National Institute for Health and Care Excellence

Medical technologies evaluation programme

GID-HTE10007 Digital technologies for delivering specialist weight-management services to manage weight-management medicines: early value assessment

Consultation comments table

There were 156 comments from 32 consultees:

- 46 comments from 10 individuals
- 67 comments from 12 companies
- 31 comments from 5 patient and professional organisations
- 7 comments from NHS England
- 5 comments from the Office for Health Improvement and Disparities, Department for Health and Social Care (DHSC)

Some of the comments have been split because they represented multiple themes. The following themes have been identified:

- Recommendations: comments 1 to 14
- Care pathway: comments 15 to 40
- Clinical effectiveness: comments 41 to 54
- Cost and resource use: comments 55 to 62
- Equality considerations: comments: 63 to 76
- Evidence generation and research: comments 77 to 100
- Implementation: comments 101 to 108
- Managing risk: comments 109 to 113
- Multidisciplinary support: comments 114 to 118
- Patient perspectives: comments 119 to 121
- Patient population: comments 122 to 130
- Process: comments 131 to 135
- The technologies: comments 136 to 154

- General: comment 155 and 156

Comment no.	Consultee ID	Group	Section	Comments	Responses
Recommendations (n= 14)					
1.	3	Patient or professional organisation	1	It should be clear that Tier 2 should not be regarded as a gateway to the digital and medication route. There remains an underlying perception that public/patients prefer digital interventions and this should be compared against demand for (and impact on demand for) conventional in-person programmes. Any final recommendations should include broad recommendations for the general impact of digital interventions and also the specific styles of digital intervention as each provider (Liva, Oviva, Roczen and Second Nature) will each have a different format and these may achieve different outcomes.	Thank you for your comments. The guidance has been amended to make it clear these technologies are to be used to deliver specialist weight-management services for adults who are eligible for weight-management medicines following clinical referral and assessment. Additional information has been added to section 2.1 of the guidance to provide further detail on the technologies considered in this evaluation. Technologies considered in this evaluation included those that facilitate weight-management medicines monitoring or prescribing and so do not need to provide an in-house prescribing service. All digital technologies are expected to meet NHS England's digital technology assessment criteria (DTAC) prior to procurement as stated in the section 1 recommendations. Additional information in relation to the prescribing of weight-management medicines has been added to section 1 to clarify that recommendations made by NICE, the British National Formulary and General Medical Council should be followed when using these technologies. Wording has been amended in section 1 and in the care pathway (section 2.3) to provide additional information on the multidisciplinary teams involved in specialist weight-management services. The aim of NICE's early value assessment (EVA) programme is to support earlier patient access to
2.	8	Company	1.1	The situation/recommendation around DTAC needs clarifying. Section 1.1. suggests that none of the 4 technologies have DTAC approval yet - Oviva and some other technologies already have DTAC approval. The statement might be taken as a generic reminder that any of the technologies needs DTAC approval before use. However, the press release from NICE: https://www.nice.org.uk/news/article/digital-services-to-enable-easier-access-to-weight-management-support specifically suggests that only Liva has DTAC approval and is ready for use in the NHS whilst the other 3 are not. "Liva is available to be deployed into use by the NHS while Oviva, Roczen and Second Nature can be used once they have appropriate Digital Technology Assessment Criteria approval from NHS England." This statement is incorrect - Oviva has received DTAC approval from both NHS England (as part of our participation in the NHS Diabetes Prevention Programme, like Liva) and	

				from local ICB commissioners (most recently NHS North East London ICB in 2023) as evidenced in our original submission to NICE as part of this EVA. Please can this misleading public statement be rectified as soon as possible.	technologies that have the potential to meet current system needs. Unlike other NICE guidance, EVA does not require selected technologies to have generated a large amount of evidence on clinical and cost-effectiveness meaning NICE can assess them at an earlier stage. For a technology to be conditionally recommended, it needs to be plausible that the technology will address the unmet need and it is acceptable for the technology to be used in practice while further evidence is generated. Where evidence is limited or absent, a research recommendation would be made due to the uncertainty around whether the technology could have the potential to solve the unmet need. The committee considered additional evidence from CheqUp, Gro Health W8Buddy and Juniper. It concluded that there was enough evidence to conditionally recommend Gro Health W8Buddy whilst further evidence was generated. However, they considered that there was too much uncertainty around the evidence for CheqUp and Juniper to conditionally recommend these technologies, suggesting further research should be done using company, research, or non-core NHS funding instead. An addendum detailing the evidence and description for Juniper is published alongside this guidance. The eligibility of including additional technologies has been checked by the NICE team. It has been confirmed that Counterweight does not meet the criteria to facilitate weight-management medicine monitoring or prescribing.
3.	11	Company	Draft guidance	Are the recommendations sound, and a suitable basis for guidance to the NHS? No. [redacted] believe that this early value assessment (EVA) should be in line with the recently updated section “1.10 Surgical interventions” of CG189: Obesity: identification, assessment, and management.	
4.	14	Company	Guidance development process	We have significant concerns about the use of this type of assessment for technologies that include access to medicines. We do not think that the implications for medicines prescribing, supply and patient monitoring have been fully assessed. Specific recommendations on access to medicines via these technologies needs to be included in the final guidance.	
5.	14	Company	1.1	If these technologies are intended to be an alternative to standard Tier 3 services, they should all provide the same level service, including prescribing medicines. We understand that Liva does not currently have in house prescribing for weight management medicines, and therefore should not be recommended as an equitable alternative to the other technologies. If Liva is recommended in the final NICE guidance, there needs to be clear technical guidance for medicines optimisation and finance teams highlighting the differences between the services, to ensure that budgets are allocated appropriately e.g. if GPs are expected to prescribe, funding	

				for weight management medicines should allocated to the GP prescribing budgets. Note we believe that prescribing via the primary care route would be problematic - see comments in section 2.	
6.	14	Company	3.9	You acknowledge that there is limited evidence based evidence for these technologies. In other NICE recommendations involving medicines, this lack of evidence would result in a negative recommendation. We do not think it is appropriate for this type of assessment to be used where the technology includes access to medicines. A more robust approach to assessing safety, efficiency and cost effectiveness is required. The proposed recommendations appear to support evidence generation and attempt to address inequity of access to weight management services without good evidence that such a strategy will result in positive outcomes for patients, and the best use of NHS resources.	
7.	16	Company	1	Obesity is a major public health problem in England which costs the National Health Service £6.1 billion in 2019. Recent pharmacotherapy innovation means that for the first time, medication is (Semaglutide – GLP-1) or will be (tirzepatide – GLP-1/GIP) available which will have a transformational impact on the health of those living with overweight or obesity. However, the delta between the volume of people with the qualifying prescribing criteria and the available tier 3 capacity is such that the vast majority of eligible patients face frustration in being prescribed this medication on the NHS. Unfortunately, we believe that the guidance consultation document as currently drafted is a missed opportunity for NHS patients to benefit from the use of digital and virtual	

				technologies for the provision of weight management services. The guidance consultation puts too much emphasis on limited-quality research data; the vast majority of which is not even related to any anti-obesity medications (let alone the new-generation medications), but to lifestyle changes. Currently there is a shortage of GLP-1 based treatments in the UK precluding others, including CheqUp, from generating our own research data using these treatments. The next EVA review in four years is excessively long given the fast pace of technological change; and that consequently it presents a missed opportunity to provide substantial additional capacity to address unmet need. Consequently, we argue that, subject to the appropriate clinical governance, all seven companies who formed part of the EVA should have the right to operate in core NHS services while conducting research in accordance with NICE guidelines as laid out in section 1.4 of the report; and that the next review of the technologies and health and economic outcomes should take place within two years, rather than four. We would request the Medical Technologies Advisory Committee to reconsider the draft guidance on the basis that: - Patients stand to benefit in the medium-to-long term from the NHS gaining real world evidence on the efficacy of a whole range of different tier-3 type support systems used in conjunction with second generation GLP-1 / GIP medications - The NHS too stands to benefit if different types and 'levels' of technology are compared, again when using second generation GLP-1 / GIP medications, for weight-loss outcomes vs cost-effectiveness in comparable patient cohorts over a statistically relevant time period - NO company or technology can claim to have presented sufficient relevant evidence given that given the emphasis on	

				"diet and lifestyle research" and that no second generation GLP-1 / GIP medications are currently available - That CheqUp's proposed technology is among the closest, if not the closest, solution presented to the Committee to existing and proven NHS tier-3 weight management services - That the patient clinical risks associated with tier-3 weight management services post prescription are not so grave as to prevent the testing of our technology in a real world system, and that the greater test is whether a virtual tier-3 system delivers sufficient cost-savings to make it a valuable investment - Four years is, in any case, an unnecessarily long-time between reviews of such technologies given the pace of digital innovation and the vast need for weight management services in the UK We look forward to continuing to engage with the Committee on this and second, related EVA over the coming weeks and months.	
8.	16	Company	1.4	CheqUp has designed a service which mirrors the way the global clinical trials for liraglutide and semaglutide were structured and the criteria laid down by NICE for TAs 664 and 875. It is a full tier 3 equivalent service delivered virtually through physicians who connect to patients through the CheqUp health platform, thus delivering a myriad of benefits to the NHS. The patient pathways have been put together using clinicians from the weight management service at University College London Hospital, a site for the STEP trials for semaglutide and one of the most respected weight management centres in the UK. There is ample evidence that in-person tier 3 services have already delivered significant and sustained weight loss in the absence of GLP-1 medications, and the clinical trials of both Semaglutide (Wegovy) and tirzepatide (Mounjaro) have shown that such medications supported by tier 3-equivalent services will deliver average weight loss of between 14.9% and 22.5% over c. 60-70 weeks. Additionally, all the data,	

				including the most recent data on cardiac benefits from the SELECT study, points to very wide-ranging health benefits. The fact that we have presented no evidence to the committee is because we created this system specifically to support the prescribing of Wegovy (licensed, but not commercially launched) and Mounjaro (awaiting licence indications). Our system was complete, fully tested and ready to accept patients in 2022. However, the launch of Wegovy has been continuously delayed in the UK, while Mounjaro is unlikely to be approved by NICE until well into 2024. As a result, we have 'tested' our system with a small number of patients (about 100) using Saxenda to ensure clinical excellence and patient usability. All indicators point to weight loss being equal to or greater than that experienced within the clinical trials with very strong retention and engagement. On 18 July 2023, the NHS issued a National Patient Safety Alert urging clinicians to only prescribe GLP-1 medications for their licensed indications and not to initiate new patients. Unlike other companies in the sector, CheqUp has never prescribed Ozempic off-licence for weight management, even though the drug was licensed by the MHRA in February 2018. Counter-intuitively, if we had prescribed off-licence we would have had a bigger research cohort to present to the EVA yet this would have been derived from depriving patients with type 2 diabetes of Ozempic. At the same time, we are currently working through the process of DTAC compliance. One of the key elements of this is risk reduction and ensuring clinical safety of patients. What is clear in the weight management therapy area is that the clinical risks associated with the provision of Tier-3 weight management services, assuming correct prescription of the relevant medications by prescribing doctors or nurses, are relatively minor.	

				We would therefore respectfully ask the committee to reconsider their draft guidance on the basis that plentiful evidence already demonstrates the success of tier 3 weight management services delivered in person; and that, a priori, one could surmise that an identical, but virtual, service would deliver the same health benefits but with reduced cost (our cost base being +/- £100 p/m against the current NHS estimate of +/- £150 p/m for in person tier 3 services). To use a sporting analogy, we have completed our warm up and are ready for the game to start. For the Committee to adopt a binary 'yes/no' approach and rule out any technology for NHS use at this stage is, in our view, akin to the referee handing out a red card before the whistle to kick off has even been blown. To bar CheqUp, which has taken the proven patient pathways of the clinical trials / NICE TAs and made the appointments available virtually would be counter-intuitive.	
9.	21	Patient or professional organisation	Draft guidance	We welcome the recommendation to approve the four digitally enabled weight management-technologies for use on the NHS. This will increase the availability of specialist weight management services for people living with obesity and type 2 diabetes who face barriers to accessing these services such as those in isolated communities. Additionally, this will increase the capacity to refer individuals to specialist weight management services which will increase treatment of obesity using weight loss medication, reducing obesity-related complications including development of type 2 diabetes. We also welcome the reference to equality when looking at managing risk. It is essential that different treatment options are offered to those who would not be suitable for digital services, for example those with learning disabilities. Personal preference is also a key factor in adherence to treatment and so will provide the best outcomes.	
10.	27	Company	1	[redacted] welcomes the publication of this guidance, and entirely supports its aims in ensuring that people living with	

				obesity are able to access appropriate care. We recognise that across England there is significant variation in weight management service availability and capacity. As noted in the draft guidance, in many areas services do not exist, meaning GPs have nowhere to refer patients or patients are required to travel long distances to access support. As such, we are pleased that this guidance recommends the launch of digital services which can build on the (tier two) NHS Digital Weight Management programme and support patients living with complex and severe obesity to access timely care, as well as supporting NHS services to manage capacity constraints.	
11.	28	Company	1.1	We believe that Juniper should be included among the selected technologies. In subsequent comments, we have detailed the rationale for our inclusion. In brief: 1. We are confident we meet the criteria for inclusion in the scope of this Early Value Assessment (EVA) and believe the Juniper Weight Reset programme is well-suited for delivering specialist weight management in the NHS 2. We have evidence that supports the efficacy of the Juniper weight loss programme (and have obtained ethics approval to conduct three clinical studies into the outcomes of the Juniper weight loss programme) 3. We have relevant experience in the scope of the assessment, having effectively managed over 40,000 patients on weight-management medications across 3 geographies (United Kingdom, Australia and Germany) via our programme 4. We are able to safely support patients through our clinical governance procedures. Juniper's Australian based platform is the only tele-health platform in Australia to receive independent certification from the Australian Council on Healthcare Standards (EQuIP6 accreditation). Juniper in the UK follows these same procedures. In addition to the comments on this document we have separately provided the EVA evaluation committee with 2 Appendices:	

				* Appendix 1 - our complete response to the 16 questions detailed in Appendix E of the draft assessment report * Appendix 2 - a spreadsheet summarising the outcomes of our clinical study ("clinical outcomes"), and a summary of additional indicators and measures across our complete patient database We would welcome any queries or requests for additional information from the evaluation committee relating to the information we have provided in these comments or in our submitted content.	
12.	28	Company	1.6	We are currently developing published studies (detailed in table 13.1 of Appendix 1, shared separately with the Evaluation Committee), which we are using to externally validate the outcomes for the patients on our platform to date. These studies, which have already received ethics approval, cover the effectiveness of the Juniper weight management programme. Table 13.2 in Appendix 1 provided separately to NICE summarises the key clinical outcomes that we expect to publish in these studies. Appendix 2 contains a summary of all clinical outcomes that we expect to use for the publication of our studies. The composition of our MDT is defined in our comment response to section 2.1. Our UK study includes the following outcomes: * Percentage change in weight and BMI (change in weight) * Side effect incidence, severity and response (monitoring and reporting of adverse events) We also evaluate several continuity of care and programme engagement metrics in a real-world context. Through Juniper's technology, we maintain data-rich systems and have relevant insights from having treated over 40k weight loss patients across three geographies. As we	

				continue to grow our programme, we look forward to further publicly sharing our clinical outcomes.	
13.	29	Company	Draft guidance	MANUAL applauds the intention of NHS England and NICE to utilise the latest technology to assist with the delivery of weight management programmes and medication. Given that we currently supply 8000 patients across all parts of the UK we stand ready to support the rollout of this agenda as quickly as possible.	
14.	32	Company	Draft guidance	Counterweight has over 40 publications supporting its evidence base, including being the intervention used in the Diabetes Remission Clinical Trial (DiRECT). Unfortunately, Counterweight registered as a Stakeholder instead of a provider with NICE and therefore was never notified of the need to submit provider evidence. Would the NICE Committee consider reviewing a late application from Counterweight to inform guidelines for digitally enabled technologies to support treatment with weight-management medication in specialist weight-management services? We look forward to hearing from you.	
Care pathway (n = 26)					
15.	1	Individual	3.2	How will accessing digital technologies and any potential weight loss medications with the developer, feed into Tier 4 services, and how will they impact the service/pre-requisite for patients to access tier 3 before tier 4?	Thank you for your comments. The care pathway is described in section 2.2 and 2.3 of the guidance and refers to the technology appraisal guidance on semaglutide and liraglutide as well as NICE's clinical guideline on obesity: identification, assessment and management and NHS England's guidance for Clinical Commissioning Groups (CCGs): Service Specification Guidance for Obesity Surgery (2016). These provide information on care pathways and the prescription of weight-management medicine. Weight-management medicine that is prescribed through the technologies should only be used in
16.	5	Patient or professional organisation	Draft guidance	3. Structure and Functioning of CAVUHB Level 3 Weight Management Service As a level 3 weight management MDT we work hard to adapt each intervention plan to the complex needs of our service users. We provide digital treatment options where appropriate and accessible for service users. Our digital treatment options: · Telephone monitoring calls	

				· Videocall intervention appointments · Videocall psychological therapy groups · Text reminders However, we find that delivering several aspects of our level 3 service in a face-to-face format is essential, including: · Initial intake assessments which help our team to develop a biopsychosocial formulation and treatment plan for each service user. · Medical and nursing appointments requiring physical examinations, monitoring and investigations. · Physiotherapy appointments requiring physical examinations and interventions. · Assessment of suitability of onward referral for bariatric surgery in level 4 services. · Occupational therapy assessments, involving assessment of the home environment and planning adaptation to service user needs. · Psychological therapy interventions addressing the complex and often trauma-related roots of emotional eating. · Where a complex risk is identified via digital intervention e.g. suicidal ideation disclosed during a telephone monitoring call or complex gastrointestinal side effects potentially attributable to Saxenda use, we are able to quickly arrange face-to-face appointments to further assess and manage these risks. A particularly challenging time for the service was during the height of the covid-19 pandemic, where the majority of our services moved to digital options, given the increased risk of	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 medicines remotely through a technology, healthcare professionals should follow the General Medical Council's remote prescribing high level principles. Detailed information around how technologies will be implemented in the NHS is outside of the remit of this evaluation. The committee acknowledged that although face to face specialist weight-management services exist, 30% to 70% of people do not have access based on expert opinion. The EAG clarified that in absence of published or available data from the National Obesity Audit or the National Mapping of Tier 3 Services by Public Health England, the EAG consulted with clinical experts for this topic who advised on this range. The EAG noted that local accessibility to Tier 3 and Tier 4 specialist weight-management services may vary within the areas covered by the integrated care boards. The committee concluded that digital specialist weight-management services could provide access to those who are eligible for weight-management medicines. The text in section 1 of the guidance has been modified to clarify that a referral and full clinical assessment from a qualified healthcare professional is needed before accessing services through these technologies. Section 2.3 was amended to acknowledge that most specialist weight-management programmes last between 12 and 24 months, but some may only be 6 months.

				covid-19 to the health and mortality of people living with obesity. During this period of time, where face-to-face appointments weren't possible, clinicians observed a decrease in engagement, a deterioration in weight loss outcomes, impaired accuracy of assessment, reductions in service user satisfaction reports, an increase in service user dropout rates and an increase in requests to delay intervention until face-to-face care was available. Based on the information outlined above regarding the functioning and structure of our level 3 weight management service we have concerns about the ability of digitally enabled technologies, without the option for face-to-face care, to adequately provide effective and safe care for service users eligible for Level 3 Specialist Weight Management Services.	
17.	8	Company	1.6	This is a fundamental misunderstanding of the clinical pathway/model. All 4 of the digital providers conditionally recommended by NICE operate a comprehensive Tier 3 weight management service whereby they provide the entire specialist multidisciplinary team alongside the technology. GPs would refer in to the Tier 3 service (whether a "traditional"/face to face service or a digitally-enabled service) but GPs would not be equipped to undertake a detailed assessment of suitability for weight management medication. So, in essence the statement should be something like "Clinical Assessment: Patients need a clinical assessment and referral into a Tier 3 service which includes those provided by the technology providers. Within these digitally-enabled weight management services patients will be comprehensively assessed for weight management medication to ensure that they are suitable."	
18.	8	Company	3.7	As per the comment above, this is a fundamental misunderstanding of the clinical pathway/model. All 4 of the digital providers conditionally recommended by NICE operate a comprehensive Tier 3 weight management service whereby they provide the entire specialist multidisciplinary team alongside the technology. GPs would refer in to the Tier 3	

				service (whether a "traditional"/face to face service or a digitally-enabled service) but GPs would not be equipped to undertake a detailed assessment of suitability for weight management medication. Patients will receive a comprehensive medical assessment to ascertain suitability for weight management medication once they are in the Tier 3 service (whether that is a "traditional"/face to face Tier 3 service or a digitally-enabled Tier 3 service provided by one of the 4 providers). Where such choice exists the GP may be able to make a judgement on the relative suitability or patient preference between a "traditional"/in person service and a digitally enabled service. Often such choice does not exist and in many areas neither type of service is available. There is no scope for a comprehensive specialist assessment before referral as it would add unreasonable, unaffordable and unsustainable complexity to the patient pathway.	
19.	9	Individual	Draft guidance	How does this fit in established pathways? It isnt clear if this is T2 or T3, or some sort of T3 lite? How will this feed into T4 surgery?	
20.	14	Company	1.6	There needs to be assurance that the patient will be appropriately assessed as being eligible for referral to specialist weight management services in line with national and local guidance. Thresholds for access to these technologies needs to equitable for patients being treated by established T3 weight management services. If patients are already using an app for T1 and T2 equivalent services, will an additional referral be needed for them to progress to digital services equivalent to T3 services to ensure they meet criteria?	
21.	14	Company	2	There needs to be greater clarity on the prescribing and supply of weight management drugs when accessed via these technologies. Where the provider does not currently have in house prescribing, what will be the mechanism for supplying patients using the technology?	

				Will GPs be requested to prescribe? If so, will they have the capacity to do so? Who will be responsible for monitoring and follow up and safety issues if care is split between the technology provider and the GP? Will there be a need for a shared care arrangement? What additional payments will be needed for GPs to take on this work and have these been taken into account in the economic model.? If GP prescribed, how will they access the confidential PAS/CAA price for weight management medicines specified in the NICE TAs that makes them cost effective for the NHS? If the medicine is to be supplied by the providers of the technology, how will they access the confidential PAS/CAA price specified in the NICE TAs that ensures the technology is cost effective for the NHS. There needs to be a mechanism to make sure that ALL data is captured on medicines prescribing e.g. if prescribed and dispensed by a private provider, including all on costs. This is not currently captured at a national level for medicines supplied by non-NHS providers of Tier 3 services, as ICBs are billed directly by the provider and the data does not appear in NHSBSA or secondary care data sources. What medication will these services be permitted to prescribe? Will prescribing be required to be in line with NICE guidance? Will this be specified in a contract with the provider?	
22.	15	Individual	1.6	Does this include a psychological screen?	
23.	15	Individual	2.1	It is essential to consider transition from childhood into adult services in the care pathway section. If a young person is currently on a weight management medication or if they have received bariatric surgery their transition will need additional considerations. E.g. if they are on a medication and a technology solution is considered appropriate for them then it will need to be one of the technologies that can support medication. The post bariatric surgery issue is relevant for those who had their surgery as an adult too. The type of	

				procedure will be important here as follow up needs and advice vary according to procedure.	
24.	15	Individual	3	Agreed	
25.	18	DHSC	2.3	Is tier 4 obesity surgery guidance the best source for the definition of a tier 3 service? In the supporting information the NHSE joined up clinical pathways for obesity (2014) report was cited. • Is it worth adding that the MDT should include a specialist obesity physician, specialist dietetic, psychological and physical activity input, whilst recognising that the MDT support varies. • Is it also worth reflecting that the majority of services are between 12 – 24 months, whilst recognising that they might be 6 months in some areas?	
26.	18	DHSC	3.1	The clinical experts estimated that 30% to 70% of people do not have access to a local specialist weight-management service. • There is large variation in this estimate, and I wonder whether a definition of 'local' would be useful to provide context? • To note that the APPG Report: The Current Landscape of Obesity Services (2018) reported that 57% of CCGs commission Tier 3 Services. They cite a 91% response rate to this survey from CCGs.	
27.	18	DHSC	3.6	The clinical experts also highlighted that a full clinical assessment and referral for weight management medication is needed before using these technologies, to make sure they are suitable. • Is there any standard process for this or is this for local determination? In the supporting documentation there is reference to the fact that specialist assessment might be needed for circumstances where it is difficult to weigh or measure the height of people with physical conditions or learning difficulties. I have assumed this means by a community dietitian or physiotherapist who would have access to specialised weighing devices. It is unclear whether these people would be in scope for treatment using a digital technology. I am also not clear if the technologies are	

				suitable for people with more complex health needs, such uncontrolled comorbidities.	
28.	20	Individual	1.6	NICE may consider approaching Community Pharmacy England's IT Policy Manager ([redacted]) for some additional info on apps and app standards from a community pharmacy perspective. See also: https://cpe.org.uk/briefings/psnc-briefing-08617-features-of-higher-quality-health-apps-and-how-to-give-app-feedback-november-2017/ In addition to DTAC one consideration in regards to apps 'approved' by NICE/ NHS is the extent to which they are interoperable with NHS and patient records, and the extent to which some relevant data flows into patient records (with appropriate IG modeals in place...). I'm not yet placed to yet fully assess all of the findings / recommendations.	
29.	22	Patient or professional organisation	Draft guidance	In addition, the integration of NHS-based level 3 Specialist Weight Management Service within the core NHS service structure enables information-sharing and collaboration with other services supporting the management of comorbidities. In particular, information sharing with neurology, cancer, lymphoedema and eating disorder services have enabled timely access to the most appropriate care for each individual. For example, [redacted] Level 3 Specialist Weight Management Service have developed a direct referral pathway to local Eating Disorder Services to enhance access to evidence-based psychological therapies for binge eating disorder where this plays a significant maintaining factor in complex obesity. The extent to which digitally enabled healthcare technology providers can offer a service that integrates with other relevant NHS services in a timely and safe manner remains unclear from the information currently available.	

30.	24	Individual	1.6	Since the time GLP-1 RA drugs (example Liraglutide/ Saxenda) were accepted by NICE TA for non-diabetic obesity, we have been using Saxenda for weight management in patients who are at risk from weight-related/ obesity-related co-morbities. As a SCOPE certified obesity doctor and a Certified Lifestyle Medicine Physician, I can definitely state that the patients will need close monitoring clinically - especially at the BMI cutoffs they are going to selected for. They will have other deficiencies that prevent them from getting the best outcomes. This is what happens in the real world weight management.	
31.	25	NHS England	Draft guidance	3.1 The text states “The clinical experts estimated that 30% to 70% of people do not have access to a local specialist weight-management service.” With 37 of the 42 ICBs currently commissioning a specialist weight management service, either tier 3 or 4, we feel the number may need revising. Alongside the terminology to “eligible people”.	
32.	26	Individual	1.6	this should not be seen as "instead of local specialist services" This should still be the priority to commission Tier 3 services in all areas so it's not a post code lottery. Digital can assist alongside this.	
33.	26	Individual	1.6	The demand for face to face services will not be reduced by digital. If waiting lists start to fall more patients will be referred as currently patients put off asking for support as they know the waits are huge.	
34.	26	Individual	3.1	even where there are services waiting times have gone up exponentially.	
35.	27	Company	1.6	In reference to 'clinical assessment': [redacted] believes that further detail should be provided on the process for clinical assessment. We assume assessment would be virtual but there would be value in understanding how consultations will be conducted, how eligibility criteria will be met and how patient safety is safeguarded. Should consultations vary between technologies, a minimum standard should be defined.	

36.	27	Company	2.1	[redacted] suggests that the care pathway embeds a link to para 1.8 in NICE CG198 (or GID-NG10182 when published) to provide an exhaustive list of pharmacological interventions that have been recommended in weight management. This is suggested to reduce off-label use of medicines, and provide clarity on starting and stopping criteria.	
37.	27	Company	2.1	[redacted] suggests that consideration is given to the mechanism for digital prescribing of weight management medicines in this guidance, indicating how this programme will reduce barriers to access and remove the requirement for physical collection in a hospital setting.	
38.	27	Company	3.4	[redacted] welcomes the reference to obesity as a long-term, relapsing chronic condition in this guidance.	
39.	29	Company	5	There is a lack of clinical experts in the digital care space. How will NICE evaluate the nuances of this area and ensure that the pathways are appropriate and scalable?	
40.	31	Company	General	[redacted] response to draft NICE guidance 'Digitally enabled technologies to support treatment with weight-management medication in specialist weight-management services: early value assessment' [GID-HTE10007]: Obesity related liver disease is a major cause of liver failure (Ahn & Sundaram, 2019) (Schiavo, et al., 2018) (Ioannou, et al., 2003) and a modifiable risk factor for cardiovascular disease (Roca-Fernandez, et al., 2023). As demonstrated in the NICE Diagnostic Assessment Programme for developing guideline DG50 'MRI-based technologies for assessing non-alcoholic fatty liver disease', following recommendations by some NICE clinical expert committee members (such as Dr Pinelopi Manousou, Consultant Hepatologist, Imperial NHS Trust), the resultant economic modelling performed by the Liverpool External Assessment Group (Liverpool Reviews and Implementation Group [LRiG]) evaluating the utility of MRI technologies was based entirely on liver biopsy assessment for the diagnosis of steatohepatitis. Alongside being technically challenging in individuals with obesity (Alizai, et al., 2019), liver biopsy is not fit for population health management, as evidence shows the percentage of patients	

				who refuse to undergo liver biopsy may exceed 50% in some centres whilst the proportion of physicians reluctant to subject patients to a biopsy may be as high as 30% (Chen, et al., 2011) (Sporea, et al., 2008). Therefore, it seems disproportionate that patients with obesity-related liver disease being assessed for eligibility for weight-loss medication must see a specialist and undergo a painful liver biopsy, which exposes them to the risk of biopsy related complications, whereas those with other obesity-related metabolic conditions (such as obesity-related diabetes or hypertension) which have similar cardiovascular risk profiles, can be managed without any specialist intervention or the need for an invasive liver biopsy. This risks creating a two-tier access problem between different obesity-related diseases that share the same outcomes and can be addressed by the same treatments. Indeed, as obesity related liver disease is now better understood, there is a paradigm shift in management, nomenclature, diagnostic criteria, and therapeutic approaches towards metabolic associated liver disease, or steatohepatitis, which have been spearheaded by global experts in the field (including those from UK) (Rinella, et al., 2023). Metabolic dysfunction-Associated Fatty Liver Disease (MAFLD) now focuses on the bidirectional interplay between fatty liver and metabolic alterations (Rinella, et al., 2023) (Pipitone, et al., 2023). In the presence of hepatic steatosis, the MAFLD/MASLD diagnostic criteria (for both adults and children) focus on the finding of any of: a cardiometabolic risk factor using a combination of body measurements (BMI, waist circumference), clinical and health measurements (blood pressure, treatment, type 2 diabetes status) and biochemical markers (fasting serum glucose, HbA1c, plasma triglycerides, cholesterol levels) (Rinella, et al., 2023). Liver biopsy is not mentioned as one of the deciding factors. Therefore, since MAFLD does not have histological criteria, would NICE, with a commitment to equity and precision medicine, agree to the use of non-invasive technologies, like	

				LiverMultiScan, to assess steatohepatitis and provide much-needed access to treatment? LiverMultiScan is a DTAC-approved MRI-based digital assessment tool which can be easily accessed across the UK in community diagnostic centres (CDCs) and provides the best assessment of key liver characteristics pertaining to MAFLD (liver fat and disease activity [associated with ballooning and fibro-inflammation]). LiverMultiScan's proprietary biomarker, cT1, correlates with histology (Andersson, et al., 2022) (Banerjee, et al., 2014) predicts liver- and cardiac-related clinical outcomes (one of the only noninvasive liver test to do so) (Pavlides, et al., 2016) (Jayaswal, et al., 2020) (Roca-Fernandez, et al., 2023) and outperforms other less technically advanced elastographic tests (VCTE and MRE) in the diagnosis of MASH. Unlike these other tests, cT1 also strongly correlates with ballooning (a key defining feature of MASH) in MAFLD cohorts (Eddowes, et al., 2018) (Andersson, et al., 2022). Unlike other tests that are focused on late-stage disease identification, LiverMultiScan is more sensitive to MAFLD/MASH at the point where obesity treatments will be most effective. It is also the only liver test that can accurately be used to monitor patients' response to treatment (including obesity medications) due to its best-in-class repeatability, reproducibility, coefficient of variation as shown by its use in multiple clinical trials. Most importantly, cT1 could easily be incorporated into weight-management apps to support efficient and integrated patient management due to its secure cloud data management platform. LiverMultiScan improves patients' understanding of their liver disease (McKay, et al., 2021) and is presented in a patient-friendly format, unlike all other liver tests. This latter point should not be underestimated. There are serious problems in the UK with health literacy, access and outcomes, all of which are linked; the easier information is to digest for patients, the more likely they are to understand and therefore adhere to treatment course,	

				especially for non-communicable diseases that often can show few symptoms until advanced disease occurs. Currently, an estimated 1 in 5 people in the UK are affected by MAFLD (British Liver Trust, 2023) (NICE, 2023); however, as rates of obesity increase so will the prevalence of MAFLD (Ye, et al., 2020) (Younossi, et al., 2018). Therefore, incorporating accurate metrics into the digital assessment using these apps could support efficient patient management by providing clinically relevant data to support justifying who would be eligible for weight-management medication (in-line with clinical society guideline recommendations (ElSayed, et al., 2023)) to ensure the right patients receive the right treatment at the right time, as well as providing a robust way to manage patients over the long-term.	
Clinical effectiveness (n = 14)					
41.	1	Individual	3.4	A very small pool of mixed quality evidence, along with recognition that weight loss is at least equivalent to no access to weight management services is not a strong indicator for introducing the use of weight loss medications into these digital technologies.	Thank you for your comments. Clinical and economic evidence for the early value assessment (EVA) was considered for the technologies listed in the final scope and followed the process described in section 2 of NICE's health technology evaluations: the manual and the interim process and methods for EVA. For EVAs, it is expected that there will not be a comprehensive evidence base available for technologies included. When making decisions for EVA, the committee will make a range of considerations based on section 3.28 of interim process and methods for EVA. The interim methods and process also states that a full critical appraisal of studies using a validated tool is not needed, but there should be discussion on the potential biases in key studies and how the risk of bias could affect key outcomes. Comments on the generalisability of the results to clinical practice in the NHS should also be made. Evidence synthesis of the key findings should be provided in
42.	1	Individual	3.4	"*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*." Is this cost effective?	
43.	1	Individual	3.4	"The committee heard that longer-term follow up is needed because obesity is a chronic condition." 100% agree.	
44.	7	Company	3.10	It's not clear which Second Nature evidence was included or excluded after the fact-checking consultation, but Second Nature did submit 4 examples of evidence demonstrating sustained weight loss after 2 years and beyond:	

				– A recently completed internal analysis that is awaiting publication after it's presented at the UK Congress on Obesity in September: A Retrospective Analysis on the Impact of Second Nature's Digital Lifestyle Intervention as a Specialist Weight Management Service in NHS-Referred Patients [redacted]. This study was not included in the original submission due to time constraints, but was submitted during the initial fact-checking consultation period. The analysis involved 1,194 NHS-referred participants with a mean age of 49.9 (SD 12.0) years, a mean baseline BMI of 46.3 kg/m2 (SD 31.6), and composed of 787 females (66%). Out of these, 281 participants (24%) recorded weight readings after two years, with a mean weight loss of 11.8% (SD 11.9; p<0.001). – Weight-loss outcomes from a digital behaviour-change programme in overweight or type 2 diabetes populations: A service evaluation of real-world data after 24 months (P270: https://onlinelibrary.wiley.com/doi/10.1111/dme.32_14245#dme32_14245-sec-0537-title) – Outcomes of weight loss achieved through a digital behavioural change programme in overweight or type 2 diabetes populations: Quantitative evaluation after 36 months (P142: https://onlinelibrary.wiley.com/doi/10.1111/dme.14810). – Weight loss outcomes achieved through a digital behavioural change program in an overweight population: Quantitative evaluation after 5 years (P195: https://onlinelibrary.wiley.com/doi/10.1111/dme.15048). Second Nature feel that the guidance should acknowledge these studies to provide the most accurate description of the evidence considered.	a simple narrative and descriptive format, a quantitative meta-analysis is not expected. Where there is a limited evidence base, the inclusion criteria should be expanded to look at a broader evidence base. Here, broader evidence was considered due to the known limitations in evidence on the use of these technologies alongside weight-management medicine. The EAG acknowledged the limited evidence base for digitally enabled weight-management technologies alongside weight-management medicines. They have described the strengths and limitations of the available evidence in Section 5.2 of the EAG report and made recommendations for evidence generation to address uncertainties in Sections 8.5 and 8.6 of the EAG report. The lack of long-term evidence is noted in section 3.10 of the guidance. It is also highlighted as a need for future evidence generation in NICE's evidence generation plan. The committee stated that it could not properly assess the potential benefits and risks of conditional use with further evidence generation for technologies that had very limited clinical evidence at the time of the committee meeting, and so CheqUp, Juniper and Wellbeing Way were recommended for further research in the final guidance. The EAG provided the following additional responses to comments regarding the evidence: • The EAG notes that no clinical evidence was identified that addressed the comparator of having no access to specialist weight-management services considered within the decision problem. The EAG acknowledge this as a limitation
45.	8	Company	1.6	We have just had an abstract accepted for the UK Congress on Obesity (Sept 2023) that reports on adverse events for patients receiving GLP-1 Receptor Agonist Medication in	

