NICE National Institute for Health and Care Excellence

NICE guidance

Digital technologies for delivering specialist weight-management services to manage weight-management medicine: early value assessment

Health technology evaluation
Published: 26 October 2023

www.nice.org.uk/guidance/hte14

Your responsibility

This guidance represents the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, healthcare professionals are expected to take this guidance fully into account, and specifically any special arrangements relating to the introduction of new interventional procedures. The guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

All problems (adverse events) related to a medicine or medical device used for treatment or in a procedure should be reported to the Medicines and Healthcare products Regulatory Agency using the Yellow Card Scheme.

Commissioners and/or providers have a responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity, and foster good relations. Nothing in this guidance should be interpreted in a way that would be inconsistent with compliance with those duties. Providers should ensure that governance structures are in place to review, authorise and monitor the introduction of new devices and procedures.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should assess and reduce the environmental impact of implementing NICE recommendations wherever possible.

Contents

1 Recommendations

Can be used in the NHS with evidence generation

1.1 Five digital weight-management technologies can be used in the NHS while more evidence is generated, to deliver specialist weight-management services for adults who are eligible for weight-management medicine. The technologies are:

- Gro Health W8Buddy (DDM Health), for prescribing and monitoring weight-management medicine
- Liva (Liva), for tracking weight-management medicine
- Oviva (Oviva), for prescribing and monitoring weight-management medicine
- Roczen (Reset Health), for prescribing and monitoring weight-management medicine
- Second Nature (Second Nature), for prescribing and monitoring weight-management medicine.

  These technologies can only be used once they have appropriate Digital Technology Assessment Criteria (DTAC) approval.

1.2 The companies must confirm that agreements are in place to generate the evidence (as outlined in NICE's evidence generation plan) and contact NICE annually to confirm that evidence is being generated and analysed as planned. NICE may withdraw the guidance if these conditions are not met.

1.3 At the end of the evidence generation period (4 years), the companies should submit the evidence to NICE in a form that can be used for decision making. NICE will review the evidence and assess if the technologies can be routinely adopted in the NHS.

Can only be used in research

1.4 More research is needed on using the following digital weight-management technologies:

- CheqUp (CheqUp Health)
- Juniper (Juniper Technologies UK)
- Wellbeing Way (Xyla Health and Wellbeing).

1.5 Access to the technologies in section 1.4 should be through company, research, or non-core NHS funding, and clinical and financial risks should be appropriately managed.

Evidence generation and research

1.6 More evidence generation and research are needed on:

- change in weight
- adherence and completion rates, including reasons for stopping a programme
- how the technologies monitor and report adverse events
- health-related quality-of-life and psychological outcomes
- impact on resource use, including the number and type of healthcare appointments and cost of the medicine.

  More information will be included in the evidence generation plan.

Potential benefits of use in the NHS with evidence generation

- **Unmet need:** Digital weight-management technologies are an option to deliver specialist weight-management services. They provide weight-management programmes that prescribe or monitor treatment with weight-management medicine. They can be used for adults who are eligible for weight-management medicine after referral and clinical assessment. They will particularly benefit people who do not have access to specialist weight-management services in their area or who are on a waiting list, so are not currently supported by a specialist weight-management service. Weight-management medicine can only be accessed alongside a specialist weight-management service, so by providing these services, these technologies may also improve access to medicine.
- **Clinical benefit:** Early evidence suggests that weight loss with the technologies is similar at 2 years, compared with face-to-face specialist weight-management services.
- **Resources**: The technologies may reduce the demand for face-to-face specialist weight-management services. This may release resources and increase access or reduce waiting times.
- **Access:** The technologies may provide more flexible access to services for people who are unable to travel or who prefer to access services remotely.

Managing the risk of use in the NHS with evidence generation

- **Prescribing:** Weight-management medicine that is prescribed through the technologies should only be used in line with NICE's technology appraisal guidance for overweight and obesity and the British National Formulary (BNF)'s prescribing information for drugs for obesity. Prescribing must be done by a suitably qualified healthcare professional. When prescribing weight-management medicine remotely through a technology, healthcare professionals should follow the General Medical Council's remote prescribing high level principles.

- **Clinical assessment:** A healthcare professional should do a referral and full clinical assessment before offering access to treatments through these technologies, to make sure the technologies are suitable. Some people may choose not to use a digital service and may prefer another treatment option. Everyone has the right to make informed decisions about their care.
- **Multidisciplinary support:** The technologies provide support from a multidisciplinary team (MDT) of qualified healthcare professionals. This must include psychological support and monitoring to reduce the risk of harm, including from disordered eating.
- **Equality:** Some people are less comfortable or skilled in using digital technology, or may have limited access to equipment and the internet. These people may be less able to benefit from the technologies and may need additional support or prefer a different treatment option. Some people may need additional support because of a visual, hearing or cognitive impairment, reduced manual dexterity, a learning disability or being unable to read English or understand health-related information. Autistic people may also find the technologies unsuitable or may need additional support. The technologies may not be suitable for some people, even with additional support.
- **Costs:** Early results from the economic modelling show that the technologies could be cost effective. This guidance will be reviewed within 4 years and the recommendations may change. Take this into account when negotiating the length of contracts and licence costs.

The evidence generation plan gives further information on the prioritised evidence gaps and outcomes, ongoing studies and potential real-world data sources. It includes how the evidence gaps could be resolved through real-world evidence studies.

2 The technologies

2.1 Digital weight-management technologies can be used to deliver specialist weight-management services. They can be accessed online or through an app, and provide a multidisciplinary programme and support from the service's multidisciplinary team (MDT) of healthcare professionals. Some technologies offer weight-management medicine prescribing and medicine reviews with a prescribing clinician, alongside regular reviews with other members of the service's MDT. Other technologies collect and share medicine adherence data with the person's NHS team, to support the NHS team with prescribing weight-management medicine. The frequency of reviews may vary depending on the technology, user preference and stage of the programme. NICE has assessed 8 technologies that can deliver specialist weight-management services. The criteria for including technologies in this early value assessment (EVA) and further details of each technology are in section 2.2, table 2 and appendix E of the assessment report, and in the assessment report addendum on the NICE website. The technologies are:

- CheqUp (CheqUp Health): this is an online platform that provides a multidisciplinary weight-management programme and weight-management medicine prescribing. CheqUp does not have a CE or UKCA mark because it is not classed as a medical device.
- Gro Health W8Buddy (DDM Health): this is an online platform that provides a multidisciplinary weight-management programme and weight-management medicine prescribing. Gro Health W8Buddy is a CE-marked class I medical device.
- Juniper (Juniper Technologies UK): this is an app that provides a multidisciplinary weight-management programme and weight-management medicine prescribing. Juniper does not have a CE or UKCA mark because the company states it is not classed as a medical device.

- Liva (Liva): this is an online platform that provides a multidisciplinary weight-management programme and weight-management medicine tracking. It does not include weight-management medicine prescribing. Liva is a CE-marked class I medical device indicated for type 2 diabetes.
- Oviva (Oviva): this is an app that provides a multidisciplinary weight-management programme and weight-management medicine prescribing. Oviva is a CE-marked class IIa medical device.
- Roczen (Reset Health): this is an online platform that provides a multidisciplinary weight-management programme and weight-management medicine prescribing. Roczen does not have a CE or UKCA mark because it is not classed as a medical device.
- Second Nature (Second Nature): this is an app that provides a multidisciplinary weight-management programme and weight-management medicine prescribing. Second Nature does not have a CE or UKCA mark because it is not classed as a medical device.
- Wellbeing Way (Xyla Health and Wellbeing): this is an online platform that provides a multidisciplinary weight-management programme and weight-management medicine prescribing. Wellbeing Way does not have a CE or UKCA mark because it is not classed as a medical device.

Care pathway

2.2 Semaglutide for weight management must be used within a specialist weight-management service that provides multidisciplinary management of overweight or obesity, including but not limited to tier 3 and tier 4 services (see NICE's technology appraisal guidance on semaglutide for managing overweight and obesity). Liraglutide for managing overweight and obesity must be prescribed in secondary care by a specialist multidisciplinary tier 3 weight-management service (see NICE's technology appraisal guidance on liraglutide for managing overweight and obesity).

2.3 Tier 3 and 4 specialist weight-management services for people with overweight and obesity are defined in NHS England's guidance for Clinical Commissioning Groups (CCGs): Service Specification Guidance

for Obesity Surgery (2016) and NICE's guideline on obesity: identification, assessment and management. A typical MDT should include an obesity doctor, specialist nurse, specialist dietitian, psychologist and physiotherapist. It should also have access to healthcare professionals with expertise in surgical assessments. The intensity, frequency and variety of support from an MDT of healthcare professionals varies between NHS specialist weight-management services. It may be offered in person, remotely by telephone or video call, or as a combination of in-person and remote support. Most programmes offered by these services take between 12 and 24 months to complete, but some may only take 6 months. The criteria for accessing these services may also vary depending on the geographical area and local funding.

The comparator

2.4 The comparator is standard care to manage treatment with weight-management medicine for adults who are eligible for weight-management medicine. Standard care includes specialist weight-management programmes (including, but not limited to tier 3 and 4 services). They may be delivered face to face, remotely or as a combination of remote and face-to-face support.

2.5 No or delayed treatment is also a relevant comparator. Some people are on waiting lists to access services or have no access at all.

3 Committee discussion

NICE's medical technologies advisory committee considered evidence, from several sources, on digital technologies to deliver specialist weight-management services for adults who are eligible for weight-management medicine. This includes an early value assessment (EVA) report by the external assessment group (EAG), and an overview of that report. Full details are in the project documents for this guidance on the NICE website.

Unmet need

3.1 There is an unequal distribution of specialist weight-management services across the NHS, and in some areas there is no access to them. In areas where there are services, there is an increasing number of people on waiting lists because of limited resources and funding. Also, waiting times for accessing services have been rising significantly. The clinical experts estimated that 30% to 70% of people do not have access to a specialist weight-management service in their area. They also estimated that 10% to 30% of people are unable to attend face-to-face appointments because of time commitments or for mental health reasons.

3.2 Limited access to specialist weight-management services may also limit access to weight-management medicine for people who are eligible. Weight-management medicine can only be accessed alongside a programme from a specialist weight-management service. The clinical experts explained that if there are no specialist services available, people may be referred to other tier 1 or tier 2 weight-management services. These services cannot provide or manage weight-management medicine and do not offer appropriate support for treatment with medicine. The clinical experts also said that people who cannot access services may go to private providers that are not regulated and could be harmful because there is no wrap-around support. The clinical experts agreed that there are limited treatment options for people who cannot access specialist services in their area. The committee concluded that there is an unmet need, and access to specialist weight-management services should be improved.

Clinical effectiveness

3.3 The evidence suggests that 5 out of the 8 technologies (Gro Health W8Buddy, Liva, Oviva, Roczen and Second Nature) have a potential benefit for adults who are eligible for treatment with weight-management medicine. But only 1 published full-text study included people who were taking weight-management medicine. There was limited evidence for CheqUp and Juniper and no evidence for Wellbeing Way.

3.4 The evidence base consists of 26 studies reported across 31 publications. Four studies for Second Nature were excluded from the EAG assessment report because they were not considered relevant to the decision problem. But these studies were later considered relevant to the assessment by the committee. The evidence included 1 randomised controlled trial (RCT), 4 non-randomised comparative studies, 1 pilot RCT (which did not compare the technology with standard care), 13 non-comparative studies and 7 unpublished studies that were provided by the companies. The EAG explained that comparative evidence reported equivalent or more weight loss when using the technologies compared with face-to-face specialist weight-management services, but that this evidence is limited. The statistical significance beyond 1 year is uncertain, but the evidence suggests equivalence with standard care at 2 years. The evidence generally reported weight loss for the technologies when compared with baseline (for Liva, Oviva, Roczen and Second Nature). The clinical experts agreed that the non-comparative evidence was enough to demonstrate at least equivalent weight loss when the technologies were compared with having no access to specialist weight-management services. The committee heard that longer-term follow up is needed because obesity is a chronic condition.

3.5 There is some evidence on programme adherence, programme engagement, health-related quality-of-life outcomes and psychological outcomes. The RCT for Liva reported no difference in the EQ-5D-5L or Short Warwick–Edinburgh Mental Wellbeing Scale scores compared with face-to-face support or with baseline at 6 months and 12 months. The committee concluded that more evidence is needed for these outcomes.

3.6 During consultation, further evidence was submitted for CheqUp, Gro Health W8Buddy, Juniper, Oviva and Second Nature. Gro Health W8Buddy provided an additional poster report on weight loss outcomes and an unpublished paper. The committee concluded that the additional evidence provided was enough to support the use of Gro Health W8Buddy in the NHS while further evidence is generated. Second Nature provided a conference poster of a retrospective cohort study, and Oviva provided an abstract on adverse event data when using Oviva with weight-management medicine. This conference poster and abstract did not change the outcome of the assessment.

3.7 CheqUp submitted a preliminary data summary of an ongoing study using the technology alongside weight-management medicine, and Juniper provided interim results on 2 ongoing studies and details of a third ongoing study. The committee concluded that the evidence provided was not of good enough quality to recommend CheqUp and Juniper for use in the NHS while further evidence is generated, but recommended that further research is done through company, research or non-core NHS funding.

Risk management

3.8 Further evidence will be generated while 5 technologies (Gro Health W8Buddy, Liva, Oviva, Roczen and Second Nature) are used in the NHS to address the immediate unmet need, with appropriate risk-management processes in place. The clinical experts and committee stressed the importance of clinical risk management. The companies advised that they have risk-management processes and safeguarding systems in place. Most of the technologies have monitoring systems to pick up any key words relating to safety or adverse events, as well as regular contact with healthcare professionals. The committee highlighted that there is a lack of evidence relating to how the technologies monitor and report adverse events, and limited evidence for people taking weight-management medicine. The committee concluded that these technologies can be used, while evidence is generated, as an option to deliver specialist weight-management services to manage weight-management medicine. But they should only be used with appropriate safeguarding and risk-management processes in place.

3.9 The clinical experts raised that there is limited information on how multidisciplinary teams (MDTs) are used in the programmes offered by the technologies. But they noted that this is also the case for standard care and that MDTs can vary significantly between weight-management services. The clinical experts also highlighted that a full clinical assessment and referral for weight-management medicine is needed before using these technologies, to make sure the technologies are suitable. They also noted that the programmes' MDTs must include psychological support because obesity is a complex condition that requires a lot of support. People may have additional co-morbidities and a large proportion of people with obesity have mental health issues. The clinical experts said that it is important to monitor behaviour on restricted diets to minimise the risk of potential harms, such as developing disordered eating. The committee concluded that both psychological monitoring and appropriate referral procedures are important.

Equality considerations

3.10 The technologies may not be suitable for everyone. The clinical experts estimated that 7% to 30% of people may find digital programmes unsuitable, for example, because of reduced manual dexterity or a learning disability. They also noted that some people are less comfortable or skilled in using digital technology, or may have limited access to equipment and the internet. Autistic people may also find digital technologies unsuitable or may need additional support. The EAG said that the economic model included costs for a tablet computer and monthly internet access, to reduce the risk of excluding people because of digital inequality. The committee noted that language could also be a barrier to accessing the technologies' programmes. The companies confirmed that most of the technologies offer their programmes in multiple languages. The clinical experts said that there is a lack of evidence available to identify which groups may or may not be able to access the technologies, or who may benefit the most from them. The committee accepted that some people may need additional support or equipment when using the technologies. The committee agreed that NHS teams should consider providing a tablet computer and mobile internet connection when offering these technologies, to reduce digital inequality. It concluded that there may be some people who may not

benefit from the technologies, but that more data is needed.

Costs and resource use

3.11 The preliminary results of the early economic modelling showed that the technologies are cost effective when compared with face-to-face services. The EAG said that there was limited data to populate the parameters of the model, and that the results are uncertain. Based on the sensitivity and threshold analysis, the biggest factor affecting the results is the estimate of standard care costs used for current tier 3 services. The threshold analysis showed that if standard care costs were reduced by approximately 25%, or the technology costs were increased by 35%, then standard care would become the cost-effective option. The committee concluded that further evidence on clinical effectiveness including health-related quality of life and resource use is needed to reduce uncertainty in the cost modelling.

