National Institute for Health and Care Excellence

Medical technologies evaluation programme

Digital technologies for delivering multidisciplinary weight-management services
Consultation comments table

There are 88 consultation comments from 14 consultees:

- 56 comments from 11 companies
- 25 comments from 2 professional organisations
- 7 comments from 1 patient organisation

The comments are reproduced in full, arranged in the following groups (**some comments contain multiple issues and have been split**):

- Recommendations: comments 1 to 10
- Care pathway: comments 11 to 25
- Clinical evidence: comments 26 to 29
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- The technologies: comments 78 to 86
- Factual inaccuracy: comments 87 to 88

#	Consultee ID	Role	Section	Comments
Recommendations				
1	1	Company	General	No comments at this time from Weight Loss Clinic (Virtual Health Partners), thank you for including us and we agree with the assessment.
2	2	Professional organisation	1	1.1 and 1.2 This is a fast-moving field. In time, providers not selected might well produce new data to support their services. On the other hand, some selected providers might prove unsatisfactory (poor

				feedback on one of them by some of our patients) and need to modify their programmes or be deselected if they can't offer safe services and scale up. Perhaps selection ought to be provisional.
3	2	Professional organisation	1.2	NICE should adopt a cautious approach to the providers because of their limited and selected data reporting (big questions over the components that are important, and adherence and completion rate) and their commercial imperative.
4	3	Company	1.1	For those providers who are endorsed to be prescribing should there not be a stipulation around the need for CQC registration from a clinical governance perspective (as well as DTAC from a technology perspective)
5	4	Company	1	Juniper has provided new evidence in this submission, which NICE should take into account in considering whether Juniper can be added to the list of approved providers of weight loss management services to the NHS. All data and results of the new study submitted in these comments (and separately via appendices) should be treated as confidential.
6	4	Company	1.3	We anticipate that we will be DTAC compliant by the end of December 2023.
7	5	Company	2.1	[redacted] welcome the draft recommendations for this early value assessment (EVA) for 'Digital technologies for providing specialist weight-management services: early value assessment'. We believe that the recommendations are suitable and can be used to help fulfil the unmet need by providing support to those who require access to specialist weight management services and the additional treatment within the care pathway. To fulfil the unmet need, digitally enabled services must deliver the same standard of service to individuals who have access to a face-to-face weight management services within the care pathway, as stipulated in the recently updated, section "1.10 Surgical interventions" of, CG189: Obesity: identification, assessment, and management. This includes the ability to: 1. Submit referrals to Specialist weight management services conducting clinical assessments to determine a patient's suitability for bariatric surgery (Tier 4) and 2. The inclusion of a bariatric surgeon or surgeon with a special interest in obesity. This has been reflected in this draft guidance for digitally enabled technologies and aligns with the recently updated CG189: Section 1.10. We welcome the recommendations within this draft EVA.
8	6	Company	General	Thank you for the opportunity to comment on this document. We are disappointed to have been allocated to the "only-in research" recommendation. Consequently, following discussions with members of the NICE team, we have submitted two further documents for consideration: 1. From the consultation document, we recognised that we did not present our available evidence in a manner useful for the Committee. This was our mistake and we have consequently created a new data

				analysis for the Committee that demonstrates the effectiveness of GLP-1 medication in the context of a tier-3 equivalent weight management service in England, as delivered by the CheqUp programme. The analysis shows that through a combination of medication, dietetic support, physical activity advice, psychological support, and physician guidance, the 196 participants in the programme achieved a mean absolute weight loss of 8.71kg (7.9%) from baseline over a period up to 36 weeks. The mean absolute weight loss is greater than shown in the pivotal clinical trials for the weight loss medications semaglutide and liraglutide. Our detailed Preliminary Analysis data, which is new work not previously presented to this Committee, forms part of this response. Crucially, it is our understanding that this is the only research shown to NICE as part of this EVA which demonstrates the impact on patients of GLP-1 medication delivered using a tier 3 obesity weight management-equivalent setting. Again, we apologise to the Committee for the delay in presenting our data in the appropriate manner. We believe that this new analysis of the current CheqUp clinical dataset demonstrates that our service shows significant promise to improve obesity outcomes and address the unmet need set out in the Early Value Assessment guidance documents. We accept that the quality of data presented is not high (an issue the Committee has grappled with for all technologies examined) and that further evidence generation is needed to improve both the quantity and quality of the evidence. In light of the above, please see our new data analysis: "Chequp Health Limited Preliminary Analysis". 2. We also welcome the opportunity to provide some clarification on the nature of our services. In developing CheqUp, we have combined a replica of the use of weight loss medications as used in their pivotal clinical trials with an NHS tier 3 equivalent service, delivered through a more efficient and less costly remotely provided platform. We would therefore humbly repeat our request that the Committee reconsider its decision in light of BOTH the new data analysis on our existing patients AND the reality that CheqUp's system presents no fundamental technological innovation but rather offers a remote tier-3 service delivered at a 33% cost-saving to the current NHS model. Please see our accompanying document : "CheqUp - response to HTE10023"
9	6	Company	1.2	Although CheqUp is not listed in this section, it is worth noting that we are DTAC accredited
10	6	Company	1.5	Please see our accompanying documents "Chequp Health Limited Preliminary Analysis" and "CheqUp - response to HTE10023"
Care pathway				

