Annex A: ICB Funding Variation survey – October 2024

Through an online survey, NHS England (NHSE) sought the views of Integrated Care Board (ICB) representatives on the proposed Funding Variation for tirzepatide (Mounjaro®), to provide the National Institute of Health and Care Excellence (NICE) with a broad range of ICB views as part of their Funding Variation consultation.

The survey opened on Friday 4 October 2024 and closed on Friday 18 October.

The survey posed thirteen questions for ICB representatives covering:

- The approach to phasing and prioritising access to the treatment through the Funding Variation.
- The specifics of the request to vary the implementation period.
- The selected “qualifying comorbidities” found in the alternative implementation plan.
- The strength of ICB support for the Funding Variation request and the proposed alternative implementation plan.
- The impact of accommodating NICE’s recommendation under the standard funding mandate.

Summary of the results

1. Most ICBs (89% of respondents) do not believe that a positive NICE recommendation for tirzepatide for primary care/general practice could be safely and appropriately offered to patients within a 90-day implementation period. This compares to 91% in April’s survey.

2. There remains widespread and decisive support (90%) for a Funding Variation request to be entered to amend the introduction of tirzepatide for obesity into the NHS. This compares to 91% in April’s survey.

3. ICBs clearly support the principle of creating a prioritised approach to access based on clinical need. A majority of ICBs believe the NHSE proposal does this.

4. There is strong support for both an additional 90-days for implementation (96% agree or strongly agree) and a Three-Year review of Funding Variation progress (87% agree or strongly agree). Opinion on the length of the Funding Variation is more divided, but still a majority of ICB respondents (58%) agree or strongly agree with the length.

5. Opinion is divided as to whether the NHSE proposal is supportive of minimising/reducing health inequalities.

6. Most respondents (60%) agreed with the NHSE proposal to limit the 'qualifying comorbidities' to the five conditions for the duration of the Funding Variation period.

Monitoring Information

- 55 valid responses were received.
- Responses received from 38 different ICBs across the seven NHS regions.
- Multiple responses were received from six ICBs and all ICB responses have been included in the analysis.

List of responding ICBs

NHSE region	Integrated Care Board represented
North West	[redacted]
North East and Yorkshire	[redacted]
Midlands	[redacted]
South East	[redacted]
South West	[redacted]
East of England	[redacted]
London	[redacted]

Non-ICB responses

Additionally, NHSE received 10 submissions from authorities other than ICBs (namely, NHSE regional teams, secondary care providers, primary care providers and local authorities). These responses have reviewed and noted, and comments from these respondents can be found, appropriately labelled, in this analysis.

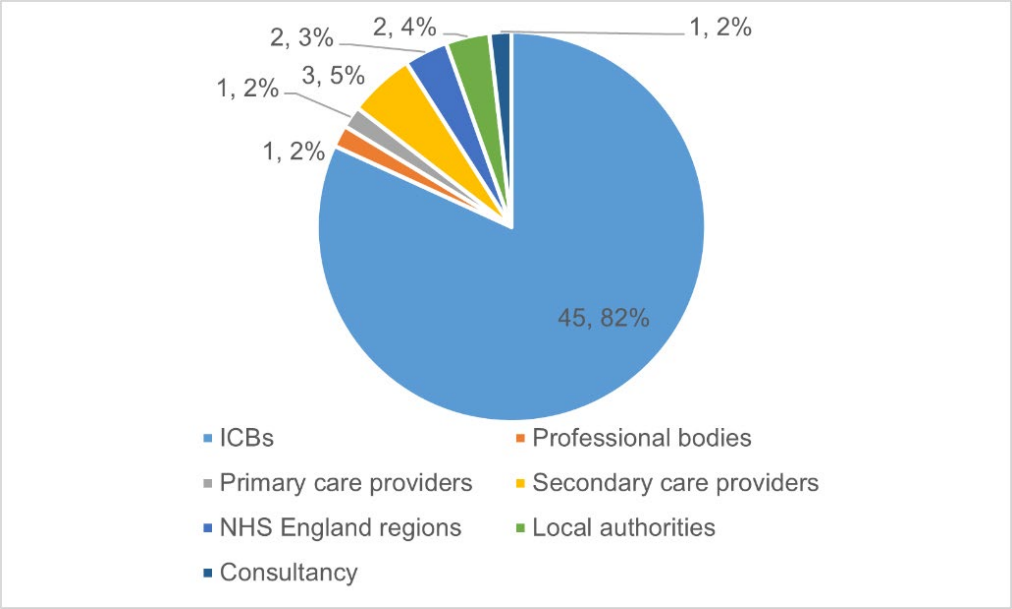
However, for quantitative analysis purposes, they have been excluded from the statistical analysis to allow NHSE to present the survey findings as the collected views of ICBs.

Respondent
British Dietetic Association - Specialist Obesity Group
Gloucestershire County Council
Guys and St Thomas's Hospital
Hart Health Partnership
Health Innovation Manchester
NHS England - Midlands
NHS England – South West
Royal Berkshire NHS Foundation Trust
Royal Cornwall Hospital
Stockport Council

Methodology

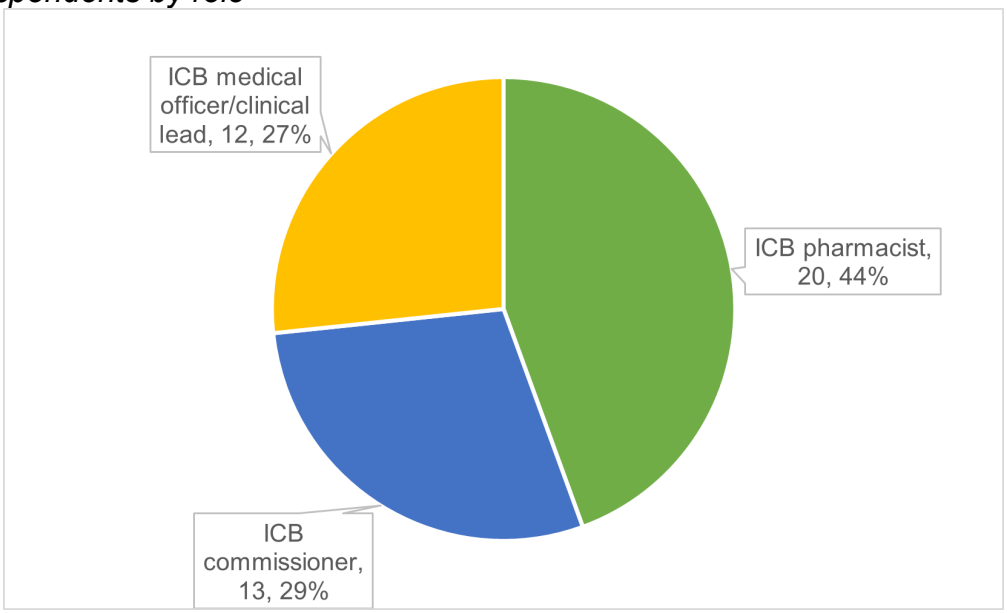
The full list of 38 ICB respondents has been used for the analysis of the survey results. While this approach provides multiple responses from some ICBs, the survey was circulated to a variety of ICB contacts both medical and non-medical (Chief Medical Officers, Pharmacy Leads and service commissioners) and each discipline and/or profession offers unique perspectives on how the Funding Variation – or lack of one – would impact their ICB. NHSE does not believe it should not decline to receive this advice, nor to judge which of multiple submissions is preeminent for analysis.

Total responses by sector



Total responses by sector (excluding ICB responses)

ICB respondents by role

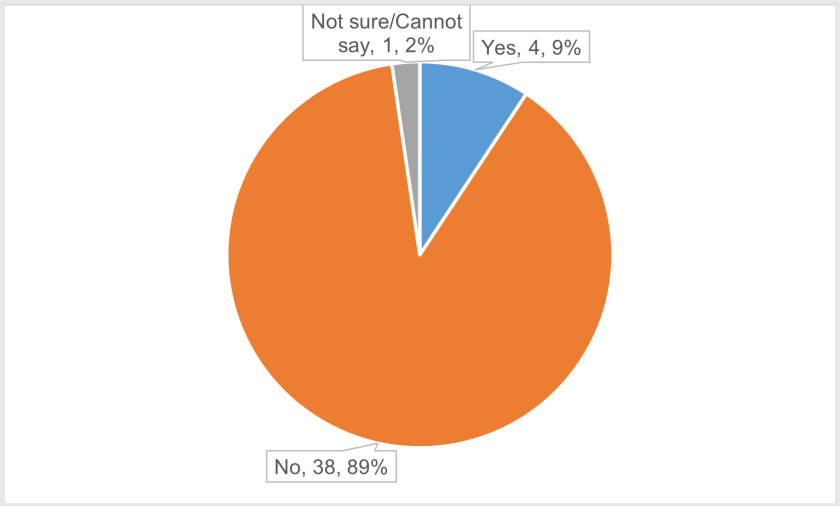


Survey Analysis

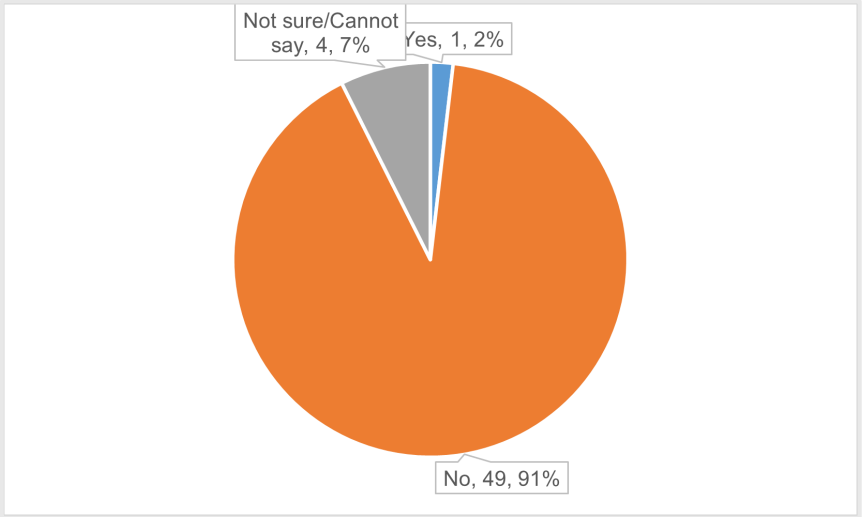
Support for the Funding Variation

1. We asked ICB representatives whether they believed that a positive NICE recommendation for tirzepatide for primary care/general practice could be safely and appropriately offered to patients within a 90-day implementation period.

   In October 2024, they answered:
   - 89% (38/43) No.
   - 9% (4/43) Yes.
   - 2% (1/43) Not sure/Cannot say



   In April 2024, in response to the same question, ICBs responded:
   - 91% (49/57) No.
   - 2% (1/57) Yes.
   - 7% (4/57) Not sure/Cannot say



2. We asked ICBs to outline what they believe would be the impact – positive and negative – if 90-day implementation was attempted.

> *"There is not the resource, capacity or funding to implement. This will have a detrimental effect on GP access as many patients will approach for treatment. This will have adverse effect on all patients. There would be no prioritisation of patient groups which will widen inequalities. There would be a large cohort of patients who would expect to be able to access straight away but this will not be possible and a poor experience for those patients. There could be legal challenge to the ICB."*
>
> *Lead ICB pharmacist*

There were concerns that primary care services, already struggling to meet demand, would become overwhelmed.

> *"Primary care services would be overwhelmed. Appropriate workforce would not be available. If publication was in December implementation would inevitably be delayed due to winter pressure management. There would not be sufficient time to procure any required wraparound service."*
>
> *ICB Clinical Programme Senior Manager*

Some expressed concern that while the medicine would be prescribed, the required wraparound care would not be supplied.

> *"Prescribing may still happen regardless of our formulary position. Wraparound support would also be an issue as this wouldn't be in place for these patients. There might be more tension between primary care and secondary care around prescribing and where the responsibility sits for this."*
>
> *Senior Commissioning Manager*

There was a risk raised that the required investment to meet the recommended patient cohort would mean funds diverted from other services.

> *"If primary care is directed to deliver this service that will have significant impact on their delivery of general primary care capacity and divert already insufficient resources to this area."*
>
> *ICB Chief Medical Officer*

Some ICBs stated that, in the event of a 90-day funding mandate, they would be non-compliant whether they attempted to implement or did not.

> *"We would probably we will be in breach EITHER of our statutory duty to implement within 90 days OR our duty to remain within our agreed financial control total. Inequalities would increase because of the need to find resource from elsewhere to fund this drug."*
>
> *ICB Chief Pharmacist*

> *"As we would certainly breach the 90-day implementation by some margin it would leave our organisation open to legal challenge, as well as patient complaints and negative press."*
>
> *ICB Medicines Optimisation Pharmacist*

Inequity of access to the treatment after the 90-days was a common theme.

> *"Each ICB will likely need to ration leading to disparity across the system and postcode lottery with patients trying to access services out of area."*
>
> *ICB Head of Health Improvement*

Some stated concerns over patient safety if they attempted to comply.

> *"We could be non-compliant in delivering the wrap around service which is integral to safe prescribing of medication."*
>
> *Senior Programme Manager*

The capacity of primary care, particularly staffing to offer this treatment, was cited as a concern.

> *"Concerns that capacity within primary care would not meet demand and overwhelm primary care services, who are already struggling to meet demand."*
>
> *Assistant Director of Pharmacy*

> *"We would have to prioritise treatment to those that would get the most benefit. There is no capacity in any local services and there is a risk of destabilising current services."*
>
> *Health Innovation Programme Manager*

But some respondents believed that 90-day access would see patients access the treatment sooner.

> *"More patients are likely to be able to access treatment more quickly. However, this would be in an ad hoc way, without the level of prioritisation required. This may result in extension of health inequalities and would certainly result in an untargeted cost pressure for the ICB."*
>
> *ICS Chief Pharmacist*

But many also noted the deficit between 'ability to offer' and patient expectations if 90-day implementation was required, inviting patient dissatisfaction.

