

# NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

## Early value assessment final draft guidance

# Digital technologies for providing specialist weight-management services

### Guidance development process

Early value assessment (EVA) guidance rapidly provides recommendations on promising health technologies that have the potential to address national unmet need. NICE has assessed early evidence on these technologies to determine if earlier patient and system access in the NHS is appropriate while further evidence is generated.

The medical technologies advisory committee has considered the evidence and the views of clinical and patient experts. EVA guidance recommendations are conditional while more evidence is generated to address uncertainty in the evidence base. NICE has included advice in this guidance on how to minimise any clinical or system risk of early access to treatment.

Further evidence will be generated over the next 4 years to assess if the benefits of these technologies are realised in practice. NICE guidance will be reviewed to include this evidence and make a recommendation on the routine adoption of this technology across the NHS.

NICE has evaluated [digital technologies for delivering specialist weight-management services to manage weight-management medicine: early value assessment \(HTE14\)](#). That guidance is for technologies that deliver a multidisciplinary specialist weight-management service, including prescribing, monitoring or tracking weight-management medicine.

**This document has been prepared for consultation. Due to the overlap in the technologies, evidence base and potential risks, this document combines the**

recommendations from [HTE14](#) with this topic ([GID-HTE10023](#)). The final version of this document will replace HTE14. It summarises the evidence and views that have been considered and sets out the recommendations made by the committee. Recommendation 1.1. and sections 3.3 to 3.10 of the document have been finalised and cannot be changed. But, NICE invites comments from registered stakeholders, healthcare professionals and the public on the remaining sections of this document. This document should be read along with the evidence on the NICE website (an EVA report by the external assessment group and an overview of that report).

The advisory committee is interested in receiving comments on the following:

- 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 recommendations sound, and a suitable basis for guidance to the NHS?

### **Equality issues**

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 recommendations may need changing to meet these aims. In particular, please tell us if the recommendations:

- could have a different effect 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 effect on disabled people.

Please provide any relevant information or data you have about such effects and how they could be avoided or reduced.

**Note that this document is not NICE's final guidance on digital technologies for providing specialist weight-management services. The recommendations in section 1 may change after consultation.**

After consultation, NICE will consider the comments received. The final recommendations will be the basis for NICE's early value guidance.

**Key dates:**

Closing date for comments: 17 November 2023

## **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, for prescribing, monitoring or tracking weight-management medicine and delivering specialist weight-management services for adults. 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.

1.2 Seven digital weight-management technologies can be used in the NHS, while more evidence is generated, to support specialist weight-management services for adults without prescribing, monitoring or tracking weight-management medicine. The technologies are:

- Counterweight (Counterweight)

- Gro Health W8Buddy (DDM Health)
- Liva (Liva)
- Oviva (Oviva)
- Roczen (Reset Health)
- Second Nature (Second Nature)
- Weight Loss Clinic (Virtual Health Partners).

These technologies provide programmes to increase physical activity levels and improve eating behaviour and diet.

### **For all technologies**

- 1.3 These technologies can only be used once they have appropriate Digital Technology Assessment Criteria (DTAC) approval.
- 1.4 The company 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.
- 1.5 At the end of the evidence generation period (4 years), the company 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**

- 1.6 More research is needed on using the following digital weight-management technologies:
  - CheqUp (CheqUp Health)
  - Gloji (Thrive Tribe)
  - Habitual (Habitual Health Ltd)
  - Juniper (Juniper Technologies UK)

- Wellbeing Way (Xyla Health and Wellbeing).

1.7 Access to the technologies in section 1.7 should be through company, research, or non-core NHS funding, and clinical and financial risks should be appropriately managed.

## **Evidence generation and research**

1.8 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, cost of the medicine and NHS staff time needed to support using the digital technologies.

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 for delivering or supporting specialist weight-management services. Some provide weight-management programmes that prescribe, monitor or track weight-management medicine. They can be used for adults who are eligible for specialist weight-management services 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 in-person specialist weight-management services.
- **Resources:** The technologies could reduce the demand for in-person 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:** An NHS healthcare professional should do a full clinical assessment and referral before offering access to 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.
- **Resource:** There is a lack of evidence relating to the impact of implementing the technologies alongside current NHS services and further evidence is needed.
- **Multidisciplinary support:** The technologies provide support from a multidisciplinary team of qualified healthcare professionals. This must include or have access to 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.

## 2 The technologies

2.1 Digital weight-management technologies can be used to deliver or support 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. The frequency of reviews may vary depending on the technology, user preference and stage of the programme. Other technologies, or versions of technologies, do not include weight-management medicine prescribing, monitoring or tracking. These technologies can be used to support specialist weight management services, including treatment with weight-management medicine. NICE has assessed 12 technologies that can deliver or support specialist weight-management services. The criteria for including technologies in this early value assessment (EVA) and further details for technologies that prescribe, monitor or track weight-management medicine are in [Section 2.2, Table 2 and Appendix E of the assessment report, and in the assessment report addendum on the NICE website](#). For technologies that support specialist weight-management services, further details are in the [final scope](#) for the assessment. 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.
- Counterweight (Counterweight): this is an app that provides a multidisciplinary weight-management programme. Counterweight does not have a CE or UKCA mark because the company states 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.

