Tirzepatide for managing overweight and obesity [ID6179]

Questions for NHS England

The response to the questions below is based on the following output from the first committee meeting:

- The target population proposed by the company, which is people with a BMI of 30kg/m2 or more with at least 1 weight-related comorbidity, is appropriate.
- The primary comparator for tirzepatide is likely to be diet and exercise support delivered via multidisciplinary team (MDT) services in primary care.

The proposed clinical service and associated costs are mapped to the SURMOUNT-1 trial which is the main evidence source in the company submission. NHSE has no specific recommendations as to setting of care, although it is likely that the majority of care would be by community led services in primary care with a minority in secondary care.

Currently no MDT approach to obesity management routinely delivered in the NHS, at present, in primary care. However, weight management pilots are being designed to evaluate Specialist Weight Management Service (SWMS) delivery outside of a secondary care setting. The nature of these pilots is still being defined and, whilst it has not been included in the response, the pilots could potentially provide a mechanism for firming up assumptions about the model of care delivery required to support treatment with tirzepatide, or other weight loss drugs.

Question 1. **How the multidisciplinary team (MDT) approach for obesity management is delivered in the NHS at present. Consider the services as they are today, indicating if the services described are covered by the weight management pilot.**

- Which professionals are included in the MDT?

There is no MDT approach to obesity management delivered in the NHS, at present, in primary care.

Within specialist services, the MDT approach, via SWMS aligned per NICE Clinical Guidance [CG 189] requirements for MDT support with pharmacotherapy and, whilst precise local service configurations will vary, it is generally understood by NHSE to include:

- Clinical Lead – Consultant Endocrinologist/Bariatric Surgeon
- Consultant / GP with special interest
- Specialist Dieticians
- nurses,
- psychologists and psychiatrists, and,
- exercise/physical activity professionals (E.g. physiotherapists).

- In which settings it is currently available and delivered (for example, primary and secondary care or secondary care only)?

An MDT approach is available, via SWMS, is delivered in specialist services only. There are several ‘community-based SMWS’ which are affiliated as satellite services of existing secondary care-based SWMS, which allow for access to and clinical governance from the SMWS clinical lead/consultant and the prescribing rights to be extended for the current available GLP-1’s into a community setting.

We are aware that NICE has recently published an Early Value Assessment of remote and digital delivery of SWMS, some of which are being deployed locally in the NHS. However, there appears to be little evidence to date relating to the clinical effectiveness of these models of delivery, hence the EVA approach to build the evidence base.

- What are the eligibility criteria for access to MDT?

The eligibility criteria for SWMS and subsequent MDT varies by ICB. Also, to note, there are ICB’s without SWMS and where SWMS do exist referrals can be restricted once services are at capacity.

However, typical eligibility criteria can include the following (all BMIs should be adjusted for ethnicity):

- GP referral
- >30 BMI ≥30 with Type 2 Diabetes or BMI ≥ 35 plus comorbidities or BMI ≥ 40 (we would emphasise that this is highly variable across ICBs)
- Insufficient change from weight management intervention (achieving/maintaining weight loss)
- Exclusion criteria are often used. This can include pregnancy, cardiac conditions and mental health or substance abuse issues that are not stable or sub-optimally controlled.
- How long does MDT last? Is there a limit?

NHSE cannot provide insight on this point as this will vary based on locally commissioned services. However, the understanding is they can often last for a year or more – but commonly two years. However, this is subject to clinical judgement and criteria set by the local commissioners.

- Is assessment needed for the eligibility of multidisciplinary services? If so, who is doing the assessment?

Initial review of current Clinical Pathway into the tiers of weight management is predominantly conducted by General Practice in line with the assessment guidance of overweight, obesity and central adiposity as per NICE CG189.

Generally, as part of the clinical management of weight associated comorbidities and increased risk, and not an opportunistic review.

Referral for assessment is made by General Practice based on NICE CG189 and the local ICB referral pathway.
Once referred; SWMS will generally undertake an initial assessment of the patient, and this assessment would usually include assessment/identification

of weight-related and other relevant comorbidities, across physical and mental health, and functional wellbeing.

- What main components of the current multidisciplinary approach and service for obesity in the NHS are being adapted or updated? Please highlight the most relevant for the delivery of anti-obesity drugs.