> *"There is a potential patients may access treatment sooner, but in reality it won't happen, the result will be patients with expectations they will access treatment quickly and they will end up on a waiting list, which leads to dissatisfaction."*
>
> *Associate Director: Pharmacy and Medicines Optimisation*

> *"We believe a 90-day implementation period set against the background of all the noise around this treatment would cause a surge in demand, a surge in disappointment and increased complaints which would take colleagues away from implementing the guidance."*
>
> *ICB Chief Pharmacist*

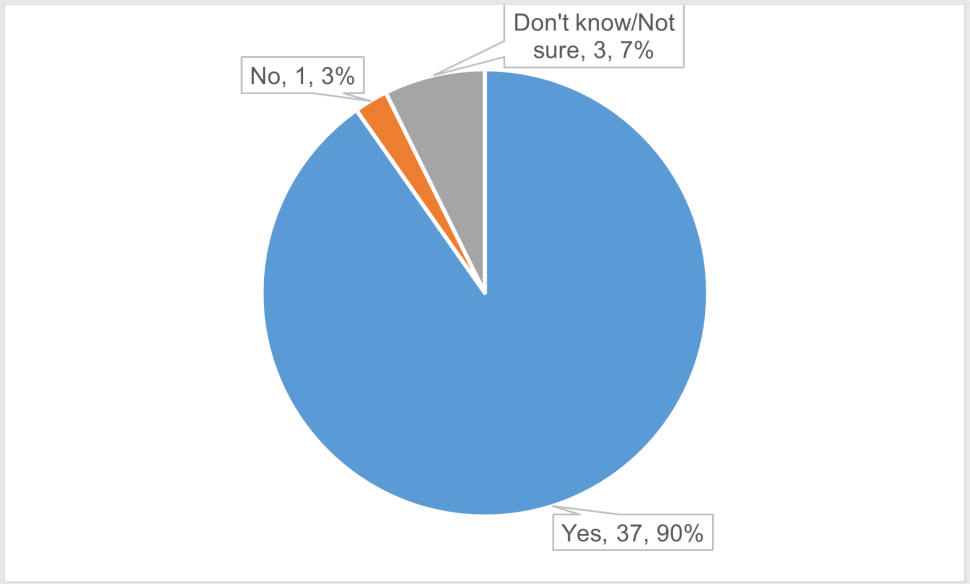
And there were also positive comments about the potential for this treatment to improve patient care.

> *"We would expect within the first year to see a considerable increase in primary care drug costs with associated improvements in our populations weight. Over a long term we would expect to see our current growth in type 2 diabetes of 10% per year to reduce with associated clinical benefits to CVD and other outcome measures."*
>
> *ICB Chief Pharmacist*

3. We asked ICB representatives whether they supported the creation of a Funding Variation for tirzepatide.

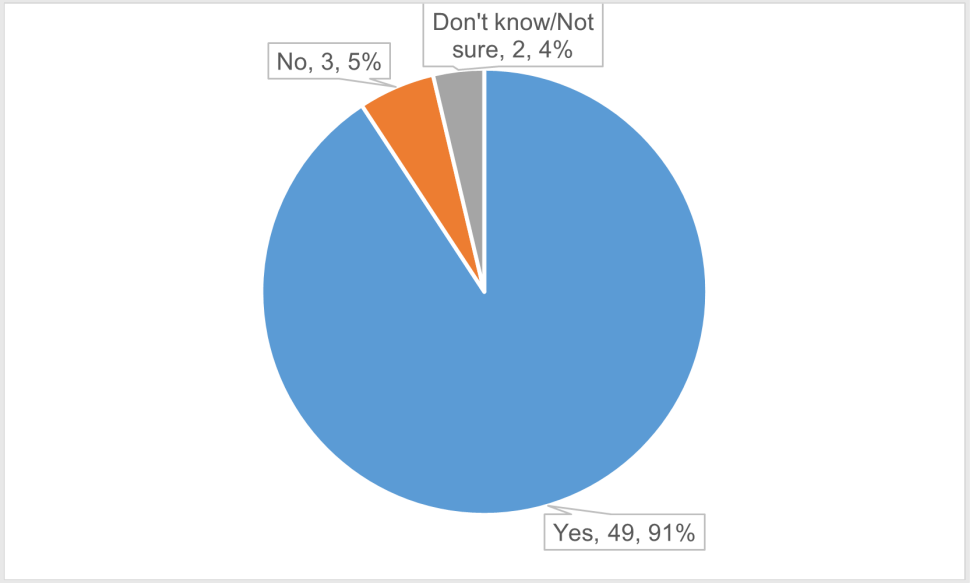
   In October 2024, they answered:

   - 90% (37/43) Yes.
   - 3% (1/43) No.
   - 2% (3/43) Not sure/Cannot say



   In April 2024, in response to the same question, ICBs responded:

   - 91% (49/57) Yes.
   - 5% (3/57) No.
   - 4% (2/57) Not sure/Cannot say



4. A similar question to Question 2; we asked ICB representatives what would happen if there is no Funding Variation and normal 90-day implementation timeline applies.

   Some of the same themes were presented.

> *"This would be extremely challenging for us and primary care would likely be swamped with the demand. We currently do not have capacity in any services and there is a risk of destabilising services due to the demand. It will take some time to grow capacity and expertise. We would be unable to implement in the 90-day period."*
>
> *Health Innovation Programme Manager*

   One theme was that development of the treatment pathway, redesign of existing services to accommodate this and upskilling existing staff could not be conducted within this timeframe.

> *"A 90 day timeline is insufficient to plan implementation and upskill clinicians. Reality is that 90 days is not sufficient to stand up a service, develop robust pathways and get referrals in, so you will end up with a hypothetical service to tick a box, without anyone actually getting effective treatment."*
>
> *Associate Director: Pharmacy and Medicines Optimisation*

   Another was the lack of available workforce to safely and effectively offer the treatment also featured.

> *"Services are so stretched, there isn't the workforce out there for the supportive weight management services. I support what NHSE are trying to do but it just feels like kicking the can further down the road and the reality is that significant investment is needed alongside this implementation."*
>
> *Hospital Chief Pharmacist*

> *"We do not have the staff or infrastructure to roll this out safely withing 90 days & we need robust funding and staffing, dieticians, psychology otherwise the project is doomed to failure."*
>
> *General Practitioner*

   Multiple responses exhibited doubts that they would be complaint with the funding mandate without a Funding Variation.

> *"I think we would almost inevitably breach the 90 day requirement but with a defence that no NICE TA has had such wide scope and additional support requirements."*
>
> *Clinical Director, Medicines Management and Optimisation*

Some also noted the risks associated with non-compliance.

> *"[Withheld] will not be able to implement and comply with the NICE TA, leaving the organisation open to reputational damage and legal challenge."*
>
> *ICB Medical Director*

Balancing competing legal duties was again raised.

> *"We would have to take to board that we would not be able to be compliant with NICE TA if we are to be complaint with the statutory duty to break even financially."*
>
> *ICB Chief Pharmacist*

> *"We feel that introducing this TA without the funding variation will mean ICBs either breech their statutory financial responsibilities, their statutory responsibilities with respect to NICE guidance or both."*
>
> *ICB Chief Pharmacist*

Some respondents laid out the actions that their ICB would take in this situation.

> *"We will follow our due process of formulary approval for patients within the criteria set by NICE. The financial risk score to the prescribing budget will be increased. I will recommend that we review the current formulary status of Wegovy and look to extend use to the same cohort of patients NICE has approved for Tirzepatide use - so patients and clinicians are given a choice."* [1]
>
> *ICB Chief Pharmacist*

> *"We would need to work across the region and with the national team to agree a consistent approach. It's unlikely that primary care will have the capacity and as we do not have a tier three service in [withheld], we would not have an alternative provider in place."*
>
> *Population Health Portfolio Director*

> *"If no Variation and it becomes mainstream then we would seek to do a pharmacy first model which is already widespread and mainstream for those that can pay for it."*
>
> *Chief Medical Officer*

> *"The Tier 3 services would be the only route for accessing this medication in 75% of our places. These services already have very long waiting lists and would not be able to accept any more patients, but tirzepatide could be offered to those already under this service."*
>
> *Healthy Weight Lead*

[1] To note: the above would not comply with the NICE Technology Appraisal 875 recommendation for semaglutide for managing overweight and obesity.

"We would add this to our formulary but it would only be made available in the Acute Trusts and not primary care due to funding this. It would then be rag rated accordingly in our formulary (grey status) until a prescribing pathway has been agreed across the System and clinical policies have been reviewed and updated."

Senior Commissioning Manager

Some discussed developing their own local clinical prioritisation criteria, in addition to the NICE recommendation.

"We would have to develop our own clinical criteria to ensure patients with the greatest clinical needs were prioritised."

Clinical Programme Senior Manager

"Primary care organisation will be unable to comply with the NICE funding mandate and will create their own prioritisation. As mentioned before some ICBs will be able to deliver in this time frame to existing service, though with less than ~50% having access to appropriate services this could widen health inequalities."

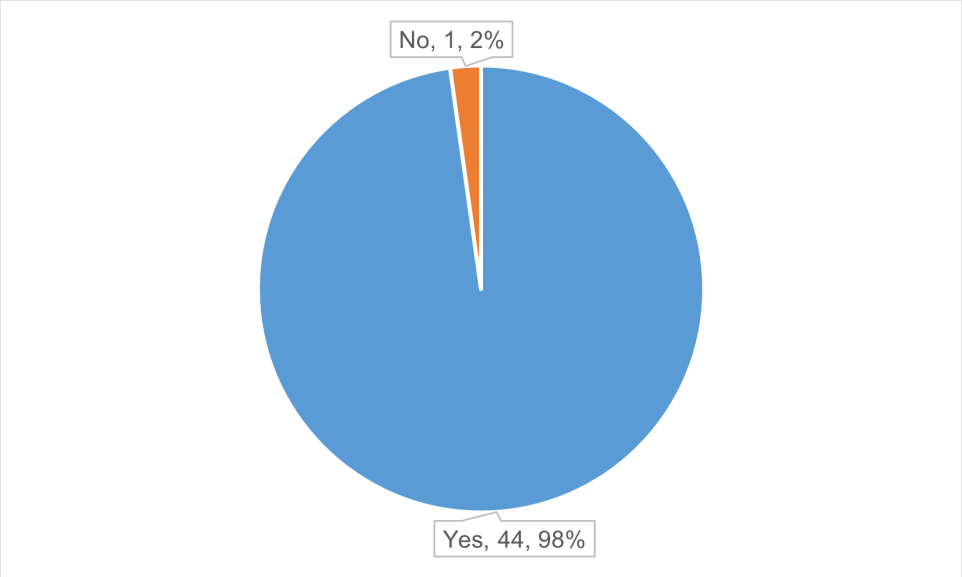
Chair, Specialist Interest Group

"The only way we could comply with the 90-day mandate would be to use specialist weight management services, this would overwhelm services and increase already long wait lists. However, we would not be able to implement fully without phasing due to the number of eligible patients as we would overwhelm services. Phasing locally would increase the already present postcode lottery."

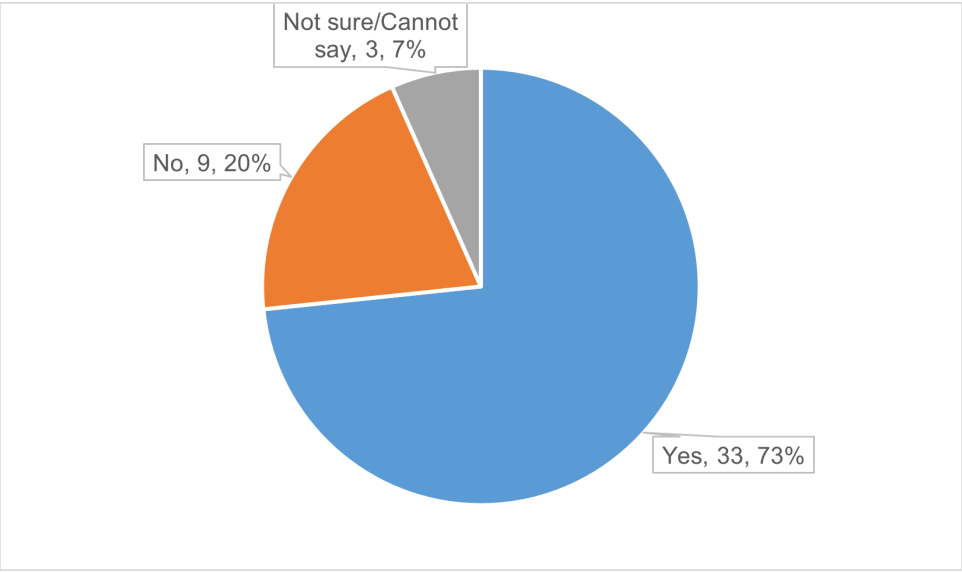
Obesity pharmacist

A phased and prioritised approach

5. 98% of respondents (44/45) supported the principle of creating a prioritised approach to accessing tirzepatide for weight managed, based on clinical need. Only one respondent (2%) disagreed with this principle.



6. 73% of respondents (33/45) stated a belief that NHSE's alternative implementation proposal provides access based on clinical need.
    - 20% (9/45) did not believe that NHSE's proposal provides access based on clinical need.
    - 7% (3/45) were not sure or could not say.



ICB comments

> *"The phased approach to implementation, based on clinical need, feels to me like the only way this treatment can be made available to the public fairly, sustainably (for primary care and local weight management pathways), and in a way that helps to mitigate the potential for this treatment to widen existing weight related health inequalities. I [have] real concerns about the risk of overwhelming primary care, and of treatment being prioritised towards those with the highest levels of health literacy (as opposed to need) if the proposed approach is not supported."*
>
> *ICB Head of Commissioning*

Most respondents were supportive of a prioritised approach to access.