11	7	Professional organisation	1.8	In specialist weight management, the full clinical assessment is usually carried out face to face by the obesity physician and specialist dietitian. It needs to explicitly state that the clinical assessment is by a NHS healthcare professional who are is experienced in specialist obesity management. This may add to the workload of the specialist NHS team.
12	8	Company	1.8	Does NICE plan on elaborating on what the full clinical assessment should entail, and provide guidance on how healthcare professionals can assess the suitability of certain technologies? Various methods are used across the technologies assessed, with some using patient intake forms reviewed asynchronously rather than in-person or remote assessment where the clinician might be able to form a clinical judgement.
13	8	Company	2.3	Saxenda (liraglutide) is recommended in secondary care only, but Wegovy (semaglutide) in more flexible circumstances. Do you plan to review the guidance on where liraglutide can be prescribed in light of the move towards providing specialist weight management services outside the traditional and limited secondary care settings?
14	8	Company	2.4	Tier 3 and Tier 4 services are defined in this (and externally linked) guidance. Will NICE provide similar detailed guidance for a 'specialist weight management service'?
15	9	Company	1.8	Clinical assessment: This should state that referral to specialist weight management services including offering access to these technologies, should only be made 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?
16	9	Company	2.1	NICE guidance on obesity management is currently under review. Overweight and obesity management In development [GID-NG10182] Expected publication date: 27 March 2024 The draft guidance which is out for consultation until 28th November 2023, currently contains no reference to the use of these technologies or their place in therapy. The guideline should include reference to this early value assessment, and include clear guidance on the place of these technologies in therapy.
17	2	Professional organisation	2	The distinction between "new" "digital" Weight Management services and existing providers is more blurred than comes through in the guidance. Existing Specialist Weight Management Services already use telephone, zoom, teams, email, text for 1:1 and group meetings on a frequent basis. Some do all the time. What the "digital" bit actually adds is far less clear – but clearly research-worthy. In-person support may be the most valued part of the "remote" interventions. The "technology" is more properly conceptualised as remote Weight Management and prescribing for severe and complex obesity. A better model (for at least some areas) would be NHS investment in more staff to support remote NHS Weight Management services, and our region a number of my colleagues have expressed this view. We are

				sure the subject area experts would have appreciated this in full. It seems less clear whether the technology committee did.
18	10	Company	2.1	It is essential that there is clear guidance on how the pathway of care involving digital technologies will be delivered in clinical practice: • Can a healthcare professional in primary care prescribe a patient the digital technologies in both recommendations 1.1 and 1.2? • How does NICE envisage these digital technologies fitting alongside current tier 3 services? • Based on section 3.1 and 3.2, can NICE recommend patient escalation criteria for healthcare professionals in primary care for using digital technologies where tier 3 services are limited or are not available?
19	11	Patient organisation	General	The lack of consistent tier 3 services across the country means that most people living with obesity are not able to access the level of support that these technologies offer. Broader insight work into barriers to weight management services by Diabetes UK carried out recently highlights key issues impacting the success of these technologies. The insight work included perspectives of providers of tier 3 and 4 services and the perspectives of people living with type 2 diabetes. Diabetes UK found that: • People with type 2 diabetes, who could benefit from the support offered by these technologies, report that they are not regularly offered advice about weight management or signposted to information on how they can be supported to manage their weight. • For people with type 2 diabetes stigmatising exchanges with healthcare professionals can have a huge impact on both accessing and completing weight management services. For technologies to work it is important that people are referred without experiencing stigma within primary care. • Many people with type 2 diabetes report that having access to peer support is a key component in achieving weight loss aims. Technologies that facilitate peer support for those that wish to access it are likely to achieve better results. • The person-centred support that people experience within tier 3 services is an integral component. This is particularly the case for people weight related comorbidities such as type 2 diabetes. People who have accessed tier 3 services repeatedly report that the personalised focus and emotional support received was key to their successful weight management. In addition, research comparing the effectiveness of digital/remote and F2F services found the mean baseline weight of those using digital weight management services was higher than those using remote or F2F, likely due to the weight stigma resulting in avoidance of group-based environments. Digital services were also reported to have a lower completion rate, particularly for those with a greater body weight, so it is vital that the issue of stigma is addressed so that the most appropriate and effective service delivery method can be used. Barron E, Bradley D, Safazadeh S, et al. Effectiveness of digital and remote provision of the Healthier You: NHS Diabetes Prevention Programme during the COVID-19 pandemic. Diabet Med. 2023;40(5):e15028. doi:10.1111/dme.15028

				Albury C, Strain WD, Brocq SL, et al. The importance of language in engagement between health-care professionals and people living with obesity: a joint consensus statement. Lancet Diabetes Endocrinol. 2020;8(5):447-455. doi:10.1016/S2213-8587(20)30102-9
20	2	Professional organisation	1.8	It would be appropriate to understand how remote prescribers will discharge their responsibilities under GMC guidance for prescribing. ie Prescriber takes full responsibility the prescription and its consequences. How will this be accomplished for safe “remote” prescribing and repeat prescribing?
21	2	Professional organisation	1.8	Perhaps not NICE’s problem, but how will GP services receive extra funding for their contributions? Without any, they do not have capacity, knowledge or training to take this on. In specialist weight management services, the clinical assessment is usually undertaken by the obesity physician and specialist dietitian.
22	2	Professional organisation	1.8	How would remote providers access medical records in order to safely prescribe? This is an aspect of risk management and safe prescribing.
23	2	Professional organisation	1.8	How will arrangements be handled for psychological evaluations eg Binge Eating Disorder, emotional eating – in the remote healthcare context.
24	2	Professional organisation	1.8	A critical issue is how remote providers will signpost patients to their local resources for Weight Management, and into local pathways? E.g. How would Binge Eating Disorders and Eating Disorders be detected if not by appropriately skilled Health Care Professionals; Referrals for specialist investigation; psychology referrals; appropriate counselling for bariatric surgery without involving local teams and pathways? Local patient support groups are often important parts of Weight Management services. These issues must be assessed and solutions identified before any remote provider gets commissioned
25	10	Company	2.2	Tier 2 includes referral into the NHS Digital Weight Management Programme, which is 12 weeks in duration and is provided by some of the providers outlined in section 1.1 (Liva, Oviva, Second Nature). From a patient perspective, if they have already completed a tier 2 NHS Digital Weight Management Programme with a provider in section 1.1, and at the end of the 12-week programme did not achieve 5% weight loss, should there be additional considerations for these patients?
Clinical evidence				
26	3	Company	3.12	As detailed in our feedback to the EAG document, the study by Ross et al, (2022) is not a comparative study and should not be referred to as "comparing Liva, Oviva and Second Nature", as this is a misrepresentation of the paper. I have added the full feedback to the EAG report below for reference: This study looked at the Digital Diabetes Prevention Programme (DDPP); it is a controversial publication with the study having significant methodological flaws that limit its usefulness in this evaluation or more widely as detailed below: 1. This study was not designed as a “comparative study”. As per the paper, the aim of this study was absolutely not to compare between different providers of the DDPP (for the reasons outlined below). The aim was to assess the overall impact of the DDPP on weight and HbA1c. It is therefore incorrect and misleading for the EAG report to refer to this study on p.19 as a “comparative study between Liva, Oviva and OurPath”; on p.13 to report “this study compared Liva, OurPath and Oviva”; on p.16 as a

