NICE National Institute for Health and Care Excellence

Tirzepatide for managing overweight and obesity [ID6179]

Draft guidance comments form

Consultation on the draft guidance document – deadline for comments 5pm on Tuesday 25 June 2024. Please submit via NICE Docs.

	Please read the checklist for submitting comments at the end of this form. We cannot accept forms that are not filled in correctly. The Appraisal Committee is interested in receiving comments on the following: • has all of the relevant evidence been taken into account? • are the summaries of clinical and cost effectiveness reasonable interpretations of the evidence? • are the provisional recommendations sound and a suitable basis for guidance to the NHS? NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others. Please let us know if you think that the preliminary recommendations may need changing in order to meet these aims. In particular, please tell us if the preliminary recommendations: • could have a different impact on people protected by the equality legislation than on the wider population, for example by making it more difficult in practice for a specific group to access the technology; • could have any adverse impact on people with a particular disability or disabilities. Please provide any relevant information or data you have regarding such impacts and how they could be avoided or reduced**.**
Organisation name – Stakeholder or respondent (if you are responding as an individual rather than a registered stakeholder please leave blank):	Royal College of General Practitioners

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Disclosure Please disclose any funding received from the company bringing the treatment to NICE for evaluation or from any of the comparator treatment companies in the last 12 months. [Relevant companies are listed in the appraisal stakeholder list.] Please state: • the name of the company • the amount • the purpose of funding including whether it related to a product mentioned in the stakeholder list • whether it is ongoing or has ceased.	No disclosures
Please disclose any past or current, direct or indirect links to, or funding from, the tobacco industry.	No disclosures
Name of commentator person completing form:	Michael Mulholland/ Adrian Hayter

Comment number	**Comments** Insert each comment in a new row. Do not paste other tables into this table, because your comments could get lost – type directly into this table.
Example 1	We are concerned that this recommendation may imply that …….
1	Overall, we are concerned that the recommendations are not a suitable basis for guidance to the NHS due to insignificant emphasis on support required for improvement in **food quality** – this is a particular risk to those from more deprived communities who face rising food insecurity and are most likely to suffer with **obesity and malnutrition** (the double burden of obesity). A “caloric

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	restriction" only approach to weight loss in these groups risks greater adverse effects from malnutrition including poor metabolic health outcomes, vitamin deficiencies and sarcopenia. It is important to recognise the risks of managing obesity with pharmacotherapy and the risks in older people living with frailty of reductions in muscle mass as well as bone density. (Mwala NN, et al, Challenges in identifying malnutrition in obesity; An overview of the state of the art and directions for future research. Nutrition Research Reviews. Published online 2024:1-10)
2	**Support for improved dietary quality omitted from guidance** Section 1. 1.1 The statement "alongside a reduced-calorie diet and increased physical activity" does not adequately reflect the need for support to improve dietary quality rather than just a focus on a reduction in calories. See wider and extensive literature on ultra-processed food and obesity and work of Kevin Hall proving causality of UPF in obesity (metabolic ward studies). This is a particular concern as the SURMOUNT studies did not include the UK population which is known to have the highest UPF consumption in Europe/OECD countries. Malnutrition is a risk particularly in those with obesity (many with obesity are already malnourished i.e. have vitamin, mineral and fibre deficiencies as well as dysbiosis of microbiome and sarcopenia – see WHO work on double burden of obesity). Malnutrition is a significant risk if a poor quality diet continues to be consumed but in smaller quantities due to appetite suppression with Tirzepatide – in real world practice this is likely to be a greater risk than seen in trial populations. (this may also explain why people with prediabetes in the SURMOUNT trials who lost weight with Tirzepatide and reversed pre-diabetes, saw it return at 2/3 years when the support for diet and physical activity stopped see section 3.19 "prediabetes reversal loss") We would suggest an increased emphasis on dietary quality and a holistic assessment. So an improved statement might include "alongside a holistic assessment including support for improved dietary quality with reduced caloric intake with increased physical activity".
3	**Guidance needs to include new and wider roles in the NHS that have weight management expertise e.g. GP with Extended Role in Lifestyle Medicine** Section 3.2 Treatment pathways; the guidance would benefit from reflecting the increasing skill diversity within health care teams that now include clinicians of many backgrounds with Lifestyle Medicine training. Of particular note this guidance should explicitly list the GP with extended role in Lifestyle Medicine as a suitable provider of weight management services (see https://www.rcgp.org.uk/your-career/gp-extended-roles/Lifestyle-medicine-framework-practice). Although there may be some support of an MDT through ARRS-funded roles, the skills and capacity of dieticians and other team members may be limited in many areas to deliver a universal service. This would need careful consideration if the teams are devolved down to a local or PCN level.
4	**Guidance needs greater emphasis on recognition of the increasing safety risks and need for deprescribing in the case of significant rapid weight loss (particularly for those with polypharmacy)** Section 3.2 Weight management services prescribing Tirzepatide will need the support of the patient's own GP/employ a GP to review the need for deprescribing for those on multiple medications. This already occurs for some digital weight management services and additional medication reviews and titration of medication as a result of this work needs to be considered and funded for General Practice. Evidence suggests that significant weight loss can improve or even reverse many health conditions including hypertension, sleep apnoea, type-2 diabetes (although these patients will receive medications through other pathways) heart failure, osteoarthritis, chronic pain, depression, atrial fibrillation etc. Therefore deprescribing or down-titration of medications for these conditions is likely to be needed and in some cases, without deprescribing, serious harms can result e.g. from hypotensive falls, hypoglycaemia, sedation, rises in INR whilst on warfarin etc Polypharmacy is common in real life practice and uncommon in trial based participants so the risks of these complications are unlikely to have been fully understood. We need to be mindful of an approach which takes into account realistic medicine / prudent health principles / personalised care approach.