> *"Focussing on those with greatest clinical needs will allow managed entry of the drug to the health economy to help the ICB address financial and workforce pressure and support equitable access. The ICB is already financially challenged, and the phased implement will hopefully allow an early return on investment as improving health outcomes for those with greatest need will reduce their use of other health resources in the ICB."*
>
> *Director of Pharmacy and Medicines Optimisation*

Some felt this type of approach was the best way to minimise inequality of access.

> *"We believe there will be high demand for this treatment and similar product and our experience suggests that those who shout loudest are potentially more likely to access treatment than those whose clinical priority is the greatest. We therefore feel that the principle of creating a prioritised approach will help ICBs target the treatment to those who are likely to gain maximum benefit from it."*
>
> *ICB Chief Pharmacist*

But others also believe that efforts in this regard may not go far enough.

> *"Prioritisation should also include specific targeting of inequalities and not just based on clinical need as well as consideration of those who have already been waiting some considerable time on a waiting list."*[2]
>
> ICB Medical Director

[2] It is not clear whether an alternative implementation proposal based on deprivation would be permissible under NICE regulations. This would, in effect, provide differing levels of access to the medicine among identical patients depending on where they live. NHSE is recommending phasing of patient access based upon a clinical prioritisation, not levels of deprivation, but believe clinical prioritisation includes a factor for deprivation (given the links between obesity and deprivation).

Some respondents questioned NHSE's choice of prioritised approach.

> *"It's hard to see how all those who have a high clinical need for consideration of the medicine are given access to this through this approach, yes you could argue that this approach will target those with a higher BMI and with multiple co morbid conditions which suggest higher need but we have no way of know whether this is the OPTIMAL approach because treating an 18 year old with a BMI of 36 and at this time only one or no co-morbidity may be a far better use of the medicine. If we do agree and see this as the right way to go then we MUST be clear and track the use of other medicines to understand the wider implications of reduced burden of care clinically and fiscally to demonstrate overall benefits at population and personal level."*
>
> *Programme Director*

> *"The clinical criteria relies on BMI which is based on 18th Century male physique. [Withheld] feels that this is outdated and does not represent the whole population. [Withheld] suggests that waist circumference could be used instead of a BMI or multi model assessments."*
>
> *ICB Medical Director*

While others endorsed the approach.

> *"We believe that NHSE's approach provides the best chance of being able to target this intervention at those with greatest clinical need and to manage implementation given current workforce challenges."*
>
> *Clinical Programme Senior Manager*

> *"This approach gives clarity on priority areas and will enable better consistency across England. The proposal is more realistic for systems to achieve than the standard 90-day implementation period. The proposal does focus on physical rather than mental health priorities but appreciate this is because you are taking an evidence-based approach."*
>
> *ICS Chief Pharmacist*

> *"Looking at our patient numbers this approach seems a realistic introduction into the NHS. We would support that those with the highest number of co-morbidities and greatest BMI are considered first."*
>
> *Deputy Chief Pharmacist*

Some respondents noted that prioritisation by clinical need is based on providing corrective action for the effects of obesity, rather than prevention. However, given the NICE recommendation, some could see why this may be the case.

> *"This becomes a treatment for obesity not prevention. In that context, it is absolutely correct to risk stratify our population and treat accordingly. That process is no different to many other therapies we adopt."*
>
> *ICB Medical Director*

Some respondents compared this approach to the recommendation made for the glucagon-like peptide-1 obesity drug semaglutide, highlighting differences between the approaches.

> *"This approach currently excludes most patients under 'Phase 1' criteria as defined by SFE/OMC-UK for the Wegovy roll-out, e.g. patients that need to lose weight for life-saving therapy e.g. renal transplants, heart transplants, cancer treatment, raised intracranial pressure requiring lumbar punctures etc. It also relies on BMI as a measure of disease which is of course not a good way to define adiposity. It would for example penalise patients with a BMI of 35 with 3 complications vs those with BMI of 40 with 2 complications who would be treated much earlier in the algorithm (by several years)."*
>
> *Hospital Physician Lead - Medical Obesity*

> *"Would wish to see the scope for prioritised access to be expanded to all weight loss drugs to ensure equity and manage service pressures."*
>
> *Assistant Director of Pharmacy*

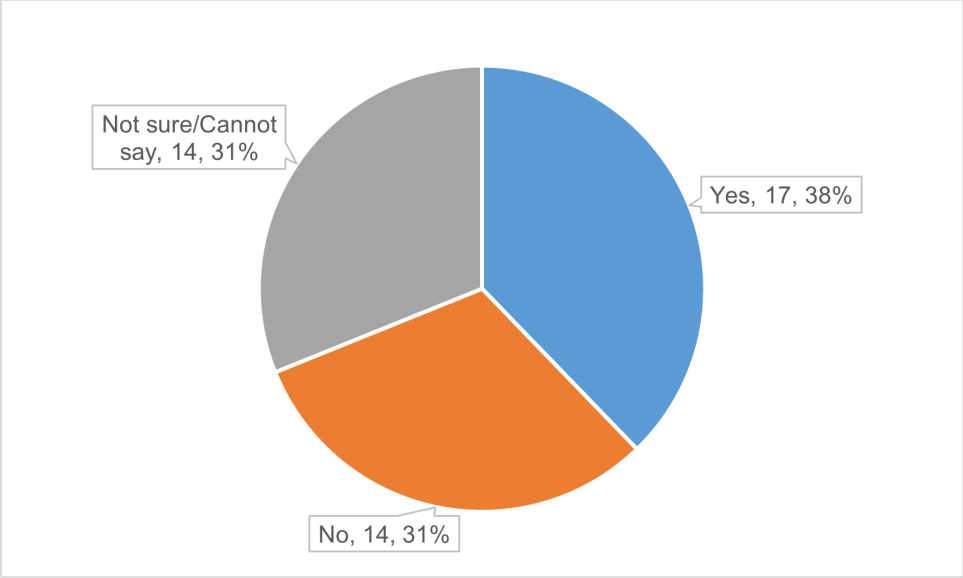
> *"We are also concerned that this needs to be considered alongside other weight loss medications like Semaglutide which has still not been fully implemented. For example, there are small cohorts not included in the NHSE plans as recommended by the society of endocrinologists that I am concerned will still be waiting due to the wait for Tier3 services and unequal access to those services across the system. We think these clinical conditions should be included in cohort 1."*
>
> *Head of Health Improvement*

One respondent highlighted the variance between the qualifying comorbidities in the Funding Variation request and the broader definition of comorbidities in the draft final recommendation.

> *"We believe the NICE TA should reflect the co-morbidities within the funding variation to better reflect the population with the greatest need."*
>
> *Healthy Weight Lead*

Impact on health inequalities

7. 38% of ICB respondents believed that NHSE's alternative implementation proposal is supportive of minimising/reducing health inequalities.



ICB comments

Opinion was divided on whether the Funding Variation proposal is itself supportive of minimising/reducing health inequalities.

> *"We feel that the Funding Variation and the proposed prioritisation will minimise any health inequalities impact associated with the introduction of this treatment. We also feel that the proposed review at 3 years will help to ensure that if any negative impacts on health inequalities do occur, they are identified and further steps taking to minimise / mitigate the risks."*
>
> *ICB Chief Pharmacist*

> *"NHSE's FV proposal addresses inequalities of access to treatment but does not address health inequalities. The FV does try to address those with highest benefit but due to the nature of this drug there is still risk that it is prescribed for the patients that are most engaged and shout the loudest. There is no heath inequalities targeting mentioned in the FV. It would be beneficial to have a section in the FV for health inequalities, with ICBs able to choose which Core20 cohorts to target and which BMI/comorbidities. This may be an adapted/tailored version of the models we have chosen – it would be better for the FV to make this explicit and allow flexibility to the models.*
>
> *Lead diabetes and obesity integrated pharmacist*

Some suggested additional measures that could help bridge any gap.

> *"Allocation of a ring fenced sum or each GP practice to be used specifically for treating a cohort of high risk patents i.e, self funding is not an option."*
>
> *Lead Pharmaceutical Adviser*

"Could consider the first cohort to also include a deprivation criterion e.g. most deprived quintile by LSOA."

ICB Lead Pharmacist - Clinical Effectiveness

"We would support the creation of a national case finding tool that can be run through GP databases to identify people who are in the first 18-month cohort to ensure not only those who shout loudest are invited for a weight management discussion and potential treatment."

ICB Chief Pharmacist

Some respondents suggested that the alternative implementation plan should do more to earlier target those experiencing health inequalities.[3]

"Consider populations from LSOAs in high areas of deprivation, other high-risk groups eg LD, mental health patients, other protected characteristics."

ICB Chief Medical Officer

"I think that the FV could have an element of socioeconomic determinants as part of the cohorting to improve economic outcomes."

ICB Pharmacy Lead

It was noted that those with the available means could access the treatment via private services, and this is already creating an inequality of access. Therefore, the length of the Funding Variation was posed as a risk for creating further inequality.

"Having a longer roll out period will mean people with either financial means to buy the drug or the knowledge and background to articulate their need to go and get it on prescription and while people from deprived backgrounds may end up being delayed due to the prolonged rollout."

Bariatric Surgery Lead

"As the timeline is extended over 12 years, those able to pay, and with fewer or no co-morbidities will be able to access the product much earlier than those in lower socioeconomic groups – who may have higher need. i.e. those in Cohort V have high need but will need to wait up to 9 years to qualify for the product. In this time their co-morbidities may have exacerbated. The timeline needs to be reduced to ensure those who would benefit from the product are not waiting excessively."

Programme Lead

[3] As previously noted, it is not clear whether an alternative implementation proposal based on deprivation would be permissible under NICE regulations. This would, in effect, provide differing levels of access to the medicine among identical patients depending on where they live. NHSE is recommending phasing of patient access based upon a clinical prioritisation, not levels of deprivation, but believe clinical prioritisation includes a factor for deprivation (given the links between obesity and deprivation).

There were identified implementation challenges related to providing access to more socially deprived groups, especially in primary care settings.

> *"We know that primary care demand is greatest in areas of high deprivation, and where primary care capacity is already stretched, this will place a disproportionate burden on the healthcare system."*
>
> *Prevention Programme Manager*

Many respondents raised the importance of good communications to patients to ensure that those eligible for the treatment are aware of their eligibility.

> *"Clear communication to patients and primary care is essential to ensure the right patients get the drug in the order outlined by NHSE."*
>
> *ICB High Cost Drug Pharmacist*

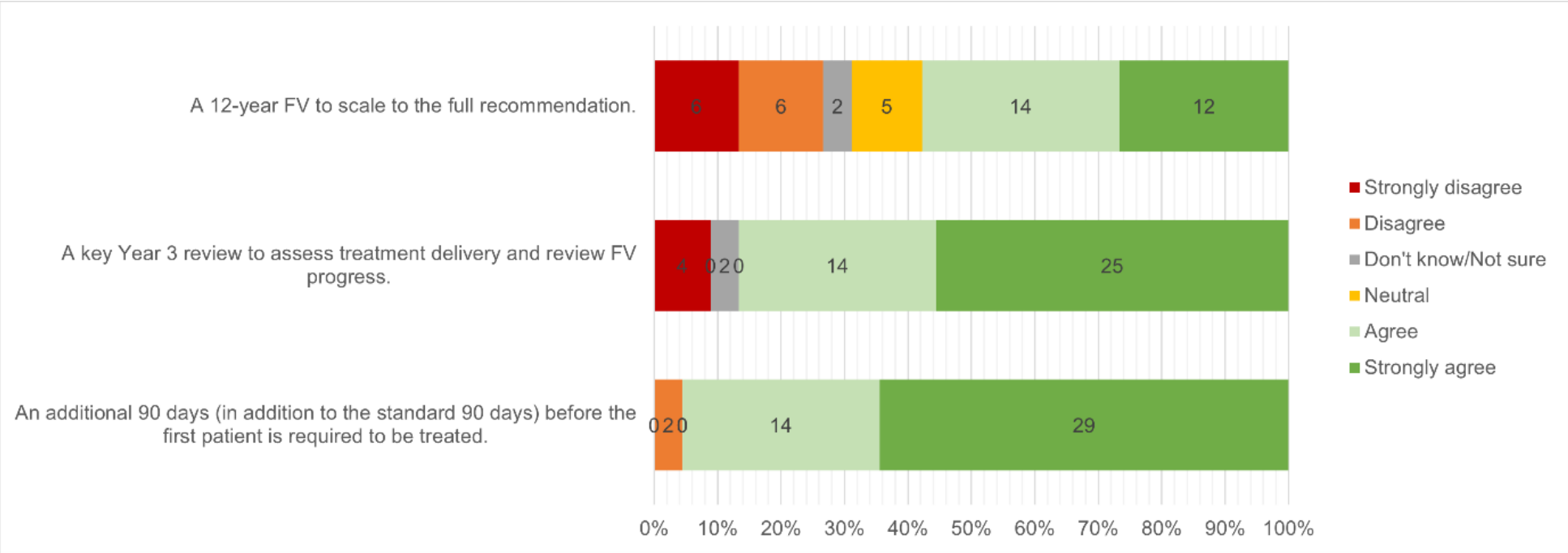
Alignment to the semaglutide recommendation was again raised, this time as a potential cause of inequity.

> *"It is highly likely that access to semaglutide via providers such as [withheld] will dramatically widen health inequalities within the context of the 12-year funding variation period. This will discriminate against those who are not digitally savvy, those whose first language isn't English, and those who are less able to persuade their GP to make a non-local referral."*
>
> *Consultant in Public Health*

Alternative Implementation Proposal content

8. We asked for views on the three main elements of the alternative implementation proposal.
    - The additional 90-days – totalling 180-days - before the first patients is required to be treated.
    - The Three-Year review of FV progress and implementation.
    - The 12-years to scale to full recommendation.

These are how the ICBs respondents viewed each element.