				comparative study; in the table 4.2b on p.94 as “a non randomised comparative study”; and again in table 5.1 on p.111 comparing weight loss outcomes between providers. 2. Because this was not intended as a comparative study, the names of the individual providers have never been published. Each provider is allocated a number by the authors in the paper to maintain anonymity - the names of the providers and their outcomes are not in the public domain and we do not consent for our details to be placed in the public domain via this EAG report. 3. We suspect that the study is being knowingly misrepresented as a comparative study by one or more providers of the DDPP who are participating in this EVA, hence its inclusion in this report. 4. The study should not be given the level of prominence that it has been in the report (including the very surprising decision to reproduce the bar chart on p.19 Figure 1 with named providers. This chart does not appear in the publication and has presumably been created by one of the companies participating in the EVA). The study does not look at the same population as a specialist weight management service (Tier 3 or Tier 4). It is looking at people with non-diabetic hyperglycaemia – a significant proportion of these patients will not have obesity and many will be normal weight. 5. The study cannot be utilised as a comparative study because the populations, clinical pathways, completeness of data and method of weight measurement differed significantly between the different providers. 6. Some of the methodological flaws and heterogeneity between providers, (populations, clinical pathways, data collection, data completeness) that prohibit comparative analysis include: A) All providers had the same recruitment target of 1000 patients. Oviva was the only provider to achieve this recruitment target. Other providers recruited far fewer than this target which suggests that there were accessibility challenges/barriers e.g. an inability to support patients whose first language is not english. B) Each of the providers was supporting different geographic areas/cohorts of patients. This means that each provider’s population of patients had completely different age, sex, ethnicity and socioeconomic profiles. C) The clinical pathway varied between providers supporting these different areas, with some areas offering a choice of a face-to-face or digital program (choice model), some only offering a digital program (digital only), and some reserving the offer of a digital program for people who had already declined to attend a face-to-face program (decliners only) D) The methods for collecting data and providing this to NHSE differed dramatically between providers. Oviva went to great lengths to ensure that data was provided for all patients who enrolled in the programme, even those who did not complete (supporting an “intention to treat” analysis) whereas other providers are likely to have only provided data for those more motivated patients who completed the programme (“completer analysis”). This can be seen in the significantly lower percentages of patients with reported data at the end of the study for the other providers compared to Oviva. (further details available if required) E) Weight data was collected in different ways between the different providers with some providers such as Oviva utilising only validated data from GP and pharmacist systems and other providers utilising self-reported weights.
27	4	Company	1.2	NEW STUDY

				Juniper has separately submitted to NICE the following appendices to these comments: 1. Appendix 1 - The results of a new study on the effectiveness of liraglutide supported by the Juniper Weight Loss Programme. 2. Appendix 2 - Comparison of Juniper's new study against studies submitted by other providers approved by NICE to provide specialist weight-management services to the NHS. The study focuses on the following key evidence pillars as identified by NICE: (1) change in weight, (2) monitoring and reporting adverse effects, and (3) adherence and completion. Key results of the study are set out in our response to section 1.8 below. The study concludes that comprehensive real-world weight loss programmes such as Juniper can be highly effective, supporting Juniper's suitability to deliver specialist weight management services in the NHS. Compared with the SCALE (2015) daily 3.0mg liraglutide trial cohort, Juniper patients lost significantly more weight, which we believe reflects the personalised behavioural intervention and/or the psychological benefits of feeling part of a supportive real-world care community. The results of this study can be applied to Juniper's support of patients in the UK prescribed with a range of GLP-1s including Wegovy, Ozempic, Mounjaro and Saxenda through the NHS. The table set out in Appendix 2 sets out the evidence limitations of the studies submitted by NICE's approved providers, and how the Juniper study addresses these limitations. Key strengths of the Juniper evidence relative to other provider evidence include superior weight loss outcomes, larger sample size of patients, exclusively overnight / obese patients, use of a comparator, and use of a MDT among others. Collectively, these Appendices highlight the superior effectiveness of the Juniper Weight Loss Programme, and the higher quality of Juniper's evidence, when compared against other NICE approved providers of support specialist weight management services. ORCHA ENDORSEMENT As the world's leading, independent health and care app evaluation and distribution organisation, ORCHA helps governments, and health and social care organisations, to choose and deliver quality assured apps. As noted on its website, ORCHA's review process aligns in many respects with reviews undertaken by the NHS, and ORCHA also provides review services directly to the NHS and NHS organisations, therefore an ORCHA review provides valuable insight into whether an app complies with standards expected within the NHS. ORCHA has endorsed inclusion of the Juniper App in its ORCHA App Library, and has confirmed that the endorsement will be published in the ORCHA App Library by 17 November 2023. CONCLUSION We request that, in light of the above new evidence and further details shared in our comments regarding Juniper's more detailed plans to generate more high quality evidence, NICE consider including Juniper among the selected technologies to deliver specialist weight management support in the NHS.