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5	**Need for appropriate <u>medical screening</u> of high risk patients particularly those with polypharmacy and multi-morbidity through a holistic medical review ideally by a medical generalist prior to starting Tirzepatide.** Section 3.2 Rapid, significant weight loss is also strongly associated with an increased risk of biliary disease which in some cases can be serious/life threatening e.g. acute cholecystitis. Patients will need to be screened for biliary disease and advised of the symptoms and risks. Similarly, contraception may need to be reviewed as women with obesity have reduced fertility and may have stopped relying on contraception – patients need to be advised about a potential rapid return in fertility that can occur with significant weight loss and to use appropriate contraception. Complex co-morbidity in those with obesity may not have been identified in the medical record or by a medical professional previously – these may only be identified after a comprehensive assessment by an experienced medical clinician e.g. GP or weight management doctor.
6	**The Guidance needs to reflect the uncertainty around risks and benefits of Tirzepatide for those from more <u>deprived communities</u> who are more likely to have multiple co-morbidities and polypharmacy** – these groups were not well represented in the trial data and are more likely to have greater risks of side effects from polypharmacy, malnutrition, treatment failure and need for deprescribing of other medications. This group is also most likely to be facing food insecurity and therefore be at risk of malnutrition with obesity which can be exacerbated by an overall food reduction approach than a food quality approach. This should be reflected in guidance that requires a comprehensive medical and food quality (rather than just caloric quantity) assessment for higher risk groups such as these. We need to ensure that we don't widen the health inequality gap unintentionally for deprived communities who may not have access to wider MDT teams for weight management services and the personalised approach and intensive support which might be required.
7	**The Guidance should be stronger around statements on the needs for <u>investment and implementation support</u> particularly in primary care –** There is a clear consensus amongst primary care leaders and policy makers that General Practice is not in a position to carry out any extra unfunded work and not currently in the position to prioritise weight management support services without significant additional training and long term investment. The guidance team should be aware that complications arising from rapid and significant weight loss e.g. biliary disease, medication side effects (those prescribed for other conditions improved by weight loss) will default to primary care teams without proper planning.
8	**The guidance should offer <u>prioritisation guidelines</u> that could be used whilst stocks or services are in short supply (section 3.30)** – these could include, as suggested, those patients awaiting surgery, infertility, IVF, or suffering severe complications etc.
9	**The guidance should be clearer that there <u>will</u> be system challenges (as opposed to may be) due to severe challenges in local availability of appropriate staff, training and services as well a funding limitations. (section 4.1)**
10	3.7 – It is unclear whether this can be prescribed in primary care or requires referral to secondary care for diabetes and weight management
11	3.7 – for generalisability - Would depression/mental health issues be included in co-morbidities for those patients with a slightly lower weight/BMI?
12	3.22 – If a patient stops the medication, is there a time limit within which they can re-start the medication, or does it each time require a first review for weight loss over 6months.

Insert extra rows as needed

Checklist for submitting comments

- Use this comment form and submit it as a Word document (not a PDF).
- Complete the disclosure about links with, or funding from, the tobacco industry.
- Combine all comments from your organisation into 1 response. We cannot accept more than 1 set of comments from each organisation.

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- Do not paste other tables into this table – type directly into the table.
- Please underline all confidential information, and separately highlight information that is confidential in turquoise. If confidential information is submitted, please submit a second version of your comments form with that information replaced with the following text: 'confidential information removed'. See the NICE Health Technology Evaluation Manual (section 5.4) for more information.
- Do not include medical information about yourself or another person from which you or the person could be identified.
- Do not use abbreviations.
- Do not include attachments such as research articles, letters or leaflets. For copyright reasons, we will have to return comments forms that have attachments without reading them. You can resubmit your comments form without attachments, it must send it by the deadline.
- If you have received agreement from NICE to submit additional evidence with your comments on the draft guidance document, please submit these separately.

Note: We reserve the right to summarise and edit comments received during consultations, or not to publish them at all, if we consider the comments are too long, or publication would be unlawful or otherwise inappropriate.

Comments received during our consultations are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the comments we received, and are not endorsed by NICE, its officers or advisory committees.

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