- Gloji (Thrive Tribe): this is an app that provides a multidisciplinary weight-management programme. The regulatory status of Gloji is unclear and there has been no engagement from the company.
- Habitual (Habitual Health Ltd): this is an app that provides a multidisciplinary weight-management programme. Habitual does not have a CE mark but the company are in the process of applying for regulatory approval.
- 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.

- Weight Loss Clinic (Virtual Health Partners): this is an online platform that provides a multidisciplinary weight-management programme. Weight Loss Clinic does not have a CE or UKCA mark because the company states it is not classed as a medical device.

## Care pathway

- 2.2 [NICE's guideline on obesity: identification, assessment and management](#) recommends that people should be considered for referral to specialist weight-management services if the underlying causes of obesity need to be assessed, the person has complex needs that cannot be managed adequately in tier 2, conventional treatment has been unsuccessful or if specialist interventions may be needed.
- 2.3 Semaglutide for managing overweight and obesity 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](#)).
- 2.4 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

2.5 The comparator is standard care, including managing 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 in-person support.

2.6 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 provide specialist weight-management services. 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. 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 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 in-person 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.

## **Technologies used to deliver specialist weight-management services, including prescribing, monitoring or tracking weight-management medicine**

### **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 in-person 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 in-person 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 or have access to 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.

### **Costs and resource use**

- 3.10 The preliminary results of the early economic modelling showed that the technologies are cost effective when compared with in-person 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.

## Technologies used to support specialist weight-management services

### Clinical effectiveness

- 3.11 The evidence suggests that 7 technologies (Counterweight, Gro Health W8Buddy, Liva, Oviva, Roczen, Second Nature and Weight Loss Clinic) have a potential benefit in supporting specialist weight-management services. But, only 4 studies included people in tier 3 or 4 specialist weight-management services, only 1 study met the decision problem in all areas, and there is an unknown likelihood of crossover between some of the publications. There was limited evidence for CheqUp, Habitual and Juniper and no evidence for Gloji and Wellbeing Way. The committee concluded that the evidence provided was not of good enough quality to recommend CheqUp, Habitual and Juniper for use in the NHS while further evidence is generated.
- 3.12 The evidence base consists of 53 published studies for 7 technologies (Oviva [n=20], Counterweight [n=11], Second Nature [n=8], Gro Health W8Buddy, Liva [n=5], Roczen [n=3] and Weight Loss Clinic [n=3]) and 21 unpublished studies for 7 technologies (Liva [n=6], Oviva [n=6], Habitual [n=3], Juniper [n=2], Roczen [n=2], CheqUp [n=1] and GroHealth [n=1]). Published evidence included 4 randomised controlled trials (RCT), 7 non-randomised comparative studies, 1 pilot RCT (which did not compare the technology with standard care), 40 non-comparative studies and 1 study comparing Liva, Oviva and Second Nature. The EAG explained that comparative evidence reported equivalent or more weight loss when using the digital technologies compared with in-person 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. Non-comparative evidence generally reported weight loss when using the



technologies compared with baseline. There was a lack of evidence comparing digital technologies to no treatment. The committee heard that longer-term follow up is needed because obesity is a chronic condition.

- 3.13 There is some evidence on programme adherence, programme engagement, health-related quality-of-life outcomes and psychological outcomes. An RCT for Counterweight reported an increase in health-related quality of life in the intervention group compared with the control group. The RCT for Liva reported no difference in the EQ-5D-5L or Short Warwick–Edinburgh Mental Wellbeing Scale scores compared with in-person support or with baseline at 6 months and 12 months. The committee concluded that more evidence is needed for these outcomes and highlighted the importance of consistency in the patient reported outcome measures used when collecting psychological outcomes in future research and evidence generation.

### **Risk management**

- 3.14 The clinical experts stated that there is limited information on what the digital specialist weight-management programmes consist of and how they differ between technologies. But, they noted that this is also the case for standard care and that offerings can vary significantly between in-person specialist weight-management services. The clinical experts highlighted the importance of having appropriate qualifications (such as a SCOPE certification) and suitable levels of experience managing obesity. They also noted that the programmes' MDTs should include access to physiotherapy and psychological support because obesity is a complex condition that needs a lot of support. People may have additional comorbidities 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 digital specialist weight-management programmes should be delivered by

appropriately qualified and experienced healthcare professionals and must include or have access to psychological monitoring.