				We would welcome any queries or requests for additional information from the evaluation committee relating to the study.
28	4	Company	1.8	The new Juniper study provides valuable evidence on (1) change in weight, (2) adherence and completion rates, and (3) monitoring and reporting adverse effects. (1) Change in weight: [redacted] (2) Adherence and completion rates: [redacted] (3) How the technologies monitor and report adverse events: [redacted] Separately to the study, we refer to pages 26-28 of Attachment 7 of our original submission titled 'NICE Medical Technologies Evaluation Programme - Application to the for evaluation in the Digitally enabled weight management programmes to support treatment with weight management medication (alternative service model): early value assessment' (the 'Original RFI Response'), where we have detailed Juniper's robust processes for monitoring and reporting adverse events. In summary, Juniper has well-established clinical incident response processes, a clinical audit function (auditing over 6000 interactions per month between clinicians and patients), clinical guidelines and policies for our MDT to follow, in-built clinical decision support to identify clinical flags, and clinical support processes. Juniper's processes are comprehensive and thorough, however Juniper will continue to evaluate, and as applicable implement improvements to, its risk management and safety processes.
29	4	Company	General	We have submitted to the Medical Journal of Australia (the MJA) for publication a perspective/content analysis on why we urgently need to deliver empirical evidence of the quality and safety of our weight loss services.

				Once the MJA has provided feedback on the above analysis, we will submit our Australian retrospective study on weight loss program (liraglutide) effectiveness (the study we have shared separately as Appendix 1 as part of our response) for review and publication. Below is a list of the studies that we currently plan to submit for review and publication. These will include UK-specific studies that will address each of the criteria NICE has indicated in the evidence generation plan as requiring further evidence and research. We are sharing these details to demonstrate to NICE the wealth of high quality evidence that we will publish in the coming months and years on the effectiveness and safety Juniper weight loss program, which NICE can review to assess the longer-term adoption of Juniper in the NHS. 1. UK retrospective study on weight loss program (semaglutide) effectiveness and care continuity 2. UK RCT - weight loss & strength sustainability over 12 months (6 months treatment + 6 month follow up) 3. AU RCT - weight loss & strength sustainability over 12 months (6 months treatment + 6 month follow up) 4. AU retrospective study on prescribing error rate 5. AU retro study on dispensing error rate 6. UK retro study on prescribing error rate 7. UK retro study on dispensing error rate 8. AU survey-based study - Reasons for patient use of Juniper/Pilot (Pilot is a mens health brand of the Eucalytus Group), a separate vs traditional in-person alternatives + regular GP use + satisfaction with care continuity features 9. UK survey-based study - Reasons for patient use of Juniper/Pilot vs traditional in-person alternatives + regular GP use + satisfaction with care continuity features 10. DE survey-based study - Reasons for patient use of Juniper/Pilot vs traditional in-person alternatives + regular GP use + satisfaction with care continuity features 11. AU retrospective analysis of care continuity markers - mean number of clinician-patient messages with 3/6 months, mean maximum period without contact, mean response time to patient
30	9	Company	1.1	The cost of medicines provided from weight management services commissioned from non-NHS providers can be substantially higher than the costs used in NICE TA appraisals of the drugs. For example, providers may add on significant dispensing and delivery charges. Have these been fully taken into account when assessing the financial impact of using these technologies to supply medicines? Will medicines supplied via these services be at a price that makes them cost effective to the NHS?
31	9	Company	1.8	Prescribing: The cost of medicines provided from weight management services commissioned from non-NHS providers can be substantially higher than the costs used in NICE TA appraisals of the drugs. For example, providers may add on significant dispensing and delivery charges.

				Have these been fully taken into account when assessing the financial impact of using these technologies to supply medicines? Will medicines supplied via these services be at a price that makes them cost effective to the NHS?
32	9	Company	3.21	As well as the cost for the equipment and internet access, does the economic evaluation fully consider the costs of administering the provision of these services to patients? The need for and therefore the financial impact of providing a tablet computer and internet access will be larger in more deprived areas, introducing even greater inequity
Equality considerations				
33	7	Professional organisation	1.8	Equality bullet point: People living with severe mental illness may also be less comfortable or skilled in using digital technology and have no or limited access to equipment or the internet. Furthermore, there needs to be acknowledgement regarding digital poverty. The prevalence of obesity is higher in those experiencing poverty and these are the people that might struggle to gain access to these technologies. It is important that provision is offered to ensure that these digital programmes do not increase health inequality.
34	11	Patient organisation	General	In terms of who is most likely to be actively engaged in tier 3 services, healthcare professionals reported to Diabetes UK that it is more likely to be affluent, younger, white women who they see. Further efforts need to be made to make services inclusive of the diversity of local communities. There is also a postcode lottery in access to weight management services provided by ICSs that negatively affects those in more isolated, rural communities. A 2019 House of Lords select committee on the 'Rural Economy' highlighted the issues with access to local healthcare services, and so providing a service that can be accessed remotely will address one of the barriers faced by this group. However, both lack of connectivity and digital literacy are a problem in these communities and so digitisation of these services can only be beneficial if these are also addressed. https://www.culturehive.co.uk/resources/fixing-the-digital-divide-facts-and-stats/ Chadwick, D., Ågren, K. A., Caton, S., Chiner, E., Danker, J., Gómez-Puerta, M., Heitplatz, V., Johansson, S., Normand, C. L., Murphy, E., Plichta, P., Strnadová, I. and Wallén, E. F. (2022) 'Digital inclusion and participation of people with intellectual disabilities duringCOVID-19: A rapid review and international bricolage', Journal of Policy and Practice in Intellectual Disabilities. ONS (2019) Exploring the UK's digital divide. Available at: https://www.ons.gov.uk/releases/exploringtheuksdigitaldivide (Accessed: 28th June 2023).
35	11	Patient organisation	General	Research has found that people who are limited users of the internet are 1.5 times more likely to be from Black, Asian or other minority ethnic backgrounds, and many of these have English as a second language and will require further support. In addition, there is a higher prevalence of diabetes amongst people with learning disabilities and there are higher proportions in the more severe category of obese (37% of people with learning disabilities compared to 30.1% of people without learning disabilities). Both groups are, therefore, at risk of being digitally excluded.
36	12	Company	1.8	Please consider using more appropriate language. In practice we support people living with obesity and neurodiversity rather than 'Autistic people". Thank you.

37	13	Company	1.8	Specifically it would be good to include here the need for more evidence on the long term effectiveness and outcomes as this appears to be lacking.
38	1	Company	Evidence generation plan	“Are there any additional implementation factors that need to be considered, for example for the technologies, or for the design of the proposed evidence collection?” No
39	2	Professional organisation	Evidence generation plan	The NICE guidance should emphasise the need for a flexible approach to the adoption of new models of care. NICE should advise that commissioning organisations (ICB being the most recent incarnation of these) should assess their local needs carefully, involving existing professionals, services and pathways, in order to assess the possible place of additional digital providers, and exactly what these providers can and cannot contribute. In the present disjointed NHS management landscape, with ICBs still bedding in, there are often few links with clinical teams (there have been none in some regions). If there are hasty, uninformed commissioning decisions made off the back of zero evidence-based NICE advice, there is potential for harm to existing services.
40	3	Company	Evidence generation plan	The key thing to remember is that the companies are not providing the technology as a standalone offer (except DDM health). This will have a significant impact on how to collect real world evidence of effectiveness vs "standard care" and differs significantly from the majority of "medtech" used within the NHS. The majority of the companies provide a comprehensive weight management service themselves incorporating the technology. The challenge is to find a fair, accurate and reliable way of comparing these digitally enabled weight management services with "standard" Tier 3 weight management services. "standard" Tier 3 service are highly variable in clinical model, MDT composition, length of programme, eligibility criteria etc. We therefore need to be explicit in what we mean by "standard" tier 3 care. Furthermore, there is a paucity of published outcomes data for "standard" UK Tier 3 services and in essence no-one really knows "what good looks like" in Tier 3 weight management. It is important that the digitally enabled services are compared to realistic outcomes of "standard" tier 3 service and not held to an artificially high standard for which there is no published evidence. The evidence collection for this exercise is an opportunity to learn more about "standard" care as well. In our experience, one of the barriers to evidence generation has been the reluctance of funding bodies such as NIHR to fund the actual costs of the treatments being investigated. In this instance this will include the cost of delivering the specialist weight management service (whether using a “standard” model or a digitally-enabled model) alongside the costs of the weight management medication. This will mean that evidence generation will still require local commissioners (Integrated Care Boards- ICBs) to commission and pay for both “standard” and digitally-enabled weight management services alongside paying for the associated medication. Given the financial pressures on local ICB commissioning budgets this is likely to be problematic and highly variable, especially whilst NICE’s recommendation for the technologies remains conditional. This means that generating evidence will still be reliant on securing commercial contracts with local NHS commissioners. Oviva has a number of these contracts in place but to our knowledge few, if any, of the other providers are yet providing this comprehensive service within the NHS (including the prescribing/monitoring element). Ideally the opportunities around funding for

				evidence generation would be aligned with funding from OLS/NHSE to support the treatment costs incurred by local commissioners partnering in the consortia.
41	3	Company	Evidence generation plan	This is not the correct study design for the majority of the technologies. The majority of the 7 companies do not provide standalone technology/a SaaS solution. The majority of companies provide a comprehensive integrated solution which includes all the healthcare professionals (and on costs), the technology, any required training for their staff and any other associated overheads. Therefore it is not possible to evaluate a service providing "standard care", then implement the technology and then measure the performance of the existing service in addition to the technology. The technology is not provided as a standalone offer (except for DDM Health) and the standard care service and the digitally-enabled service (which operate in completely different ways) must be evaluated in parallel. I am very happy to discuss this in more detail if it helps, as I have already done with NICE's Resource Impact team.
42	3	Company	Evidence generation plan	ideally for a parallel real world study, a "standard care" service should be run supporting the same population (so that demographics, etc are the same) at the same time as one of the digitally enabled services with as many elements as possible standardised between the two services e.g. referral criteria, length of programme, composition of the MDT. However, it is highly unlikely this scenario will exist naturally through NHS commissioning and it may need to be fully funded through research programmes e.g. via NIHR
43	3	Company	Evidence generation plan	see previous comments, rather than "multiple centres" we should be thinking of "multiple Integrated Care Systems" each having both a standard care service and a digitally enabled service running in parallel.
44	4	Company	1.4	We confirm that if Juniper is approved to provide its weight-loss management technology to the NHS, Juniper will have agreements in place to generate the evidence outlined in NICE's evidence generation plan, and will contact NICE annually with updates. In our comments on NICE's Evidence Generation Plan, we have set out the studies that we propose to publish globally including specific studies for the UK. This study plan will produce high quality evidence that NICE can review to assess the long-term adoption of Juniper in the NHS. Juniper seeks NICE's approval for use of its program by the NHS on the same conditional basis as other approved providers, while more evidence is generated, with the understanding that NICE may withdraw its guidance if it is not satisfied with Juniper's generated evidence provided for annual assessment. We are confident that the wealth of high quality evidence that we will generate in the coming months and years in accordance with our detailed study plan will satisfy NICE that Juniper's weight loss program should be routinely adopted in the NHS.
45	8	Company	Evidence generation plan	At this stage, we do not foresee any issues in collecting the suggested data and outcome information. However, it is essential to note that issues may arise during the test implementation, which may impact data/outcome information collection. We do not foresee any barriers to implementation on the condition that appropriate funding is provided/sourced for this evidence generation and allows for proper resource levels to be allocated.

46	8	Company	3.3 Evidence generation plan	“Differences between self-reported and clinically measured weight loss outcomes are also a potential source of bias, particularly if these vary between comparison groups, so a consistent measure should be used” This will be difficult to implement when comparing technology usage to standard care, as F2F services traditionally measure weight at each appointment, whereas remote/digital services require self-reported weight input.
47	8	Company	3.4 Evidence generation plan	“resource use, including the number and type of healthcare appointments attended, cost of medicine, NHS staff time needed, and rates of referral to bariatric surgery” This may be difficult to implement, and support from primary care, including access to clinical systems may be required (depending on who is conducting data collection for this element of the study).
48	12	Company	Evidence generation plan	What about assessing outcomes where additional support is provided to people who are not normally use digital technology. Evidence is lacking on what type and providers support people living with obesity during onboarding and if this support shows any benefit in the adoption of the digital technology or leads to programme withdrawal etc.
49	12	Company	Evidence generation plan	“NICE's assessment of digital technologies for providing specialist weight-management services recommends that further evidence is generated for 7 technologies (Counterweight, Gro Health W8Buddy, Liva, Oviva, Roczen, Second Nature and Weight Loss Clinic) while they are being used in the NHS. Five other technologies can only be used in research and are not covered in this plan.” This is excellent.
50	2	Professional organisation	1.1	Specialist weight management teams have experienced healthcare professionals specialising in obesity with core members including an obesity physician and specialist dietitian. It is essential that patients are able to have direct access to these professions.
51	2	Professional organisation	1.8	NHS specialist weight management teams employ obesity physicians and specialist dietitians. These skilled healthcare professionals are able to provide psychological support and monitoring and identify those who need more specialist additional support from psychology or psychiatry. It is not clear that all digital programmes can provide this.
52	7	Professional organisation	General	Source: (Supporting Documentation: Information pack 2.2) This section states that in this EVA that NICE is considering digital weight management programmes that specialist weight management programmes. In NICE CG189 and also in the current consultation on Guideline Overweight and obesity management, it recognises that both the dietitian and obesity physician are core members of the MDT. This is also mentioned in section 4 page 9; however it does not appear to be recognised in digital programmes as section 2.2 states “facilitate communication with an MDT of healthcare professionals which could include dieticians, nutritionists, specialist nurses, psychologists, psychiatrists, physiotherapists, pharmacists and obesity physicians.” In specialist weight management services, generally both the obesity physician and dietitian are the lead professionals. Registered Dietitians are the only qualified health professionals that assess, diagnose and treat dietary and nutritional problems at an individual and wider public health level. Registered nutritionists are qualified to provide information about food and healthy eating, but not about

				special diets for medical conditions. Therefore, they may work in tier 2 weight management services but are not qualified to work in tier 3 specialist weight management services.
53	7	Professional organisation	General	Source: (Supporting documentation pg 5-8) From the information provided by the different companies, it is not clear what access patients with severe and complex obesity will have to an obesity physician and specialist dietitian. There is mention of health/weight loss coaches, personal trainers however, these are unlikely to have the specialist skills in management of people living with severe and complex obesity. What checks will be in place to ensure that people living with severe and complex obesity will have direct access to physicians, dietitians and psychologists/psychiatrists specialising in this area, and that the company is delivering a specialist weight management programme rather than a tier 2 programme?
54	7	Professional organisation	General	Source: (Supporting documentation section 4: pg10) What is meant by “The difference between the medical speciality in tier 3 and 4 will be qualitative level of experience in complex patient management”? All The majority patients referred to tier 3 and 4 are complex, and all healthcare professionals working in these areas need to be skilled in specialist weight management or metabolic and bariatric surgery.
55	7	Professional organisation	1.2	This guidance is for “technologies that deliver a multidisciplinary specialist weight-management service, including prescribing, monitoring or tracking weight-management medicine”. Therefore, all companies should employ a team of specialist dietitians and obesity physicians as these are core members of specialist weight management services to individualise the support to patients with complex issues. Given that there may also be the need to liaise with other health professionals regarding management of co-morbidities e.g. sleep apnoea, idiopathic intracranial hypertension, infertility, it is not clear who will lead on this and how the digital programme plan to refer onto these service.
56	7	Professional organisation	1.8	Multidisciplinary support bullet point: It is important to state that the qualified healthcare professionals should include an obesity physician and specialist dietitian.
57	7	Professional organisation	2.1	Given that these technologies are to provide specialist weight management support and “provide a multidisciplinary programme and support from the service’s multidisciplinary team (MDT) of healthcare professionals”, it is important that all of them employ obesity physicians and specialist dietitians. Some appear to be tier 2 providers with health coaches/ personal trainers/ nutritionists rather than healthcare professionals.
58	7	Professional organisation	2.2	This makes clear that the specialist weight management service is for those where the underlying causes of obesity need to be assessed, the person has complex needs that cannot be managed adequately in tier 2, conventional treatment has been unsuccessful or if specialist interventions may be needed. Therefore, it is important that the technologies employ obesity physicians and specialist dietitians.
59	7	Professional organisation	2.3	Patients who are prescribed semaglutide or liraglutide need access to specialist dietetic support given the impact on nutritional intake and potential nutritional deficiencies. This support should be given by a specialist dietitian.
60	7	Professional organisation	2.4	We welcome that the composition of the specialist MDT is stated. Although the composition of the specialist MDT may vary, all NHS specialist MDTs employ obesity physicians and dietitians as core members.

61	7	Professional organisation	3.2	This acknowledges that tier 2 services are not able to provide or manage weight-management medicine and do not offer appropriate support for treatment with medicine. It is therefore essential that all of the technologies employ obesity physicians and specialist dietitians.
62	7	Professional organisation	3.9	Although MDTs can vary significantly between weight-management services, all NHS specialist weight management services employ obesity physicians and dietitians are core members of the team. The obesity physician and specialist dietitian are able to undertake full clinical assessments, provide psychological support, identify eating disorders, and refer on where needed for further psychological assessment and support. It is not clear who will provide this in the digital technologies.
63	8	Company	1.8	Other than outlining the need for psychological support, this definition seems vague. A traditional specialist weight management MDT is usually defined as a physician, consultant or GP with a Special Interest in obesity, a specialist dietitian, a psychologist and a physical activity specialist. The guidance should reflect this.
64	9	Company	1.8	"Multidisciplinary support: 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."
65	12	Company	1.8	Across all NICE documents relating to this EVA there are inconsistencies in the definition of an MDT. People living with obesity deserve to know what the minimum standards of an MDT team. If NICE do not have a position on this make it clear that this is not defined, but is part of the generation of evidence over the next 4 years.
66	13	Company	1.8	How is this to be monitored/assessed between providers? This seems to vary from provider to provider in terms of provision and if this is a requirement then this needs to be defined and monitored to ensure this is the case across all providers. Who does the psychological support need to be provided by and how often?
67	13	Company	3.9	“The clinical experts raised that there is limited information on how multidisciplinary teams (MDTs) are used in the programmes offered by the technologies” This is a crucial point and more information is needed to define exactly what is included and required in the MDTs and how the different providers utilise/include the MDT as this appears to vary from provider to provider. The guidance would benefit from more specificity here.
Patient population				
68	8	Company	2.2	“if the underlying causes of obesity need to be assessed” This patient group may be less suitable for referral to digital services if further physical examination/investigations are necessary.
69	11	Patient organisation	General	The mode of delivery of the service itself has been shown to make a positive difference to people’s lives. A review by Diabetes UK of the NHS Diabetes Prevention Programme (DPP), a weight management service run by organisations including Xyla Health and Wellbeing and Oviva that aims to reduce the risk of developing type 2 diabetes for high-risk individuals, used an online survey and structured focus