				Oviva's Tier 3 Weight Management Service. I will forward the document to the NICE EVA team.	within the economic model. Based on the available evidence, the EAG chose current standard care as the comparator, which in the base case is assumed to be in-person Tier 3 MDT. This is described within Section 7.4 of the EAG report. • The EAG considered identified evidence for Second Nature separately within Section 5.5 and Appendix B3 of the EAG report and also described in Section 6 of the supporting documentation for this topic. The Puddick et al. (2023) study was not submitted to the EAG during the assessment. The EAG has reviewed this conference abstract and notes that this does describe the use of an MDT weight loss programme (12-month programme including an MDT which comprised of a dietitian or health coach, exercise specialist and GP or nurse), meeting the final scope. This retrospective cohort study recruited 1,194 people (12 month programme: 3 core, 9 sustain). This reported a mean weight loss of 11.8% (SD 11.9, p<0.001) at 2 years with a 24% response rate. The EAG noted that the MDT comprised a dietician or nutritionist, an exercise specialist and a GP or nurse; it is unclear whether this reflects an MDT within current specialist weight-management services. The EAG consider that the assumptions used for the handling of missing data may not be appropriate and that results may not be representative of the population. There is also a lack of information on the number of people taking weight loss medicine, NHS setting, and the number of people who did
46.	8	Company	3.5	Oviva did provide published evidence on psychological outcomes (PHQ-9 improvement) for patients in our Tier 3 weight management service. This appears to have been erroneously overlooked in the separate evidence generation plan document and is not highlighted specifically in this document. I will flag this omission to the evidence generation team separately and provide them with a copy of the study paper.	
47.	8	Company	3.6	as above, we have new evidence in the form of an abstract reporting on patient experience and adverse events for patients receiving weight management medication within Oviva's Tier 3 weight management service.	
48.	8	Company	3.10	As highlighted above, this does not acknowledge that Oviva has provided published evidence of improvement in psychological outcomes (PHQ-9) within our Tier 3 weight management service. Very few, if any, "standard"/"traditional" Tier 3 weight management services in the UK will have provided similar published data around psychological outcomes to date. It is important that digitally-enabled weight management services are not held to a disproportionately higher standard of evidence compared to "traditional"/face to face counterparts and are treated equally. Very few "traditional" Tier 3 services publish any physical or psychological outcomes data (and they have highly variable MDT composition, delivery models, costs, outcomes etc).	
49.	12	Company	1.1	On reviewing the MT597 Digital Weight Management Technologies EVA Report, we have identified that there has been a misconception with regards to the evidence base behind the effectiveness of the Gro Health W8Buddy app, which has limited its inclusion in the list of 'approved/recommended' specialist digital weight management services. In the MT597 Digital Weight Management Technologies EVA Report, it states: 5.5. [Page 81] "Furthermore, DDM offer a Low Carb Tier 2 level programme, which has also been used	

				within the NHS DPP. Similarly for completeness, the EAG have summarised 3 full publications (Hanson et al. 2021; Summers et al. 2021; Scott et al. 2022) and 1 abstract (Kelly et al. 2020) identified with relevant outcomes relating to this technology." Following on from this, as highlighted in the Executive summary [Page 12], it states "Clinical evidence relevant to the decision problem was identified for 4 out of the 8 technologies included in this EVA (Gro Health, Liva, Oviva, Roczen)." Despite this, in the 'Early value assessment guidance consultation document', it states that "there is limited evidence related to the decision problem for Gro Health W8Buddy" [page 13]. The comments do not support each other; however, we appreciate this may be due to a misconception about the differences between the "Low Carb program" and "W8Buddy", the former of which we have evidence highlighting its effectiveness. There has been no appreciation throughout the document that W8Buddy was formally called the Low Carb Program. The evidence that exists for the Low Carb Program, is therefore relevant for W8Buddy. Hanson et al. 2021 "Low Carb Program Health App Within a Hospital-Based Obesity Setting: Observational Service Evaluation" (https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8462489/) documents the successful implementation of the Low Carb Program app's architecture within Tier 3 Weight Management Services at UHCW. The study conclusively showed that the app and remote consultations were effective in achieving comparable weight loss outcomes as traditional, hospital-based/traditional interventions. This acted as the only Tier 3 Service during COVID, coupled with remote appointments. The study found meaningful improvements in weight, BMI, blood glucose levels and dyslipidemia with a weight loss of 3% or more at 7 months. Despite the app's name, it functioned as a comprehensive Tier 3 Weight Management Service, not merely a "low carb tier 2" service. To further reiterate, this app directly precedes Gro Health W8Buddy,	not provide a baseline weight measurement. • In response to an Oviva submitted abstract, the EAG acknowledges that this was unpublished evidence not submitted during the EVA process. The EAG stated that the abstract did not address any of the evidence gaps outlined in the EAG report. The study reported patient satisfaction using feedback provided by 32 patients using the 12-month programme. It reported no serious adverse events in 111 patients receiving liraglutide. The EAG noted that it is unclear how adverse events were defined or recorded. • In response to evidence on the Gro Health W8Buddy app, the EAG summarised the evidence for Low Carb Programme is section 5.5 and appendix B3 of the assessment report. They noted that the level of MDT input with Low Carb Programme was poorly described across all studies. The EAG considered a poster by Hanson et al. (2023), which was not submitted by the company during the EVA process, nor identified by the EAG literature searches. This study reports app engagement alongside specialist weight-management services in the NHS aligning with the decision problem. At a mean follow up of 3.5 months for 68 people, a mean weight loss of 3.3 kg (SD 6.6, 95% CI 1.7 to 4.9) was reported from baseline and was considered statistically significant. This presents preliminary evidence for weight outcomes explicitly for Go Health W8Buddy.

				and effectively was replicated and delivered through the Gro Health W8Buddy platform to separate the services. The intervention used in Hanson et al. 2021 (“Low Carb Program app”) comprises structured education (based on a Tier 3 syllabus), MDT consultations (dietitians, psychologists, pharmacists), health tracking and behavioural change support. The app complemented the Tier 3 syllabus with guidance on following their chosen nutritional approach (low carb, Mediterranean, or Balanced). In “Gro Health W8Buddy”, there are identical features (structured education, MDT consultations, health tracking, behavioural support, medication management) further enhanced with physiotherapist and GP support. As such, the intervention meets the criteria set forth in the draft specification. The technologies’ features are identical, not the name. Furthermore, our solution does not exclusively provide a “Low Carb Tier 2 level programme”. Gro Health offers a full suite of weight management programmes across Tier 2, Tier 3, and Tier 4. All are accessible through the Gro Health app. This has been significantly misunderstood and misrepresents our Tier 2, 3 and 4 weight management services. These programmes are diverse and cater to various dietary requirements, not confined to low carb options. A recent poster presentation at the British Obesity & Metabolic Surgery Society (BOMSS) Conference, available in "GroBOMSS.pdf" [redacted], further underscores the efficacy and versatility of the W8Buddy digital tool in Tier 3 weight management. It offers a comparative analysis between two specialist weight management centres, Coventry and London, detailing demographic and outcome data, thus further validating the utility and effectiveness of our tool. The document provides detailed demographics and outcome data for both regions, including differences in activation rates, gender distribution, mean age, weight, BMI, and prevalence of type 2 diabetes and OSA.	• In response to evidence provided by Juniper, the EAG states that no evidence was submitted by Juniper for evaluation during the EAG EVA report development. The EAG consider that this evidence may be relevant to the decision problem and may address some of the evidence gaps for this technology. However, it notes that there is a lack of detail to fully assess alignment to the decision problem, particularly relating to population eligibility and characteristics. The EAG have summarised the evidence relating to Juniper in a brief report for NICE published as EAG Report Addendum 1. • In response to a comment on published psychological outcomes, the EAG included evidence from Lawson et al. (2022) which reported PHQ-9 outcomes at baseline, 3 months and 6 months in 54 patients using Oviva within Table 15 of the EAG report. The EAG included this study within Table 31 of the report for the Evidence Gap Analysis. • In relation to a comment on the duration of intervention, the EAG note that the duration of intervention in the evidence included by the EAG was at least 3 months to distinguish Tier 3 specialist weight-management services in all but 1 publication (Pedersen et al. 2019). Median and maximum time on the platform was 82 and 595 days respectively.

				Furthermore, the observational study designs employed during previous studies that demonstrate the effectiveness of W8Buddy (previously Low Carb Program) in accordance with the outcomes assessed, are comparable to the study designs used for Second Nature (previously Our Path), one of the 'approved' apps outlined in the MT597 Digital Weight Management Technologies EVA Report. In addition to this, as highlighted in Table 2 [page 20], which summarizes the functionality of included technologies, Gro Health (W8Buddy) is one of only two apps which satisfy all the domains considered. In light of the evidence and clarification provided above, we hope to have demonstrated that Gro Health W8Buddy (previously Low Carb Program) does indeed fully satisfy the requirements for inclusion of the app as an 'approved' specialist weight management tool.	
50.	16	Company	1.1	Chequp is clearly disappointed that NICE's draft EVA guidance suggests that it will not recommend our technology for use in the core NHS until more evidence is gained about the use of digital technologies to support weight management treatment in adults. We understand that this was because Chequp, alongside two other technologies, was unable to supply evidence to demonstrate that the use of our technology demonstrated change in weight, adherence and completion rates on our programmes, our ability to monitor and report adverse events, and impact on resource use. Whilst demanding such evidence before recommending use of such technologies would be understandable in normal circumstances, in this case that logic is questionable because the medications have not yet been made available in the UK and none of the companies selected can demonstrate research in real world conditions. Instead, what has been presented to the Committee, consists mostly of tenuously-connected and flimsy examples of	

				technologies being utilised in adjacent or even non-medicated weight management settings. - Your report ("GID-HTE10007 Digitally enabled weight management programmes to support treatment with weight management medication") stated that of the published evidence, only 1 full publication and 1 abstract included patients taking weight loss medication" with much of it comparing proprietary lifestyle / diet plans with a placebo cohort. This implies that the vast majority of the research submitted was interesting, but only tangentially-related to the central issue at hand – the prescription of weight management medication in a tier 3 equivalent setting. - None of the evidence submitted was conducted using the class of drugs (second-generation GLP-1 receptor agonists, in the case of semaglutide, and GIP/GLP, in the case of tirzepatide) which is creating the unmet need which the EVA was ultimately set up to address. - Some of the research presented was undertaken over as short a period as "14 days", which would be an unusual reference point for programmes intended to last 24 months. - We also note the admission that "the EAG notes that outcomes were poorly described across the included evidence" so it is possible that while the research has been undertaken, the positivity of its impact is unclear - The Committee has included Second Nature on its "Evidence Generation" list of companies, yet the above-mentioned report states "The EAG identified 4 full publications and 6 abstracts relating to the use of a Second Nature programme not representative of a Tier 3 specialist weight management service and is considered out of Scope for this EVA". Given that Second Nature has now been included on the Evidence Generation list of four companies and comment supplied to this affect, it seems that valid questions can be asked to why evidence which was not	

				related to Tier 3 weight management services was considered out of scope and subsequently included? By contrast, even though we have had very successful weight loss among our cohort of customers (c. 10% greater than reported in the clinical trials), the period of time in which our private patients have been in our service is six months at the maximum. We have not tried to present this to the Committee into seeing as scientifically-robust; by corollary, the Committee should treat much of the other research in the same way. The purpose of the above points is not to belittle any of the research which has been undertaken or any company mentioned. Indeed, we sympathise with the Committee's predicament over the quality of the research. But given that very little, if any, evidence presented to or referenced by the Committee can be considered scientifically robust, sufficiently peer-reviewed or directly relevant to the matter before the Committee (Tier 3 weight management services) it stands to reason that this should not be the sole criteria for a binary in/out decision. In our opinion, it is therefore too early, and the evidence base too thin, to either rule in, or rule out, any technology at this stage, especially with a four-year timeframe before the next review	
51.	18	DHSC	1.6	Evidence on longer term impact (2 year +) of digital technologies is missing/unavailable. Some insights from other condition related digital technologies (e.g., diabetes) might also be relevant. Did the committee consider research from other similar digital technologies, such as the NHS Digital Weight Management Programme?	
52.	22	Patient or professional organisation	Draft guidance	Quality of Current Evidence Considered We were concerned by the quality of evidence considered and the analysis process presented in the consultation documents. In particular we noted:	

				The evidence document states that “formal critical appraisal checklists” (p.32) were not applied to the studies included and this is a key methodological weakness in a review of this importance. Of the 19 published studies included, 8 were not available in full text and only as abstracts, leaving 11 peer-reviewed studies available in full, of which only 4 were set in the UK. Only one RCT is included (other studies include pilot, feasibility and retrospective designs), and this was conducted in Denmark, so did not have a UK Level 3 Specialist Weight Management Service as a comparator. This study Hesseldal et al. (2022), reports a 1.5% improvement in BMI after 12 months, which we did not find compelling as evidence for the effectiveness of digital interventions. Many of the studies have small sample sizes and therefore run the risk of being underpowered. The comparator is listed as level 3 & 4 weight management services, yet the population in seven studies was not specified as obese, and included participants with BMIs which would not meet the eligibility threshold for level 3 weight management services (BMI 40+). It could therefore be argued that these studies did not include a population with the complex needs equivalent to the Level 3 Specialist Weight Management Service population. The lack of meta-analysis and the heterogeneity of studies included makes it challenging to draw firm conclusions. There is also a high risk of confound as some studies include low calorie diets and others include weight loss medication. The evidence document acknowledges that the studies included rely on self-report as well as clinically measured weight outcomes. The heterogeneity of the reported outcomes reduces the confidence that can be placed on any conclusions as a result.	
53.	25	NHS England	Draft guidance	Potential benefits Clinical benefit: ideally NICE should not compare RCT clinical trials with real world data. Can NICE provide a link to the Research Data for tier 3 from which the comparison was made?	

				3.3 The text “The evidence suggests that 4 out of the 7 technologies (Liva, Oviva, Roczen and Second Nature) have a potential benefit for adults who are eligible for treatment with weight-management medication. But only 1 published study included people who were taking weight-management medication” Can NICE clarify what evidence has been provided by the other 3 providers who meet the evidence threshold but did not submit evidence in the form of a study?	
54.	28	Company	3.3	Juniper has received ethics approval to publish 3 clinical studies that show positive clinical weight loss outcomes for patients taking weight management medication (reduction in weight and BMI). Our studies span across 2 geographies (UK and Australia) and two different medications (semaglutide and liraglutide). We believe this evidence is relevant for evaluating the efficacy of medication-assisted weight-management programmes. Study 1: UK Cohort Analysis * Retrospective analysis of Juniper (semaglutide) programme efficacy and care continuity standards among sample of UK patients * Efficacy measures include both weight loss and side effect outcomes * Continuity of care measures include mean number of patient communications, mean maximum period without communication, and mean response time to patient questions. Study 2: Australian Efficacy Analysis * Finalising planning for a retrospective analysis of Juniper's (liraglutide) weight-loss programme among Australian sample cohort * Assessing impact of GLP-1 RA type on the efficacy of Juniper’s weight loss programme * Uses the same efficacy measures as the retrospective UK study to enable comparison	

				Study 3: UK Prospective Cohort Study * Addressing long-term sustainability concerns of weight-loss medications * Compares weight loss and strength gain outcomes at start, end and 6 months after Junipers programme intervention. * Subjects divided into 2 groups: standard weight loss programme and weight loss programme with strength training component. Preliminary outputs from the UK study (study 1) show positive clinical outcomes. Our programme also measured positively against key continuity of care indicators. Among the cohort of 1,915 selected “programme path” patients, we observed the following key outcomes: - An average weight loss of 9.23kg (9.72%) after follow-up 1 (5 months), and 12.06kg (12.72%) after follow-up 2 (11 months) for patients taking up to 1mg doses of semaglutide. - An average reduction in BMI of 3.41kg/m2 (9.78%) at follow-up 1 (5 months) and 4.4kg/m2 (12.86%) at follow-up 2 (11 months) - Patients engaged with a member of the Juniper team on average 5.86 times per month - 45% of patients reported side effects and were engaged by a member of the MDT at a median first response time of 9.9 hours from reporting side effects - Patient satisfaction at follow-up 2 was 40% higher than satisfaction when patient initiated the program Table 13.2 in Appendix 1, shared separately with the evaluation committee, includes further key clinical outcomes that we expect to publish in our studies. A broader collection of measures, including patient outcomes outside of these studies, can be viewed in Appendix 2, also shared separately.	

				In addition to the outcomes of our clinical study, some key internal indicators of patient adherence and engagement for (paying patients) of the Juniper (UK) include: - 76% 12-week programme retention; - 85.9% patient satisfaction (since Oct '22); and - 85.1% engagement from new patients with our mobile app Table 13.3 in Appendix 1 summarises key outcomes for patients outside of our study cohorts. As above, the broader collection dataset can be viewed in Appendix 2.	
Cost and resource use (n = 8)					
55.	8	Company	3.8	One of the critical areas of this evaluation relates to the health economic/cost-effectiveness analysis: a) Intuitively, one of the benefits of digital delivery is that it will be cheaper as it eliminates fixed estate costs. Have the fixed costs of delivering face to face services, including expensive estates costs and general NHS trust administration costs, been factored into the estimated price of the standard face to face care model or is this based solely on healthcare professional staffing costs + on costs? b) It is understandable why the Liva cost has been used for the base case for the digital model cost given the use of the Liva RCT for the clinical modelling. However, the Liva cost is not representative of the cost of a digitally delivered tier 3 service in the NHS (it is by far the most expensive of the 4 digital provider costs). Oviva's cost is approximately 50% of the Liva cost quoted and is an accurate real world cost for the exact service in the EVA scope (including primary care support around making referrals). This is the total cost being incurred right now by the NHS for a digitally-enabled Tier 3 service including GLP-1 medication prescribing and monitoring. Roczen and Second Nature have also provided	Thank you for your comments. Early value assessment guidance does not come with a funding mandate and local commissioners will be able to decide whether or not to fund digitally enabled technologies at their centres. The objectives of the economic evaluations for EVA are to: • identify likely impacts of using technologies (while further data is collected) • identify additional uncertainties that would not be apparent from technology related studies • identify uncertainties that are likely to be key drivers of model results and decision-uncertainty to inform decision making about further evidence generation. Any limitations and assumptions used in the early economic model are listed in the EAG report. NICE and the EAG acknowledge that assumptions need to be used due to the limited evidence base usually associated with technologies being considered in

				costs but to our knowledge neither are yet providing this full service within the NHS (including the prescribing/monitoring element). Changing the input cost of the digitally enabled tier 3 service will have a significant impact on the comparative cost effectiveness analysis, and so does this not merit an explicit sensitivity analysis at a minimum? c) In order to be accurate and fair, comparative analysis of the costs of each model should consider similar inputs. If we are considering adding the "access costs" of tablets and data plans to the cost of the digitally-enabled Tier 3 service, should this only be added for the small percentage of people going through the service who will need it e.g. 10-20% of patients, rather than for every patient? The vast majority will not need this financial input from the NHS i.e. most people will have their own access to a device and to data/internet. Also, if including the cost of a device/data in the digital delivery should one not include the "access costs" of transport, parking, childcare etc in a face to face model? These costs are a significant barrier to access to face to face services for many and can be very significant given the limited availability of tier 3 services, with people being asked to travel large distances in order to access scarce face to face services.	the EVA programme. Further evidence on the clinical and cost-effectiveness of the technologies will be generated over the next 4 years to assess if the benefits of these technologies are realised in practice. NICE will review the evidence and produce full guidance and make recommendations about the routine adoption of these technologies across the NHS. The EAG provided additional responses to comments included in this theme: • The EAG included all fixed costs, including overheads and estates costs, incurred in the delivery of in person Tier 3 services. • The EAG acknowledge that model was a de novo early economic model, which made several assumptions with major limitations because of lack of available data. The limitations and assumptions that underpin this early modelling as part of the Early Value Assessment of these technologies have been summarised in Section 7.5 of the EAG report. Section 9 of the EAG report states that in order to fully evaluate the cost-effectiveness of delivering weight-management services using digitally enabled technologies (as part of a future HTA evaluation) we would also need to take into account the various complexities of obesity and a sufficient time-horizon to capture these complexities. • The EAG acknowledges that the costs of digital health technologies applied to our base case analysis were sourced from a single digital technology. The EAG notes that it is currently unclear how
56.	9	Individual	General	All of this has a cost when there are free and equally effective alternatives - who will be funding these?	
57.	18	DHSC	3.8	• Have the costs for a tablet and internet access been applied to all users of the programme or a subset (i.e., an estimate of the proportion who may not be able to afford these)? Is this standard practice for other digital services? The implications of this could be significant for clinical practice, specifically if the evidence on longer-term use (such as in the recent SELECT trial from which cardiovascular disease outcomes were reported in the media) leads to a longer prescription duration for Semaglutide. • There needs to be clear guidance on who the apps are most likely to benefit as a means of reducing health inequality and not widening it.	

				• Digital literacy should also be considered as this can vary across age and communities. An approach as used by the HEAT tool may mitigate some of the effects of these recommendations.	generalisable these estimates are to the other digital technologies, given the different delivery models of each technology and this is acknowledged in Section 7.5 of the EVA report. However, the sensitivity analyses conducted suggest that there is some scope for variation in the cost of the digitally enabled weight-management services. The EAG noted that costs submitted by Juniper are within the range of costs made available by the other companies and may plausibly be cost-effective if the range of outcomes in the model can be generalised to Juniper
58.	22	Patient or professional organisation	Draft guidance	The evidence document provides minimal information on sign-up and attrition rates for the studies included. In particular, we noted: The information that is provided highlights concerns about low uptake: 55% uptake & only 34% engagement in the Gro Health study by Hanson et al. (2023). Attrition rates are known to be higher for digital interventions than for face-to-face across different conditions (Meyerowitz-Katz et al., 2020) and a systematic review by Beleigoli et al. (2019) highlights the high risk of attrition bias on weight loss outcomes (those for whom the intervention is not effective are more likely to drop-out). Information from the largest study for which the data is available (Pedersen et al, 2019) shows a 54% non-attendance rate at 12-month follow-up and a completion rate of just 3.7% for Liva. In addition, the data from Mc Diarmid et al. (2022) on Oviva and Pedersen et al. (2019) on Liva both acknowledge that a higher BMI was associated with a lower completion rate. These attrition rates are important as the sensitivity analysis shows that cost-effectiveness is only plausible if drop-out rates are similar to existing Level 3 Weight Management Services. Based on this data we have concerns that vulnerable service users with the highest BMIs and most complex presentations will frequently drop out of digitally enabled healthcare provider offers. Therefore, we believe that the piloting of digitally enabled technology providers should be carried out in close collaboration with existing NHS-based Specialist Weight Management Services who are able to offer face-to-	• The EAG notes that the rationale behind the threshold analysis used was to determine how much the cost of the interventions would need to change in order to alter the direction of the cost-effectiveness results (all other factors being equal). The EAG, therefore changed the cost parameters in the economic model and found that in order for standard care, defined as in-person delivery of Tier 3 services, to become cost effective: 1) either the Tier 3 costs would need to be 25% less costly than the estimate included in the base case analysis; or 2) the cost of digitally enabled technologies would need to be 35% more expensive than the cost assumed in our base case analysis. • The EAG noted that the removal of the costs for provision of tablets and internet would not change the conclusions of the analysis • The EAG agreed that there may be currently unknown and potentially considerable administration costs

				face care options for service users with the most complex presentations.	associated with the delivery of digitally enabled Tier 3 services. Engagement, uptake, and attrition were also poorly reported • The EAG note that initial engagement and uptake of the digitally enabled technologies was poorly reported and defined across the evidence identified and is confounded by multiple factors, including patient preference and digital inequalities, see Sections 3.4 and 5.3 of the EAG report. Attrition and ongoing engagement was also poorly defined across the included evidence although the proportion of patients attending or providing data fell over time, including with in-person services, see Table 5 of the EAG report.
59.	22	Patient or professional organisation	Draft guidance	The consultation documents identify the cost-effectiveness findings are “highly uncertain and subject to a number of strong assumptions”. We were concerned about the costings data in the following respects: The costing assumptions made about Level 3 Specialist Weight Management Services are questionable. Level 3 Sepcialist Weight Management Service models are highly variable and it is unclearwhat assumptions have been made about “usual care”. For example, the document states a duration range of 14 days to 2 years, with 2 years as the typical follow up time. As an example, Derbyshire Community Health Services NHS Foundation Trust, Level 3 Specialist Weight Management Service provides up to 1 years’ intervention for each service user. Therefore, if the modelling of NHS Level 3 Specialist Weight Management Services has assumed 2 years care per service user, the cost of the Derbyshire service will have been a huge overestimation of costs. The document states that the “differences in net monetary benefit between the alternative treatments (Level 3 and digitally enabled technologies) were relatively small for the average patient” (p115). As described above the studies cited do not appear to represent the average Level 3 Specialist Weight Management Service patient and appear to be more related to a Level 2 cohort, in terms of BMI. Whilst acknowledging that dropout rate is a key sensitivity in the analysis, the assumption is made that that this would be equal to Level 3 services. The clinical experts make the point that a “full clinical assessment ....is needed before using these technologies”- it is not clear whether this assessment has been factored into costings. Neither is it clear whether the clinical capacity and resource for this has been factored into any potential pilot- see p. 87 “some technologies rely on inclusion of NHS staff to deliver the Level 3-like service”- it is unclear how the use	

				of digitally enabled programmes will impact already sparse NHS capacity. There is insufficient evidence to say that “digitally enabled weight management programmes are potentially less costly and more effective than care delivered as part of an in-person specialist weight management service delivered in a secondary care setting”. We agree that “providing a robust estimate of (cost of current specialist weight management services) should be prioritised”.	
60.	23	Company	1.6	Will the cost-effectiveness of these models be assessed against standard care on an ongoing basis? With differing levels of care and budgets available across the country, what cost will be used as a basis?	
61.	23	Company	3.9	“The threshold analysis showed that if standard care costs are reduced by approximately 25%, or the technology costs are increased by 35%, then standard care would become the cost-effective option.” It would be helpful to include the basis for this calculation in this guidance or make this statement more clear.	
62.	28	Company	3.9	As detailed in Q10 and Q15 in Appendix 1, Juniper's technology has data on health-related quality of life outcomes which would allow us to contribute to the existing economic cost modelling. Based on our own costs and resource use, we are also able to estimate the cost-effectiveness of our technology to contribute to the existing analyses that have been conducted by the EAG.	
Equality considerations (n = 14)					
63.	1	Individual	3.8	“The committee accepted that some people may need additional support or equipment when using the programmes and agreed that NHS teams should consider providing a tablet computer and mobile internet connection when offering these technologies, to reduce digital inequality” Good	Thank you for your comments. Section 3.9 of the guidance states that the technologies may not be suitable for everyone. The clinical experts estimated that 7% to 30% of people may find digitally enabled programmes unsuitable, for example, because of reduced manual dexterity, a learning disability, or less digital knowledge or access to equipment and the internet. The clinical experts said that there is a lack of evidence
64.	2	Company	1.6	You've identified that these technologies might not be suitable for everyone. However you haven't selected any solutions which could mitigate this issue. In particular we	

				know people from low social economic background and from BAME communities will likely have lower adoption of these services yet they are most at risk. At Tuli we have developed a hybrid digital/pharmacy model which combines f2f delivery in community pharmacies by trusted community members with digital technology. Our solution could potentially mitigate this equality gap that you have identified. Perhaps we can provide more info to you on our service?	available to identify which groups may or may not be able to access the technologies, or who may benefit the most from them. Healthcare professionals should discuss the language and cultural content of digitally enabled programmes with patients before use. The EAG said that the economic model included costs for a tablet computer and monthly internet access, to reduce excluding people because of digital inequality. The equality impact assessment published alongside the guidance also notes that people's ethnic, religious, and cultural background may affect their views of digitally enabled weight-management interventions. Section 1 of the recommendations has been amended to include autistic people in the equality considerations in response to the comments received. The equality considerations have also been amended to acknowledge that these technologies may not be suitable for some people even with support. Details on the features of the technologies can be found in section 2.2, Table 2 and Appendix E of the EAG assessment report, and in the EAG assessment report. A reference to this has been added to the guidance. In terms of access to services, section 3.1 and 3.2 of the guidance acknowledges that there is an unequal distribution of specialist weight-management services across the NHS, and in some areas there is no access to them. Limited access to specialist weight-management services may also limit access to weight-management medicines for people who are eligible. Clinical experts and the committee agreed that these technologies would benefit those where there are
65.	2	Company	3.8	You've identified that these technologies might not be suitable for everyone. However you haven't selected any solutions which could mitigate this issue. In particular we know people from low social economic background and from BAME communities will likely have lower adoption of these services yet they are most at risk. At Tuli we have developed a hybrid digital/pharmacy model which combines f2f delivery in community pharmacies by trusted community members with digital technology. Our solution could potentially mitigate this equality gap that you have identified. Perhaps we can provide more info to you on our service?	
66.	4	Individual	3.7	This is important to stress the impact on equality and access to services who are not able to access digitally due to learning difficulties, digital skills or poverty.	
67.	5	Patient or professional organisation	Draft guidance	5. Equality and Accessibility Issues Based on our clinical experience we would agree with the risks around equality and accessibility identified by the committee. In particular, our extensive clinical experience and research (Zhang et al., 2021; Lynch et al., 2019; Oliver, Foot & Humphries, 2014) would suggest that the following groups of would be discriminated against should a digitally enabled technologies only model of level 3 services be established: · Older people. · People with financial difficulties prohibiting access to smart technologies including smart phones, tablets and access to mobile or wi-fi internet.	

				· People with learning disabilities, information processing impairments, literacy issues. · People with a range of physical disabilities (visual impairment, hearing impairment, muscular skeletal conditions impacting manual dexterity). · People with significant experience of adverse childhood experiences and/or current significant mental health difficulties, due to the engagement and trust barriers to service engagement. At present we do not feel there is adequate information provided about the adaptations possible through digitally enabled technology providers to meet the needs of the groups outlined above. Therefore we would strongly advise against the provision of digitally enabled technology providers as level 3 services in trusts and health boards where a face-to-face service option is not available alongside this.	limited treatment options for people who cannot access specialist services in their area. Considerations on access to weight-management medicines are outside the scope of this evaluation and are discussed in NICE's guidance for weight-management medicines (Liraglutide and Semaglutide).
68.	13	Company	Draft guidance	It's vital that more consideration is given to the accessibility of the dietary approaches being promoted for people from diverse backgrounds (different ethnicities and people from different socioeconomic status for example). In addition age should be considered and what is in place to support those who are less confident in accessing digital schemes.	
69.	14	Company	3.7	We accept that there may be inequity in access to these technologies for people who do not have access due to digital inequality. However, we do not believe that it is the role of the NHS to reduce digital inequality. The responsibility for the provision of IT equipment should sit with the wider Local Authorities who need to support vulnerable people to access a range of web based services, not just health related services. The resources required for NHS Teams to provide patients with technology and internet access would be considerable.	

				Does the economic evaluation fully consider the costs associated with administering this proposal, as well as the cost for the equipment and internet access? The financial impact of this proposal will be larger in more deprived areas, introducing even greater inequity. The differences in availability in multiple languages needs to be made clear so that the technology that meets the needs of local populations can be commissioned.	
70.	15	Individual	3.7	Efforts need to be prioritised to support a technology that allows people with learning difficulties and autism to use it and benefit from a resource like this. In the complications of excess wieght clinics (CEW) for children and young people we are seeing about 1/3 with a learning disability and / or autism.	
71.	22	Patient or professional organisation	Draft guidance	Equality and Access Issues in Specialist Level 3 Weight Management Services We agree with the committee that should digitally enabled technology providers, without the option of face-to-face care, be offered as a level 3 specialist weight management service, the service provision would significantly discriminate against certain vulnerable groups. The research (WHO, 2021) and our clinical experience ([redacted], recent inequalities evaluation) identify the following groups would be discriminated against: Older adults People with learning disabilities People without access, finances or digital capability to utilise a smart phone, Wi-Fi or mobile internet (socioeconomically disadvantaged groups will likely be living in the most remote areas where broadband access can be problematic, as well as in the areas with the highest levels of economic deprivation, where people living with obesity are overrepresented).	

				People with physical disabilities e.g visual impairment, hearing impairment, manual dexterity impairments. People who require support with literacy, language and cultural adaptations. In addition, the consultation document argues that a digital solution will improve accessibility for those who struggle to physically access Level 3 clinics (because of physical disability, lack of mobility, social anxiety or cost of travel). However, use of digital technologies to increase the accessibility of specialist level 3 weight management services is common-place in existing NHS-based level 3 specialist weight management services through the use of telephone appointments, videocall appointments and text reminders. Therefore, the extent to which digitally enabled technology providers could be said to offer a novel solution to accessing care is questionable. Based on the consultation documents available we did not feel that adequate adaptations have been identified to mitigate discrimination agaist these groups. Existing Level 3 services make adaptations to address the barriers individuals face. We are concerned that digitally enabled technology providers risk exacerbating these barriers, rather than resolving them, because model appears to be a standardised approach, rather than one tailored to individual needs. Therefore, we strongly recommend against utilizing digitally enabled technology providers as a replacement for level 3 Specialist Weight Management Services with face-to-face care options, or as the only option available to patients in some areas. The WHO (2019) Global Strategy for Digital Health identifies that this balanced approach should be taken: “The guideline also makes recommendations about telemedicine, which allows people living in remote locations to obtain health services by using mobile phones, web portals, or other digital tools. WHO points out that this is a valuable complement to face-to-face interactions, but it cannot replace them entirely. It is also important that consultations are conducted by qualified health workers and that the privacy of individuals’ health information is	

				maintained. The guideline emphasizes the importance of reaching vulnerable populations and ensuring that digital health does not endanger them in any way." In the field of weight management services this is particularly relevant given evidence demonstrating the app-based interventions may be a helpful addition to face-to-face services, but that their utility as a stand-alone intervention is questionable (Ghelani et al., 2020). In addition, evidence that weight loss apps can increase vulnerability to developing eating disorder symptoms (Eikey, 2021) identifies the risks of potential harms, and indicates the need for caution in the role out of these technologies.	
72.	24	Individual	1.6	It has been known for many years now that SE Asians, due to the genetic predisposition to metabolic syndrome MetS, will develop obesity related T2DM, pre-diabetes and all the other sequelae of obesity at a much lower BMI than 30. Saxenda was one good drug that had a marketing authorisation for BMI of 27 with the relevant metabolic abnormalities. By making semaglutide (Wegovy) the choice of drug for the NHS, and by cherry-picking those patient with 30+ BMI, you will find that the majority of those getting treated by these programs are White Caucasians. SE Asian (Indians) in general have a much lower BMI (23+) which marks overweight, and their BMI of 25 gives the same body composition of white caucasians with BMI of 30. Reference: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9587616/ The disproportionate metabolic risk among different Asian groups across all weight categories and underscore the desirability of broadening prediabetes and diabetes screening recommendations for higher-risk middle-aged Asian subgroups to include screening at healthy BMI levels.	
73.	24	Individual	1.6	Following on from my previous comment: This digital program provision is unfortunately reflective of the NHS's	

				typical attitude to abdicate weight management to remote providers. This will only serve to increase the disparity we have in health outcomes in different groups of people: 1 - patients who have been "pre-diabetic" or have "liver fat" for years, yo-yo-ing with their GP and the local Tier 3 service - but their BMI is 29.5 - I have some of these on my list - will still be left untreated with this new digital venture (even if they are white). 2 - Women with PCOS (polycystic ovaries) will not get it at the right time. 3 - The SE Asian / Indian patients with MetS and the predisposition for central abdominal obesity but a BMI below 30, will be actually ignored by providing Wegovy as the sole option for treatment. I believe that the choice of this drug for such ease of access via digital platforms is discriminatory for an entire ethnic group whose genetics mean they need prevention sooner. It looks very much like indirect discrimination against this ethnic group and also women with pcos - the choice of entry criteria and the drug selected. Thank you [redacted]	
74.	25	NHS England	Draft guidance	Obesity is an ongoing issue for people with a learning disability and autistic people and we are always keen to see innovative ways to support people to manage their weight. With these technologies there is potential to widen access and availability which will be very positive for all of the population including those with a learning disability and autistic people for whom having non-adapted or adjusted, timed, face to face appointments can be too challenging for many reasons. However, we note that these technologies that have been assessed appear to be linked to the use of novel weight loss medications	

				1) There is limited evidence around the use of semaglutide and liraglutide in people with a learning disability or autistic people and there is some evidence to suggest that for at least people with a learning disability with genetic metabolic conditions or congenital conditions further research is required. The evidence base for this needs to be explored in advance of the evidence base for the assistance of digital technologies. 2) For many people who have a learning disability digital applications are not accessible either because they have data poverty (cannot afford the data), the application itself is not in an accessible format, for example the font is too small, the layout is not simple or accessible, it does not meet the new Accessible Data standard about to be published or in many cases individuals may not have a smart phone or other device which goes on the internet. The increasing reliance on digital resources across services such as weight management and the wider NHS continues to exacerbate the health inequalities faced by some people with a learning disability and autistic people and any evaluation of such digital resources by NICE should take factors such as this into account.	
75.	26	Individual	1.6	Even with additional support many of these sub groups will still not be able to use these technologies	
76.	28	Company	3.8	As outlined in our response to section 3.2 above, the Juniper programme has been designed in part to enable access to patients who require access to weight-management services but lack access due to any number of external factors, including; living with limited mobility, living in remote or rural areas of the country, or who don't feel comfortable with face to face consults. This is evidenced by the fact that almost 30% of our Australian patient base is from regional, rural or remote areas of the country.	
Evidence generation and research (n = 24)					
77.	1	Individual	1.2	Good to have this process in place in addition to the DTAC criteria.	Thank you for your comments.

78.	1	Individual	1.6	Need to have baseline weight at beginning and end of intervention and longer term follow up weight e.g. - 1 year in order to be able to assess efficacy.	The benefit of early value assessment (EVA) is to support earlier patient access to technologies that have the potential to meet system needs. Unlike existing NICE guidance processes, EVA would not require selected technologies to have generated a large amount of evidence meaning NICE can assess them at an earlier stage. Technologies with plausible promise of addressing an unmet need have the potential to be recommended for use in the NHS while further evidence is being generated over a 4-year period. After the evidence has been generated, NICE will produce guidance stating whether the technology is clinical and cost-effective compared to an appropriate comparator and whether it should be widely adopted. Only evidence considered in scope (such as evidence including the interventions listed) was considered in this evaluation. The guidance includes key outcomes in section 1.6. These recommendations form the basis of a more detailed evidence generation plan created by the NICE team and published alongside the final guidance. The committee considered these comments and were happy with the prioritised outcomes listed in the guidance. NICE's resource impact assessment team will develop a resource impact assessment tool that will detail the potential impact of the guidance on local finances and other resources (workforce, capacity and demand, infrastructure and training and education). NICE followed the recruitment procedure for specialist committee members outlined in section 3 of the early value assessment interim process and methods. NICE also notified the relevant professional societies and internal and external contacts to ensure specialist committee members representative of specialist weight-management service providers were recruited. NICE could not
79.	3	Patient or professional organisation	1.6	Consider change in weight over time, during the digital intervention and post digital intervention.	
80.	3	Patient or professional organisation	1.6	Rates should also consider enrolment, participation, level of app interaction and 1:1 interaction, completion and outcomes (self-reported vs clinician reported/confirmed). The level of follow-up to sustain engagement should also ideally be recorded. Universal definition of the rates and applied consistently throughout the digital interventions.	
81.	3	Patient or professional organisation	1.6	'Adverse events' need to be clearly defined	
82.	3	Patient or professional organisation	1.6	A RoI assessment would be useful	
83.	4	Individual	3.9	Evidence on adverse effects and management of these adverse effects in community with escalation of care.	
84.	5	Patient or professional organisation	Draft guidance	Prioritize the NHS Obesity Audit; Throughout the documents the point is made that an accurate record of the structures, resources and outcomes of NHS-based Level 3 Specialist Weight Management Service is not available and therefore comparisons to digitally enabled technology providers to NHS-based services, with face-to-face options, have little meaning at this point.	
85.	13	Company	Draft guidance	In response to the key questions asked in the document, please find below [redacted] comments. Has all of the relevant evidence been taken into account? We note that the dietary/nutritional intake of people following the suggested programmes is very limited. We're concerned with the lack of evidence/consideration given to the diet quality of people accessing these programmes, in addition to those taking medication, and what the long-term health implications of this will be for patients. This seems to be a	

				significant gap in the current evidence base to date and also in the new data/evidence collection being proposed. There is no long-term evidence provided and therefore no effectiveness of weight loss maintenance is included. This again is a significant gap in the evidence reviewed. Are the summaries of clinical and cost effectiveness reasonable interpretations of the evidence? Again, there appears to be a lack of evidence in terms of supporting people to have a nutritionally balanced and healthy diet and in the long-term outcomes of these programmes. We see this as an evidence gap that should be addressed going forwards. There is little detail about the dietary advice provided by the four selected programmes and very little evidence of the diet quality of those accessing the programmes. In addition, there is a gap in the evidence around people taking weight loss medications and then impact on their nutritional status. How will potential deficiencies be monitored and supported through these programmes?	identify a clinical psychologist with the relevant experience for recruitment for this topic. The consultation period allows stakeholders from various background to comment on the draft guidance for additional consideration after the committee discussion.
86.	13	Company	Draft guidance	Are the recommendations sound, and a suitable basis for guidance to the NHS? It isn't clear from the document how long patients will be able to access support for and how long they will be prescribed the medication as part of the service. It is also unclear what longer-term support will be offered. Given the evidence to date shows significant weight regain as soon as the medication is stopped, what plans are in place to ensure ongoing support is provided to prevent weight regain? It's not apparent if longer term weight outcomes and follow up are factored into the proposed evidence collection, we would suggest this is essential.	
87.	15	Individual	1.5	Changes in rates and severity of complications associated with excess weight eg type 2 diabetes, obstructive sleep	

				apnoea and social isolation (consider physical health and pychosocial health) would be really useful to look at impact and cost effectiveness.	
88.	15	Individual	1.6	BMI would be a more helpful change to measure and % weight loss / gain. Change in weight alone does not tell you enough.	
89.	22	Patient or professional organisation	Draft guidance	Aims and Outcomes in the Development of Specialist Weight Management Services We agreed with the committee that further outcomes need to be gathered from digitally enabled technology providers to understand the impact of their interventions on service users with complex obesity. In addition, we agreed that the NHS Obesity Audit is a necessary development in developing and understanding the efficacy of all level 3 specialist weight management services. We were concerned to see that weight loss remains an overvalued outcome in the consultation documents, as it often is in the field of weight management. Whilst weight loss is an important aspect of what level 3 specialist weight management services should aim to enable, it should also be recognised that obesity is a chronic condition requiring lifelong treatment and/or self-maintenance amongst those most vulnerable to this condition. As a result aims/outcomes should also factor in the health benefits of modest weight loss, improvements in functioning, mobility, quality of life, psychological distress and the reduction in risk factors for maintenance of weight management issues. Moving beyond weight loss and overall BMI to a more sophisticated measure of physical health risk, such as the Edmonton Obesity Staging Systems, would be of benefit to UK services and service users. Recent research suggested that measuring the prevalence of emotional eating through standardised outcome measures may be helpful in identifying and developing effective interventions for the psychological factors maintaining obesity. A sample of 70 service users' data collected in Cardiff & Vale University Health Board Level 3 Specialist Weight Management Service between December 2022 and	

				March 2023 demonstrated moderate- severe emotional eating (as measured by Emotional Eater Questionnaire; Garaulet, 2012) in 80% of service users entering the service. Emotional Eating (EE) is a form of disordered eating and is a developmental pathway to obesity (Eichen, 2017 as cited in Smith, 2023). Reductions in EE are associated with greater weight loss in individuals living with obesity. The selection of psychological outcome measures requires the input of a specialist psychologist with expertise in the area of weight management and therefore we recommend the recruitment a Specialist Psychologist working within Weight Management to join the committee to inform any further developments of guidance for weight management services.	
90.	22	Patient or professional organisation	Draft guidance	The evidence gaps we were most concerned about in our reading of the consultation documents include: Insufficient evidence of the mechanisms by which digitally enabled technology providers would effectively monitor and manage the risks of service users living with complex obesity, and the physical and mental health comorbidities this often involves. Insufficient evidence that the digitally enabled technology providers working with level 3 specialist weight management clients provide equivalent or improved health and wellbeing outcomes to NHS-based specialist weight management services, with face-to-face care options. We were very concerned to see Kmietowicz (2023) identify the that lists the removal of 145,000 clinical hours as a benefit of these technology-led solutions. Whilst efficiency and prudent use of resources should be key in the delivery of any publicly-funded service, reducing the amount of time service users have access to specialist therapeutic clinical care increases risk of ineffective and unsafe care. At present cost-saving data appears to have been given greater weight than efficacy, quality and safety of services. Insufficient evidence that digitally enabled technology providers are able to provide adaptations to their service to reduce discrimination against and increase access for the following groups; people with learning disabilities, older	

				people, people experiencing financial poverty impacting their access to smart technology and internet, people with physical health difficulties presenting barriers to access including visual and hearing impairments and disabilities affecting manual dexterity. Insufficient evidence that weight loss medications, including semaglutide (wegovy), provides long term positive weight loss outcomes that warrants the current investment in digitally enabled technology providers as a vehicle for delivery, particularly in light of the unavailability of this medication in the UK at present. We have significant concerns given the weight regain data (participants regaining two thirds of weight they have lost in the year following discontinuation of prescription; Wilding et al., 2022) and the limited prescribing period of two years specified by NICE, that there is limited benefit to long term physical health of these interventions and significant risk of psychological harm posed by weight regain (Tolvanen et al., 2022). We agree with the committee that there are a number of gaps in the evidence base that are of concern. Based on the number and extent of these evidence gaps we strongly recommend that digitally enabled technology providers are piloted in partnership with existing NHS-based level 3 Specialist Weight Management Services, in order to ensure effective, quality care with appropriate patient safety measures and clinical governance. References All Wales Weight Management Pathway (2021) Available at: https://www.gov.wales/sites/default/files/publications/2021-06/all-wales-weight-management-pathway-2021.pdf Beleigoli, A. M., Andrade, A. Q., Cançado, A. G., Paulo, M. N., Maria De Fátima, H. D., & Ribeiro, A. L. (2019). Web-based digital health interventions for weight loss and lifestyle habit changes in overweight and obese adults: systematic review and meta-analysis. Journal of medical Internet research, 21(1), e9609. Belli, H., Ural, C., Akbudak, M., & Sagaltıcı, E. (2019). Levels of childhood traumatic experiences and dissociative	

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91.	25	NHS England	Draft guidance	NHSE Response Guidance development process 1. Recommendations 1.2 Does NICE evidence generation plan stipulate that technologies are required to generate evidence in the UK? As evidence gathered in Europe / worldwide may not be appropriate for comparisons to be made to the way the NHS deliver weight management through the Tiering system.	
92.	25	NHS England	Draft guidance	4.1 Evidence generation As part of the strive to attain further evidence, does the wording need to clearly reference prescribing of obesity medication (as is in the last point) in relation to the following: • change in weight • adherence and completion rates • how the technologies monitor and report adverse events	

				• impact on resource use, including the number and type of healthcare appointments and cost of medication.	
93.	27	Company	1.3	[redacted] welcomes the decision to generate evidence from recommended digital technologies prior to routine use. We would recommend that – in addition to the outcomes to be measured (1.6) – providers also collect data items as required by the NHS National Obesity Audit (including CYP001 Master Patient Index and Risk Indicators and CYP007 Employment Status). We believe this will be important to provide a full picture in answering the seven questions set out by the Audit, as well as generating evidence on the range of interventions and settings that are most effective for different groups of patients.	
94.	27	Company	1.3	To measure the efficacy of interventions, we suggest data are submitted at regular intervals throughout the four-year period to ensure patients receive the best quality care and experience, and enable providers to tweak their offers based on the suite of interventions that have greatest efficacy and adherence.	
95.	27	Company	1.6	[redacted] suggests that additional outcomes be considered as part of the four year evidence generation period: - Change in BMI as well as change in weight - Data on interventions within the programmes that patients engaged and responded to the most (ie psychological support). This will support existing and future providers to hone their offers and provide a richer evidence base as part of the Obesity Audit - Patients accessing weight management medication will have one weight-related comorbidity. Collecting data on these, including improvements in outcomes, reductions in other medicine use as well as reductions in resource use related to those comorbidities could also be captured -Many providers issue satisfaction surveys. Measuring satisfaction could be included provided a single survey could be developed and used by all providers so comparisons could be made	

96.	27	Company	2	In reference to 'other programmes can collect and share medication adherence data with the NHS team': Novo Nordisk would suggest that a minimum standard is set for data collection that all providers meet to allow for comparison of data and to contribute to the National Obesity Audit.	
97.	27	Company	3.5	[redacted] suggests that consideration is made to monitor the measures noted in this subsection as part of the four year evidence generation and suggest that a data collection framework is designed to allow for evaluation and comparison between technologies and interventions.	
98.	28	Company	1.2	If we are accepted, we would ensure that the necessary agreements are in place to generate evidence for the evaluation of the technologies for adoption by the NHS.	
99.	28	Company	2.3	In Table 13.2 of Appendix 1 shared with the evaluation committee, we have included relevant comparators from literature to our clinical results.	
100.	30	Patient or professional organisation	Draft guidance	Page 4. 1.6 Evidence Generation Will adherence and completion metrics also include disease/condition specific PROMs/PREMs as part of the evidence needed – end user experience and feedback will be helpful to inform potential refinements and changes to not only the technology but also the care pathway (the latter of which will be important from a commissioning perspective and could supplement data captured on healthcare resource utilisation). Page 5 Potential benefits: managing risk Clinical assessment: Can further clarity be given regarding data/information sharing particularly if referrals are made from areas in which there is limited or no access to a specialist tier 3 service? Will clinical information be relayed via the digital provider – meaning selection of the chosen provider by the referring healthcare professional? Page 13 Evidence Gap Review Should the current standard of care be included in terms of the evidence gap? There are limited data regarding long-term outcomes for current tier 3 service delivery.	

				Generation of evidence for current tier 3 services over a 4 year period in terms of clinical and cost effectiveness would be helpful to include – particularly given challenges with access. Page 13 3.10 Outcomes Are there specific HRQoL measures for obesity which can be included? IWQOL for example? [impact of weight on quality of life – as used in the STEP trials] General question: both currently licensed agents have a 6 month review period to assess % weight reduction and potential discontinuation of the pharmacological agent – if the drug is discontinued because of not achieving the desired level of weight loss – can people still continue to use the digital solution to access on-going non-pharmacological support? Page 2 & 4 1.1 Resource use and Evidence Gaps Can each technology also be asked to provide insights into end user experience beyond adherence to the programme – both from the patients perspective and also from those referring into the service? Perhaps with an exit survey – this will be helpful in terms of improvements. In addition to evidence in terms of weight loss – it may also be helpful to include parameters such as HbA1c, blood pressure, LDL cholesterol at baseline and on programme completion – a reduction in these parameters will be associated with a reduction in cardiovascular disease burden and in turn will feed into clinical and cost effectiveness. Page 3 Adherence and completion From a health inequalities perspective it would be helpful to capture data relating to geographical location (urban vs rural vs coastal) in terms of uptake and persistence with the technology.	
Implementation (n = 8)					

101.	4	Individual	1.6	Who takes clinical responsibility for the service? The NHS provider or commissioner who signpost patients to the service? Does this need to be risk assessed and managed.	Thank you for your comments. NICE's evaluation focuses on digitally enabled technologies for delivering specialist-weight management services to manage weight-management medicines. The care pathway and commissioning are outside of the remit of this assessment. Commissioning of the technologies is decided on a local level and may vary depending on location. NICE's early value assessment recommendations are not mandatory, and local trusts and centres are not mandated to fund recommended technologies. A decision to refer patients to use the technologies should be made based on shared decision making between the patient and relevant qualified healthcare professional. The NHSE Prevention Obesity Team and NICE have adopted a collaborative working relationship in relation to jointly understanding the current landscape of available remote service provision, utilising technology, which may be appropriate for use as part of the NHS Specialist Weight Management Service Prescribing Pilot Programme. Technologies with plausible promise of addressing an unmet need have the potential to be recommended for use in the NHS while further evidence is being generated over a 4-year period. After the evidence has been generated, NICE will produce guidance stating whether the technology is clinical and cost-effective compared to an appropriate comparator and whether it should be widely adopted. Implementation considerations will be made as part of the evidence generation plan.
102.	5	Patient or professional organisation	Draft guidance	Pilot the use of digitally enabled technology providers in close integration and collaboration with existing WM services; Due to the gaps in the evidence-base identified throughout the report, the limited information about how risks to service-users will be monitored and managed, and the risk of discrimination towards marginalized groups, we would strongly recommend the use of digitally enabled technology providers in level 3 weight management services be piloted in close collaboration with health trusts/boards with existing Level 3 Specialist Weight Management Services, to provide guidance and an alternative service offer.	
103.	5	Patient or professional organisation	Draft guidance	4. CAVUHB Level 2 Weight Management Service Pilot with Digitally Enabled Technology Provider As a service we are keen to integrate new digitally enabled technologies into our offer and our level 2 service has recently undertaken a waiting list initiative with a digitally enabled technology provider for service users with a BMI of 30 kg/m2+ to access a digital weight loss intervention. Our preliminary results demonstrated an opt in rate of 34% to the digital offer from the 1154 patients invited. Of the participants who did engage with the service positive outcomes to date included an average to date of 4.3kg weight loss for those who successfully completed the programme. In addition, qualitative feedback thus far has demonstrated that people valued the dietetic advice given, increased exercise and felt motivated by their contact with coaches. However, the pilot also demonstrated that 54% of patients failed to opt in to the offer whilst a further 10% contacted NHS services to specifically decline the digital offer and request an NHS face-to-face intervention. It's unclear what the views and preferences are of the 54% of service users who did not respond to the offer. As a minimum it is suggestive of the benefit of clinical triage to allow	

				signposting to the most appropriate clinical service. Feedback from service users expressing a preference for NHS-based care, with the option of face-to-face services, included the inappropriateness of app-based support for service users with: · Impaired capacity · Learning disabilities and difficulties · Without access to a smart phone · Sensitive physical health complications connected to obesity (e.g. gynaecological conditions) · Mental health difficulties · Neurological conditions · Where whole family approaches are requested · Where there was a preference for meeting with a clinicians face-to-face without specified reason Service users who accessed the digital service also provided qualitative feedback on the challenges of using the service including finding the "onboarding" process confusing, feedback that the advice and intervention was not personalised to their presentation, and feedback that the limited amount of one-to-one contact available was insufficient to support them to make change. In summary, the preliminary results of this pilot have identified that digitally enabled technology providers are suitable, convenient and helpful for a specific sub-group of level 2 weight management service users, however are inappropriate and inaccessible for many. Further analysis of these pilot outcomes is necessary to ensure the validity of these early reported results. Exploring the implications of this	Sections 3.1 and 3.2 of the draft guidance discuss the unmet need for people who cannot access current in-person specialist services. The committee agreed that there is a need to expand these services to allow access for more people who are eligible. Section 3.8 of the guidance states '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 limited evidence for adherence and engagement is discussed in section 3.5 of the draft guidance. The committee concluded that more evidence is needed for these outcomes and included them in section 1.6 and in the evidence generation plan to be collected during the evidence generation period.

				pilot for the use of digitally enabled technology providers in level 3 services it would be reasonable to conclude that this service would be inappropriate for a higher proportion of level 3 specialist weight management service users. Based on this pilot we would recommend against the use of digitally enabled technology providers as stand-alone providers of level 2 or level 3 weight management services. We believe that continuing to pilot these technologies in close collaboration with existing NHS-based services, with face-to-face care options, is indicated at this stage.	
104.	14	Company	1	The guidance should state who will be the responsible for commissioner for these technologies. If commissioned by individual ICBs, there needs to be a standard NHS contract between commissioners and providers to ensure that consistent access and funding arrangements are in place across all systems.	
105.	16	Company	4.2	On 6 June, the Prime Minister and Secretary of State for Health and Social Care announced a two-year pilot scheme to explore ways to make obesity drugs accessible to patients living with obesity outside of hospital settings. Given the points already made, CheqUp believes that it would be internally consistent to allow our company to take part in these pilots, subject to an appropriate procurement process, as well as the four technologies already recommended in the guidance. On a left-to-right continuum, where the left side is every single eligible patient receiving in-person tier-3 weight management support and the right side is a 100% digital app-based support system with no human contact at all, our approach is closer to the left than the right. Our health coach, dietician, nutritionist, physical exercise specialist and psychologist appointments are all in-person but delivered virtually.	

				It makes sense for the pilots to explore the health benefits and economic costs of a range of providers on that left-right continuum and to exclude any company, not least for the range of reasons listed previously, would be counter-productive. One interpretation of the current guidance is that the three technologies being recommended for 'further research' would already be eligible to be included on the NHS England pilots because such work would be 'research' and thus outside of the "core" NHS funding mentioned. It is our reading of the current consultation that all seven companies are eligible to take part in the NHS England pilots.	
106.	25	NHS England	Draft guidance	In relation to the NHSE Pilot Programme to expand prescribing and the use of digital platforms, NHSE prevention considers the NICE EVA to indicate where there is likely to be interest and potentially the ability to provide services against the requirements for the pilot project, however NHSE intend to run a compliant, competitive open tender process with no limitations on the number of commercial providers able to bid for a contract, to deliver the required services against the detailed specification, to meet the needs of the pilot. NHSE will base their decision to contract with commercial providers on the evidence submitted as part of the provider company bid, which will incorporate areas not assessed by the EVA to include, the bidders' experience, financial standing and status as an organisation, how the bidders will perform the contract, technical capabilities inclusive of security and data management, service accessibility, and the ability to mobilise. As such contracts to provider companies for the delivery of the pilot will not be based on the four named companies in the NICE EVA, however these companies would be able/welcome to participate in the open tender, through the process described, but issue of an NHS contract for the	

				delivery of the pilot is not guaranteed to any of them, through this transparent and competitive process. The current wording of the EVA suggests that the NHS could only consider contracting with the named four companies, which is misleading, and not in line with an open competitive process as described.	
107.	27	Company	3.8	Further information could be provided on how patients can access these technologies (ie can patients choose which provider they would like to use). This is particularly pertinent if some patients have specific language needs.	
108.	27	Company	3.8	Further information on how patients are referred to digital technologies (including whether referring clinicians can indicate a preference) would be welcome.	
Managing risk (n = 5)					
109.	1	Individual	3.6	This does not fill me as a senior clinician working in a tier 3 weight management service with reassurance. The processes sound vague as the committee has identified and the conclusion of the committee to use these technologies for weight management medications seems to contravene their concerns. All care and treatment should be safe from the outset especially when it is not medical emergency.	Thank you for your comments. Considerations for managing potential risks are included in section 1 and section 3.7 of the guidance document. Additional text was added to section 1 to provide information relating to the prescription of weight management-medicines. When making decisions for EVA, the committee make a number of considerations based on the interim process and methods statement (section 3.28).
110.	4	Individual	3.6	This is very important to stress including clinical responsibility and escalation of adverse effects.	
111.	5	Patient or professional organisation	Draft guidance	7. Risks of Providing a Service without Face-to-Face Care Options Based on our expert knowledge, clinical experience and reading of the documents available for consultation we have identified that following risks of providing level-3 services through digitally enabled technology providers, where a local face-to-face option is also not available: · Risk of providing a service model that discriminates against older persons, persons with learning difficulties, persons with financial difficulties limiting access to smart technology and internet access, persons with a range of physical health difficulties and persons with complex engagement difficulties	

				due to adverse childhood experiences or significant mental health difficulties. · Risk of providing a service model that has limited links with level 4 weight management services and limited intervention around the psychological and physical preparations necessary for preparation for bariatric surgery. Therefore limiting access to necessary and sometimes life-saving access to bariatric surgery. · Risks of providing a service model with poorly integrated care with other relevant NHS services e.g. mental health services, neurology, lymphoedema, physiotherapy, acute services to manage significant side effects of obesity and complications from GLP-1 agonists. · Providing a service with insufficient monitoring processes to manage complex physical or mental health presentations. · Risk of neglecting the development of level 3 weight management services for clients with the most complex presentations requiring face-to-face MDT physiotherapy services, occupational therapy to manage safety in the home environment and evidence-based psychological interventions. · Risk of over-investment in rapid access to Wegovy, which has thus far limited evidence of long-term benefit in the way NICE has approved this; 2 year prescribing limit with participants regaining two thirds of weight they have lost a year following discontinuation of prescription (Wilding et al., 2022). · Risk of over-investment in treatment with significant risk of psychological harm following discontinuation, based on a recent service evaluation we completed exploring service users' experiences of the time-limited nature of liraglutide (Saxenda) for pre-diabetes and obesity (see data (8) below).	

112.	13	Company	Draft guidance	It's not clear from the guidance the level of governance that will be provided to ensure people taking weight loss medications, which are known to have side effects, are well supported. It's worth noting that these are still relatively new drugs with little real-life application through services like this and we are therefore concerned that they are being made available via digital platforms so soon in their lifespan, with no 'safety net' of a period of time when they're prescribed by NHS professionals, who are able to monitor their impact more closely. Digital services by their nature, where there isn't in person, regular face to face interaction, make it difficult to achieve close monitoring, consequently there is a risk that people may provide misleading results, or slip through the net accidentally. More guidance and consideration needs to be given in this area.	
113.	22	Patient or professional organisation	Draft guidance	Managing Risks in Level 3 Specialist Weight Management Services Due to the comorbidities outlined above staff in Level 3 Weight Management Services work collaboratively with people living with complex obesity to monitor and manage a number of risks: Self-harming behaviours (large scale population samples have identified that up to 60% of people with grade 2 obesity have engaged in self-harm; Muller et al., 2016) Risk of suicide (large scale population samples have identified that 33% of participants with a BMI of 40+ had engaged in suicidal behaviour; Wagner et al., 2013) Risk of physical health deterioration due to a number of complex physical health comorbidities; lymphoedema, cardiac problems, idiopathic intracranial hypertension, non-alcoholic fatty liver disease, diabetes. Increased psychological distress and development of addiction transfer (Ivejaz., 2017) as weight loss increases, particularly where overeating and weight have had a protective function (O'Loughlen, Galligan & Grant, 2023; Gustavson and Sarwer, 2004). Risk of the development or reemergence of eating disorders (Golden et al., 2016; which requires additional assessment	

				and monitoring where people are prescribed weight loss medication) Safeguarding risks; due to the prevalence psychosocial complexity and trauma history Specialist Weight Management Services are a common place for first time disclosures of current or historical trauma. Close liaison with the service users and safeguarding agencies is often required to manage risks to service users and the wider public. Based on the information available within the current consultation documents we are significantly concerned about the ability of digitally enabled technology providers to work collaboratively with service users with complex obesity to monitor and manage the risks outlined above, particularly without the option of face-to-face care for more intensive monitoring and management ,or direct access to a specialist psychologist. This could result in significant risks being missed and potential physical and psychological harm to self-users.	
Multidisciplinary support (n = 5)					
114.	5	Patient or professional organisation	Draft guidance	6. Defining and Setting Clear Standards for the "Multidisciplinary Team" We would recommend further thought is given to what constitutes a "multidisciplinary team" and therefore meets the standards for the intensive multidisciplinary team intervention that national guidelines deem necessary within level 3 weight management services (All Wales Weight Management Pathway, 2021; BOMSS, 2014; NICE, 2014). On reading the documents available for this consultation the main staff groups that appeared available to service users accessing the digitally enabled technologies were dietetic and nutrition staff, and medical staff. It was concerning to see that the input of physiotherapy was often missing through these providers, and that occupational therapy was rarely mentioned in the document. In our level 3 service physiotherapy and occupational therapy staff are crucial in helping people living with obesity to reduce pain and safely	Thank you for your comments. Section 2.3 has been amended to clarify the composition of a multidisciplinary team (MDT) to reflect NICE's clinical guideline on obesity: identification, assessment and management. Section 3.8 acknowledges clinical expert opinion that there is 'limited information on how MDTs are used in the programmes. But, they noted that this is also the case for standard care and that MDTs can vary significantly between weight-management services'. Additionally, they stated that '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

				reengage with exercise, adapt their home environment to ensure they can engage in activities including food preparation, bathe safely and engage in meaningful occupation, respectively. We were also concerned to see that psychology input was variable among digitally enabled technology providers and that there was no mention of the provision of evidence-based psychological interventions for complex obesity. In our service specialist clinical psychologists provide one-to-one and group-based psychological therapies, including Dialectical Behavioural Therapy (Rahmani, Omidi, Asemi & Akbari, 2017; Mushquash & McMahan, 2015) Cognitive Behavioural Therapy (Dalle Grave et al., 2020) and Acceptance and Commitment Therapy (Richards et al., 2022), which are evidence-based therapies essential in helping our service users with complex needs overcome the pervasive psychological barriers to weight loss they experience.	people have mental health issues. They said that it is important to monitor behaviour on restricted diets to minimise the risk of potential harms, such as developing disordered eating'. Evaluation of the mode of delivery for psychological interventions such as cognitive behavioural therapy is out of the remit of the scope for this assessment.
115.	11	Company	1.6	[redacted] believe that this early value assessment (EVA) should be in line with the recently updated section "1.10 Surgical interventions" of CG189: Obesity: identification, assessment, and management. The NICE committee acknowledged that "because of a variation in commissioning of services there may be differences in the structure of the multidisciplinary team and that this assessment for surgery might currently lie in tier 3 or tier 4 services". In accordance with this observation the updated guidelines, (CG189: section 1.10 – "Surgical interventions"), "The committee agreed that ideally the multidisciplinary team should have access to or include a physician, surgeon or bariatric surgeon, registered dietitian and specialist psychologist" (page 57). However, this is not reflected in the draft guidance for digitally enabled technologies. For the digitally enabled services to fulfil the unmet need, they must deliver the same standard of service to individuals who have access to a face-to-face services. This includes the ability to submit referrals to "Specialist weight management services"	

				conducting assessments to determine a patient's suitability for bariatric surgery. We respectfully ask that the wording in the "Potential benefits – Managing risk – Multidisciplinary support" section be amended to read "The technologies provide support from a multidisciplinary team (MDT) of qualified healthcare professionals who have expertise in conducting medical, nutritional, psychological and surgical assessments. This includes psychological support and monitoring to reduce the risk of harm, including from disordered eating." This amendment will maintain consistency between this early value assessment and NICE CG189 and ensure equity of access for all patients who access the digitally enabled technologiesN.	
116.	14	Company	1.6	There should be a standard for the MDT support provided by these technologies to ensure safe and consistent patient care. If providing medicines, the MDT must include an expert in medicines.	
117.	22	Patient or professional organisation	Draft guidance	The Role of Evidence-Based Psychological Therapies in Specialist Level 3 Weight Management Services The consultation makes several references to psychological support as an aspect of level 3 specialist weight management services. Whilst the development of positive therapeutic relationships between staff and service users, leaving service users feeling understood and supported to embrace change is important, specialist level 3 weight management services are commissioned to provide access to evidence-based psychological therapies for complex obesity, in addition to lower-level psychological support. From the evidence available about digitally enabled healthcare technology providers, it is unclear whether access to evidence-based psychological therapies is part of their level 3 offer and further information is needed. Additionally, we urge the committee to consider the evidence showing that even well-	

				established psychological interventions such as Cognitive Behavioral Therapy are not as effective as initially thought, if delivered alone, in the absence of an in person therapeutic relationship (Gilbody et al., 2015). Evidence-based psychological therapies are intensive treatment programmes that enable service users to understand the psychological roots of their relationship with food (often trauma and emotion dysregulation related) and utilise cognitive and behavioural strategies, within a professional empathic relationship, to challenge the patterns that maintain their current relationship with food. Recent research identifies the efficacy of cognitive behavioural therapy (Jacob et al., 2018) and third wave cognitive behavioural therapies (Lawlor et al., 2020), including Acceptance and Commitment Therapy, Dialectial Behavioural Therapy, and Compassion Focussed Therapy, in addressing psychological barriers to weight loss and in promoting weight loss. In addition, there is developing research in the applications of trauma-focused therapies to enable reductions in emotional eating and help service users with complex needs achieve weight loss (Katrine, 2015; Volery, 2015). NHS-based specialist Level 3 Weight Management Service provide evidence-based psychological interventions for weight loss facilitated by specialist psychologists with the necessary expert training. For example, a recent 12 session Dialectical Behavioural Therapy Group for Emotional Eating delivered by Dr Kellie Turner, Psychologist at Aneurin Bevan University Health Board Level 3 Specialist Weight Management Service achieved a reduction in emotional eating in 100% of participant (on average 34% reduction) and a reduction in psychological distress in 80% of participants (on average 50% reduction). Another example is the “Mind Over Food” psychology group developed by Dr Meryl James, Weight Management Psychology Lead, Hywel Dda University Health Board, aimed to help people overcome emotional eating and barriers to change. This group has enabled participants to achieve 80% reduction in emotional eating, 73% reduction in anxiety, 80%	

				reduction in depression, 87% reported increased self-efficacy in relation to eating and 73% reported weight loss (although it is not a weight loss group, with an average of 3.67kg weight loss over 8 weeks (range 0-12.7kg)). In addition, at Hywel Dda UHB Binge Eating Disorder is treated within the level 3 specialist weight management service, as the local eating disorder service is not commissioned to treat Binge Eating disorder. Outcomes provided by Dr James identify that over of the 15 service users accessing one-to-one psychological therapy for Binge Eating Disorder over the past year, 93% of service users achieved resolution of binge eating symptoms. There is an increasing evidence-base attesting to the value of group-based interventions in Level 3 Specialist Weight Management Services (Paul-Ebhohimhen and Avenell, 2009; Renjilian et al., 2001) and it remains unclear how digitally enabled technology providers could enable access to group-based interventions for service users. Based on the consultation documents provided it remains unclear whether digitally enabled technology providers are able to offer evidence-based psychological therapies for service users with complex obesity in a safe and effective manner. Furthermore, professional empathy may be necessary to improve patient-safety (Xin Zhang, et al, 2023) and it remains unclear how this would be established through app-based provision.	
118.	27	Company	1.6	In reference to 'multidisciplinary support': We feel that further detail should be provided on the MDT support to be provided by recommended technologies. While [redacted] recognises the value in variation between approaches to test efficacy, adherence, resource use and response, we believe a minimum standard MDT should be set, in addition to a minimum standard of number of patient contacts.	
Patient perspectives (n = 3)					
119.	5	Patient or professional organisation	Draft guidance	8. Service User thoughts of discontinuation of Saxenda after two years	Thank you for your comments.

				Service User A- Direct Quote “The fact that in 2 years it will be taken from me is a concern if I had diabetes would they remove treatment from me after 2 years ????” Service User B- Patient Story “She understandably feels worried about her ability to access the medication and is concerned about being able to achieve a level of weight loss necessary for a referral for orthopaedic surgery.” Service User C- Direct Quote “I don’t like things finishing as I’m scared and I may fail”	NICE’s recommendations for weight-management medicines are outside of the remit of the scope for this assessment.
120.	10	Individual	Draft guidance	I am a member of the public, diabetic and used to have weight issues but they are now controlled by diet. My BMI has varied between 29 and 30 since Nov 21 when I first got the App. I was married to my first wife for 30 years and my second wife for 22 years. Both have struggled with obesity. I lived with my second wife in South Africa. She was prescribed Victoza sometime in 2017 and lost weight steadily. Then we returned to the UK in 2019 and we could not get a prescription for some years. despite all attempts she put the weight back on. I cannot remember when but she then got a prescription for Saxenda, the weight came off again. However apparently Saxenda is currently unattainable due to misuse encouraged by the media, and the weight is starting to increase. Her experience seems to mirror this study https://protomag.com/clinical-research/prescription-thin/	
121.	10	Individual	1	I am not qualified to comment but if I could make some comment as a layperson. I do believe that the Digital Technology will lead to much more efficient treatment for levels 1 and 2 which I would suggest be prescribed by the dietician who is well qualified to assist the patient and will relieve the GP with their workload. I am not sure why the NHS has to spend money in developing 4 digital systems when one would do. It also costs the NHS lots of money to assess and monitor each technology.	

				I do believe strongly that Tiers 3 and 4 do need assistance of medication which should be prescribed. Again I think a dietician could be trained to do the prescribing. Leading to the dietician being the specialist in weight management and obesity. I confirm that each time my wife has started her prescription she has felt nauseous but this passes after 2 or 3 weeks. When she is forced to stop the prescription she does experience water retention as well as weight gain. As the US study indicates the prescription is for life, not 2 years which will be a total waste of money. We do not know as yet what effects long term use of prescriptions might have. My wife takes the view that obesity is the biggest risk and obviously this should be monitored over time. She does have a goal weight which is similar to mine top end of Tier 2 and she will probably attempt to lower the dosage when she reaches it rather than to stop it completely. I do think a way must be found to stop the many people at Tiers 1 and 2 now using prescriptions. However, I admit I cannot think of a way to do this other than stopping self prescribing online. People are not honest. I do worry that those with eating disorders manage to get supplies In conclusion I think this proposal is not only first class but absolutely a necessity to combat obesity. Hopefully bariatric surgery will become a thing of the past.	
Patient population (n = 9)					
122.	5	Patient or professional organisation	Draft guidance	2. Complexity of Level 3 Service User Presentation Our Level 3 Specialist Weight Management Service MDT work with clients with a BMI of 40 kg/m2 + offering specialist evidence-based and formulation-led treatment plans to enable weight loss, improve functioning and quality of life. Service users who access our level 3 weight management service experience a range of complex physical health, mental health and psychosocial comorbidities. In addition, it is common for service users to have BMIs within the 50-70 kg/m2 range.	Thank you for your comments. The population specified in the scope for this early value assessment is adults with obesity referred for treatment with weight management medicines in line with NICE's guidance including but not limited to: • NICE's technology appraisal guidance for semaglutide for managing overweight and obesity

				Common physical health comorbidities include: · Diabetes · Lymphoedema · Idiopathic Intercranial Hypertension · Non-Alcoholic Fatty Liver Disease · Gynaecological issues with significant impact on fertility · High risk cardiac conditions Common mental health/cognitive comorbidities include: · Learning disability · Literacy issues · Neurodevelopmental difficulties, excluding but not limited to autism spectrum condition · Moderate depression and anxiety · Borderline personality disorder · Post-traumatic stress disorder · Current self-harming behaviours · Suicidal ideation In addition, many of the service users we work with experience: · Housing instability	• NICE's technology appraisal guidance for liraglutide for managing overweight and obesity Eligibility criteria differs between weight-management medicine. NICE's recommendations for weight-management medicines are outside of the remit of the scope for this assessment. Section 1.1 of the guidance has been amended to state that the population is adults who are eligible for weight-management medicines. Section 3.8 of the guidance acknowledges that people may have additional co-morbidities and a large proportion of people have mental health issues. Section 1 of the guidance acknowledges that these technologies may not be suitable for everyone. An additional statement has been added to section 1 of the guidance to acknowledge that 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. Amendments to section 1 information on multidisciplinary support states that support must include psychological support and monitoring to reduce the risk of harm, including from disordered eating. Section 1 has also been amended to include a statement on prescribing weight-management medicines. Unmet need is discussed in section 3.1 and 3.2 of the guidance. The guidance notes that there is an unequal distribution of specialist weight-management services across the NHS, and in some areas there is no access to them. It also states that the technologies may not be suitable for everyone, but may particularly benefit people who do not have access to specialist weight-

				· Poor housing conditions · Financial poverty · Food poverty · Current risk of harm through abusive family relationships · Carer stress Adverse Childhood Events (ACEs) screening data collected by our level 3 service, between March 2017 and May 2021, identified that 57% of service users entering the level 3 service had experienced four or more ACEs, compared to 14% of the general population. In addition, 27% of service users had experienced childhood sexual abuse. Comprehensive research into the impact of ACEs on wellbeing and service engagement demonstrates that service users with experience of multiple ACEs face additional barriers to asking for help, trusting healthcare professionals and engaging with complex healthcare systems (Traumatic Stress Wales & ACE Hub Wales, 2022). In addition, a sample of 70 service users' data collected in our level 3 service between December 2022 and March 2023 demonstrated moderate to severe emotional eating in 80% of service users entering our level 3 service. Emotional eating has been defined as "eating in response to a range of negative emotions, such as anxiety, depression, anger and loneliness" (Faith et al., 1997). Emotional Eating (EE) is a form of disordered eating and is a developmental pathway to obesity (Eichen, 2017 as cited in Smith, 2023) and reductions in EE are associated with greater weight loss in individuals living with obesity. These findings demonstrate the mental health and psychological complexities of service users with weight management difficulties accessing level 3 specialist weight management services.	management services in their area or who are on a waiting list so are not currently supported by a specialist weight-management programme.

				Given these common and significant physical and mental health comorbidities we are concerned about the capacity of digitally enabled technology providers, without face-to-face care options, to provide safe, effective and well-integrated care for many of our level 3 weight management service users	
123.	6	Individual	Draft guidance	The comparator only seems to be to those eligible for weight loss medication ie BMI greater than 35. For those with a BMI between 30-35, they will continue to be referred to traditional NHS funded weight loss services such as Weight Watchers or Slimming World. This leaves a gap that should be explored as many in this category struggle to access physical meetings, yet also have prediabetes / high blood pressure. It could drive perverse outcomes where those with a BMI of 33/34 further overeat to get a high enough BMI to allow prescription of a digital app.	
124.	13	Company	Draft guidance	What is the pathway for those who don't want to access digital support or for whom the medications are not effective? Has this been considered and what guidance is being provided for this?	
125.	16	Company	3.1	The NHS England figure of 25.9% of adults being classified as living with obesity is widely quoted. This implies some 12 million adults being eligible for weight management treatment. A lower, but still very high, number would qualify for treatment under NICE TAs 664 and 875 – probably many millions. We understand that there are roughly 35,000 places currently available on tier 3 weight management services. Presuming NICE prescribing guidelines for Wegovy are followed, and those for Mounjaro are very similar, it is clear that there is a huge delta between demand and supply for weight management services, and an unacceptable 'postcode lottery', with some areas having no service at all. We understood that the purpose of this Early Value Assessment was to consider those health technologies which have the potential to address this national unmet need as a means of bridging the gap between those patients who meet	

				the qualifying criteria and the existing Tier 3 capacity. Unfortunately, it is our view that the proposed solution – to recommend for use just four technologies - will not provide anything like enough capacity to address the unmet need. An opportunity will thus be wasted and the vast majority of patients will face a continued wait for treatment for many years to come.	
126.	22	Patient or professional organisation	Draft guidance	Understanding and Managing Psychological Complexities in Specialist Level 3 Weight Management Services The psychological and physical complexities of people living with obesity are significant and well documented (Johnston et al., 2022; British Psychological Society, 2019). A meta-analysis by Rajan & Menon (2017) identified that people living with obesity are 5.8 times more likely to experience depression, 1.4 times more likely to experience anxiety, 3.8 times more likely to experience difficulties with alcohol use and 4.5 times more likely to experience an eating disorder. Binge Eating Disorder (BED) is of particularly high prevalence with research identifying that 30% of people in weight management programmes have co-morbid BED (de Zwaan., 2001). People living with complex obesity and BED are also more likely to be affected by dissociative coping strategies, including dissociative eating (Belli et al., 2023). Women living with obesity are two times more likely to experience a personality disorder and severity of personality disorder symptoms has been found to be positively correlated with severity of obesity (Rajan & Menon, 2017). This research is supported by data collected by NHS-based Level 3 Specialist Weight Management Services. For example, Dr Meryl James, Weight Management Psychology Lead, Hywel Dda University Health Board informed that of 57% of people who presented Hywel Dda UHB Weight Management Services reported Moderate to Severe psychological distress and 63% reported poor wellbeing, often indicative of the presence of mental ill health (based on 283 people receiving biopsychosocial service entry assessments between April 2022 and July 2023). In addition,	

				92% of this sample presented with physical and psychological weight-related comorbidities. The identification of these diagnoses only goes so far in understanding the lived experiences of people with complex obesity. Specialist psychologists working in established NHS-based Level 3 Specialist Weight Management Services use a formulation-based approach to understand the life experiences which have contributed the challenges faced by a person living with obesity, and the factors which are maintaining the difficulties they face now. The British Psychological Society's Psychological Perspectives on Obesity: Addressing policy, practice and research priorities (2019) recommends the use of a biopsychosocial formulation approach identifying the biological, psychological and social factors that have influenced a persons' development of weight management difficulties. A case study example is outlined below identifying the biopsychosocial factors that have contributed to Jenny's development of complex obesity. This case study is an anonymised amalgamation of patient stories collected through psychologists' practice in Specialist Weight Management Services. Jenny described having difficulties with her weight and relationship with food throughout her life. She grew up in a loving family, where home-cooked family meals were a highlight. During her childhood she was sexually abused by her neighbor and Jenny understandably felt upset and confused about this experience at the time. She found herself going into the cupboards at home to get snacks at times she felt upset and overwhelmed. Jenny was able to talk to her Mum about what had happened some years later and the whole family were shocked and upset to hear what Jenny had experienced. Cooking hearty family meals continued to be a comfort to the whole family, particularly at this difficult time. As she got older Jenny began to experience bullying at school, with her peers often commenting on her weight and appearance. Jenny preferred to avoid P.E. as she didn't want the other children making comments about her in her P.E. kit. As she went through puberty Jenny developed a passion for	

				writing and particularly enjoyed art, making some good friends through art club. Jenny began to experience irregular periods, put on further weight in her late teens and was diagnosed with polycystic ovary syndrome. At this time Jenny and her Mum went to Slimming World and Jenny was able to lose 3 stone, but felt she regained this weight quickly when she wasn't following the diet rules. She felt powerless to change her health and body-shape. Jenny went to university to study journalism, enjoying local reporting at this time. During her time away from home she missed her supportive family and experienced significant low mood. At times she felt she wasn't taken seriously in her seminars due to her weight. She began to feel lonely, and that life wasn't worth living at times. Jenny developed a habit of drinking heavily on nights out with university friends to reduce her feelings of low self-confidence and found that she gained further weight at this time. Jenny has recently started her first job as a journalist and describes really enjoying chasing down local stories. She's noticed that when things are stressful at work, she calls into shops and takeaways for food several times a day. She feels very frustrated that she eats this way, but feels she's on automatic, reaching for high-calorie, highly-processed food to get her through her days. Jenny recognizes she began putting on weight as a child at the time of her abuse. Jenny wants to lose weight but has felt extremely uncomfortable in the past when she's managed some weight and people begin to comment on her appearance. As identified by this case study, people living with obesity may have developed a complex relationship with food over their lifetime. A strong link has been evidenced between Adverse Childhood Events and Obesity, with a recent met-analysis (Wiss and Brewerton, 2020) identifying a 46% increased likelihood of developing adult obesity in people who have experienced 4 or more adverse childhood events. Adverse Childhood Events include experiences of childhood sexual, physical or emotional abuse, neglect, having a parent who has been sent to prison, having a parent who experiences mental health difficulties and being bullied at	

				school. Adverse Childhood Events have also been linked to decreased healthcare enrolment, increased primary care appointment booking, decreased attendance of primary care appointments and increased attendance at accident and emergency departments (Diaz et al., 2022). These findings are borne out in UK-based Level 3 Specialist Weight Management Services; Adverse Childhood Events (ACEs) screening data collected by Dr Sinead Singh at Cardiff & Vale Level 3 Specialist Weight Management Services, between March 2017- May 2021, identified that 57% of service users entering the level 3 service had experienced four or more ACEs, compared to 14% of the general population (Welsh Government, 2021). In addition, 27% of service users had experienced childhood sexual abuse, compared to 10% of the general population (Welsh Government, 2021). In adulthood, there is a well-established association between stress and obesity. Exposure to chronic stress, such as financial insecurity, family discord, the stress of feeling stigmatised because of their weight, or mental ill health, results in the person's stress response system being constantly activated which in turn, increases the risk of excessive weight gain. Being stigmatised can also lead to feelings of distress, shame, guilt and failure and people often turn to food as a way of coping with difficult feelings. In addition, stigmatisation of obesity and idealization of underweight body shapes contributes to the development of eating disorders (Culbert et al., 2015). Evidence shows that stress increases the risk of excessive weight gain both directly and indirectly, resulting in biological, psychological and social mechanisms that maintain weight gain (i.e. increased appetite, sensitivity to food cues, cravings that lead to eating more or choosing more calorie-dense foods; British Psychological Society, 2019). In summary, people living with complex obesity experience increased prevalence of significant mental health difficulties, adverse childhood events and are likely to experience difficulties engaging with routine care, often presenting with	

				acute mental health or physical health needs. In response to the complex challenges faced by people living with complex obesity, improved trauma screening and detection and trauma informed care are recommended (Traumatic Stress Wales & ACEs Hub, 2022; Wiss & Brewerton, 2020; British Psychological Society; 2019). We have significant concerns that digitally enabled technology providers, without access to face-to-face care options and without direct access to specialist psychologist, would not be able to work effectively and in a trauma-informed way with level 3 specialist weight management service users, affected by the challenges and experiences outlined above. Therefore, we would strongly recommend against the piloting of these providers in areas without level 3 face-to-face weight management services, as the care provided would be at risk of being effective and also doing harm to service users through not providing trauma-informed care.	
127.	24	Individual	1.1	Currently, the "Tier 3"/ digital weight management service provided via these platforms only cater to those with BMI > 30 plus co-morbidity. A suggested 2.5 lowering for several ethnic minorities is mention on some of these platforms, but this has not been addressed with any degree of detail. This is what is stated on Oviva regarding who can access their program: People with BMI of 40 or over without any other health conditions OR a BMI (Body Mass Index) of 35 or over and living with a long term health condition such as diabetes OR a BMI of 33 or over if they are of South Asian descent such as Bangladeshi, Indian or Pakistani and you have a long term health condition such as diabetes As a specialist doctor in the medical management of obesity since 2019, I note that there is still not enough clarity on what constitutes obesity as a disease, in those who suffer its consequences most. For instance: South-east Asian (Indian) heritage, women with Polycystic ovarian disease, people with	

				abnormal LFT's due to hepatic fat deposition. The experience of digital platforms has mostly been with online coaching, not with potent medication and simultaneous safety netting and managing the adverse effects from GLP-1 RA's (described in another comment). The platforms are functional, but are they in a position to manage a prescribed self-injected medication program, and deal with the consequences - think pancreatitis, vomiting, electrolye imbalances - all of which are seen in real life medical weight management.	
128.	26	Individual	1.6	weight management patients can be very complex and simple apps won't be enough for these patients and could be detrimental. it's important more complex patients are signposted to specialist tier 3 services. Weight alone is not a good indicator. Patient's self esteem and ability to do things that are important to them as a result of losing weight are also very important. Getting feedback from patients about how useful they find apps etc is important. How easy are they to use. Do they offer any personal contact or coaching are all important to know	
129.	26	Individual	1.6	weight loss is not the only marker that should be looked at and it is important compare similar patient groups. Often patients attending face to face are more complex than those that opt for virtual. There is a great need to increase face to face provision as well as increasing digital technologies. This patient group also really benefit from face to face specialist groups	
130.	26	Individual	3.7	ensure that staff supporting patients are adequately trained and are able to get support with very complex patients and that staff have the insight to realise the patient is too complex for their level of training. Patients who have previously yo-yo dieted or had eating disorders shouldn't be considered for very low calorie programmes.	
Process (n = 5)					
131.	5	Patient or professional organisation	Draft guidance	This consultation is submitted on behalf of specialist weight management clinicians at Cardiff & Vale University Health Board (CAVUHB) level 2 and 3 Weight Management	Thank you for your comments.

				Services. CAVUHB Level 3 Specialist Weight Management Service comprises a multidisciplinary team of Consultants in Metabolic Medicine, a Clinical Nurse Specialist, Specialist Weight Management Dietitians, a Dietetic Assistant Practitioner, Clinical Psychologists, Physiotherapists and an Occupational Therapist. CAVUHB Level 2 Weight Management Services comprises Dieticians, a Dietetic Assistant Practitioner and Clinical Psychologists. 1. Key Recommendations · Extend the consultation period by a further month and work with relevant organizations to recruit clinician and service user feedback; We have been concerned at the very short time frame for this consultation and that this consultation has reached us through the media, rather than relevant professional networks. Relevant professional networks include- The British Obesity & Metabolic Surgery Socety (BOMSS), Obesity UK, The Association for the Study of Obesity (ASO), The British Psychological Society's Obesity Faculty Network, The Obesity Empowerment Network.	The recommendations are based on a mixture of research of various methodologies (including 1 RCT) as well as real-world evidence and unpublished data provided to NICE by the companies. The wider care pathway is out of the remit of this assessment. NICE followed the processes stated in the early value assessment interim statement when developing the guidance. NICE's comms team developed a press release which was released alongside the draft guidance for consultation on 15th August. Consultation closed at 5pm on 24th August but comments were accepted until 5pm on 25th August due to an incorrect date published in the press release and the media. NICE followed the recruitment procedure for specialist committee members outline in section 3 of the early value assessment interim process and methods. NICE also notified the relevant professional societies and internal and external contacts to ensure specialist committee members were representative of specialist weight-management service providers were recruited. The consultation period allows stakeholders from various background to comment on the draft guidance for additional consideration after the committee discussion.
132.	5	Patient or professional organisation	Draft guidance	9. Valuing Practice-Based Evidence We request that the period of consultation on this early value assessment be extended by an additional month to ensure that the wealth of specialist practice-based evidence be drawn upon in making plans to pilot digitally enabled technologies in level 3 weight management services. Whilst the current recommendations are based on the review of randomized control trials, and we recognize these are key in the development and commissioning of weight management services, there is also a wealth of unpublished data and insight within existing NHS-based level 3 weight management services, which would helpfully inform the guidance under development. For example, in CAVUHB Level 3 Specialist Weight Management Service we have recently undertaken a mixed-methods service evaluation with	

				a sample of 15 service users currently accessing a two-year prescription of liraglutide (Saxenda) for pre-diabetes and obesity. Analysis of the qualitative data has revealed that service-users highly valued the face-to-face education, monitoring and therapeutic role of a clinical nurse specialist and felt that they would have been unable to learn to take and continue with liraglutide without the input of a clinical nurse specialist. This kind of practice-based evidence is key in informing the future development of level 3 services and understanding the needs of level 3 service users, however, will not be gathered from peer-reviewed papers or randomized control trials. Clinical specialists working in the field need more time and awareness of this current consultation to inform this early impact assessment. This evidence and knowledge-based is key alongside the current RCTs considered as by their very nature RCTs exclude people with complex presentations (Fortin et al., 2006) who represent the majority of level 3 weight management service users and therefore have questionable external validity for the full range of clients who access our level 3 weight management services. We were very concerned to see the omission of a specialist weight management psychologist, physiotherapist and occupational therapist from the committee and would recommend recruitment from these groups to ensure a thorough specialist assessment of the current data and options is enabled. 10. References All Wales Weight Management Pathway (2021) Available at: https://www.gov.wales/sites/default/files/publications/2021-06/all-wales-weight-management-pathway-2021.pdf British Obesity & metabolic surgery society (2014) Commissioning guide: Weight assessment management clinics (tier 3).	

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133.	22	Patient or professional organisation	Draft guidance	Consultation on Digitally enabled technologies to support treatment with weight-management medication in specialist weight-management services: early value assessment Submitted on behalf of UK-Wide Weight Management Psychologists Network. Signatories:	

				[redacted] Key Recommendations: 1. Extend the consultation period for this early value assessment to enable more professional and lived experience contributions to the development of these recommendations.	

				2. Recruit a Specialist Psychologist working within Weight Management to join the committee to inform any further developments of guidance for weight management services. 3. Pilot the delivery of digitally enabled technologies in level 3 services with guidance from and in close collaboration with existing NHS-based Level 3 Specialist Weight Management Service, offering the option of face-to-face care.	
134.	22	Patient or professional organisation	Draft guidance	In addition, the absence of a specialist psychologist in weight management services in the committee for this early value assessment suggests the expert assessment of this aspect of digitally enabled technology providers remains inadequate. Based on the limited information available at this time we strongly recommend against the use of digitally enabled technology providers as sole providers of psychological interventions for service users with complex obesity.	
135.	24	Individual	Draft guidance	I was surprised to see that 24th August was the last date for commenting, since there was no clear indication of this - I picked up the link from the Guardian this morning!! No other articles actually provided this. Perhaps more publicity for such an important draft consultation would have been better - especially when the platforms recommended have little experience of complex medical prescribing for a whole patient in real life with the attendant co-morbities. Also, the drugs that have been promoted are currently not on the best supply chain - so is this really the right time to inflate demand even more for these products which the relevant manufacturers and patent holders are not able to guarantee. Any "intermittent" supply would adversely impact outcomes as well as cause the state of readiness of the patient to deteriorate. These manufacturers are as yet unable to supply enough product, due to various capacity issues. Should the NHS digital program have to give false hope to more patients at this point, driving them to desperation, when the overally supply is sporadic?	
The technologies (n = 19)					

136.	1	Individual	1.1	Whilst this offers a great outline for ensuring any adopted technologies are of a high standard, this set of criteria is not exhaustive enough for NICE to rely on as a sole reason for including such technologies in any guidelines. E.g. It asks developers "Describe clearly the intended or proven benefits for users and confirm if / how the benefits have been validated". If benefits are only intended - this is not evidence based. It is not clear whether the criteria would reject approval if a developer was only able to confirm intended benefits. Secondly, there is no mention of considering any conflict of interests in this set of criteria, which in my opinion should be considered to ensure technologies are not approved without due merit.	Thank you for your comments. 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 EAG assessment report, and in the EAG assessment report addendum. The criteria for technology inclusion in the evaluation is listed in the scope. Any technologies which do not meet these criteria cannot be considered. NICE considered additional technologies listed in the consultation comments. No further information was provided by MANUAL and so eligibility could not be verified. So, this technology was not assessed and was not included in the recommendations. Two companies (Slimming World and ADDVantage Technologies) suggested the addition of their technology into the guidance. NICE reviewed the eligibility of these technologies and they do not meet the criteria listed in final scope. NICE confirms that Juniper meets the criteria for inclusion in this evaluation. The committee reviewed the evidence and concluded that there was too much uncertainty around the evidence to conditionally recommend Juniper, suggesting further research should be done using company, research, or non-core NHS funding instead. An addendum detailing the evidence and description of Juniper is published alongside this guidance. The population specified in the scope for this early value assessment is adults with obesity referred for treatment with weight-management medicines. Prescription of weight-management medicines should be in line with NICE's guidance for weight management medicines (Liraglutide and Semaglutide) and local and national guidelines. The care pathway should also be in line with NICE and
137.	1	Individual	3.2	Need to be mindful of the following:- 1) why are weight loss medications currently only available in tier 3/4? 2) Does the digital technology pathway run long enough and frequently enough to see through to the end of patients treatments with weight loss medications? 3) If patients suffer adverse reactions from weight loss medication, how does the digital technology manage this? 4) What are the stipulations around repeat prescriptions being issued - are these automatic or do they depend on the patient evidencing certain parameters? Also need to be mindful not to plough too much focus into digital technologies that face to face weight management services are not invested in, as not all patients have mobile phones and not all patients want to have input remotely.	
138.	1	Individual	3.8	Again, quite vague and would be good to know if these languages fit the profile of languages we see across the UK	
139.	4	Individual	2.4	Be helpful to understand how this interacts with NHS services, such as in the case of adverse reactions or supply of medicines.	
140.	13	Company	Draft guidance	From the evidence provided, only one of the four proposed providers has any evidence of working with patients who have been prescribed weight management medication and this is a significant gap in the evidence to date. We'd suggest	

				NICE should consider opening the brief up more widely and including organisations such as Slimming World who have a proven track record of working with the NHS, and of delivering effective digital support. Given that evidence/a track record of working with weight management medication seems to be non-essential, we'd question why other digital providers with published evidence of successfully supporting people with weight management haven't been considered.	NHS guidance. These considerations are outside of the remit of this assessment. Implementation considerations will be made as part of the evidence generation plan published alongside the guidance. The final scope has been amended to correct the factual inaccuracy in the description of the technology. Risk management and adverse events monitoring is discussed in section 3.6 of the draft guidance. The companies confirmed that medicine programmes are aligned with the recommended treatment lengths in the relevant guidance. The committee carefully considered the benefits and risks of the technologies as well as the available evidence when conditionally recommending technologies. Further evidence on the clinical and cost-effectiveness of the technologies will be generated over the next 4 years to assess if the benefits of these technologies are realised in practice. NICE will include all technologies that meet the eligibility criteria in the assessment, review the evidence and produce full guidance and make recommendations about the routine adoption of these technologies across the NHS.
141.	17	Company	2.2 (of final scope)	Within the Final Scope document published in July 2023: We have noticed in the Supporting Documentation document provided alongside the public consultation that it states regarding Roczen 'Ongoing follow up is provided by the clinical team at 12 and 24 weeks.' This is factually incorrect and, contrary to this, the clinical team follow up with patients every 4 weeks as long as they remain on the programme (up to and beyond 2 years, as per patient preference). The patient is also able to send a message to the clinician via the App 24 hours a day, 7 days a week. If this could be amended, that would be appreciated so that it better reflects the level of clinical oversight provided from the Roczen team to patients.	
142.	19	Company	Draft guidance	ADDVantage Technologies – have a Digital First Technology for Weight Management - Approved on the NHS's DFOCVC Framework (https://buyingcatalogue.digital.nhs.uk/catalogue-solutions/10033-001/features) – we are currently in the process of getting formal DTAC also (Though getting on the DFOCVC Framework included these measures) See also attached document on the solution (called healthya) We would like healthya added onto the NICE Guidance – we are currently working with the National Insititute of Obesity – and Prof Louisa Ells is on our advisory panel also.	
143.	22	Patient or professional organisation	Draft guidance	Integration of Digitally Enabled Healthcare Technologies with Current Care Pathway From the information available within the consultation documents, we believe there are a number of unaddressed	

				concerns about the integration of digitally enabled healthcare technology providers as level 3 specialist weight management services within the stepped-care model of weight management interventions recommended through national guidance (All Wales Weight Management Pathway, 2021; Public Health England, 2017). One area which requires further planning and delineation is how the digitally enabled healthcare technology providers' offer differs between the level 2 and 3 services they enable. If specialist level 3 services are designed to offer an intensive multidisciplinary intervention for service users with higher BMI and more complex presentations further information is required to evidence the capacity of digitally enabled healthcare technology providers to offer this in service models which offer 100% digital care, with dietetics and nutrition staff as the main offer. In addition, one of the core functions of level 3 specialist weight management services is to assess suitability for and where appropriate prepare service users for bariatric surgery in level 4 weight management services. Again, based on the information provided it remains unclear how digitally enabled healthcare technology providers offering level 3 services would fulfil this role. Further information about the referral and information-sharing pathways between digitally enabled healthcare technology providers and level 4 specialist weight management services is required to assess this. In addition, it would be helpful to understand what knowledge base and training digitally enabled healthcare technology providers have around screening and preparation for bariatric surgery for service users with complex obesity. Establishing direct relationships between levels 3 and 4 weight management service within NHS-based services has enabled prompt and appropriate access to bariatric surgery for service users with complex obesity. For example, Cardiff & Vale University Health Board Level 3 Specialist Weight Management Service cofacilitates joint assessment clinics with the Welsh Institute for Metabolic and Obesity Surgery (WIMOS; Level 4 Weight Management Service for Wales) to enable appropriate access to bariatric surgery. In addition, Dr Caroline Savidge,	

				Level 3 Specialist Weight Management Services, Derbyshire Community Health Services NHS Foundation Trust, has developed joint working with colleagues in level 4 services in order to develop clear and direct referral pathways, patient consultation and prompt and appropriate access to bariatric surgery.	
144.	25	NHS England	Draft guidance	2.1 Technologies NHSE are only aware of one provider (Oviva) currently prescribing or monitoring weight management medication as options for supporting treatment with weight management. Other providers may be doing that away from NHS contracts in the private market; however, can we deem a private (paid for by the consumer) programme as a credible weight management programme which adheres to NICE guidance on weight management? 3.2 The text “They 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.” Provides a question as to how NICE has approved four providers in the draft EVA.	
145.	26	Individual	1.6	“Access: The technologies may provide more flexible access to services for people who are unable to travel or prefer to access services remotely.” agree completely with this and is a great opportunity	
146.	27	Company	1.6	In reference to 1.6 'unmet need': In addition to weight loss medication, Novo Nordisk believes that the wraparound MDT support patients receive is a critical component of weight management programmes, which we understand will continue to be provided via these digital technologies. This section should be explicit that access to these digital technologies will include wraparound MDT support in addition to medication only where appropriate.	
147.	27	Company	3.2	[redacted] is very concerned about the increase in illicit sales of weight management medicines in unregulated settings, as well as an increase in pharmaceutical crime including counterfeit and diversion.	