Additional 90-days

- 64% of respondents (29/45) strongly agreed with the proposal for an additional 90-days before first access is required. 96% of ICB respondents either strongly agreed or agreed with this element.

Three-Year Review

- 56% of respondents (25/45) strongly agreed with the proposal for a Third-Year review of the Funding Variation, once implemented. 87% of ICB respondents either strongly agreed or agreed with this element.

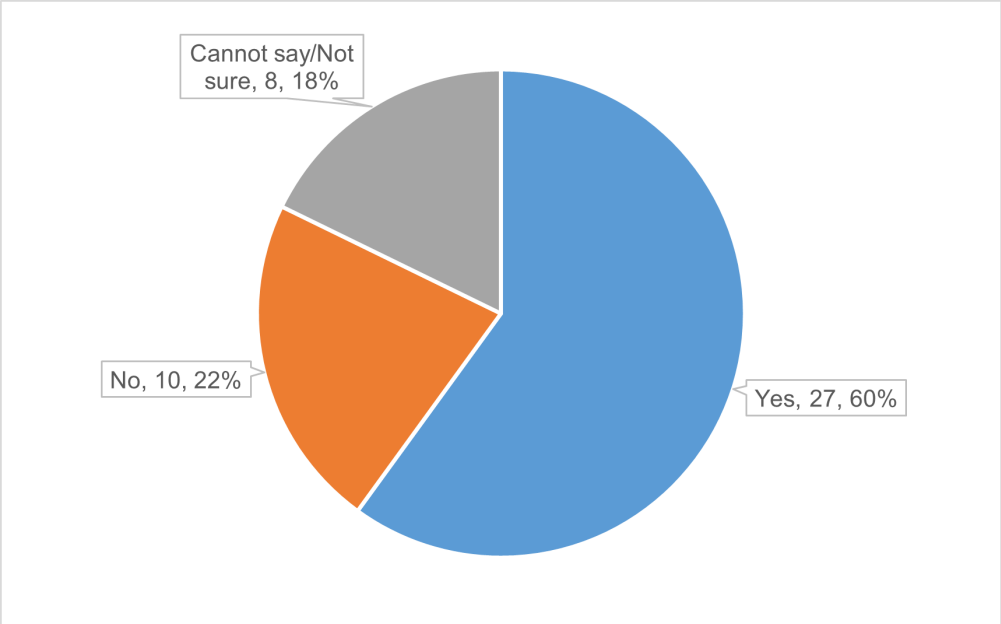
12 Year Funding Variation length

- 27% of respondents (12/45) strongly agreed with the proposed Funding Variation length. 58% of ICB respondents either strongly agreed or agreed with this element.
- 13% of respondents (6/45) strongly disagreed with the proposed Funding Variation length. 27% of ICB respondents either strongly disagreed or disagreed with the proposed length.

Qualifying Comorbidities

9. On the question of the NHSE proposal to define the 'qualifying comorbidities' for the duration of the Funding Variation period to the five conditions of Hypertension, Dyslipidaemia, Cardiovascular Disease, Obstructive Sleep Apnoea and Type 2 Diabetes;

    - 60% (27/45) of people agreed
    - 22% (10/45) of people disagreed
    - 18% (8/45) of people could not say/were not sure whether they agreed or not.



ICB comments

"Obesity isn't a morbidity in its own right, it is a high-risk metabolic state and so these five co-existing conditions aren't really 'comorbidities' but are aligned risk factors which make the risk of morbidity much higher."

Lead Pharmaceutical Adviser

"If the priority is to prevent disease and lower downstream costs then it maybe it would be better to prioritize the BMI>40 with HTN (i.e. 1 comorbidity) over BMI>40 with previous MI + T2DM (i.e. 2 comorbidities). You could again argue the other way depending what the goal is and what the priority-setting principles or values are. It would be useful if there were some clear (debated and agreed) priority-setting principles underpinning this – which would need to go beyond clinical need."

Head of Health Improvement

In line with the results of Question 6, some respondents approved of the proposed the qualifying comorbidities in the Funding Variation proposal.

> *"These are the comorbidities used in the clinical trial I believe, so good evidence-based practice. General weight related comorbidities is very vague and can potentially encompass anything so support having specific 'qualifying comorbidities'."*
>
> *ICB High Cost Drug Pharmacist*

> *"The five qualifying comorbidities reflect those used in the clinical trials demonstrating the efficacy of this treatment. We do, however, reflect that trials are ongoing and if other clinically important cohorts do emerge then the qualifying criteria are modified accordingly."*
>
> *ICB Chief Pharmacist*

> *"In general, they appear to cover the most prevalent and important conditions in this group but there are others (e.g. respiratory, gall bladder disease) which could also benefit."*
>
> *Public Health Registrar*

Many respondents, when considering the definition of qualifying comorbidities, implied that the definition was too narrow and offered alternative suggestions.

> *"As identified previously these five 'qualifying comorbidities' misses out key condition/disease that require urgent treatment i.e. transplantation, oncology treatment, and fertility. In addition, if these conditions are well controlled with medications, this does not mean that they are at greater clinical need/risk than someone with one condition i.e. liver disease."*
>
> *Chair, Specialist Interest Group*

> *"The comorbidities listed are too narrow. For example, women experience sub-fertility attributable to obesity and offering them access would be cost saving. Other health conditions need to be considered, including mental health conditions, surgical waiting lists whose recovery will be improved by a reduction in weight e.g. hip/knee, those who have arthritis, those with learning disabilities and those transitioning from a children's weight management service."*
>
> *ICB Medical Director*

> *"It should include patients that are waiting for hip/knee surgery, and bariatric surgery but need to lose weight first. This treatment can have a long-term positive impact on these patients, and they should only need the drug for a period pre-surgery."*
>
> *Hospital Chief Pharmacist*

"I would question whether we should include mental ill health as a comorbidity. While this might lead to us identifying a significant number of people as having an 'additional' comorbidity, there's an argument that the stigma and low self-esteem linked to obesity increases the severity of anxiety and depression, and that these also lead to comfort eating, exacerbating both issues in much the same way as the physical health conditions listed. It is possible that a 'parity of esteem' argument is being missed here."

Consultant in Public Health

"Appendix to the SURMOUNT-1 paper includes Osteoarthritis as a baseline characteristic and the physical function score on SF-36 was a secondary outcome measure. MSK conditions are the third highest cause of disability adjusted life years in England and the leading cause of years lived with a disability in England."

Clinical Lead - Policy Development

By contrast, others considered the qualifying comorbidities to be too broadly defined, raising concerns about their practical implementation

"Cardiovascular disease is too broad a term and overlaps with e.g. hypertension, dyslipidaemia and diabetes (which is essentially a cardiovascular syndrome)."

Regional Chief Pharmacist

"Sleep apnoea is a very difficult condition to identify and not readily available within our risk stratification data, also many people who have it are undiagnosed."

Integration and Transformation Manager - Weight Management Lead

"While seemingly straightforward, they can be difficult to identify in practice as they are catch-alls for a number of individually recorded conditions. Some guidance around specific condition codes would be useful."

Public Health Registrar

"I am also concerned that whilst it may be quite easy to specify on paper, clinical identification may not be quite as clear with a potential for scope creep."

Clinical Director, Medicines Management and Optimisation

The inclusion of diabetes prompted some related comments.

> *"I would prioritise type 2 diabetes as a prequalifying condition in this first cohort-2 issues addressed in one, the other risk factors do have some evidence behind them."*
>
> *ICB Medical Director*

> *"I think there needs to be further clarification about the overlap between the TA for diabetes and the TA for weight loss. The specific criteria for diabetes need to be reinforce so that diabetic patients who are overweight are not prioritised inadvertently."*
>
> *Clinical Director, Medicines Management and Optimisation*

> *"We agree with limited qualifying comorbidities but do not agree with inclusion of type 2 diabetes which were excluded from the trials. Access for this group should be via the other relevant NICE TA for type 2 diabetes."*
>
> *Lead Pharmacist - Clinical Effectiveness*

Any other comments

The following comments were also provided to NHS England as a more general response to the Funding Variation request. Only relevant comments directly relating to the Funding Variation, not covered by the answers to the previous questions, feature here.

> *"We would like to comment on workforce planning for the dietetic profession. There are considerable concerns about the amount of dietetic time predicted with the proposal i.e. 75% at 1 years and 116% at 2 years. This needs wider discussions with the British Dietetic Association, NHS Trust, primary care, and Higher education institutes to ensure what we have adequate staffing to be able to deliver this service and maintain current clinical workload i.e. nutrition support, diabetes, cardiovascular disease, paediatrics."*
>
> *Chair, Specialist Interest Group*

> *"[Withheld] does not agree that a review should be carried out at year 3. [Withheld] believe that the review of the FV should be undertaken sooner e.g. 6 monthly. [Withheld] would like to see more details on the assessment measures, what these will include, and how the impact on the rest of the system will be measured and monitored. From a legal perspective [withheld] broadly supports the FV of 12 years but aim to deliver more quickly if possible."*
>
> *ICB Medical Director*

NICE National Institute for Health and Care Excellence

Tirzepatide for managing overweight and obesity

Consultation on the application to vary the funding requirement – deadline for comments by 5pm on Thursday 24 October 2024. **To return, please upload to NICE Docs. If you have any queries, please contact TATeam1@nice.org.uk**

Please read the checklist for submitting comments at the end of this form. We cannot accept forms that are not filled in correctly.		
Organisation name –		British Obesity and Metabolic Surgery Society
Disclosure Please disclose any past or current, direct or indirect links to, or funding from, the tobacco industry.		None.
Name of commentator person completing form:		[redacted]
Comment number	**Section 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 …….. ……..
1		The British Obesity and Metabolic Surgery Society (BOMSS) welcome the NICE guidance for use of Tirzepatide to support treatment and improve health and quality of life of people living with obesity. This drug has rightly been described as game changer in the management of obesity and we welcome its introduction as an opportunity to highlight and discuss the importance of multidisciplinary management of obesity. However, despite its importance there are a number of limitations to this medication which need to be highlighted. 1. Tirzepatide does have a number of side effects and a number of patients do not lose weight on this medication. There needs to be a pathway to ensure patients who are either intolerant or hormonally resistant to medication are able to access to other appropriate treatment options. 2. The weight loss for this medication, whilst impressive, is still significantly less than that seen following bariatric surgery. This is of particular relevance in partnership with very high Body Mass Index's for whom the weight loss achieved with medication may not be sufficient to maximise health outcomes. 3. In order to prevent weight regain there is a requirement for continued medication which impacts on both cost effectiveness calculations and on estimates of the feasibility and tolerability of life long medication.

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		4. There is a limited infrastructure to support the roll out of medication- there has historically been an under provision of Tier 3 services in the UK; and whilst digital technology may well have a role in delivery of services, it is important that existing effective delivery models utilised. With respect to the specific areas for comments outlined in the NICE consultation document: **1.Roll out** - Whilst we agree in principle with the need for a phased rollout, and for a pause to ensure that the appropriate pathways are both developed and securely funded, the proposed timeline is too long. In particular, as proposed it would take 9 years for patients who meet the draft NICE criteria to access this medication. In reality, due to the numerous medications currently in development, this is likely to mean those patients will not ever access this medication as others may take its place. The delay will also lead to a continued increase in health inequalities; with those able to access the drug privately doing so. **2.Prioritisation** - Patients in Cohort 1 (ie Body Mass Index >40 and >3 co-morbidities) may be better served with weight loss surgery and this should be formally considered as an alternative option in this group before referral into medical pathway. **3.Delivery of service**- Existing Specialist weight management services have expertise and experience that may with appropriate investment be better able to support initial assessment and triage of patients into either a medical or surgical pathway. A Multi-Disciplinary Team framework and assessment which includes access to bariatric physicians, bariatric surgeons, psychologists and dieticians will enable referral of patients for medication or surgery depending on their individualised needs, preferences and choice. Overall, we are concerned at the "one size fits all model" which seems to be embedded in this proposal. We feel that patient choice should be the key determinant in treatment and that patients should be assessed within a Multi-Disciplinary Team which can recommend both medication and surgical options as needed.
2		
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Insert extra rows as needed

Checklist for submitting comments

- Use this comment form and submit it as a Word document (not a PDF).

NICE National Institute for Health and Care Excellence

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- 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.
- Do not paste other tables into this table – type directly into the table.
- Please underline all confidential information in turquoise. If confidential information is submitted, please also send a 2nd version of your comment with that information replaced with the following text: 'confidential information removed'. See the Health Technology Evaluations manual (section 5.8.51) 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 appraisal consultation 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.

NICE National Institute for Health and Care Excellence

Tirzepatide for managing overweight and obesity

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Please read the checklist for submitting comments at the end of this form. We cannot accept forms that are not filled in correctly.		
Organisation name –		Diabetes UK
Disclosure Please disclose any past or current, direct or indirect links to, or funding from, the tobacco industry.		None
Name of commentator person completing form:		[redacted]
Comment number	**Section 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 …….. ……..
1		We are concerned that there is no acknowledgment of the role that Tirzepatide could play in reducing people's risk of developing type 2 diabetes. The draft NICE decision for Tirzepatide stipulates that it can be used for people with a BMI over 35 and at least 1 weight related comorbidity. The marketing authorisation for Tirzepatide names 'prediabetes' (non diabetic hyperglycaemia (NDH)) as one of the comorbidities that it is indicated for. The funding variation references every comorbidity in the marketing authorisation with the exception of NDH. Data from the SURMOUNT-1 trial (https://pubmed.ncbi.nlm.nih.gov/37700443/) have demonstrated significant reduction in the progression of prediabetes to type 2 diabetes. The funding variation acknowledges that it plans to rollout treatment to 1.6 million after 12 years but that the eligible population without the funding variation is 2.8 million people. This leaves over 40% of the eligible population in the draft decision excluded.
2		While Diabetes UK supports the right of everyone to access NICE approved treatments they are eligible for and we understand the need for a funding variation to allow time for services and pathways to be established. We are concerned over the length of this Implementation Plan and the fact that people with diabetes won't be receiving Tirzepatide for obesity for a number of years.
3		There is currently little details and guidance on the level of support that NHS services will have to offer with prescribing Tirzepatide. The first cohort of patients to be treated are likely to be some of the most complex cases. Giving the NHS 180 days to set up a new service to treat people with a BMI over 40 and three comorbidities needs to be done with sufficient resource and expertise. There is a risk that only digital support offers will be available in time for a cohort of complex cases who may be least suitable for digital support.
4		While the lower BMI requirements for ethnic minorities is referenced in the implementation plan its low prominence means that it could be easily missed and we feel that it needs to be more clearly laid out to ensure prescribers do not miss this important detail.