### **Monitoring engagement and user experience**

3.15 Engagement and adherence should be monitored and followed up throughout the duration of the programme. Clinical experts explained that there is a lack of information about why people stop using digital programmes. The companies explained that engagement is monitored during regular meetings with healthcare professionals. If this drops below a pre-determined threshold, users may be prompted to reengage through automated messages, nudges, peer mentoring or direct contact with a healthcare professional. Some companies also stated that engagement can be tracked automatically through user interaction with app content. The committee concluded that referral procedures are important, and more evidence is needed to establish why people stop taking part in programmes.

3.16 Digital programmes should be personalised and incorporate user feedback. The companies explained that user feedback is continuously sought throughout the programmes. Some companies stated that users are sent feedback questionnaires and suggestions can be incorporated into the programme on a bi-weekly basis. Some companies stated that using digital technologies allows detailed levels of feedback to be collected for each piece of content, which can be amended immediately. The clinical experts highlighted the importance of user feedback and how this can be used to enable individualised care for people with obesity. They also acknowledged that implementing user feedback and improvements may be faster and more consistent with digital technologies compared with in-person services. The committee concluded that collecting feedback to improve user experience and enable individualised care is important when delivering specialist weight-management services using digital technologies.

## Costs and resource use

- 3.17 The preliminary results of the early economic modelling showed that the technologies are cost saving and cost effective when compared with standard care and a 6-month delay to standard care. With a 12-month delay to treatment, or when compared with no treatment, the technologies become cost incurring but increase quality of life. The EAG said that there was uncertainty in both the cost and quality of life outcomes because there is limited data and long-term outcomes are not included in the model. 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.
- 3.18 The technologies may release NHS resources and increase access to specialist weight-management services, but more evidence is needed. The clinical experts stated that the implementation of digital technologies in the NHS could impact current NHS staff workload positively or negatively. The companies stated that some of their staff previously worked in the NHS, some have worked privately and some continue to work in the NHS alongside their work with digital technologies. The EAG said that there was a lack of evidence related to the cost of implementing digital technologies alongside current NHS services. The model does not take into account the potential inefficiencies of these 2 services working together to deliver specialist weight-management services. The committee concluded that further evidence should be collected on the NHS staff time needed to support using the technologies.

## Evidence gap review

- 3.19 For 7 technologies (Counterweight, Gro Health W8Buddy, Liva, Oviva, Roczen, Second Nature and Weight Loss Clinic), the committee agreed that the evidence is limited. It agreed that the key evidence gaps relate to study design and duration, population, the technologies, comparator, outcomes and decision modelling. The committee concluded that there is

enough evidence of potential benefits from the 7 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:
  - For technologies used to deliver specialist weight-management service, including prescribing, monitoring or tracking weight-management medicine, only 1 published full-text study reported the proportion of people taking weight-management medicine and only 9 unpublished studies reported outcomes in people using semaglutide or liraglutide.
  - For technologies used to support specialist weight-management services, only 4 studies included people in tier 3 or 4 specialist weight-management services and only 1 study met the decision problem in all areas.
  - The clinical experts and committee highlighted the importance of generating evidence in people taking weight-management medicine 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.
- 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 NHS National Obesity Audit could enable these services to be monitored in the future. The committee concluded that it is important to

capture this in further evidence generation because it may also impact the cost-effectiveness results.

- **Outcomes:** there is limited evidence reporting several outcomes including health-related quality of life, psychological outcomes, engagement and adherence. For digital technologies that prescribe or monitor weight-management medicine, 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. The committee highlighted the importance of measuring health-related quality of life and psychological outcomes. It said that patient-reported outcome measures for quality of life (EQ-5D, SF-12, SF-36), anxiety or depression (GAD-7, HADS, PHQ-9), eating disorders (TFEQ-R18, DEBQ), binge eating (BEDS-7, BES) and emotional eating (EEQ) should be considered.
- **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 technologies and standard care to reduce uncertainty in future economic modelling.

3.20 The committee concluded that there was not enough clinical-effectiveness evidence to recommend CheqUp, Gloji, Habitual, 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 are 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, cost of the medicine and NHS staff

time needed to support using the digital technologies. Research studies should address the evidence gaps outlined in this guidance to assess the benefit of using these technologies to provide specialist weight-management services for adults.

## Equality considerations

3.21 The technologies may not be suitable for everyone. The clinical experts estimated that 7% to 30% of people may find digital technologies unsuitable, for example, because of reduced manual dexterity or a learning disability. Some people may be less comfortable or skilled in using digital technologies, 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. It concluded that there may be some people who may not benefit from the technologies, but that more data is needed to identify who may benefit or not benefit from digital technologies.

## 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 and experts**

#### **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

#### **Helen Parretti**

Consultant clinical associate professor in primary care, University of East Anglia

#### **Jennifer James**

Physiotherapy lecturer, University of Liverpool

#### **Karen Coulman**

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

#### **Laura Power**

GP, Priory Medical Centre, Liverpool

**Rebecca Fahey**

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

**Richard Cordes**

Lay expert

**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: