Submission Template - Variation to the funding period

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Technology Appraisal

Tirzepatide for managing overweight and obesity [ID6179]

All relevant health bodies must comply with technology appraisal recommendations and make a health technology available for patients within 3 months of publication of final guidance. When it considers it to be appropriate, NICE can specify a longer period of compliance.

Please see the National Institute for Health and Care Excellence (Constitution and Functions) and the Health and Social Care Information Centre (Functions) Regulations 2013, (the 'Regulations'), for more information.

This template document should be used by commissioners to submit a formal request that NICE consider a longer period of compliance. The questions and prompts are there to guide you. You do not have to answer every question. Please provide short, focused answers, giving a commissioning perspective on the issues you think NICE needs to consider.

1. Name of organisation:	NHS England (NHSE)
2. Your name:	[redacted]
3. Job title or position:	[redacted]
4. Please state the reason for applying to vary the funding period (please tick all that apply):	☒ The technology exceeds the Budget Impact Test (BIT) level of £20million in any of the first 3 years following implementation The health technology cannot be appropriately administered until: • certain health service infrastructure requirements including goods, materials or other facilities are put in place • other appropriate health services resources, including staff, are put in place • training is put in place
Additional rationale to support the funding variation request	
5. What is the duration of, and the justification for, the proposed variation? *[Include information on* *- how the request is in proportion to the size of the budget impact (where appropriate)* *- how the request takes account of the severity and acuity of the condition to which the guidance relates]*	This request, on behalf of NHS providers and Integrated Care Boards (ICBs), is for a variation to the funding requirement for the tirzepatide for its proposed indication of managing overweight and obesity recommendation (ID6179). An alternative funding mandate is sought, in the following three phases: • **Part A**: an additional 90 days before any requirement on ICBs to fund the medicine, providing a 180-day implementation period.

	• **Part B**: following the 180 days, a period of three years where eligibility will increase in stages to around 220,000 patients, selected based on health need and clinical benefit. • **Part C**: Following this, up to a maximum of a further nine years, dependent upon maturation of the obesity treatment pathway in primary care. **Terms of the Funding Variation request** NHSE applies for this Funding Variation request on behalf of the NHS in England, the proposed secondary care providers of this medicine, and Integrated Care Boards (ICBs) as the proposed commissioner of this technology. ICBs will be the main commissioning bodies for services in which tirzepatide is prescribed for patients. In order to understand the readiness of ICBs to support a NICE funding requirement for tirzepatide in the assessed indication, NHSE undertook a survey of ICBs in March 2024. 91% (49/54) of respondents (**Annex G**) said they would support the creation of a FV for tirzepatide if the medicine was to receive the proposed broad recommendation for use in primary care. Weight management services are not routinely commissioned in primary care. Poor to the introduction of the new obesity medications, the treatment interventions available to primary care clinicians is diet/exercise support (typically a local authority commissioned service)/tier 2) or referral into acute specialist weight management services for specialist treatment (E.g. tier 3 & 4 / bariatric surgery). As such, NHSE makes this alternative proposal in partnership with ICBs and as the result of a consultative process with ICB representatives. NHSE does not seek to obligate ICBs to a fixed model of delivery, nor seek to commit their financial spend in relation to primary care services, but to offer an approach by which ICBs can make this new NICE recommended treatment available through coordinated and sustainable service models. In the absence of an FV there is a high likelihood of an inconsistent rollout of tirzepatide, with inequalities of access and patient outcomes both within and between ICBs based on different patterns of patient demand and health-seeking behaviours rather than on clinical need and prioritisation. In attempting to comply with the recommendation, ICB representatives have told us that they would be required to take tough decisions regarding the decommissioning of other critical services in order to free up the capacity and resources to offer this medicine. NHS England wants to ensure that patients gain access to this treatment on an equitable basis prioritising clinical need and

	maximising health gain that can be achieved. This requires the NHS to stand up an entirely new tier of weight management services in circumstances where consensus on a service model is yet to emerge and with the objective of making that service accessible to a significant proportion of the total population. NHSE is proposing a realistic but challenging uptake trajectory that satisfies the requirement to make this clinical and cost-effective drug available to as many patients as possible without overwhelming providers (including general practice) in a way that is highly damaging to wider population access. Therefore, NHSE enters this FV request on behalf of, and with the support of, ICB partners, as well as in representation of secondary care providers. **FV rationale** While encouraging the adoption of innovative medicines, NHSE recognises the need for the safe and sustainable roll-out of new technologies in new settings and as part of new services. The justification for the FV request is therefore driven by this need. The rationale for the FV is multifactorial. • The recommendation cannot be safely introduced, as scoped, to primary care within the standard 90-day implementation period. This is due to the absence of primary care weight management service (PCWMS), resulting in unavailability of the proposed wraparound services required to deliver this treatment safely and effectively. ○ In March 2024, NHSE conducted a survey with ICB pharmacy contacts to inform the content of this Funding Variation (FV) request (analysis of this survey can be found in **Annex G**). This survey was able to identify significant ICBs concerns about the required pace (within a 90-day funding mandate) for creating a new service for the proposed patient population. 91% (49/54) of ICB respondents did not believe that a positive NICE recommendation for tirzepatide within a primary care setting could be safely and appropriately offered to patients within the required 90-day implementation period. • The recommendation cannot be safely introduced as proposed due to insufficient clinical capacity to offer and accommodate the indicated patient population in the recommended setting (community/non-specialist services). Additionally, the new demand resulting from the recommendation would create unrealistic pressures on primary care services that would negatively impact

	other primary care patients and potentially risk their access to services for other conditions. ○ NHSE developed a service resource estimate for the deployment of tirzepatide, based on the SURMOUNT-1 trial delivery model and with clinical consensus including the NHS England National Clinical Director for Diabetes and Obesity and the Obesity Expert Reference Group. This estimate was submitted and accepted by the NICE appraisal committee on 4 June 2024 as a reasonable scenario for the service resourcing requirements to roll out the drug safely and effectively according to its licence. • The recommendation cannot be safely introduced due to the identification of a need for rapid and expansive upskilling of healthcare professionals to provide support to patients. Additionally, the required comprehensive education curriculum and materials to support this activity do not yet exist. • The anticipated costs of adopting this recommendation would breach the Budget Impact Test (BIT) level of £20million in all of the first three years following implementation (see **Annex A**). **Implementation proposal** As part of the FV request, NHSE is proposing an implementation proposal (IP) to replace the standard 90-day implementation period. A fuller explanation of the IP can be found in **Annex D,** but a summarised version is provided below. This proposal been created and endorsed by the National Medical Director, National Clinical Director (Diabetes & Obesity), and the Obesity Prevention programme team. It has been socialised with ICB Medical Directors and ICB Pharmacy Leads. **Implementation proposal – Part A (180-day period)** Part A of the IP seeks to provide an additional 90-days before there is any legal requirement for a patient to be offered the treatment, extending the whole implementation period to 180-days. This additional time will provide the Department of Health and Social Care (DHSC), NHSE, ICBs and providers with a window within which the planning work already underway can be operationalised and the framework of a tirzepatide treatment pathway can be established for a small number of complex and clinically prioritised patients. A full capacity service will not be fully operational by the end of the 180-day period, but the requirements of the service will be identified, and work will be

	sufficiently progressed that the first cohort of patients can be welcomed for pre-screening and treatment initiation. The 180-days will be used to: • Begin procurement of digital weight management support services to accommodate some of the dietetic and psychological support requirements in the treatment pathway for this medicine. • Provide appropriate guidance/support on developing extensions of weight management services, outside of a specialist setting, including the implementation of new and future NICE treatment recommendations. • Identify and agree any additional funding packages to support implementation. • Make the required legal and regulatory changes to system levers to support obesity management, including introducing new contractual frameworks for the creation of a new Primary Care Weight Management service. • Upskill existing staff in the requirements of wider tirzepatide treatment. **Implementation proposal – Part B (Cohorts I, II and III)** Part B of the IP seeks to phase the availability of the treatment by creating uptake cohorts prioritised by clinical need and benefit. This would see three cohorts introduced to the treatment over a three-year period. The cohort phasing will provide commissioning ICBs with the opportunity to: • Expand the use of the medicine gradually, without major disruption to existing NHS service provision for other treatments offered in primary and secondary care. • Identify the additional funding required, year-on-year, to provide the medicine. • Continuously build and grow the multidisciplinary teams/skillset model to safely offer a treatment pathway for this medicine in primary care. • Further develop the wraparound support needed to offer the medicine as per the recommendation. This time will also provide NHSE with the time to: • Build up a body of real-world evidence to consider the feasibility of accelerated roll out of the recommendation to wider patient populations in a safe and effective way. The proposed phased implementation of the technology reflects the current demand management and clinical capacity challenges facing the NHS, and the need for a balanced

	approach. The approach prioritises earliest use for those who can benefit the most from the technology and is intended to optimise effective and safe implementation of the technology, without adding undue pressure to already stretched community teams, specialist weight management services, and clinical teams. It will manage the clinical risk associated with the introduction of this new first in class therapy, at scale, in the absence of any Phase 4 trials. The phasing approach has been designed by NHSE, with input from clinical experts, on behalf of the whole NHS ecosystem and considers inequalities on an England-wide basis. While this is sympathetic to local identified inequalities, by its nature this approach considers the population of England as a whole regardless of where patients in these cohorts reside. This means some geographic areas will have a higher proportion of patients accessing tirzepatide through the cohorts, but this access is driven by clinical criteria. NHSE is developing a package of support to aid ICBs with their implementation of the FV IP, including a financial support offer related to the medicine cost and an offer related to the costs of developing primary care weight management services. Both elements will use prevalence of need in the geographic footprint as a factor for determining the size of the support for that footprint. More detail on the five cohorts can be found in **Annex D**. **Implementation proposal – Part C (Cohorts IV-VII).** Following the onboarding of the initial three cohorts over the first three years of the IP, NHSE requests a further maximum implementation period of nine years. Based on the modelled resource requirements associated with the deployment of tirzepatide (as presented by NHSE to NICE as part of the appraisal and considered as a plausible scenario by the appraisal committee) a further nine-year implementation period would manage the impact upon primary care services and avoid the risks associated with a significant displacement of appointment volume to deliver tirzepatide. However, NHSE recognises that there are uncertainties about the potential service resource implications of the tirzepatide recommendation. These include: • Patient demand for the medicine; • Average treatment duration; • Scale of wraparound support required, and how intense this support is required as we move down the scale of clinical need; • Optimal care pathway under NHS provision, including the potential use of digital delivery models • Long lasting clinical impact. NHSE therefore proposes a multistakeholder review of the FV to reconsider its appropriateness and relevance by the third

	anniversary of patient access. This review will consider the delivery of the FV to date, including examining the possibility of quickening the uptake trajectory based on: • clinical advances, • increased capacity, • access to capacity enhancing digital solutions, • progress in extended pathway development and commissioning of services, • and increased knowledge of the medicine from the real-world evidence generated. Given the evolving knowledge of GLP-1 (and related) products for the treatment of weight management, we can expect to have a much more robust understanding of the requirements for the safe and effective use of tirzepatide by the midpoint of Cohort III implementation (April 2028). The NHS will have greater experience of treating patients with tirzepatide for weight management and have experienced three years of increasing service capacity in support of the medicine. Digital weight management options will have been procured, embedded, and matured. **Without a FV** Without the use of the IP, the demands for both capacity and cost would overwhelm NHS commissioners and providers. As part of the FV request, NHS England believes that around 2.8m patients would become eligible to use tirzepatide for weight management after 90 days of the publication of the Final Appraisal Document (FAD). This determination is made using Health Survey for England data on the number of people suspected to have a Body Mass Index score of 35 kg/m^2 or more and at least one of the stated 'qualifying' weight related comorbidity. OBJ Assuming all eligible patients present in primary care in the first twelve months of use, and that 70% of patients presenting are initiated on treatment, the impact on primary care and general practice would be profound. • Around 18% of all GP appointments would be required to initiate and manage the uptake of this medicine (not including initial screening appointments for the uninitiated 30%). This is over ten weeks of GP appointment capacity. The displacement effect of this would be stark, and potentially life threatening for other users of GP services. • This one treatment would require over 100% of existing NHS dietetic capacity in its second year of use. • The cost of the medicine alone in the second year of use would come in around £2.9bn, equivalent to 28% of the entire primary care medicines budget. ---

	It is important to note that individual providers and commissioners can choose to go further than the IP. If they believe that they can and should offer the medicine to patients outside of the appropriate cohorts at that time, then the FV does not prevent them from doing this so long as the patient would be eligible for the treatment under the full NICE recommendation for its use. However, without the FV, NHSE and individual ICBs risk legal challenge if the treatment cannot be offered to all eligible patients. **Background** Considerable progress has been made in recent years to introduce pharmacotherapy as an intervention for weight management. These are currently accessible through Tier 3 and 4 weight management services which are almost exclusively based in secondary care. These services are limited by their capacity and have significant waiting list times (see **Annex G** for further information). The phased implementation of tirzepatide into a new care setting - outside of secondary care - offers the opportunity to reduce the time to access. However, it requires the creation of a new community-based service offering with substantial capacity given the identified eligible population. *Requirement for a FV* NHSE is seeking a clinically prioritised phased implementation of tirzepatide (for the management of obesity and weight management) to ensure equitable, sustainable, and affordable patient access to this technology. We are seeking this variation for the following reasons: • **Clinical capacity and service redesign.** From the NHSE ICB survey to inform this FV (**Annex H**), 98% of respondents (53/54) agreed that there is no locally commissioned weight management provision already in place to support a wraparound service model for tirzepatide. There is currently no weight management services outside of specialist weight management services (SWMS) that could safely offer this recommendation to patients. Without a variation to funding implementation, patients risk lack of access to the medicine as providers will individually determine, for their respective ICBs, that the timescale required to implement, and the potential population eligibility is too great. There is a risk that ICBs will decline to commission, and providers to provide, if they believe that offering tirzepatide would displace activity for other clinical priorities and would lead to an

	inability to honour commitments made for other treatments and for other patient groups. The challenge of creating a new/extended service/pathway could lead to ICBs risking not creating any services outside of a SWMS, in turn, creating an artificial block for patients access to the treatment. More likely, ICBs would comply with their requirements to make the medicine available for some patients, but access would be severely restricted due to patient safety concerns and the lack of supporting/wraparound care, and to all intents the impact of the availability of tirzepatide would be negligible. This would also be undesirable given it is clear that tirzepatide can provide a lot of clinical benefit for some patients. • **Building the clinical team, including training/upskilling existing staff.** From the NHSE ICB survey to inform this FV (**Annex F**), views regarding self-assessed capacity to offer this medicine varied. At one extreme, some respondents believed that they could offer the medicine to some thousands of residents in their locality. At the other, some respondents indicated that they would not seek to make the medicine available at all. With links to clinical capacity, there is a need to identify and increase the relevant skillsets of those providing support in primary care, to support safe and effective uptake of this medicine. Plus, the requirement to upskill and train staff to deliver required patient care, not just in the use and management of the drug itself but also the dietetic and psychological support essential for ensuring effective and safe use. This medicine would be the 'first in class' for the NHS in England and there is no existing primary care treatment pathway within which the medicine can be integrated into. Implementation of the existing NICE Clinical Guideline for Obesity (CG189) is patchy, and this pathway is provided for a maximum of two years. The specialist clinical input provided for this pathway is not comparable to that required for tirzepatide use in the same setting. Learning from the use of tirzepatide with the diabetic cohort will be limited as, unlike for patients with diabetes, the infrastructure and clinical expertise to manage the obese cohort does not exist outside of secondary care. Patients living with obesity are a complex and heterogenous cohort, many with secondary conditions associated with their weight. Currently weight loss

	pharmacotherapy is delivered almost exclusively through SWMSs that provide access to a multi-disciplinary team including specialist doctors, nurses, dieticians, physiotherapists, and psychologists. The new care delivery setting (out of hospital to allow for community settings) does not yet exist in the weight management pathway and as such does not have the current infrastructure (physical and digital), workforce, or training in place. To be offered in primary care, an increase in clinical capacity for the named multi-disciplinary team members will be required. Where an ICB does not commission a SMWS, they may require time and support to develop the clinical expertise to lead and implement these services safely. • **Variations in access.** Currently there are variations in the provision of pharmacotherapy via secondary care, as not all ICBs commission Tier 3 weight management services. In April 2024, NHSE surveyed all ICBs as part of its periodic capacity assessment of NHSE weight management services. Based on an 80% response rate, the 'ICB Weight Management Services 2024 survey' found that 76% of ICBs commissioned a SWMS. A further 7% had a local agreement with a neighbouring ICB and 9% had a self-defined suitable local equivalent. While existing Tier 3 weight management services may provide coverage to 92% of the England population, we cannot be confident on equity of access nor general accessibility of services. The same survey found the average Tier 3 service holds a 16-month waiting list for access. The average service also admits 1,200 new patients per year per ICB (range of 250-2500). There is also variability in eligibility criteria, mainly centred around Body Mass Index (BMI). In all, it is clear that existing Tier 3 services could not quickly expand to accommodate increased patient numbers, nor could their model quickly adapt to provide their service in primary care. In primary care (where drugs for weight management are not currently provided), clinicians with a specialist interest in obesity are low in number and are not evenly distributed across the country. There is an increasing number of local authority commissioned Tier 2 services closing. • **Variation in delivery pathways.**

	Weight management pharmacotherapy has been delivered almost exclusively via Tier 3 hospital-based services, in line with previous NICE Technology Assessments (TAs). This recommendation requests prescribing and associated wraparound care services be delivered outside secondary care. The use of digital technologies to deliver SWMS, as per NICE Early Value Assessments, is an option however exploring and then undertaking such an option cannot be facilitated within the 90-day implementation window. Additionally, it cannot be assumed that digital technology to assist service delivery is capacity enhancing – until optimised it may merely offer more flexibility in how service is provided without scaling capacity. • **Pathway redesign** As per the current NICE clinical guideline on obesity identification, assessment, and management (CG189[1]), the first treatment option for a patient with obesity is a 'multicomponent intervention,' e.g. increased physical exercise, diet, and reduced energy intake. Clinical Guideline 189 will need to be rewritten by NICE following their recommendation of tirzepatide, given the creation of a new care pathway for treatment in primary care. Without doing so, and if this guideline were to remain in place, all potential tirzepatide users should be first placed on a diet and exercise intervention in concordance with the guideline. *"1.8.1* *Consider pharmacological treatment (see table 1) only after dietary, exercise and behavioural approaches have been started and evaluated."* Programmes of this kind are largely commissioned by local authorities and their commissioning does not provide comprehensive coverage. This itself would act as a blockage to any tirzepatide treatment initiation. Additional time is required for a complete pathway redesign, commissioning and delivery changes resulting from this redesign, and the safe implementation and expansion of this new pathway in conjunction with clinicians newly trained in this pathway. • **Healthcare inequalities.** Additional complexities related to population demographics such as age, deprivation, ethnic diversity, language, income, and access to technology can all impact the uptake of weight management

[1] https://www.nice.org.uk/guidance/cg189

	pharmacotherapy and associated wraparound services. Unmanaged, we believe the introduction of this medicine on the standard 90-day timeline would see services overwhelmed by demand which risks inequitable access, with access not determined by reasonable access criteria or clinical need. • **Patient benefit.** A phased roll-out of tirzepatide will provide adequate time to develop and deliver appropriate services essential to delivering safe care with sustained positive long terms outcome of treatment. A phased approach will aid the assessment of real-world evidence to shape in real time how this medicine – and other weight management treatment options – can be offered safely and effectively in primary care. This evidence may include uptake data, data on longevity of use, as well as evidence of patient outcomes resulting from use under the five different ICB service models (detailed in **Annex D**). • **Targeted to optimise outcomes.** The phased roll-out will be considered in the context of current evidence-based weight management interventions. The aim will be to target the cohort with highest clinical need who can be safely managed without Tier 3 or 4 specialist weight management input. This request is consistent with the introduction of similar novel and complex technologies such as with diabetes treatment. It also aligns to timelines for other potentially significant innovative technologies.
6. Describe any relevant provisions of any commercial arrangement reached with the company. *[Only complete where relevant. Include information on the amount of engagement between your organisation and the company and relevant conclusions for NICE to consider whether all reasonable opportunities for reaching a commercial agreement have been pursued]*	*Commercial Arrangements – BIT* This FV is written prior to the finalised NICE cost-effective price being disclosed to NHSE. For the following financial assessments NHSE assumes the cost of tirzepatide as its list price and has used the range of prices linked to the range of dosages, factoring in dosage escalation to full titration. Should the final cost-effective price be different to list price, NHSE's calculations would require amendment and NHSE would need to reflect on the impact of this on the FV. NHS England has not entered into a commercial agreement with Eli Lilly as an alternative to managing the resource implications of the recommendation. This is because: • A commercial agreement with the manufacturer may provide a temporary reduction in the price of the medicine, but this does not manage the impact of the recommendation on service capacity and would not

change the service capacity phasing required for safe and effective implementation.

- The budget impact assessment framework only considers the net budget impact of a NICE recommendation over the first three years of implementation. The resource implications associated with the current recommendation require management over a longer time frame.

New BIT numbers

NHS England has subjected its alternative implementation proposal to the Budget Impact Test for the medicine and service, and it is clear that the alternative proposal will still breach the BIT threshold in each of the first three years of use.

Assuming a conservative 85%:15% split between tirzepatide and semaglutide, and using the IP in this FV, the BIT would still be breached **in each of its first three years of use through drug costs alone**.

(The current Budget Impact Test threshold is £20m additional costs in any of the first three years of use, following recommendation).

Following the 180-day implementation period:

Year	Net budget impact
1	[redacted]
2	[redacted]
3	[redacted]

The calculations above use the medicine's list price for each dosage, assuming escalation to full titration. This is the same methodology used to assume projected medicines costs in the FV IP.

Using the latest BIT (as supplied by NICE), and using Population Scenario C (the company's preferred scenario), the BIT results for an unvaried recommendation would be:

Year	Net budget impact
1	[redacted]
2	[redacted]
3	[redacted]

	Following Year 3, we assume a total eligible cohort of 133,214 patients out of the 2.8m assumed by the full recommendation. This represents 5% of the total eligible patient population. This demonstrates that, despite the IP, the financial impact of the recommendation will still prove challenging for NHS commissioners. Further details on the IP BIT result can be found in **Annex A**.
7. Describe the amount and phasing of funding that will be made available and how it is intended that this should be applied to patients eligible for treatment.	It should be assumed that the costs of both the new service and the treatment will be met by commissioners, including ICBs. DHSC and NHSE will consider, as part of the government's Spending Review exercise, the case for additional funding to support the new costs resulting from the availability of this treatment and the creation of a tirzepatide treatment pathway. NHSE have proposed a treatment model for tirzepatide (an overview of this treatment model can be found in **Annex B)**. All costs referenced in this FV are aligned to this model unless stated otherwise. Based on the IP, NHSE believes that an average of 130k patients would be assessed for their suitability to take the medicine in a given FV year. Assuming 70% eligibility, this equates to average 100k patients a year initiating treatment. The estimated weighted medicine cost to the NHS of the first 12 months of treatment with tirzepatide is [redacted] . The estimated weighted medicine cost to the NHS of subsequent years is [redacted] The estimated service cost to the NHS of 12 months of treatment with tirzepatide is: • Year 1: [redacted] • Year 2 onwards: [redacted] This provides a five-year average service cost of [redacted] per year. The total weighted cost of providing tirzepatide for 12 months is therefore: • First year of use – [redacted] • Subsequent years of use - [redacted] The cost of changes to pathways and infrastructure is not included in the above, and conservative workforce estimates have been used. The scaling costs for the IP are detailed in **Annex D**.