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5		Clarity is needed on when to discontinue Tirzepatide for those who it is not delivering the anticipated results for.
6		It is unclear in the funding variation what, if any implications the new treatment pathways will have on existing routes to weight loss medications. It also needs to be clear if there will be any implications for people with type 2 diabetes who are accessing Tirzepatide for treating their diabetes.

Insert extra rows as needed

Checklist for submitting comments

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- 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 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.
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Please read the checklist for submitting comments at the end of this form. We cannot accept forms that are not filled in correctly.		
Organisation name –		Eli Lilly and Company
Disclosure 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:		[redacted]
Comment number	**Section 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.
1		**Executive Summary** Lilly would like to thank NICE for sharing the funding variation proposal for tirzepatide as a treatment for patients with BMI ≥35 kg/m^2 with at least one weight-related comorbidity on behalf of NHS England, and for providing the opportunity for Lilly to comment on key aspects of the proposal. Lilly trusts that their response will support NHS England in ensuring that the weight management services required to facilitate treatment with tirzepatide can be commissioned, and that primary care capacity is not overwhelmed as a result of the NICE recommendation. Overall, Lilly support the broad concept of a Funding Variation being appropriate, and agree that prioritisation should be on the basis of clinical need. However, Lilly disagree significantly with many of the specifics of the proposed Funding Variation, as detailed below. This response has three key sections, which focus on the following aspects of the funding variation proposal: 1. the proposed implementation period, 2. the populations proposed for priority access to tirzepatide, and 3. the proposed weight management services to be provided alongside tirzepatide treatment A summary of Lilly's response to each of these issues is provided below, with further detail provided in subsequent sections. **Proposed implementation period** • ICBs should seek to deliver tirzepatide within the typical 90-day period, to allow patients living with obesity to benefit from this potentially life-changing treatment without a further 3-month delay • Positive draft guidance has been available to ICBs since 4th June 2024; provision of tirzepatide would be mandated 90 days after the anticipated publication on 19th December 2024 – i.e. on 19th March 2025, some 9 months from the positive draft guidance.

- Lilly considers the request to postpone the funding mandate to a date approximately one year after first publication of positive draft guidance to be unreasonable and unnecessary, particularly given the acute unmet need in the reimbursed population and that the proposed funding variation already includes a phased approach.
- Lilly's Market Research of GPs in England and Wales (n=381) showed that even with the immense pressure that primary care is currently under, 80% of surveyed GPs stated it was either "extremely important", "very important", or "important" that their practice was able to initiate effective anti-obesity medications.

Proposed prioritisation of population cohorts for access to tirzepatide

- Patients should be prioritised on the number of comorbidities, including T2DM as a comorbidity, and stratification by BMI beyond that specified by the NICE guidance (≥35 kg/m^2) should be removed from the cohort definitions.
- Lilly notes an important factual inaccuracy regarding the list of comorbidities: the concept of 'qualifying' comorbidities that were 'tracked', as proposed by NHS England, has no basis in the SURMOUNT-1 trial, nor the evidence appraised by the Committee, nor the economic model appraised by the Committee. Lilly insists that all weight-related comorbidities should be considered, aligning with the Committee's published final recommendation and patient clinical need.
- With respect to prioritisation of cohorts, published literature shows that it is clinically inappropriate to stratify and prioritise primarily by BMI, rather than by the number of comorbidities. Disregarding stratification of BMI, beyond that specified by the NICE guidance (≥35 kg/m^2), is necessary to ensure patients with a significant burden of weight-related comorbidities do not face considerable delays to access due to the application of an arbitrary BMI threshold.
- Lilly contends that it is inappropriate to delay access for patients with T2DM and obesity, as this directly contradicts published clinical evidence, the Committee's deliberations on the economic drivers of cost-effectiveness, and NICE's recommendation to expedite referral to bariatric services in patients with BMI 35 kg/m^2 and T2DM.[1]
- Finally, the funding variation gives no consideration to cohorts such as those who need to reduce their BMI in order to access other treatments such as renal transplant, knee replacement, or IVF. For many of these people, the ability to access effective treatments is time-sensitive and urgent. In considering the funding variation, NICE must incorporate a route to timely access for such patients.

Proposed weight management services to be provided alongside tirzepatide treatment

- Lilly request NICE assess the face-validity of NHS England's contention that treatment with tirzepatide for obesity would result in an *additional* 21 GP appointments (or 3.5 hours of GP time) in the first year per patient, as well as a further 22 appointments with other healthcare professionals, on top of however many appointments the patient already has for their pre-existing weight-related comorbidities.
- Tirzepatide has been prescribed in primary care across all 42 ICBs since February 2024 for people living with obesity (BMI ≥35 kg/m^2) with one specific weight-related comorbidity (T2DM), for the treatment of

		their diabetes. Lilly does not believe patients with obesity and T2DM, currently receiving treatment in primary care, require (or receive) the intensive number of appointments that NHS England are proposing. • Lilly request that NICE seek expert clinical input from practicing NHS GPs, especially as many GPs are currently prescribing tirzepatide (same medicine, device, and titration schedule) for people with obesity and T2DM. • Orlistat, which also requires GPs to provide guidance on a hypocaloric diet and low-fat intake, is prescribable by GPs for weight management, and has been for over 20 years. Therefore, there is existing weight management experience within primary care. • Lilly contends that this is self-evidently not a proposal grounded in the reality of NHS GP practice, as supported by real world evidence, and should not be seriously considered by NICE as a basis for estimating budget impact.
2		**Section 1: Proposed implementation period (Part A)** As part of the proposal, NHS England are proposing that the funding variation should include "*an additional 90 days before any requirement on ICBs to fund the medicine, providing a 180-day implementation period*" (Part A of the proposal). Lilly believes this proposal is disproportionate for the following reasons. Firstly, and most importantly, this additional extension to the implementation period will cause further delays to patient access, in a population with a substantial and acute unmet need for effective weight loss interventions. As noted by NICE in Digital technologies for delivering multidisciplinary weight-management services: early value assessment (HTE14), many of these patients have already faced ongoing challenges with accessing effective treatment for their obesity as a result of the capacity constraints, long waiting-lists associated with existing weight management services, and inequitable access across England.[2] As such, Lilly would stress that ICBs should seek to deliver tirzepatide within the typical 90-day period, to allow patients living with obesity to benefit from this potentially life-changing treatment without a further 3-month delay. The underlying rationale for the requested 180-day period appears to be driven by the unnecessary complications proposed by NHS England in their suggested service model, which surpasses even secondary care SWMS support and that is neither relevant nor implementable in primary care. Lilly request that NICE seek expert input from practicing GPs to contextualise their understanding of NHS England's proposal. In relation to the ability to implement within 90 days in primary care, the Lilly Market Research surveyed GPs in England and Wales with the hypothetical option of other effective weight management drugs being available in primary care for a patient with a BMI ≥30 kg/m2 with at least one weight related comorbidity. Out of 381 respondents, 100% said that offering patients additional effective treatments in primary care would add value to their patients. Furthermore, 93% of GPs said that this would add value to their practice. When asked on whether this perceived value of additional effective anti-obesity medications would help tackle capacity constraints, only 3% of GPs responded with "not at all". Lastly, even with the immense pressure that primary care is currently under, 80% of surveyed GPs stated it was either "extremely important", "very important", or "important" that their practice was able to initiate effective anti-obesity medications. For the full report and methodology, please see the Lilly Market Research document submitted as part of our NICE Appraisal for tirzepatide.

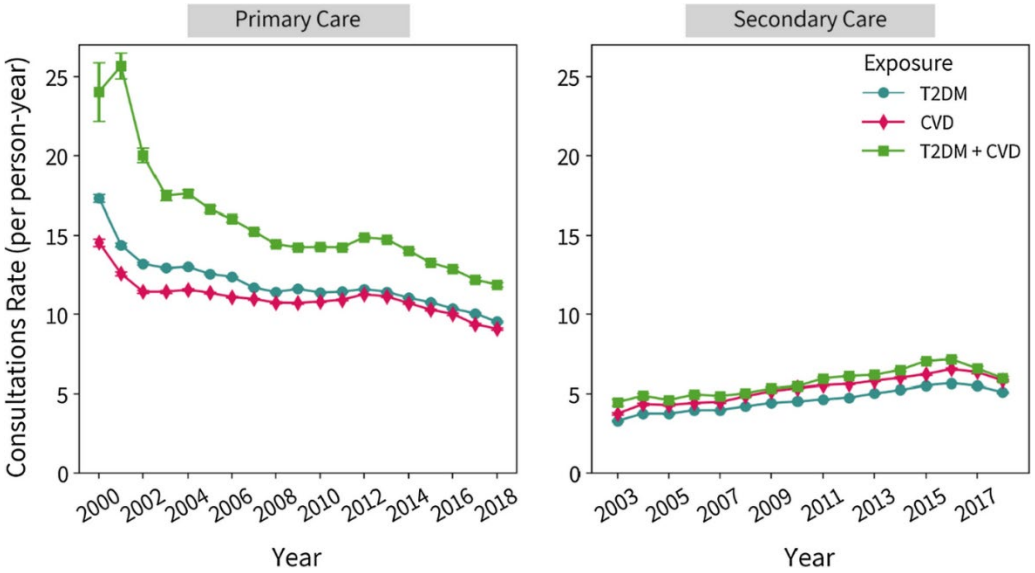
		Lilly acknowledges that the purpose of the extension is to provide ICBs with a longer window to establish and operationalise the tirzepatide treatment pathway. However, Lilly notes that the draft guidance for this appraisal (which recommended tirzepatide for patients with BMI ≥35 kg/m^2 with at least one weight-related comorbidity), has been available to ICBs since 4th June 2024. This has provided ICBs ample time to start planning for the final draft guidance for tirzepatide and for the provision of tirzepatide to be mandated. Assuming the technological appraisal guidance is published on 19th December 2024 per NICE estimates, this would mean ICBs would have until 19th March 2025 to make tirzepatide available to patients within the usual 90-day window – over 9 months after the first positive draft guidance was published. Furthermore, with the publication of the funding variation proposal on 3rd October 2024, planning for the delivery of tirzepatide to the first prioritised cohorts can begin, some 5 months before the treatment for tirzepatide will be mandated. In summary, Lilly considers the request to postpone the funding mandate to a date that is essentially one year after first publication of positive draft guidance to be unreasonable, unnecessary, and to the detriment of patient care.
3		**Section 2: Proposed prioritisation of the cohorts eligible for tirzepatide** Parts B and C of the proposal focus on outlining the proposed phased approach to the roll-out of tirzepatide, including defining cohorts of patients within the full BMI ≥35 kg/m^2 recommendation who will be prioritised. Initially, NHSE propose delivering tirzepatide to Cohorts I–III – patients with a BMI ≥40 kg/m^2 with ≥3 'qualifying' comorbidities, 2 'qualifying' comorbidities, and 2 'qualifying' comorbidities (incl. T2DM), respectively. The roll-out of tirzepatide would then expand to Cohorts IV–VII in a stepwise fashion. Cohort IV includes patients with a BMI ≥40 kg/m^2 and 1 'qualifying' comorbidity (incl. T2DM), whilst Cohorts V–VIII include patients with a BMI 35–39.9 kg/m^2 with ≥3 'qualifying' comorbidities, 2 'qualifying' comorbidities, and 2 'qualifying' comorbidities (incl. T2DM), respectively. Lilly's rationale for reprioritising cohorts is outlined below. **Factual inaccuracy: the concept of 'qualifying' comorbidities** In point 7 of Appendix D of the funding variation proposal, NHSE states that the "*clinical cohorts are based on a hierarchy of need and use the following qualifying diagnosed comorbidities only, matching those tracked through the SURMOUNT-1 trial*", listing hypertension, dyslipidaemia, obstructive sleep apnoea (OSA) and cardiovascular disease (CVD) as these 'qualifying' comorbidities. Lilly requests that the concept of 'qualifying' weight-related comorbidities is removed from the proposed framework and that the NICE recommendation of "a weight-related comorbidity" is used throughout the funding variation instead. This is because Lilly considers that this justification for the 'qualifying' comorbidities in the funding variation proposal is based on a factual inaccuracy, since this list does not reflect the eligibility criteria for patients with a BMI ≥30 kg/m^2 included in the trial (only patients with a BMI ≥27 kg/m^2 and <30 kg/m^2 were required to have one of these comorbidities mentioned to be eligible for the trial). It also does not reflect the comorbidities recorded at baseline for patients included in the SURMOUNT-1 trial since patients in the SURMOUNT-1 trial had a wide variety of weight-related comorbidities, many of which are not listed in the NHSE's list of 'qualifying comorbidities'. Finally, it does not reflect the outcomes that were measured throughout the trial duration (e.g. OSA [or relevant surrogate endpoints for this comorbidity] was not tracked as an outcome in the SURMOUNT-1 trial). Lilly are therefore unclear on what 'tracked' comorbidities NHSE are referring to and see no clinical rationale for selecting this restrictive list that would exclude patients with

		other weight-related comorbidities who are covered in the MHRA license for tirzepatide and the published Committee's recommendation for tirzepatide. **Prioritisation: inappropriate cohort stratification** To ensure the prioritisation framework reflects true clinical need, Lilly contends that patients should be prioritised on the number of comorbidities, and that stratification of BMI beyond that specified by the NICE guidance (≥35 kg/m^2) should be disregarded from the cohort definitions. This is because whilst increasing BMI is associated with the development of weight-related comorbidities in patients with obesity, it is recognised in the literature that, in general, it is the comorbidities that increase the risk of mortality except at extreme BMIs.[3] . Given this, Lilly contends that stratifying the proposed cohorts firstly by BMI, and only secondarily by comorbidities, will lead both to incorrect ordering (with respect to clinical need) and also to perverse threshold effects, whereby a person with BMI 40 + 1 comorbidity receives treatment 3 years before a person with BMI 39.9 + 3 comorbidities, whose clinical need is almost certainly greater. Defining priority groups based on the presence of the number of comorbidities, rather than both BMI and comorbidities, would avoid the current situation where 0.1 of a BMI point could be the difference between timely versus significantly delayed access to tirzepatide (potentially by several years). Furthermore, such an approach would allow NHS England to implicitly capture those with higher BMIs in the highest priority cohorts, without needing to define arbitrary BMI threshold(s) that may create significant disparities between individuals with similar BMIs. It would also still ensure primary care capacity is not overwhelmed as a result of the NICE recommendation. Therefore, Lilly requests that patients should be prioritised on the number of comorbidities, including T2DM as a comorbidity, and stratification by BMI beyond that specified by the NICE guidance (≥35 kg/m2) should be removed from the cohort definitions. **Prioritisation: inappropriate to deprioritise T2DM** Lilly would also urge NHSE to reconsider their approach to patients with comorbid T2DM, as deprioritising these patients versus those with other 'qualifying' comorbidities in the current framework is clearly not reflective of clinical need. Firstly, it is important to note that Edmonton Staging Score and Kings Criteria both state T2DM is a minimum stage 2 criterion, indicating its high importance as a comorbidity that should be considered when assessing patient need. Lilly would further remind NICE that prediabetes at baseline, and input parameters relating to modelled T2DM, were key drivers of cost-effectiveness and central to the Committee's deliberations. As such, the proposal by NHS England to deprioritise people with T2DM in the funding variation, and to exclude prediabetes from their list of 'qualifying' comorbidities, goes directly against the evidence from the literature and the Committee's deliberations on the economic drivers of cost-effectiveness. This approach would also contradict the CG189 guidelines for obesity, which explicitly state that those with comorbid T2DM would "particularly benefit from immediate weight management interventions".[1] Finally, it would be illogical to suggest that the T2DM comorbidity is of lower risk in the stratification framework whilst NICE simultaneously recommend expediting referral to bariatric services in patients with BMI 35 kg/m^2 and T2DM.[1] Therefore, Lilly requests that patients with T2D should be included as a comorbidity from the start, alongside all other weight-related comorbidities, and not delayed to later cohorts.

		Prioritisation: consideration of other cohorts with urgent unmet need In addition to the wider point regarding comorbidities, the funding variation gives no consideration to cohorts such as those who need to reduce their BMI in order to access other treatments such as renal transplant, knee replacement, or IVF. For many of these people, the ability to access such other treatments is time-sensitive and urgent. Therefore, Lilly requests that the funding variation must incorporate a route to timely access for patients with urgent unmet needs.
4		**Section 3: Proposed weight management services to be provided alongside tirzepatide treatment** Lilly was concerned to see the proposed service model proposed by NHS England. This appears unchanged from previous proposals submitted by them during the appraisal process, and the significant and detailed feedback from Lilly, clinical experts, patient expert, and EAG provided during the appraisal and ACMs seems to have been largely ignored. Lilly request firstly that NICE assesses the face-validity of NHS England's contention that treatment with tirzepatide for obesity would result in an *additional* 21 GP appointments (or 3.5 hours of GP time) in the first year, as well as a further 22 appointments with other healthcare professionals, on top of however many appointments the patient already has for their pre-existing comorbidities. Lilly contends that this is self-evidently not a proposal grounded in the reality of NHS GP practice and should not be seriously considered by NICE as a basis for estimating budget or workforce impact. Lilly provides further detailed critique below and request that NICE seek expert clinical input from practicing NHS GPs, especially as many GPs are currently prescribing tirzepatide for people with obesity and T2DM, which is reflective of the population that would also be eligible for tirzepatide under the current recommendation for obesity. **Anchoring resource use estimates in the wider context: real-world data from the management of other complex conditions in NHS primary care** Prior to considering the NHS England proposals in detail, it is important to examine real world data on existing NHS management of similarly complex conditions in primary care. A team of authors led by Kamlesh Khunti and David Webb from Leicester published a retrospective analysis of 141,328 adults in England, investigating consultation rates in people with type 2 diabetes, with and without vascular complications:[4] • The papers methods were summarised in the abstract "Observational, retrospective cohort study used linked Clinical Practice Research Datalink primary care data from 01/01/2000 to 31/12/2018 to assess consultation rates in 141,328 adults with newly diagnosed T2DM, with or without CVD." Patients who entered the study with either a diagnosis of T2DM or CVD and later developed the second condition during the study are classified as the cardiometabolic multimorbidity group. Face to face primary and specialist care consultations, with either a nurse or general practitioner, were assessed over time in subjects with T2DM, CVD, or cardiometabolic multimorbidity. Changes in the average length of consultation in each group were investigated. • The analysis compared those with cardiometabolic multimorbidity to those with T2DM or CVD alone, and also tracked changes in care patterns over time.

- Figure 1 reports “Annual crude consultation rates for primary and specialist care by exposure status. *HES outpatient data was not recorded until 2003, therefore the axes have different time periods”

Figure 1[4]



- These real-world data show that even those with cardiometabolic multimorbidity had a *combined total* of GP and nurse visits below 15 per annum in the period 2014–2018, with single morbidity patients having fewer again.

Anchoring resource use estimates in the wider context: real-world data from the management of existing tirzepatide prescribing in NHS primary care

As per NICE TA924, since February 2024, tirzepatide (identical doses, identical titration schedule, and as an adjunct to diet and exercise) has been prescribed in primary care for people living with obesity (BMI ≥35 kg/m^2) with one specific weight-related comorbidity (T2DM), for the treatment of their diabetes. This has occurred across all 42 ICBs in England within primary care.

Within the appraisal leading to TA924, NHS England did not request that these patients require 3.5 hours of GP time nor an additional 7.1 hours of HCP time within the first year. Furthermore, while these patients have obesity and receive tirzepatide, there was no suggestion from NHS England that mandatory psychological support is needed, as it is expected that this support would be provided as part of routine care. While additional advice, as per CG189 and the licence, should be provided to patients where they should follow a reduced-calorie diet and increased physical activity, Lilly does not believe this requires a complete overhaul of primary care to achieve this. A similar approach to how GPs provide diet and exercise advice when prescribing orlistat should be followed.

In the month of July 2024, approximately 20,000 new patients were initiated on tirzepatide in primary care within England (OpenPrescribing).[5] Lilly does not believe patients with obesity and T2DM currently receiving treatment in primary care require (or receive) the intensive number of appointments that NHS England are proposing. Lilly request that NICE seek expert clinical input from practicing NHS GPs.

Factual inaccuracies and detailed critique

The following factual inaccuracies should be noted for the NHSE-proposed service model:

		• No blood tests are required in the SmPC for tirzepatide, and therefore none should be required in the service model. • Lilly notes that orlistat (SmPC also states it should be used alongside a mildly hypocaloric diet) is prescribable by GPs for weight management, and has been for many years, thus NHS England's contention that no weight management pharmacotherapy is currently available in primary care is incorrect. In July 2024, 47,899 prescriptions of Orlistat was made in primary care, indicating that GPs are already prescribing weight management pharmacotherapy for more patients than the initial cohort proposed by NHS England.[5] • Lilly would also note that in during ACM3 the contention by NHS England that one in three patients would require psychological support was disagreed with by even the EAG. Furthermore, psychological support is not specified in the SmPC for tirzepatide, nor was it provided in SURMOUNT-1. Beyond these factual inaccuracies, Lilly wishes to re-iterate that the proposed service model is deeply unrealistic for primary care, and does not align with RWE on similarly complex conditions. In fact, the NHSE proposed service model is more intensive than a SWMS model, which was created for bariatric candidates requiring intensive support to manage their obesity. Such an approach is neither realistic nor implementable in primary care for patients seeking access to tirzepatide. Instead, the service model provided along tirzepatide should focus on prevention of future comorbidities and earlier treatment, to help keep treatment closer to home and patients out of costly secondary care. This could be achieved through adopting an approach akin to that provided in primary care for patients with other chronic diseases for the majority of patients with obesity. Such an approach would align with what is currently available to people with obesity in primary care (as per CG189)[1] and relies on collaboration between different primary care healthcare professionals, usually through the exchange of patient notes, rather than requiring additional resource-intensive in-person meetings. Considering both the factual inaccuracies highlighted above and the broader issues regarding the infeasibility of delivering the proposed service model in primary care, Lilly proposes significant revisions (as previously submitted during this appraisal) are made to the number, duration and assumed required resource of appointments. Lilly also requests that NICE considers the ACM 1–3 feedback from the clinical experts, patient expert, and EAG, who disagreed with various aspects of the NHS England proposed model.

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- Do not paste other tables into this table – type directly into the table.
- Please underline all confidential information in turquoise. If confidential information is submitted, please also send a 2nd version of your comment with that information replaced with the following text: 'confidential information removed'. See the Health Technology Evaluations manual (section 5.8.51) 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.
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1. National Institute for Health and Care Excellence (NICE). Obesity: identification, assessment and management [CG189]. Available at: https://www.nice.org.uk/guidance/cg189. Last accessed: August 2023.
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Organisation name –	NHS England
Disclosure Please disclose any past or current, direct or indirect links to, or funding from, the tobacco industry.	N/A
Name of commentator person completing form:	[redacted]

Comment number	Section 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.
1		NHS England, as authors of the Funding Variation request on behalf of NHS and Integrated Care Board (ICB) commissioners, endorse and support the proposed Funding Variation for tirzepatide for obesity and weight management. As lead drafters, we do not have further comments to provide on top of the content already provided to NICE in the Funding Variation documentation. We believe this submission states the case for acceptance of the Funding Variation request and we have chosen not to replicate here content provided in those materials.
2		To this end, NHS England has conducted a second tirzepatide survey of ICB representatives, to allow ICBs not registered as consultation stakeholders to be directly represented through this consultation process. The remaining content of the NHSE Funding Variation submission focusses on the feedback provided to NHSE through this survey. Please see the accompanying annex (Annex A) for the details of the remainder of the NHS England consultation submission.
3		
4		
5		
6		

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replaced with the following text: 'confidential information removed'. See the Health Technology Evaluations manual (section 5.8.51) for more information.

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Organisation name –		Novo Nordisk Ltd
Disclosure Please disclose any past or current, direct or indirect links to, or funding from, the tobacco industry.		**NA**
Name of commentator person completing form:		[redacted]
Comment number	**Section 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.
1	Annex D	**Need for a broader framework acknowledging all obesity treatments within the national health service (NHS)** Novo Nordisk (NN) welcomes the recognition of the burden of obesity on people, their families, the healthcare system and society as a whole as well as the implementation challenges of existing NICE technology appraisal (TA) guidance, such as TA875 on semaglutide for managing overweight and obesity. While we also acknowledge the importance of a sustainable approach to expand services in order to limit the impact to budgets, it is important to highlight that various mechanisms are already in place to address this. The Voluntary Scheme for Branded Medicines Pricing, Access and Growth (VPAG) defines the allowable growth from the branded medicines budget with any overspend rebated by the industry. The budget impact test (BIT) and NICE and the health technology appraisal by NICE ensures that all new treatments recommended for use by the NHS are clinically and cost-effective and that their introduction is affordable. With these mechanisms in place, the affordability of new treatments should be warranted. Given that the process requires NHSE to propose a funding variation there is a need for the implementation proposal (IP) to consider that weight management services (WMS) provide holistic multidisciplinary management, with all treatment options, allowing patients and clinicians the choice of the most suitable individualised treatment option (i.e., lifestyle intervention, pharmacotherapy and bariatric surgery). NN agrees with the position statement published by the Obesity Health Alliance (OHA) which recommends the issuing of an overarching central guidance with the publication of an overweight and obesity management pathway ensuring a whole system approach. The proposed clinical setting should therefore offer the patients and clinicians their choice of the most suitable intervention which is licensed and has demonstrated to have efficacy and to be cost-effective, and not designed around one pharmacological therapy alone.

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		The IP recommends starting with those with greatest clinical need based on body mass index (BMI) and obesity-related comorbidities however it does not account for interventions already available within existing NHS services which these patients would qualify for, including bariatric care and semaglutide 2.4mg. Based on the suggested clinical cohorts outlined in Table 3, there is a risk that people living with obesity with complex needs will not be triaged to receive multidisciplinary support which may include surgical intervention. NICE clinical guideline (CG) 189 states that surgery should be available to suitable patients with a BMI ≥40 or between 35 and 39.9 if they have a significant health condition. As stated by OHA there is a need to review the existing tiered system more broadly and explicitly acknowledge all available treatment options. This approach will ensure equitable and consistent access across England to WMS, irrespective of service setting. Patients should be empowered to make informed decisions from a range of treatment options based on their individual needs and risks. Recommendations: NN proposes that the implementation plan explicitly acknowledges the various treatment options available within the NHS and defines the treatment pathway for the clinical cohorts who qualify for them. NN also recommends that this framework is inclusive of all treatment options that could be delivered in primary care, rather than being limited to a single treatment option.
2	Annex D	**Clinical cohorts** Cardiovascular disease (CVD): It is imperative that, where there are obesity treatments available on the market for people with CVD that have both evidence supporting cardiovascular outcomes and a relevant licensed indication, these are called out and used as the first choice for patients. The NHS's suggestion to the contrary, favouring tirzepatide despite its lack of supporting evidence and a specific license, undermines the significance of evidence-based policy planning. The qualifying cohorts identified within the IP appear based on the inclusion criteria of the SURMOUNT-1 population and do not account for trial outcomes or evidence supporting use specifically in these comorbid groups. Whilst CVD was defined in SURMOUNT-1 as *'for example, ischemic cardiovascular disease, New York Heart Association (NYHA) Functional Class I-III heart failure'*, the actual proportion of patients within SURMOUNT-1 who met these criteria was not specified. Rather 'ASCVD', a broad term that encompasses ischaemic cardiovascular disease but is not synonymous with heart failure, which can be both due to ASCVD/ ischaemic cardiomyopathy but also non-ASCVD/non-ischaemic cardiomyopathy, was used, indicating misalignment from the above inclusion criteria used as a patient characteristic. Of the total patient population included in SURMOUNT-1, only 78 people (3%) were noted to have ASCVD. This extreme lack of representation means the results of SURMOUT-1 cannot reasonably be extrapolated to an entire patient population of 'cardiovascular disease. This risk is compounded by the lack of definition of 'cardiovascular' disease, which goes beyond ASCVD, within the IP. Further to this, cardiovascular outcomes were not tracked through the SURMOUNT-1 trial. Whilst surrogate endpoints of blood pressure and dyslipidaemia were tracked as secondary outcomes, there were no meaningfully tracked outcomes of CVD such as myocardial infarction, stroke, hospitalisation for heart failure, death related to CVD or

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		other relevant CVD events such as unstable angina, coronary interventions (such as coronary artery bypass graft [CABG] or percutaneous coronary intervention [PCI]), or transient ischemic attack. These events were measured on an **aggregated basis** for adverse event purposes only, and in total <1% (14 people) across the entire trial (treatment and control arm) ultimately experienced such an event. Semaglutide 2.4mg is the only available pharmacological treatment that is specifically licensed in people with cardiovascular disease and a BMI ≥27 kg/m^2 both for the reduction of major cardiovascular events. It has been recommended in this population by the European Society of Cardiology (ESC) to reduce CV mortality, myocardial infraction (MI) and stroke. This license is based on phase III cardiovascular outcomes trial data, based on a population of over >17,000 all of whom had defined cardiovascular disease, and demonstrated clear cardiovascular outcomes benefit in preventing major adverse cardiovascular events [SELECT]. Use of a pharmacological therapy for obesity in this patient group, where treatment need is based on the risk of cardiovascular disease, must be evidence-based. As the NHS have defined tirzepatide as a 'first in class therapy', any extrapolation from semaglutide (a different class of drug) and the SELECT data to cover CVD is wholly inappropriate. On this basis, cardiovascular disease should be removed as a qualifying cohort. Further, a note should be made that in management of cardiovascular risk associated with a BMI ≥27, semaglutide which has indications in cardiovascular risk management and obesity, should be used in preference because of the proven MACE benefit. BMI: The IP proposes that the treatment initially be offered to people with BMI ≥ 40 however CG189 warns of interpreting BMI with caution, as it is not a direct measure of central adiposity. This is backed by other publications that recognise the limitations of BMI as a diagnostic criterion and is in line with the proposition of the clinical experts in the 3rd tirzepatide for obesity committee meeting where, when asked which patients should be prioritised, the clinicians suggested four patient categories that were regardless of BMI classification. Inequity: The qualifying cohorts appear to be based solely on the comorbidities noted in the inclusion criteria of SURMOUNT-1 trial (hypertension, dyslipidaemia, obstructive sleep apnoea and cardiovascular disease) and type 2 diabetes (T2D)), without reference to the health need or cost-effectiveness of these groups. Obesity is linked with numerous comorbidities, as highlighted by the WHO consultation on obesity, which has documented the complications that respond to weight loss and have substantial consequences on healthcare resources and costs, patients' quality of life, and/or life expectancy. The approach taken to identification of the qualifying cohorts does not account for any level of cost-effectiveness or health need across the patient populations identified and in fact has failed to identify or isolate patient populations who could be expected to achieve the most benefit. As a result, the explicit definition of the qualifying comorbidities raises significant concerns of inequity in the identification of patients proposed to either be of 'highest need' or expected to achieve 'highest

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		benefit' from this therapy. These risks deprive and delay patients with significant comorbidities from fairly and equitably accessing the treatment they could reasonably expect to benefit from. Recommendations: Given the limitations of BMI, especially its inability to be a measure of central adiposity, NN proposes exclusion of BMI criteria as a defining tool for identifying patient cohorts. Rather, inclusion of more reliable screening tools such as the waist to height ratio which is included in the NICE draft guideline for overweight and obesity management and the Edmonton obesity staging system, used in the NHS Scotland consensus statement should be considered to ensure health need is at the forefront of patient identification. To avoid the inevitable equity and fairness issues and acknowledging the significant concerns and misalignment with evidence-based process noted for cardiovascular disease above, NN proposes that the weight related comorbidities referenced in the funding variation cohorts are not specified.
3	Annex D	**Management of existing backlog** Aspects prohibiting patient access to weight management service: The IP documents do not make any mention to the substantial number of people with obesity who already wait to be referred for obesity treatment. There is no mention of people on NHS waiting lists, despite OHA stating that waiting lists are now routinely reaching three to five years. Additionally, there are people who cannot get onto the waiting lists as they have been closed due the service being oversubscribed and finally people who have no access to WMS. Risks associated with patients waiting to receive treatment: As the clinical cohorts in the IP do not account for the severity of comorbidities and quality of life measures, individuals with a BMI≥35 and significant comorbidities will be waiting in excess of 83 months to receive treatment with no acknowledgement that worsening of their condition and increase in BMI may occur within this timeframe. Notably, there is uncertainty regarding patients in the lowest priority bands who are already on the waiting list, including whether they will need to rejoin the queue or if there will be a transitional period to address the backlog. Recommendations: NN agree with OHA that significant barriers to treatment need to be addressed. We recommend this starts with prioritising patients within services with no access to treatment. A solution for the backlog could be found via digital technologies approved in NICE's early value assessment. As stated by NICE: "They will particularly benefit people who do not have access to multidisciplinary weight-management services in their area or who are on a waiting list, so are not currently supported by a multidisciplinary weight-management service". We propose utilising dynamic triaging or waiting list management (to ensure escalation if risk changes over time). In addition, resources associated with triage of current waiting lists need to be identified as this has not been done as part of the IP documents
4	Annex D	**Funding variation governance** The IP covers an intricate delivery model with a number of specified patient cohorts and timelines however there is no mention of a mechanism to safeguard that these right cohorts of patients are accessing the services at the right time. It is also not

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		clear what performance metrics will be put in place for the delivery of the IP. Given the National Obesity Audit (NOA) is being developed to monitor and evaluate the effectiveness of NHS weight management services clarification is needed on whether the proposed IP would be in scope of the NOA. Recommendations: NN proposes that a monitoring mechanism is considered to ensure the smooth implementation of the guidance. Monitoring needs to be employed at each stage as the assumptions are based on population prevalence and do not account for patient activation. With the addition of new interventions in the health system and the considerations for expanded access there is need for a holistic approach to monitor treatment provision. Alongside this guideline, there is a need for practical resources, such as an evidence based patient pathway, to provide commissioners and clinicians with the necessary support needed to make clinical and funding decisions locally.
5	Annex D, section 12	**Data assumption inconsistencies** A set of assumptions has been used to generate the data that informed the IP including the treatment discontinuation rate. It is assumed that 5% of patients will drop out of treatment every 6 months however it is unclear where this number derived from. During the appraisal of tirzepatide the EAG's preference was to assume that for the 1st year patients will drop out due to not responding (3.74%) and due to adverse events (6.73%) however after that only 1% of patients was expected to drop out every year. Recommendations: NN would like to request clarity on the calculation of the drop-out and urges the need for consistency in the assumptions used in the process.

Insert extra rows as needed

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Organisation name –		**Royal College of General Practitioners**
Disclosure Please disclose any past or current, direct or indirect links to, or funding from, the tobacco industry.		**None**
Name of commentator person completing form:		[redacted]
Comment number	**Section 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		Submission Template Variation to Funding Period by NHSE
1	5	We are in general supportive of a phased approach in three parts as suggested (ABC) but question the rationale and evidence behind of the timescales for the phasing in stages B and C.
2	5 and Annex D	We are concerned that the implementation of 9 yrs over 7 phased cohorts shall mean that over the first 3 years the eligible cohorts shall move slowly to around 5% of the total eligible population. This shall have an unaccounted impact on general practice with regards to the potential impact of patients who do not meet the NHS criteria but who may meet the drug licence criteria seeking the support from NHS general practice. This role could be in supporting an understanding around the eligibility, making referrals into a local intermediate service or in house arrangements or accurate up to date recording of weight on a regular basis (this is not currently commissioned beyond QOF areas), There is also the risk of unintended consequences of patients seeking to increase their weight to meet the eligibility standards. We are concerned that as only 5% of the total eligible population shall in fact be **ineligible** after the first 3 years and that this may drive an increase in private clinics which may have two consequences a) not providing a holistic service which includes psychological, nutritional and exercise support b) cause a shift in the general practice workforce to support general practice weight loss clinics. There is a potential risk of this shift to private care on quality issues in NHS practice. Ongoing monitoring of chronic conditions is necessary whilst on Tirzepatide and regular medication review to ensure there is no negative impact of prescribing. There are a range of conditions where deprescribing or down titration of medication is required to avoid serious harm consequently. (This is seen currently with digital weight management services where the monitoring of prescribing disease monitoring takes place separately to a remote service). We call upon Commissioners to consider the opportunity to ensure more adequate funding to support GP retention and allow modelling for a greater GP workforce to deliver against this and other areas of new clinical practice.
3	5 and Annexe D	We are concerned that current commissioning arrangements by NHSE around weight management services are confusing (for both patients and professionals). There is a

		lack integration with services commissioned across ICBs through local authorities and health commissioners. We recognise and support the need to that in many areas of the country that diet exercise and behavioural approaches are not universally commissioned and support NICE Clinical Guideline 189 where pharmacological treatment should be considered after dietary exercise and behavioural approaches have been started and evaluated. We believe that an emphasis on dietary quality as well as reduced calorie diet is needed. The support of adequately trained dieticians and the specific support needed to consider of Ultra processed foods taking into account the evidence from metabolic ward studies. We recognise that malnutrition is also a risk in those who are living with obesity and the unmasking of mineral and vitamin deficiencies as well as conditions like sarcopenia in older patients is required to be considered in the clinical pathway. We welcome the modelling of Dietician sessions into the implementation plan in Annexe D however would need to understand the model of delivery within these sessions and how they integrate with general practice. We would support that these approaches continue alongside pharmacological treatment to deliver the improved sustainable outcomes that are needed. We are concerned about the separation of commissioning arrangements between ICBs and NHSE Specialised Services and call for a whole system approach to commissioning where commissioning occurs across the whole obesity pathway and funding is invested up front in the pathway.
4	5 Annexe D	We have concerns about the reliance on the SURMONT trial data and would recommend that during the review at the 3 yr period further evidence around the long term outcomes is taken into account with effectiveness data. The SURMONT - 4 trial showed that that withdrawing tirzepatide after 3 yrs led to a substantial regain of lost weight. If we need to adopt a sustainable long-term approach it is important that behavioural approaches continue to support patients and further health outcome data (not just weight) is collected to ensure the maximum benefit to patients with the least time on medication. The trial data was not well represented by groups from more deprived communities where confounding factors such as multiple comorbidities polypharmacy and confounding factors like malnutrition were not considered. We welcome the opportunity in the Funding variation and implementation pause at 3 yrs to consider real world evidence and would like to emphasise the need to take into account ensuring that we don't unintentionally widen the health inequality gap for deprived communities. An intensive population health driven personalised approach must be a part of future delivery and the equality impact assessment is welcomed and needs to be reviewed closely at every stage of implementation.
5	5 Annexe D	We are concerned that NHSE have identified five different delivery models in partnership with ICBs however the details of these 5 models has been redacted. We are therefore unclear on the role of general practice in these 5 models and call for openness and transparency with the RCGP. We believe that there can be increased additional capacity in general practice to meet demand with extra core funding. We believe that General Practitioners have the capability to support the treatment pathways and undertake prescribing and monitoring and recall of patients on this medication but to also coordinate a holistic personalised approach incorporating nutritional and exercise support. The RCGP GPwER in lifestyle medicine provides support and professional standards specifically around this area and we would like this to be recognised within the new models of care that are being developed.
6	6	We welcome that NHS England has not entered a commercial arrangement with Eli Lilly and recognise that this is on the basis of the first 3 years of implementation. We call for continued transparency around future funding arrangements as this has an

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		impact on workload and prescribing budgets which is under the management of general practice.
7	7	We call upon DHSE and NHSE to not only consider new costs of Tirzepatide and the creation of a new Tirzepatide pathway but to consider the opportunities for the GP workforce through extra retention of staff over this funding period. The investment in the service needs to include not only the costs of the time to deliver a service but the ongoing training and sustainability of the workforce through ongoing education and quality improvement. The current outline does not make it clear how much of this cost shall go to ongoing support for workforce retention and sustainability in general practice.
8	Whole document	We are concerned that the funding variation does not include information on the statutory duties to address the net zero emissions target. We would recommend that this is built into the implementation plan alongside the funding variation that is required. We would like to see this reflected in the commercial arrangements as well as service delivery and that a clear net zero impact assessment is made alongside the Budgetary Impact test. The RCGP remains committed to its priority of environmental sustainability and impacts to the environment.
9	9	We call upon NHSE and NICE to specifically work with RCGP in part A of the implementation period regarding clinical and pathway guidance (specifically with the Clinical policy team in RCGP). We have a team of clinical advisors many of which have experience in prescribing and weight loss support. We also have developed a framework for GPwER in lifestyle medicine which could support pathway implementation. Although we have so far not been a part of the process of design of the 5 models we feel it is important in terms of the central role of General Practitioners in delivering the pathway changes and the role of the College in supporting the delivery of quality of care by GPs. We need a clear understanding of the 5 proposed models and how General Practitioners work within each of these models and support is needed to give clarity to both the public and professionals. We would expect resources around local and national communication to be available.as well as pathway guidance at both a national and local level.