There is no planned adaptation of SWMS.
A pilot of weight management drugs is currently being developed by DHSC/NHSE to assess how and what components of a typical SWMS and an MDT approach in specialist care can be delivered outside of a specialist setting. The pilots were being designed in line with the NICE recommendation for semaglutide in specialist weight management services.

NHSE are awaiting the committee's findings to shape the pilots going forward, should tirzepatide access be supported via multidisciplinary team (MDT) services in primary care.

Question 2. How the multidisciplinary team approach for obesity management is being adapted and updated, both with and without anti-obesity medication included. Please refer to the tables at the end of this section to complete relevant answers.

This submission is what NHSE propose would be required to deliver weight management services related to the treatment with anti-obesity medication. NHSE has no specific recommendations as to setting of care, although it is likely that the majority of care will be by community led services in primary care with a minority in secondary care. There is currently no MDT approach to obesity management delivered in primary care in the NHS at present.

- What will the updated MDT service delivery model consist of:
    - Which professionals will be included?
    - How often will an individual accessing this service be seen by each professional in a year (specifying first and subsequent years, if different)?

Please use tables 1 and 2 to give your answer

The pilot programme will adapt the multidisciplinary team approach stated by NICE [CG189] for the purpose of evaluating access and acceptability (through NIHR evaluation) through a General Practitioner (not with special interest) led process for assessment for patient eligibility and appropriateness to be managed/prescribed the associated weight loss drugs and either:

- Assume all associated prescribing of the weight loss drug from initiation through to titration and maintenance and continued medical patient management.
- Referral to an existing SWMS to prescribe the weight loss drug from initiation through to titration and then, through a shared care model of patient management, General Practitioner to resume prescribing from the maintenance phase and all medical patient management
- Referrer to a digital provider of SWMS and Prescribing for GLP-1RA* (appropriateness of remote prescribing of 1st in class GLP-1 RA/GIP therapy to be considered in line with digital clinical safety models, DCB0129, and the management of patients with regards to no previous availability or BAU prescribing of specific drug and patient management in a standard care setting)

Wrap around MDT care speciality service provision outside of prescribing of the drug will be provided by either:

a) Locally (ICB) procured wrap around MDT services specifically for the pilot patients only

b) A Nationally procured digital delivery of wrap around MDT care specifically for the pilot patients only

- In which settings will it be available:
    - In which settings will the services be available and delivered?

NHSE has no specific recommendations as to setting of care, although it is likely that the majority of care will be by community led services in primary care with a minority in secondary care.

    - Will this service be entirely run outside hospital settings or across settings including hospitals depending on which setting the individuals access and start the service?

NHSE has no specific recommendations as to setting of care, although it is likely that the majority of care will be by community led services in primary

care with a minority in secondary care. As part of planned pilots of weight management drugs, it remains our intention to evaluate the feasibility of delivery of services across a range of settings, including remote and digital delivery and delivery through a hybrid model where management would be shared between specialist care and community.

    - If run in a mixture of community and hospital settings, are different costs associated with these services in each setting?

NHSE has costed for a service with GP costs and a specialist care service with consultant costings where relevant. All other costs are assumed to be the same for the purposes of this submission.

Note that the proposed pilots are intended to gather further information on the relative cost-effectiveness of delivery models in different settings.

    - Will specialist weight management services still exist and be an appropriate setting for tirzepatide treatment for people accessing these services?

Existing SWMS commissioned by local NHS commissioners are expected to continue in the current format. They were established to assess patient's suitability and readiness for bariatric surgery and that need is not expected to change.

- What are the eligibility criteria?

    - Is an assessment for eligibility going to be needed before the initiation of multidisciplinary service?

Yes, there will need to be an assessment for eligibility that includes inclusion and exclusion criteria and in particular psychological assessment informed by the relevant NICE recommendations but will also need to take account of system capacity.

    - Are the eligibility criteria going to be the same or differ across settings where the multidisciplinary service will be available?

Eligibility criteria would be set by the ICB but informed by relevant NICE recommendations.

Will the multidisciplinary service be the same for all regardless of the use of pharmacological products, or will additional support be needed if tirzepatide is recommended?

The proposed clinical service and costs are specifically for tirzepatide and mapped to the SURMOUNT-1 trial and the proposed obesity prescribing pilots.

Please use tables 1 and 2 to give your answer

- Will any of the components of the multidisciplinary services not be not needed because of the use of tirzepatide?

No. There is currently no MDT approach to obesity management delivered in the NHS at present that maps to the SURMOUNT-1 trial. It is too early to say if any changes to the MDT approach to management in secondary care would be needed.

Please use tables 1 and 2 to give your answer

- How long will this service be accessible for?
    - Does the length of time the service is accessible depend on whether the individual is taking pharmacological treatment?

      Please use tables 1 and 2 to give your answer
    - If time limited, would the service be used as long as an individual is on pharmacological treatment or would tirzepatide continue to be prescribed without the MDT support in the long-term?

NHSE has suggested that the MDT support remains in place whilst the patient is on tirzepatide, which is in line with the MHRA licence (and not less than that approved).

As a new 1st in Class therapy the effectiveness and safety of the removal of the support as provided in the trial is unknown.

- Is there any further information on the design and costs of the services needed for delivering tirzepatide that NHSE would like the committee to be aware of?

NHSE has submitted additional information in the form of an appendix attached to the bottom of this document.

Please complete the following tables with estimated resource use and associated costs for the updated obesity management service delivery model. Specify a range of values where appropriate.

Table 1 – MDT delivered in the community with anti-obesity medication

As noted above the proposed clinical service and associated costs are mapped to the SURMOUNT-1 trial

Number of appointments by profession		Year 1	Year 2	Year 3	Coverage	Cost per slot (£)	Year 1	Year 2	Year 3
GP	10 min slots	21	3	3	-	£ 41.00	£ 861.00	£ 123.00	£ 123.00
Nurse	10 min slots	4.5	3	3	-	£ 18.55	£ 83.47	£ 55.64	£ 55.64
HCA	10 min slots	1	0	0	-	£ 7.14	£ 7.14	£ -	£ -
Nurse group	10 min slots	3	0	0	-	£ 18.55	£ 55.64	£ -	£ -
Clinical pharmacist	10 min slots	3	3	3	-	£ 11.29	£ 33.88	£ 33.88	£ 33.88
Dietician	30 min slots	5	4	4	-	£ 27.19	£ 135.97	£ 108.77	£ 108.77
Psychologist	30 min slots	5.5	3	3	0.33	£ 33.88	£ 62.11	£ 33.88	£ 33.88
Total per patient cost (GP Led)							**£1,239.21**	**£ 355.18**	**£ 355.18**
Total per patient cost (Consultant Led)						**£ 23.33**	**£ 868.21**	**£ 302.18**	**£ 302.18**

The breakdown of appointments is shown in the table below:

Visit	Purpose	Duration	Assumed Resource for costing	Activity / Skill	Assumptions
Stage 1: Patient Assessment, Counselling and Training					
1	HCA Review	10	HCA	Blood Pressure, Height & Weight	
1	Initial consult	45	GP/Consultant	Alternative to GP could be used, for example: - ANP (LTC management) / other health care professionals with LTC management experience. - Senior practice nurses (diabetes specialist) However, GP will be ultimate accountability for patient care. 45 mins to include psychological support assesment.	The screening & eligibility process for the clinical trial is not appropriate in routine setting. Alternative screening and eligibility activity is based on NHSE. clinical input.
1	Blood Test + thyroid test	N/A	N/A		
2	Patient Training	30	Nurse	Checklist review + patient education (could be group sessions)	
2	Patient Education & Dietary/exercise advice	30	Dietician	Dietetic advice and guidance	
2	Clinical Review and prescription validation	15	GP/Consultant	Prescription check	
3	Week 0 - Treatment initiation (2.5mg)	15	Nurse	Patient education could be in video format for some patients.	As per SURMOUNT-1 trial
Stage 2: Titration & Weight Management Support					
4	Week 4 - dose titration (5 mg)	20	GP/Consultant	Same as above - different skills can do this, needs to be a prescriber. Contra-inidcation considerations (polypharmacy) drives requirement for senior oversight. Recognition that this could change as more long term data becomes available.	As per SURMOUNT-1 trial
5	Week 8 - dose titration (7.5mg)	20	GP/Consultant		As per SURMOUNT-1 trial
6	Week 12 dose titration (10mg)	20	GP/Consultant		As per SURMOUNT-1 trial
6	Week 12 - Dietary/exercise advice	30	Dietician		As per SURMOUNT-1 trial
7	Week 16 dose titration (12.5mg)	20	GP/Consultant		As per SURMOUNT-1 trial
8	Week 20 dose titration (15mg)	20	GP/Consultant		As per SURMOUNT-1 trial
9	Week 24 - Dietary/exercise advice	30	Dietician		As per SURMOUNT-1 trial
10	Week 26 - Medicines Review	20	GP		Activity based on clinical input
Stage 3: Maintenance (Every 12 weeks thereafter)					
10,11	Week 36 + 48 (Year 1) - Dietary/exercise advice	30	Dietician		As per SURMOUNT-1 trial
12-16	Week 60, 72, 84, 96 (Year 2) - Dietary/exercise advise	30	Dietician		As per SURMOUNT-1 trial
17-21	Week 108, 120, 132, 144 (Year 3) - Dietary/exercuse advise	30	Dietician		As per SURMOUNT-1 trial
Additional Costs					
N/A	Multi Disciplinary Team (MDT) Patient Review	15	GP/Consultant + Nurse + Clinical Pharmacist+ Psychologist	Costing will assume minimum 2 MDT discussions per patient per year. To start from week 26	Activity based on clinical input
N/A	Psychological Support	30	Psychologist / Psychiatrist	Costing will assume 1 in 3 patients will require psychologist support. Where psychologist support is required assume 5 appointments in year 1 (as per DHSC/NHS obesity prescribing pilots).	Activity based on clinical input
N/A	Sharps & disposal	N/A	N/A		Activity based on clinical input

Source for costs as follows:

- GP appointment – standard 9.22 mins – PSCC unit costs 2021/22 per surgery consultation with qualifications - Table 9.4.2 Unit Costs of health and Social Care 2022 (amended 13 July 2023).pdf (kent.ac.uk)
- GP practice nurse appointment – Table 9.3.1 same source
- Dietitian (AfC Band 5) band min for 2023/24 + 40% oncosts based on 37.5 hrs @ 39 weeks = 1,462.5 hours per year
- Psychologist (mix of assistant and counselling psychologist) (AfC band 6) then same approach as dietitian
- Pharmacist (AfC band 6) then same approach as dietitian

Table 2 – MDT delivered in the community without anti-obesity medication

N/A - There is currently no MDT approach to obesity management delivered in primary care in the NHS at present.

Category	No. per year, year 1	No. per year, 2nd & subsequent years	Anticipated duration of support	Costs per visit	Comments
GP visit					
Nurse visit					
Psychologist visit					
Dietician visit					
Other resource – please specify (add rows if needed)					

Table 3 – Specialist weight management services

Eligibility criteria – please specify anticipated eligibility criteria in the context of community-based MDT	NHSE has assumed eligibility as the target population proposed by the company, which is people with a BMI of 30kg/m2 or more with at least 1 weight-related comorbidity.
Anticipated proportion of people needing referral in the context of community-based MDT	NHSE has assumed the eligible population based on a BMI of 30kg/m2 or more with at least 1 weight-related comorbidity.
Anticipated duration of SWMS	NHSE have assumed weight management services remain in place whilst the patient is on treatment.

Appendix 1: Clinical Considerations

Clinical safety as a novel pharmacotherapy

As a novel first in class dual GLP-1 and GIP RA, new to the NHS, compulsory surveillance via the MHRA Yellow Card Scheme as per all new drug therapy will be appropriate.

Position in the clinical pathway

Pharmacotherapy represents one element of the approach to weight management as part of the wider obesity strategy. Therefore, consideration must be made as to where pharmacotherapy-based interventions will sit within the lifestyle and clinical pathway for obesity, how it will connect with other obesity interventions and the settings in which it will be delivered. It is also important to determine how patients who are not eligible or prefer to avoid drug therapy will access alternative evidence-based interventions for weight loss provided by commissioners – including local government as well as the NHS.

Service Requirements: Training & Education

Pharmacotherapy of this nature for the management of obesity has traditionally been delivered in a secondary care setting with access to a multi-disciplinary team with significant clinical experience managing this cohort of patients. Obesity is a complicated disease; aetiology is often complex and multi-faceted as is the approach to sustainable management. It should not be underestimated the significant time and training costs associated with upskilling clinical staff to provide a service that can be delivered safely and effectively alongside pharmacotherapy outside of secondary care.

Service Requirements: Workforce

Requirements for the workforce will be influenced by the size of the eligible population. Health Survey for England data reports that 26% of adults in England are living with obesity[1]. MHRA authorisation for Tirzepatide for adults is for patients with a BMI of 30kg/m² or more (obesity), as well as those with a BMI between 27-30kg/m² (overweight) who also have weight-related health problems. Hence additional workforce for this service will be necessary. Specific consideration should be given to where additional workforce will be sourced for new delivery setting without drawing on existing secondary care services or adding pressure to primary care.

This is perhaps most relevant around access to psychologists given the high association between obesity and psychological and psychiatric issues[2]. It is, therefore, essential that patients have an assessment by the appropriately skilled professional in order for psychological support to be tailored to their needs but to also ensure those that need psychiatric input are referred on. This is critical as the cohort of patients with significant mental health diagnoses were excluded from the SURMOUNT pilot population.

The BMA Mental Health Workforce 2022[3] report suggest the vacancy rate for clinical psychologists is 12% with 57% of staff reporting short staffing of clinical psychologists present during their last worked shift. The NHS Long Term Workforce Plan[4] modelling suggests that education and training places for clinical psychology needs to expand by 26% by 2031 to meet anticipated

demand. Given the likelihood of a reasonable proportion of eligible cohort requiring psychological input, this presents a key workforce constraint to consider.
In addition, the Workforce Plan suggests despite planned expansion of physiotherapy workforce and other allied health professions there will still be a 5% shortfall and 6-10% shortfall in supply by 2036/7 based on anticipated demand. This too, has the potential to impact the service required to deliver accompanying interventions to pharmacotherapy to ensure sustained effects.

Implications for wider NHS Services

An improvement in obesity and obesity related healthcare costs is expected with the introduction of weight loss drugs. Examination and understanding of long-term implications on wider NHS services is essential to ensure future demand can be responded to appropriately.

Unintended complications of new pharmacotherapy or resultant

1. Health Survey for England 2021-22. [Health Survey for England, 2021: Data tables – NHS Digital]
2. Sarwer et al. The Psychosocail Burden of Obesity. Endocrinology Metabolic Clinical Journal North America, Sept 2016. [The Psychosocial Burden of Obesity - PMC (nih.gov)]
3. BMA Measuring Progress Report. [bma-measuring-progress-of-commitments-for-mental-health-workforce-jan-2020.pdf]

NHS Long Term Workforce Plan. [NHS Long Term Workforce Plan (england.nhs.uk)]

Background information:

Lifestyle interventions included in SURMOUNT-1 for all participants (SURMOUNT-1 trial protocol):

Participants will consult with a dietician, or equivalent qualified delegate, according to local standards, to receive lifestyle management counselling at Weeks 0, 4, 8 and 12 during dose escalation and then at Week 24 and every 12 weeks thereafter through 72 weeks.

Diet and exercise goals established during the lifestyle consultation and the importance of adherence to the lifestyle component of the trial will be reinforced at each trial contact by study staff.

At Visit 3 and subsequent visits, study participants will receive diet counselling by a dietician/nutritionist, or equivalent qualified delegate, according to local standard. Dietary counselling will consist of advice on healthy food choices and focus on calorie restriction using a hypocaloric diet with macronutrient composition of:

• maximum 30% of energy from fat

• approximately 20% of energy from protein • approximately 50% of energy from carbohydrates

• an energy deficit of approximately 500 kcal/day compared to the participant's estimated total energy expenditure (TEE).

To encourage adherence, it is recommended that a 3-day diet and exercise diary be completed prior to each counselling visit. During each visit, the participant's diet is reviewed and advice to maximize adherence is provided if needed.