Evidence gap review

3.12 For 5 technologies (Gro Health W8Buddy, Liva, Oviva, Roczen and Second Nature), the committee agreed that the evidence is limited. It agreed that the key evidence gaps relate to study design and duration, population, comparator, outcomes and decision modelling. The committee concluded that there is enough evidence of potential benefits from the 5 technologies for them to be used in the NHS while further evidence is generated, once they have Digital Technology Assessment Criteria (DTAC) approval. Evidence generation is needed to address the following key evidence gaps:

- Study design and duration: there is limited comparative evidence and no long-term evidence beyond 1 year for most of the technologies, apart from a 2-year study for Liva. The committee and clinical experts highlighted the importance of long-term outcomes to evaluate if weight loss can be maintained.

- Population: only 1 published full-text study reported the proportion of people taking weight-management medicine. The clinical experts and committee highlighted the importance of generating evidence in this population to ensure that patient safety is monitored appropriately. There is also a lack of evidence for how different populations, including people who are underserved, engage with the technologies, and which groups may benefit the most.
- Technologies: there is limited unpublished evidence relating to the decision problem for CheqUp and Juniper and no available evidence for Wellbeing Way. The committee concluded that further research is needed for these technologies.
- Comparator: the number of specialist weight-management service providers and the number of people who use the services in the NHS is not known, with limited data on service delivery and MDT composition. The EAG suggested that the NHS National Obesity Audit could enable these services to be monitored in the future. The committee concluded that it is important to capture MDT composition and service delivery in further evidence generation because it may also impact the cost-effectiveness results.
- Outcomes: there is inconsistency in the outcomes reported in the evidence base. The clinical experts highlighted that the evidence base includes self-reported and clinically measured weight-related outcomes, which may introduce bias. The clinical experts agreed that key outcomes should be prioritised to ensure consistency in future evidence generation (see section 1.6). The committee highlighted the importance of measuring health-related quality-of-life and psychological outcomes using patient-reported outcome measures such as the EQ-5D, SF-12, SF-36 or PHQ-9.
- Decision modelling: there is a lack of direct economic evaluations related to all the technologies. The committee concluded that more direct data is needed for both digital weight-management technologies and standard care to reduce uncertainty in future economic modelling.

3.13 The committee concluded that there was not enough clinical-effectiveness evidence to recommend CheqUp, Juniper and Wellbeing Way for use in the NHS, other than as part of a research study. Research should include well-designed and adequately powered studies with appropriate comparators. The key outcomes prioritised by the committee and further important outcomes are outlined in section 1.6.

Research studies should address the evidence gaps outlined in this guidance to assess the benefit of using these technologies to deliver specialist weight-management services for adults who are eligible for weight-management medicine.

4 Committee members and NICE project team

Committee members

This topic was considered by NICE's medical technologies advisory committee, which is a standing advisory committee of NICE.

Committee members are asked to declare any interests in the technologies to be evaluated. If it is considered there is a conflict of interest, the member is excluded from participating further in that evaluation.

The minutes of the medical technologies advisory committee meetings, which include the names of the members who attended and their declarations of interests, are posted on the NICE website.

Additional specialist committee members took part in the discussions and provided expert advice for this topic:

Specialist committee members

Andrew Currie
Consultant in upper gastrointestinal surgery, Epsom and St Helier University Hospitals NHS Trust

Imad Mekhail
Locum GP

Irena Cruickshank
Weight-management nurse specialist, Somerset NHS Foundation Trust

Jennifer James
Physiotherapy lecturer, University of Liverpool

Karen Coulman

Research fellow and obesity specialist dietitian, University of Bristol and North Bristol NHS Trust

Rebecca Fahey
Advanced specialist dietitian in weight management, obesity and obesity surgery, Cambridge University Hospitals NHS Foundation Trust

Sarah Le Brocq
Lay specialist committee member

NICE project team

Each early value assessment (EVA) topic is assigned to a team consisting of 1 or more health technology assessment analysts (who act as technical leads for the topic), a health technology assessment adviser and a project manager.

Amy Barr and Charlotte Pelekanou
Health technology assessment analysts

Lizzy Latimer and Lirije Hyseni
Health technology assessment advisers

Elizabeth Islam
Project manager

ISBN: 978-1-4731-5510-7

Accreditation