8. Provide detail of an assessment of the impact on patients, eligible for treatment under the guidance, but whose treatments will be delayed because of the FV, taking into account NHSE's and NICE's responsibilities under equalities legislation.	A Health Inequalities Impact Assessment is provided in **Annex F**. The rationale for phased implementation is presented under Section 5 and **Annex D**, and NHSE does not anticipate an exacerbation of any existing healthcare inequalities as a result of this phasing. On the contrary, NHSE believes that the IP will reduce the risk of exacerbating health inequalities by ensuring available NHS capacity is phased by clinical need, rather than allocated according to patient demand or healthcare-seeking behaviour. NHSE believes that attempting to implement within 90 days would have a highly damaging impact on wider population access to GP services, which would be detrimental to patient outcomes and widen health inequalities. This is borne out in the advice received into NHSE from ICB representatives. To promote safe and equitable access, and direct resources to where the health need is the greatest, we believe a managed and phased approach, which will incorporate health inequality considerations, is best. In the event that the medicine is adopted within 90 days of a decision, we believe adoption and therefore access would be sporadic and disjointed. The public profile of this medicine suggests high immediate demand in primary care, and we hypothesise that those most likely to present and most likely to request the medicine are those most engaged in this public dialogue. There would be no accommodations made for geographic spread, patient characteristics (gender, race, age) or severity of disease (above the minimum level recommended by NICE). This, combined with the constraints on capacity and finance in the NHS, significantly increases the likelihood that those receiving the medicine will not be those who would benefit most from the treatment. **Services in health and justice settings** As with NHS primary care services for the general population, there is also an absence of existing weight management services for those in health and justice residential settings (e.g. prisons and secure hospitals). New services for these residents will also need to be commissioned, commensurate and linked into the services for the wider population. The IP provides for the time for the planning, commissioning, and establishing of new services that will provide both the continuity of care for those initiated on the medicine who move into such settings and allow those people in such settings to access the treatment as equivalent to the general population. **Low-income groups** While low-income groups are just as likely to accept a referral to Tier 2 Weight Management Services, evidence suggests that retention and weight loss achieved tend to be lower than in high

	income groups.[2] A phased uptake approach, in which patients are identified and solicited for an assessment, may provide the best approach to engaging such patients in sustaining and longer term tirzepatide treatment. **Minority ethnic groups** Some minority ethnic groups may face barriers to accessing services, including poor health literacy and the need for culturally compatible information. In the National Diabetes Prevention Programme, Asian and mixed ethnicity groups had significantly lower rates of completion, and Asian and Black ethnic groups lost less weight compared to the White ethnic group. In addition, both completion and weight loss increased as levels of deprivation decreased[3]. Again, implementation by design, that intentionally seeks to provide the treatment to those of highest clinical need as opposed to those who have the fortune of service accessibility, provides the best opportunity to engage groups of eligible patients who demonstrate lower levels of engagement with existing health services.
9. Provide detail of the interim commissioning policy that would be applied to phase in funding and to manage access to the technology during the extended FV period.	NHSE will use the time afforded by the IP, particularly Part A (180-day implementation period) to produce clinical and pathway guidance, including interim commissioning guidance, to support the creation of tirzepatide pathway. This time would also provide NICE with a window in which it can publish its planned tirzepatide implementation toolkit. The proposed delivery pilots would also be established during this period, to support tirzepatide use with the early cohorts in the IP and to test the best delivery models for future commissioning policy as services continue their expansion.

Thank you for your time.

Please log in to your NICE Docs account to upload your completed submission.

[2] Public Health England (2015) National mapping of weight management services: provision of tier 2 and tier 3 services in England.

[3] Valabhji J, Barron E, Bradley D et al. (2020) Early Outcomes From the English National Health Service Diabetes Prevention Programme. Diabetes Care. Vol 43(1): 152-160. https://doi.org/10.2337/dc19-1425