At Visit 3 and all subsequent visits, participants will be advised to increase their physical activity to at least 150 minutes per week.

Schedule of activities: details of how weight management support was provided for all participants:

Activity	Timing of activity (study treatment weeks)	Additional detail
Providing diary to participant and instructing use	Weeks 0, 12, 24, 36, 48, 60 and 72	Training should be repeated as needed to ensure compliance
Review study diary, including drug compliance	Started week 4, continued every 4 weeks	NA
Lifestyle programme instructions	Weeks 0, 4, 8, 12, 24, 36, 48, 60 and 72	Counselling on diet and exercise to be performed by a dietician or equivalent qualified delegate, according to local standards; to include calculation of individualised energy requirement and methods to change dietary composition and amount of physical activity. Dietary counselling will consist of advice on healthy food choices and focus on calorie restriction using a hypocaloric diet with macronutrient composition of: • maximum 30% of energy from fat • approximately 20% of energy from protein • approximately 50% of energy from carbohydrates • an energy deficit of approximately 500 kcal/day compared to the participant's estimated total energy expenditure (TEE) To encourage adherence, it is recommended that a 3-day diet and exercise diary be completed prior to each counselling visit. During each visit, the participant's diet is reviewed and advice to maximize adherence is provided if needed. Beginning at week 8, the lifestyle program instruction may be delivered by phone.
Review of diet and exercise goals	Started week 0, continued every 4 weeks	Training should be repeated as needed to ensure compliance

*provisions for changes in study conduct during exceptional circumstances, including pandemics included (relevant due to study period during COVID-19; start date December 2019; primary completion date April 2022): remote visits, and diaries acquired alternatively, for example by delivery.

<u>Current company and EAG modelling assumptions around weight management support:</u>

Company:

- Background disease-related resource use in the model encompasses general practitioner visits, nurse visits and blood tests. Frequency of resource in each category are based on Ara et al. 2012. Resource use is applied irrespective of treatment for the full-time horizon of the model.

- No other costs which imply treatment setting are included in the company's model.

Table 2: company's estimated background resource cost

Category	Quantity per year	Unit cost	Annual cost	Source
GP visits*	4	£232/hour	£154.67	Quantity per year: Ara *et al.* 2012 Cost of GP visit: GP - Unit costs (including direct care). PSSRU 2022 Cost of nurse visit: Band 6 Nurse. PSSRU 2022 Cost of blood tests: DAPS05, NHS Reference Costs 2021/2022
Nurse visits*	8	£57/hour	£76.00	
Blood tests	1	£2.96	£2.96	
Total annual cost			£233.63	

Section B3.5.2.1, company submission

EAG:

- Estimated specialist weight management service (SWMS) costs from clinical expert opinion, which were applied to all arms in the model for the entire time horizon (see table 2). EAG also presented the following

scenarios for comparisons with diet and exercise and semaglutide, either with or without 2-year stopping rules for all active treatments:

a) Removing all SWMS costs from all arms

b) Removing SMWS costs for diet and exercise arm

c) Removing SWMS costs for diet and exercise arm and tirzepatide arm

No alternative background costs were included when SWMS costs were removed.

Table 3: EAG's estimated background resource cost (specialist weight management service costs)

Category	Quantity per year, year 1	Quantity per year, second and subsequent years	Unit cost	Source
Consultant visit	3	2	£152.14	Consultant led dietetics Service non-admitted face to face OP cost
Psychologist visit	3	0	£152.14	
Dietician visit	8	4	£98.43	Non-consultant led dietetics Service non-admitted face to face OP cost
Total annual cost, year 1	**-**	**-**	**£1,645**	**-**
Total annual cost, year 2 and subsequent years	**-**	**-**	**£698**	**-**

Section 5.4.1, EAG report

<u>Costs for digital technologies for weight management support:</u>

No costs associated with the emerging digital technologies for delivering specialist weight management services to manage weight-management medicine were included in the model, by either the company or the EAG.

Details for the indicative costs used in the NICE Early Value Assessments for digital technologies for providing specialist weight management services can be found in table 25 of the assessment report for HTE14 (covering digital technologies with a prescribing function) and table 8.4 of the assessment report for Guideline in Development-HTE10023 (covering digital technologies without prescribing).