital treatments in comparison to the AEDimhs service/or similar service offer and keen to understand the reported high drop out rate, i.e. why was this?. Are patients then offered a re-assessment or is there a risk that they were seen as poorly engaged, when in fact ambivalence, individual needs, accessibility where not accounted for?	Thank you for your comment, which the committee considered. More evidence generation and research on the proportion of people

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				who do not complete the digital self-help, their characteristics and reasons for stopping has been recommended. See section 1 (What evidence generation and research is needed) in the final draft guidance.
7	Consultee 3 Leeds and York Partnership NHS Foundation Trust	3.15 Equality considerations	Reading age and language	Thank you for your comment, which the committee considered. This has been added to the final guidance document (see section 3.9)