				However, these providers and activity must be distinguished from the many private providers - some of whom have been shortlisted for this NICE guidance - who already operate in private healthcare settings and offer wraparound weight management support. For some patients who have not been able to access NHS weight management services, private providers have offered holistic support to manage their weight.	
148.	27	Company	3.7	[redacted] suggests consideration is made to how data sharing between technologies and primary care can be achieved.	
149.	28	Company	2.1	We believe Juniper fits within the inclusion criteria in the scope and should be considered in this early value assessment. Juniper was correctly identified during scoping as a potential technology. We have provided relevant evidence to support our inclusion among selected technologies via comments on this guidance and in the appendices shared with the NICE evaluation committee separately: * Appendix 1 (our responses to EVA questions); and * Appendix 2 (our outcomes data). Below is an evaluation of how Juniper satisfied the inclusion criteria in the scope: * Is intended for use by adults Juniper is intended for use by adults. We do not dispense medication to anyone under the age of 18-years-old. * Delivers a specialist weight management programme that includes behaviour change strategies to increase people's physical activity levels or decrease inactivity, improve eating behaviour and the quality of the person's diet, and reduce energy intake in line with tier 3 services Juniper delivers a holistic specialist weight management programme that assists in patients weight loss with support	

				from a digital platform and access to an MDT. Through the platform, we provide educational content and support from members of the MDT to instigate behavioural change in-conjunction with a patient's medication programme. Members of our MDT help to manage a patient's behaviours in-line with the requirements of Tier 3 services. Specifics of how our MDT provide assistance to patients is detailed below in this comment. * Facilitates weight management medication monitoring or prescribing Juniper provides weight management medication prescribing and monitoring through our programme and digital platform. Medication prescription and dispensing is provided through our registered pharmacy. With their medication, patients receive access to the Juniper platform, which assists in weight-management in-conjunction with weight loss medications via: * Progress monitoring (e.g., bluetooth connectivity with digital scales for weight tracking that can be monitored by the MDT) * Direct interaction with our MDT through in-app chat functionality (within our mobile app) or via preferred communication (e.g. email, calls) * Educational support (149 videos delivered through mobile app, 50+ recipes). The content of these videos is written by our MDT (e.g. advice on emotional eating, instructions on how to inject medication) * Fortnightly check-ins and mandated follow-ups Further, Juniper technology provides our MDT with capabilities to manage patient outcomes via: * Observations: Numerous active and passive data inputs are collected from patients (e.g., weight, side effects, satisfaction) * Trends: We have a pre-defined set of 'trends' to flag patients who may require advanced support or early intervention from a member of the MDT * Triaging: Capability to ensure that each reported patient issue is directed towards the most appropriate member of the	

				MDT * Prioritisation: The MDT's inbox is prioritised in order to respond to high urgency requests promptly in line with SLAs (e.g. side effects elevated to top of inbox) * Interventions: The MDT can leverage a number of pre-defined evidence based interventions created by experts in their field and uploaded to our platform, if they deem it is appropriate for their patient * Facilitates communication with an MDT of healthcare professionals which could include dieticians, nutritionists, psychologists, psychiatrists, physiotherapists, pharmacists Juniper employs a broad MDT, typically under full time contracts with Juniper, to support and manage our patients' weight-loss journeys. The Juniper MDT approaches weight loss from a bio psychosocial aspect, recognising that weight loss is influenced by a combination of physiological, psychological and social factors. The Juniper programme has been developed in Australia and the UK. The Australian programme is approx. 6 months ahead (as it launched 6 months earlier) than Juniper in the UK. As a result, the Australian programme has a more extensively developed MDT, a framework that the UK will emulate over coming months. Our MDT within Australia consists of: - A programme advisor (advises all jurisdictions, including the UK) | Dr Ramy Bishay - programme advisor – specialist endocrinologist and clinical lead of the Metabolic & Weight Loss Clinic at Blacktown Hospital (Sydney) - Prescribers | specialist general practitioners & nurse practitioners - Mental Health Support | specialist mental health nurse - Medical Support | registered nurses and pharmacists - Dietetics & Nutritional Support | accredited practising dieticians & clinical nutritionists - Certified exercise specialists | exercise programs and	

				advice - Health Coaching | motivation and accountability coach - Dispensing | pharmacists - dispense medications and provide additional clinical support to prescribers e.g. medication management and interactions - Patient Support | specialists - provide non-clinical patient support - Eucalyptus internal clinical team including our clinical audit function* | Clinical Director (specialist GP), doctors, registered nurses, registered pharmacists In the UK our current MDT consists of: - Prescribers | Pharmacist Independent Prescribers - Medical Support | Registered Pharmacists - clinical support for patients (e.g. side effect management) - Dispensing | Registered Pharmacists - ensure the quality, and suitability of prescribed medicines, ensure safe dispensing, while also advising patients on usage, potential reactions, and addressing inquiries. - Nutritional Support | Registered dieticians, clinical nutritionists - proactive and reactive nutritional support for patients - Health Coaching | Motivation and accountability coach We are expanding our MDT, which interfaces directly with patients. We actively recruiting for the following roles in the UK: - Psychologist I behavioural change and mental health support for patients - Physical Activity Specialists I tailored exercise programs - Physiotherapist I specialised advice Full information on our MDT, including how they meet, interact with patients and responsibilities & clinical governance, can be found in our response to question 9 in Appendix 1 shared separately with the NICE evaluation committee. *Meet the standards within the digital technology assessment	

				criteria (DTAC), have a CE or UKCA mark where required. Products may also be considered if they are actively working towards required CE or UKCA mark and meet all other standards within the DTAC The Juniper digital health-platform and programme complies with all relevant regulations in the UK. Juniper does not currently have a CE/UKCA mark certificate as it does not meet the definition of a medical device. This is because the platform acts as a decision support tool for Juniper's practitioners who provide clinical care to patients. As we continue expanding our service offering as part of the Juniper platform, we will continually reassess whether it falls within the definition of a medical device and, if so, will seek certification. We are confident that our technology aligns with the Digital Technology Assessment Criteria (DTAC) standards. We have conducted an internal assessment process, and will submit our application for DTAC compliance. *Is available for use in the NHS Our service is accessible to eligible patients throughout the UK. While we are not currently operating within the NHS framework, we have intent to collaborate and integrate with the NHS in the future. We are developing our service to mirror the provisions required for the management of Tier 3 patients, taking into consideration specific requirements that may differ regionally.	
150.	28	Company	3.2	The Juniper programme has been designed in part to address the unmet need identified by the evaluation committee and clinical experts. We agree that individuals with no specialist weight-management programme are often referred to Tier 1 or Tier 2 weight management services, which cannot offer support for treatment via medication. The Juniper programme has been designed to holistically support patients through their weight loss journey as they take their weight loss medications, providing the necessary additional resources from a MDT and the wrap-around support required so that medicines are used safely and consistently.	

				Specific subgroups that may benefit the most include: - Individuals with limited mobility; - Individuals who are housebound; - Individuals living in rural or remote areas of the country; - Individuals who don't feel comfortable in the current system (e.g. patients who don't feel comfortable leaving their homes or speaking to their GPs about their weight) - Individuals with work commitments (frequent travel, irregular shift patterns) that prevent them from accessing traditional weight management programmes; The Juniper platform uses scalable technology to provide weight management support. It has the following clinical and system benefits: - Integrated and personalised care: The Juniper patient profile summarises a number of data points that members of their MDT can view to help inform personalised and relevant interventions. For example a dietician using the platform would be able to view a patient's weight loss over time, their food diary, level of satisfaction over time, what dosage of medication they have been on, and their interactions with other members of their MDT. All this information can help them create the best treatment plan going forward. This provides personalisation and greater integrated care of a patient. - Increased access to HCPs: Most HCPs and specialists are seen in person and it can be hard for many patients to travel or be able to schedule appointments at appropriate times. Juniper allows for unlimited messaging with members of their MDT, increasing accessibility. - Improved responsiveness of intervention: Juniper's technology facilitates real-time monitoring of multiple health data points (e.g. daily logs of weight loss). Our Trends Engine flags indicators of patients who would benefit from a	

				member of the MDT's support and prompts our MDT to intervene (e.g. rate of weight loss different to expected). As a result, patients receive timely and precise care, ensuring they're always supported when they need it most. - Post Medication Support: Clinical studies emphasise that for sustainable results from weight loss medications, they must be paired with effective lifestyle interventions. Juniper blends this evidence-based dual approach, ensuring patients receive comprehensive care that boosts long-term success. Access to the Juniper MDT can also be available after a patient's medication treatment has finished, ensuring long term positive outcomes for patients. We have also received ethics approval to perform a study into post-medication support in the UK, described in Table 13.1 of Appendix 1 provided to the evaluation committee.	
151.	28	Company	3.6	At Juniper we have robust clinical governance processes and procedures, designed to provide patients with a safe, effective and quality experience. Below are some examples of this: - Incident response process: We have a well-established clinical incident response process for the escalation and management of clinical incidents. We have a dedicated Incident Response Team with direct channels to the executive team and Company Board, if required. - Clinical audit function: We have a team of clinicians (pharmacists and doctor) who manually audit over 6000 clinical interactions per month between clinicians and patients on our platform (across the UK and the AU) against our clinical protocol. We consult reguarly with our clinicians to ensure ongoing quality improvement and patient safety. For example, we run clinical analytics queries every 48-72 hours that look at patient clinical information against clinical events in the platform to identify potentially high-risk decisions to manually audit.	

				- Clinical guidelines: We have detailed clinical guidelines and protocols which are endorsed by our Clinical Director, ensuring that they reflect the latest evidence-based practices and standards. These guidelines and protocols provide a comprehensive framework for our MDT to follow. - Policies for identification and management of high-risk patients: We have implemented policies to identify and manage high-risk patients, including specific protocols for eating disorders and mental health. We provide training and support for our clinicians in managing these patients, including escalation internally or to external services where this is more appropriate for the patient. - Clinical decision support for prescribers: Our platform has in-built clinical decision support to identify clinical flags with the prescriber before a prescribing action has been confirmed. - Priority patients proactively flagged to the MDT: Our Trends Engine proactively identifies patients who may require additional support based on the various patient data points we collect. For example we send digital bluetooth scales to all patients in their first order that connects to the Juniper app, as patients step on the scale, their MDT can remotely track their weight loss progress. Our trends engine proactively flags if a patient may need additional support, e.g. expected rate of weight loss over time (too much or too little) and triages it to the relevant member of the MDT. The MDT can intervene and provide personalised guidance to prevent potential health issues. - Open channels of communication between the members of the MDT: We have systems and processes to facilitate effective communication when referral or escalation between the MDT teams is required. The MDT also meet at a regular cadence to discuss patient treatment plans for structured cross-team collaboration. All members of the MDT all have access to the patients profile, where key information is	

				summarised (e.g. weight loss, side effects, dosage, delays in orders) as well as interactions they have had with other members of the MDT. - Medical support: We provide proactive and reactive clinical support to patients e.g. side effect and adverse reaction management. We have defined first response time targets according to the severity classification of side effects and internally report on these metrics. Juniper's Australian branch is the only telehealth platform in Australia to have been independently certified by the ACHS, which is the same external body that accredits many of Australia's hospitals and GP clinics. - As outlined in section 13.2 of Appendix 1, provided to the evaluation committee, of patients who reported side-effects they received a response from a member of the MDT at median of <9.9 hours (with differing SLAs based on severity). Ongoing, support when needed can be beneficial vs the traditional requirement for face to face appointments	
152.	29	Company	Guidance development process	Has all of the relevant evidence been taken into account? We note that the EAG only considered those digital technologies listed within the Final Scope as determined by NICE as meeting eligibility criteria. Our understanding is that for this particular EVA, NICE considered digitally enabled weight management programmes that: Are intended by use by adults Deliver a specialist weight management programme that includes behavioural change strategies to increase people's physical activity levels of decrease inactivity, improve eating behaviour and the quality of the person's diet, and reduce energy intake in line with tier 3 or tier 4 services Facilitate weight management medication monitoring or prescribing Facilitate communication with an MDT of healthcare	

				professionals which could include dieticians, nutritionists, specialist nurses, psychologists, psychiatrists, physiotherapists, pharmacists and obesity physicians Meet the standard within the digital technology assessment criteria (DTAC), have a CE or UKCA mark where required. Products may also be considered if they are actively working towards required CE or UKCA mark and meet all other standards with the DTAC Are available for use in the NHS. A missed opportunity As the largest UK online healthcare provider MANUAL has already delivered the newest and most effective obesity drugs directly to 17,000 eligible patients via a Multidisciplinary Team (MDT) online pathway. On average MANUAL customers lose 8% of their body weight in three months, and 10% in six months. We are: Fully vertically integrated, with pharmacy capability direct to the patient's door CQC and GPhC registered Cost effective and cost saving Scalable and innovative And have deep data capabilities. Importantly we comprise an expert digital healthcare team consisting of digital service, clinicians, weight loss coaches, dieticians/nutritionists and psychologists. We note that Juniper was asked to contribute but they failed or declined to partake. We regard Juniper as one of our minor competitors in the private digital weight loss space and therefore conclude that NICE was open to including private providers within this pilot. What was the methodology used to select the providers in the EVA?	

				As the largest private provider in the digital weight loss space what opportunity exists - even at this latter stage - for us to be considered within the pilot? What does not being in the trial mean for providers like MANUAL? Are we able to offer our services to the NHS or what would we need to do to be able to offer services and be recommended? What does the end of the trial mean for organisations such as MANUAL?	
153.	29	Company	1.1	What was the methodology used to select the providers in the EVA? As the largest private provider in the digital weight loss space what opportunity exists - even at this latter stage - for us to be considered within the pilot?	
154.	29	Company	1.3	The four year term of the EVA trial is a significant period in the rapidly developing digital healthcare industry. Is there the opportunity for organisations and new providers to become part of the EVA trial over this period?	
General (n = 2)					
155.	24	Individual	1.6	- The supply chain failure for these drugs has not been sorted yet. - There are other healthcare providers outside the National Health Service, who have been providing weight management for many years. You should be including their experience too. - The ethnicity spread of the clinical trial cohorts have not been provided anywhere so I am having difficulty in seeing this as an equitable health policy. - The manufacturer of Wegovy did not promote this product in an inclusive manner. It seems to benefit only a particular group of patients - and interestingly, the NHS wants to improve access for this drug. This is only going to incentivise these pharma companies for their profit, not for the benefit of all the patients who are at risk (whether they know it or not).	Thank you for your comments. EVA's interim methods and process states the considerations are made by the committee. These include the extent of the evidence that supports the likelihood of the technology addressing unmet need in the system and identifying risks or uncertainties could be mitigated if the technology is used while further data is generated. Information on the technologies considered can be found in the guidance as well as Section 2.2, Table 2 and Appendix E of the EAG assessment report, and in the EAG assessment report addendum. Four years was chosen to allow companies to collect data in line with the evidence generation plan follow up (2 years) and to allow additional time for set up,

				- Environmental impact of all this plastic - prefilled syringes - is worrying. Perhaps the manufacturers should learn from why they ran into shortage (problem with filling and pens and plastic) instead of being gifted with more free access to nhs patients.	implementation and write up (as well as noting the current medicines shortages). When the topic is reviewed for full guidance, all relevant technologies at that time point will be included in the assessment. The care pathway and how technologies are implemented in the NHS are outside of the remit of this assessment. NICE followed the recruitment procedure for specialist committee members (SCMs) outline in section 3 of the early value assessment interim process and methods. NICE also notified the relevant professional societies and internal and external contacts to ensure SCMs representative of specialist weight management service providers were recruited. The supply of weight management medicines is outside of the remit of this assessment. Technologies have been included in the assessment if they were deemed to meet the eligibility criteria in the scope. The EAG were asked to respond to the comment on ethnicity in the studies. They acknowledge that there is disproportionate risk from obesity across ethnic groups and that this has also led to differences in eligibility for weight-management medicines across ethnicities, see Section 3.4 of the EAG report. Ethnic status was poorly reported across the evidence with only 3 of the 20 publicly available publications reporting participant's ethnicity. Furthermore, outcomes by ethnic subgroups were limited: • Hanson et al. (2023) reported patients ethnicity (any Black background; any Asian background; White; or other/no response) with engagement with Gro Health (interested and engaged; interested but not engaged; refused; did not
156.		Individual	General	This consultation closed on 24th August, but I'd be grateful if you could pass my email to the Project Manager. I and numerous colleagues have struggled a tight deadline over the summer when many people who might like to respond are unable to do so. You could miss out on helpful feedback. I and the team I work with have several comments about the guidance that is taking shape here. As medical lead for a large Tier 3 / 4 service ("specialist weight management") and a researcher with interests in this field, I am concerned that this series of possible providers has been identified, with inadequate description (at least in the NICE documents) of exactly what they provide and how it would support prescribing. Currently, some at least, do not support prescribing. They are varied in content and quality. Some have no data to support them, or it is largely unpublished and has not been subjected to peer review. It would be essential to see precisely what is to be offered and how it specifically supports pharmacotherapy. Major decisions should be reasonably well evidence based. As a weight management team we are also concerned that there seems to be little or no mention of how such types of support would, or would not, interface with existing local Tier 3 services. We cannot envisage how this would be done in respect of our Tier 3 population, which is highly complex, and can't be sorted out remotely purely with an app. How would the app providers communicate (if indeed they do so) with other care providers? How would they know anything about relevant local resources? How would they avoid giving conflicting advice? Where is the detailed comorbidity evaluation? Where is the psychological assessment? How are eating disorders assessed? How is possible appropriateness, or not, of other modalities like LCD, TDR, or	

				bariatric surgery assessed? How will data be collected for the proposed project? It remains to be seen how the MDT can function through these systems. There was a general feeling that these issues had not been considered sufficiently. The providers themselves tend to present and publish positive data, which is of course selective. In general, however, we know little about uptake, adherence/use, and completion. We are also sceptical that a 4 year window of assessment is appropriate in a fast moving field, and there is a risk of both obsolescence and new interventions being developed before completion of your project. So this cannot be a final list. We are also concerned that the proposal seems more likely to assist less complex patients, more along the lines of the "tier 2" profile. This type of support may well be of interest for some people especially with less complex needs,, and many would agree it is appropriate to explore it, but there are reservations to be expressed about NICE suggesting widespread adoption of specific apps in the Tier 3 setting. Lastly our team also asked whether there might be some gaps in the NICE team. In considering digital applications to support prescribing in the context of the Tier 3 MDT process, we felt that it would have been appropriate to include a psychologist, a digital health expert, and a physician with some relevant experience of the problems encountered in specialist (Tier 3) weight management. Some of our team also questioned whether a locum GP with unknown experience in the field and a bariatric surgeon were appropriate committee members for a project involving non-surgical treatment in the Tier 3 population.	respond). No statistical differences were seen between user groups according to age or ethnicity. • The abstract by Falvey et al. (2023) reported ethnicity of the participants using Roczen with 58% White, 11% Indian, 10% Black African, 7% Black Caribbean, and 14% Other (undefined). Outcomes were not reported by ethnic status. • McDiarmid et al. (2022) reported the proportion White British participants using Oviva, with 65 of 79 (82%) of the total participants. Outcomes were not reported by ethnic status.