				groups to understand the experiences and preferences of those taking part on this programme. Individuals reported that the service was easier to fit around other commitments due to the lack of travel and using apps meant that they could access resources as and when they needed them. This led to a positive difference to people's lives as they reported being able to commit to the service where without technology, they wouldn't have been able to fit it into their day. People who have taken part on the NHS DPP and the NHS Pathway to Remission Programme, another digital weight management service, highlighted improvements in their symptoms of diabetes… Additionally, they have reported improvements in their ability to complete physical activity and exercise
70	11	Patient organisation	General	Research by Manchester University saw greater weight loss for the remote and digital groups compared to the F2F groups which reenforces the effectiveness of digital weight management services. However, although remote delivery had greater completion rate than F2F, digital delivery had a lower completion rate. This supports the need for a combined approach that maximises both the accessibility and support needed for patients utilising these services. The Diabetes UK NHS DPP report referenced previously shows that key to patients was to have a choice between digital or face to face services, reenforcing the importance of clinicians considering personal preference to increase adherence. Additionally, many said they would prefer face-to-face sessions over digital due to the ability to have conversations and discuss things more easily face-to-face and so, despite potential other benefits of digital services face-to-face groups should not be removed altogether. Jonathan Valabhji, Emma Barron, Dominique Bradley, Chirag Bakhai, Jamie Fagg, Simon O'Neill, Bob Young, Nick Wareham, Kamlesh Khunti, Susan Jebb, Jenifer Smith; Early Outcomes From the English National Health Service Diabetes Prevention Programme. Diabetes Care 1 January 2020; 43 (1): 152–160. https://doi.org/10.2337/dc19-1425 Chadwick, D., Ågren, K. A., Caton, S., Chiner, E., Danker, J., Gómez-Puerta, M., Heitplatz, V., Johansson, S., Normand, C. L., Murphy, E., Plichta, P., Strnadová, I. and Wallén, E. F. (2022) 'Digital inclusion and participation of people with intellectual disabilities duringCOVID-19: A rapid review and international bricolage', Journal of Policy and Practice in Intellectual Disabilities. ONS (2019) Exploring the UK's digital divide. Available at: https://www.ons.gov.uk/releases/exploringtheuksdigitaldivide (Accessed: 28th June 2023). Reeves, D., Woodham, A. A., French, D., Bower, P., Holland, F., Kontopantelis, E., & Cotterill, S. (Accepted/In press). The influence of demographic, health and psychosocial factors on patient uptake of the English NHS Diabetes Prevention Programme. BMC Health Services Research.
71	11	Patient organisation	General	Living with obesity or overweight increases a person's risk of developing type 2 diabetes - it accounts for about 80-85% of their risk. For those who have been diagnosed with diabetes, getting support to lose weight can be very beneficial for managing the condition by improving glycaemic control and reducing risk of the long term complications of diabetes complications affecting the eyes, feet and kidneys. It can also increase the risk of heart attacks and strokes, complications which can affect a person's quality of life.

				We know from the research evidence some people with type 2 who lose significant weight loss can put their type 2 diabetes into remission. There are significant health benefits of weight loss even if remission does not occur. It reduces the risk of developing other conditions and reduction or stopping blood glucose lowering and blood pressure medications Two thirds of the UK population are currently classified as having obesity or overweight and many experience significant stigma as a result. Many of these people would benefit from being able to access support to help them to lose weight and maintain weight loss.
72	11	Patient organisation	General	Losing weight and maintaining that weight loss is complex, individual and requires a supportive environment. We also recognise that there are significant health inequalities that lead to development of overweight and obesity, disproportionately impacting less affluent communities, which should be addressed. People with obesity should be supported to understand the complex causes of obesity. Stigma, including internalised stigma, can be damaging and act as a barrier to seeking support. They should be encouraged to seek support from healthcare professionals to manage their obesity, rather than managing it alone Higher prevalence of diabetes amongst people with learning disabilities and there are higher proportions in the more severe category of obese (37% of people with learning disabilities compared to 30.1% of people without learning disabilities). As noted in the PHE 2020 to 2025 strategy, poor diets and excess body weight deprive people in England of more than 2.4 million life years through premature mortality, illness and disability each year. There are close links to broader social disadvantage, such as poverty, poor housing and social isolation, which is experienced disproportionately by people with learning disabilities.
Process				
73	2	Professional organisation	4	The main reservation to be expressed is the narrow representation of the committees involved in the draft guidance. It is not the individuals involved (at least those with weight management backgrounds who are experienced experts) rather the narrowness of the committee. There appears to be no representation of psychology, mental health(?) or indeed secondary care medicine (that hosts many current Tier 3 services). NICE ought to have established a broader expert committee that could achieve consensus. There is a risk that the draft guidance lacks authority. There are also a few perspectives that do not come through clearly in the draft guidance.
74	9	Company	1	We do not believe that this method of evaluation is appropriate for technologies that include access to medicines. Weight loss medicines recommended for use in the NHS via positive NICE TAs have been evaluated in a face to face setting. The clinical, cost effectiveness and safety of this method of supply and monitoring of weight loss medicines is unproven.
75	9	Company	1.7	The costs of weight loss medicines supplied through these services will be significant and will impact on medicines budgets. We therefore do not think it is appropriate to recommend the use of these apps in the context of evidence generation. As with all other NICE guidance relating to the use of medicines, evidence that they are a cost effective intervention is needed before they are recommended for use in the NHS.

76	9	Company	3.18	We do not feel it is appropriate to be recommending technologies which include the use of medicines for evidence generation, unless medicines use via the technologies has been fully evaluated and proven to be a safe, clinically and cost effective intervention for patients and the NHS. ICBs who fund these technologies within finite budgets will necessarily be taking funding away from other medicines and technologies that do have an evidence base.
77	9	Company	4	You acknowledge that there is a limited evidence base 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.
The technologies				
78	4	Company	1.8	Please see pages 9-11 of Attachment 7 of our original submission titled 'NICE Medical Technologies Evaluation Programme - Application to the for evaluation in the Digitally enabled weight management programmes to support treatment with weight management medication (alternative service model): early value assessment, where we have detailed Juniper's extensively developed MDT. In summary, 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 | pharmacists - dispense medications and provide additional clinical support to prescribers e.g. medication management and interactions - Accredited practising dietitians, clinical nutritionists I proactive and reactive nutritional support for patients - Health Coaching | motivation and accountability coach (non clinical) We are building out our MDT which interfaces directly with patients and we currently have job ads live in the UK for the following roles: - Psychologist I behavioural change and mental health support for patients - Physical Activity Specialists I tailored exercise programs - Physiotherapist I specialised advice
79	6	Company	2	We have provided additional information in the form of accompanying document "CheqUp - response to HTE10023" to the Committee which shows:

				That CheqUp provides an obesity service offering for NHS patients with clinical pathways and a multi-disciplinary team approach that mimicked and/or reflected: 1. The design of the clinical trials for liraglutide, semaglutide, and tirzepatide 2. The structure of tier 3 weight management services in the NHS 3. The requirements of TAs 875 and 664 (liraglutide and semaglutide for weight loss; tirzepatide has yet to get a Technology Appraisal so the service will, if needed, incorporate any new requirements once the in-progress TA is published)
80	8	Company	1.1	Whilst we appreciate that section 1.1 may not be changed (although your guidance document contradicts this), it is essential to point out that the Liva specialist weight management service has been significantly developed since we were initially approached for this EVA. We now have a partnership with a prescribing service. Like many of the other providers, we do not prescribe in-house but use a partner organisation to do so, e.g., Second Nature and Pharmalogic Chemist. We also now have an in-house prescriber in the form of our Medical Director. Therefore, it seems unfair that Liva has only been approved for medicine tracking and not prescribing and monitoring. Until this document, we had not been asked to provide feedback on this section as it currently reads. Therefore, we would like you to consider rectifying this. Liva can provide more information on our prescribing model as required.
81	8	Company	2.1	Will the guidance differentiate between technologies which offer in-house prescribing and clinical governance and those that outsource this component to a subcontractor?
82	8	Company	2.1	App. Not online platform.
83	8	Company	2.1	Since Liva first engaged with the EVA process, we have formed a partnership with an online pharmacy and broadened our clinical team to enable the prescribing and monitoring of weight loss medication. Therefore, the guidance is now outdated and not reflective of the service Liva can offer.
84	8	Company	3.15	This is considerably more than a patient in some traditional f2f services would experience, which can be an automatic discharge for missing a single appointment in some cases.
85	13	Company	1.2	No. Some of the organisations listed in this section have a track record for providing tier 2 services (and not tier 3) yet other 'tier 2' services with evidence of effectiveness, including Slimming World appear to have been overlooked. Slimming World has a well established digital service with published evidence showing clinically significant weight loss outcomes. (Toon, J., Geneva, M., Sharpe, P. et al. Weight loss outcomes achieved by adults accessing an online programme offered as part of Public Health England's 'Better Health' campaign. BMC Public Health 22, 1456 (2022). https://doi.org/10.1186/s12889-022-13847-w)) Despite being seen and referred to as a tier 2 service, the mean BMI of the population shown in this publication is over 30kg/m2 and also clearly shows data on those with BMIs of 35+ and 40+ showing effectiveness in those who would traditionally be seen as suitable for tier 3 or 4 services.

				In addition to this, there's data shown which demonstrates effectiveness for people accessing the support from different socioeconomic backgrounds. While not previously seen as a tier 3 service the service is supported by registered dietitians specialising in weight management, and registered nutritionists in addition to psychologists within an advisory panel, with expertise in disordered eating. It's not clear from the guidance exactly what constitutes an MDT for these services and having looked at the information on the identified programmes, it seems some are not offering anything over and above the Slimming World model and specialist teams described above. There is a wealth of published data demonstrating that Slimming World supports people living with obesity and with additional complexity. (Refs - Avery et al, 2019. The benefits of non-surgical weight management on weight and glycaemic control in people with complex type 2 diabetes: A primary care service evaluation of clinical outcomes at 12 months. Endocrinology, Diabetes and Metabolism. https://doi.org/10.1002/edm2.45; Avery et al, 2021. Can a community based weight management programme that is scalable provide effective diabetes management support for adults with T1D or T2D: a mixed methods evaluation. Archives of Obesity and Diabetes. DOI: 10.32474/ADO.2021.03.000172). In addition to the published data highlighted we have research about to be submitted for publication showing 1 year outcomes and strong results across all levels of deprivation. Slimming World's digital programme has been designed to incorporate the behaviour change strategies that have been shown to be effective from the group support where improvements to both physical and mental well-being have been shown. (Ref - Avery et al, 2023. Long-term weight loss maintenance in females after participation in a community weight management programme – A feasibility study. Clinical Nutrition Open Science. https://doi.org/10.1016/j.nutos.2023.07.003.) Slimming World have a strong track record of working with the NHS in partnership and are a provider of the NHS digital weight management programme, so already set up to work in this way. It's also worth noting that the NHS digital programme, and Slimming World's outcomes, are being evaluated currently with results to be available soon. We'd suggest the scope needs to be widened to include relevant additional providers given organisations like Slimming World could be an important partner in delivering this support.
	14	Company	2.1	Gro Health information is correct. Gro Health has a UKCA mark also.
87	3	Company	1.7	should this be 1.6?
88	9	Company	1.7	Should this read section 1.6?

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