Insert extra rows as needed

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Organisation name –	Hertfordshire and West Essex ICB
Disclosure Please disclose any past or current, direct or indirect links to, or funding from, the tobacco industry.	None
Name of commentator person completing form:	[redacted]

Comment number	Section 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		
1		The majority of Commissioners, ICBs, including Hertfordshire and West Essex (HWE) ICB could not implement a positive NICE recommendation for tirzepatide for primary care/general practice within a 90-day implementation period. A funding variation is supported, The resource, capacity, funding and workforce, does not exist to implement this recommendation, The infrastructure and education are also not in place. Required pathway and service re-design and procurement could not be met in this timeframe. Significant funds would have to be diverted from other services, creating further inequality. If mandated to implement within a 90 day implementation period there would be a high risk of reputational damage and legal challenge/ judicial review for ICBs. Many ICBs are faced with the affordability dilemma, of either breeching their statutory financial responsibilities, their statutory responsibilities with respect to NICE TAs or both.
2		The majority of Commissioners, ICBs including HWE ICB support the funding variation based on both clinical need and BMI. The first cohort is still large (likely larger than estimated nationally) and there is a risk of widening health inequalities if access is based on who seeks it first. There are a number of additional criteria that have been suggested to further prioritise and reduce health inequalities within each cohort, including mental health status, deprivation score, clinical need for urgent weight loss (e.g. to access life-changing therapy or surgery) and Edmonton Obesity Staging System. Some of these may need to be considered for access at a lower BMI. Ideally, this would be set out in the national funding variation, rather than locally determined.
3		The majority of ICBs, including HWE ICB support the three year review of funding variation progress, however there is concern regarding managing the patient expectations of the cohort to be eligible for this treatment in the later years and responding to patients requests for treatment indicating that they are eligible within NICE thresholds. It is essential to ensure that public communications are unambiguous and well joined both up nationally and locally.
4		Clear public information about the funding variation, including that eligibility at any one time

		is based on the funding variation cohorts (and local roll-out progress) rather than the NICE TA, must be made available when the NICE TA is published to manage demand on already stretched services, who will be further stretched in the winter months.
5		Regardless of the local delivery model, many patients interested in this new treatment (including significant numbers who are not eligible – either at all, or due to the phased roll out) will approach their GP in the first instance. This increased demand for primary care appointments will exacerbate national issues with GP access. Already insufficient primary care resources diverted to this area. This will have an adverse effect on all patients, including worsening patient experience and increased clinical risk of delays to assessment and treatment. It will also widen inequalities in GP access, depending on registered GP and the population served. This is at a time when patient satisfaction with primary care is at its lowest ever level (Darzi 2024) and as we head into Winter when service demand is at its highest. This risk needs to be carefully mitigated. Flexibility in the local models of delivery (supported by nationally produced example service specifications etc) is appreciated so that struggling GP practices are not forced to deliver this additional service. Additionally, patients must be clear who is eligible at any given time, without needing to see their GP. GPs should be supported with resources and clear messaging to manage patient interest and demand. Communications must be at the appropriate level for the general population. Mixed messaging (which is a risk with the TA vs funding variation eligibility and also national plans vs local plans) must be minimised. Any national plan for roll out therefore needs to be fully implementable locally – and the proposed funding variation will only be implementable with sufficient central funding and support.
6		Due to the large eligible cohort defined in the TA, there will be a large cohort of patients who will expect to be able to access tirzepatide for weight loss immediately. This cohort is expected to be even larger than the NICE estimate of patients who would be eligible for this treatment, as the estimate is considered to be unrealistically lower than in practice. Immediate roll out to the whole eligible cohort is not possible. Roll out to the **whole** of the first proposed cohort **on day 1** (in 180 days) is also not possible. Whilst this may seem obvious, it may not be obvious to patients eager to access this new treatment. Patient expectations of access in the later years of implementation are also a significant concern. Careful commucations are needed to manage demand and avoid a poor experience and associated complaints from patients who can't access tirzepatide yet.
7		Neither the TA nor the funding variation align with Tier 2, Tier 3 and Tier 4 services, nor do they consider the whole patient pathway including other treatments from lifestyle support to bariatric surgery. There is a risk that the patients who would benefit most from more holistic support, including more intensive psychological support, to sustainably change their lifestyle and improve their general health and wellbeing as well as their weight, will miss out by accessing tirzepatide with "light-touch" wrap around care instead of tier 2 and tier 3 programmes. These people may be left dependent on life-long use of a medication with no

		long term safety data. Meanwhile, in some areas of the country, people with lower clinical need can access semaglutide plus tier 3 support, This will increase health inequalities. There are groups of patients who would not meet the initial cohort for tirzepatide but a clinically high priority (e.g. BMI under 40 but high EOSS, or urgent need to lose weight for life-changing therapy or surgery), who may be unable to access tier 3 +/- semaglutide locally due to long waiting lists/closed services etc. This group may need to be considered in the early cohorts, to minimise the risk of widening health inequalities. Access to support for weight management will be even further fragmented, and therefore difficult for patients and clinicians to navigate. This is likely to widen health inequalities. Additionally, tirzepatide has not been compared to bariatric surgery. There may be patients who would benefit more from bariatric surgery, or where surgery would be more cost-effective. The funding variation could highlight that surgery should still be considered and offered where a clinician determines this is appropriate.
8		There should be very clear discontinuation criteria as well as initiation criteria. There also should be a requirement to counsel patients on the unknown safety of long term use. The use of patient decision aids and leaflets should be encouraged to help patients understand the benefits, risks and alternative options.
9		When considering different models of delivery for the pilot phase of the funding variation, could an option for local health systems be a NHSE nationally-commissioned and nationally-funded complete service. Community Pharmacy should also be considered as a local option to provide services as part of implementing this funding variation.
10		If there is no central funding attached to the introduction of the funding variation, then it will not be feasible to implement. As ICBs are forced to consider the risks of breeching their statutory financial responsibilities and/or their statutory responsibilities with respect to NICE TAs, patchy implementation is likely to occur. This will further exaggerate the postcode prescribing which is currently present with obesity pharmacotherapy. .
11		We agree with limited qualifying comorbidities but do not agree with inclusion of type 2 diabetes. Tirzepatide for people with type 2 diabetes was considered in NICE TA924. This considered the evidence for people with type 2 diabetes and made more restrictive recommendations based on cost-effectiveness. The new TA for obesity was based on evidence which excluded people with type 2 diabetes. No new evidence for people with type 2 diabetes was reviewed and so the “evidence-based” recommendations should not differ from NICE TA924. The patients with type 2 diabetes at the highest clinical risk will be captured within the group with multiple other qualifying comorbidities.
12		It will be very challenging to implement the first cohort within 180 days unless there is early confirmation of adequate funding for drugs, resource and wraparound care and also information and support resources for implementation including service delivery models. Given the significant implementation work involved, consideration should be given to a timescale to have plans in place by 180 days (enforced by NHSE) with requirements to commence treating the first patient group within 1 year (legal requirement in the funding variation)
13		There is strong opinion that rather than this being considered as part of the prevention agenda this is being presented as a treatment. There is a need for whole systems pathways approach from public health obesity prevention strategies to bariatric surgery not just pharmacotherapy. Lifestyle interventions should be offered first – they are safe and effective for many >50% of tier 2 completers successfully lose 5% weight in 12 weeks in our local system and are equipped to continue to lose weight with the knowledge and skills gained. Holistic lifestyle support can also have wider impacts, including improved mental health and wellbeing.
14		There are concerns that even with a funding variation, the workforce for the wrap around

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		services is not available e.g. dietitians. National, scalable, digital models of delivery will be needed to support locations where this is the case.
15		Details of the funding and nationally commissioned services, as well as public commucations explaining the funding variation, should be available at the time the NICE TA is published to support planning and commissioning decisions.
16		The scope for prioritised access should be expanded to all GLP-1 weight management drugs to ensure equity and reduce potential health inequalities; as well as address the inequity of access to the other weight management drugs that exists and is being publicly discussed.
17		There should be clarity on whether patients have a right to choose when accessing the pilot tirzepatide services.
18		There is also a risk that due to the financial restraints commissioners face, they are forced to disinvest in non-mandated, non pharmaceutical treatment to fund mandated TAs and funding variations which may increase health inequalities, reduce quality of care and increase clinical risk. For example, decommissioning tier 3, tier 4, and other non-obesity related services.
19		The very large eligible cohort and need for service development and pathway re-development requires a long-term (12 year) phased roll-out, prioritising those with the greatest clinical need, as outlined in the proposed funding variation. However, it is also recognised that during these 12 years, there will be new therapies, additional research and evidence, and likely new guidance on treating obesity. There will need to be flexibility to revisit the appropriateness of this TA and funding variation over that time (and other related TAs, e.g. TA875: semaglutide for weight management and obesity).

Insert extra rows as needed

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Organisation name –	Society of Endocrinology (SfE), Obesity Management Collaborative UK (OMC-UK), All About Obesity (AAO)
Disclosure Please disclose any past or current, direct or indirect links to, or funding from, the tobacco industry.	**None**
Name of commentator person completing form:	[redacted]

Comment number	Section 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 …….. ……..
1		**Timeframe for Feedback** The current three-week feedback period is too short, particularly given the complexity and amount of information involved. A more extended period would allow for thoughtful and comprehensive feedback that addresses the full scope of the issue.
2		**Lack of Funding for the Rollout** The rollout of Wegovy, previously approved by NICE, has been significantly delayed. According to a recent freedom of information request by Sky News, only 14 of the 42 Integrated Care Boards (ICBs) are allowing specialist weight management clinics to prescribe the medication, with just 823 individuals having received it. A key reason for this slow progress is the lack of additional funding following the NICE recommendation. Similarly, without new financial support for tirzepatide, ICBs will face challenges in financing this rollout, likely resulting in a slow, postcode-dependent uptake. By contrast, the rollout of Hybrid Closed Loop technology for treating people with type 1 diabetes was backed by £250 million over five years, raising the question of why obesity management does not receive comparable funding.
3		**Extended Implementation Period** The extension of the implementation period from 90 to 180 days is puzzling, particularly as GPs are already prescribing tirzepatide for Type 2 diabetes under a different NICE TA.

		Nearly 60,000 prescriptions were issued in July 2024, and all ICBs are prescribing it. Moreover, there is no indication of any current supply issues with tirzepatide (https://www.diabetes.org.uk/about-us/news-and-views/our-response-serious-supply-issues-drugs-people-living-type-2-diabetes). Reducing the implementation period to 90 days would enable Tier 3 weight management clinics and experienced GPs to commence treatment sooner.
4		**Concerns Regarding Target Groups for Rollout** The criteria for selecting target groups are unclear and present several issues: 1. There is no evidence to suggest that individuals with a BMI of 35–40 and three comorbidities are at lower risk than those with a BMI of 40 and one comorbidity. 2. The BMI thresholds for the rollout do not take ethnic variations into account, which could affect the fairness and effectiveness of the rollout. It is accepted that people from certain ethnic backgrounds have increased co-morbidities from obesity at lower BMIs. 3. The list of qualifying medical conditions seems narrow, relying primarily on the SURMOUNT study, while broader data exists to support the inclusion of additional conditions. 4. It is unclear why individuals with diabetes who are not able to get this under the NICE TA for prescribing tirzepatide for Type 2 diabetes (only for people with poor glucose control on three other glucose agents and a BMI of >35) are not prioritized earlier, as they would benefit from both weight reduction and improved diabetes control. 5. On the other hand, prioritizing individuals with cardiovascular disease (CVD) seems counterintuitive, given the current lack of evidence that Tirzepatide prevents future CVD events. This is particularly concerning when there is already strong evidence that Wegovy reduces CVD events, yet it has not been specifically sanctioned for use in this population. 6. Important cases, such as individuals needing to lose weight for other medical treatments (e.g., transplants, IVF, or cancer surgeries), have not been considered. We recommend that the rollout criteria be aligned with the guidance developed by the Society for Endocrinology and the Obesity Management Collaborative UK, which offers an evidence-based, phased introduction of new medical therapies. This has been welcomed by health care workers, patients and commissioners. https://www.omc-uk.org/news/guidance-phased-introduction-new-medical-therapies-weight-management
5		**Limited Scope of Treatment**

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		The goal of treating 133,000 new patients annually, or roughly 3,300 per ICB, is insufficient given that obesity is one of the most prevalent and costly conditions treated by the NHS. We believe a more ambitious target is needed, one that reflects the magnitude of the challenge.
6		**Concerns About Contact Time Requirements** The contact time required for rollout appears to be overestimated. Private providers have been able to manage the use of these medications with significantly less contact time. Additionally, experience with Tirzepatide for diabetes treatment suggests that only minimal contact is necessary for effective use. GPs have been prescribing drugs similar to tirzepatide (Incretin based therapies) for T2D for > 15 years so there already is a lot of experience of their use in the NHS.
7		**Ensuring Equity in Access** There is a lack of clarity on how equitable access to treatment will be ensured, particularly for complex obesity cases that may be challenging for GPs to manage. Many of the most complex patients are currently treated in tier 3 weight management clinics, but without additional funding (which does not seem to be included in the rollout plan), these individuals may not have access to the drug. Furthermore, if digital platforms are used, how will patients with limited literacy, digital skills, or access to smartphones be supported? Our experience with digital support services suggests they are generally more effective and safer for individuals with fewer baseline comorbidities, creating a tension between the goal of using digital solutions and the need to prioritise those with higher health risk.
8		**Redacted Information in Key Documents** Several critical documents contain extensive redactions, making it difficult to fully understand and provide comprehensive feedback on the proposed policies.

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