Surrey Heartlands Integrated Care System
Area Prescribing Committee (APC)

Integrated Care Partnership - Surrey Downs, Guildford & Waverley, North-West Surrey, and East Surrey Places & associated partner organisations.

NICE Technology Appraisals (TA) briefing paper for local implementation

NICE TA Guidance name and number	Semaglutide for managing overweight and obesity Technology appraisal guidance [TA875]		
Available at	https://www.nice.org.uk/guidance/ta875		
Date of issue	Published: 08 March 2023 Last updated: 04 September 2023 Resource impact template published March 2023, updated April 2023 and October 2023 (late)	**Implementation deadline**	within 3 months of its date of publication or commercial availability of the product

Medicine details[1]	
Name and brand name	Semaglutide (Wegovy®)
Manufacturer	Novo Nordisk Limited
Mode of action	Human glucagon-like peptide-1 (GLP-1) analogue. GLP-1 is a physiological regulator of appetite and calorie intake, and the GLP-1 receptor is present in several areas of the brain involved in appetite regulation. Improves the likelihood for people to maintain a hypocaloric diet, and so to lose weight and maintain the weight loss.
Licensed indication	Adults Wegovy is indicated as an adjunct to a reduced-calorie diet and increased physical activity for weight management, including weight loss and weight maintenance, in adults with an initial Body Mass Index (BMI) of • ≥30 kg/m2 (obesity), or • ≥27 kg/m2 to <30 kg/m2 (overweight) in the presence of at least one weight-related comorbidity. Adolescents (≥12 years) Wegovy is indicated as an adjunct to a reduced-calorie diet and increased physical activity for weight management in adolescents ages 12 years and above with • obesity* and • body weight above 60 kg. Treatment with Wegovy should be discontinued and re-evaluated if adolescent patients have not reduced their BMI by at least 5% after 12 weeks on the 2.4 mg or maximum tolerated dose.

Formulation	Solution for injection in pre-filled pens: 0.25mg, 0.5mg, 1mg, 1.7mg and 2.4mg
Dosage	For Adults: Monthly dose escalation from 0.25mg to 1.7mg, maintenance doses may remain at 1.7mg or increase to 2.4mg
Comparison of NICE TA with Summary of Product Characteristics (SmPC)[2] *See appendix 1 for comparison table*	• The NICE TA only applies to Adults. The license includes the treatment of adolescents, but this service is being commissioned directly by NHSE • The NICE TA only supports 2 years of treatment. There is no such limit in the SPC • The NICE TA requires there to be an obesity associated co-morbidity before patients are eligible for treatment, however the license only has this requirement for people with a BMI between 27.5 and 30, People with a BMI over 30 can be prescribed semaglutide for the treatment of obesity even if they do not have an associated co-morbidity NOTE that many of the patients eligible within this NICE TA, do not meet eligibility criteria for Tier 3 services, see appendix 1

NICE TA recommendations[2]

Recommendations

- it is used for a maximum of 2 years, and within a specialist weight management service providing multidisciplinary management of overweight or obesity (including but not limited to tiers 3 and 4), and
- they have at least 1 weight-related comorbidity and:
- a body mass index (BMI) of at least 35.0 kg/m^2, or
- a BMI of 30.0 kg/m^2 to 34.9 kg/m^2 and meet the criteria for referral to specialist weight management services in NICE's guideline on obesity: identification, assessment and management.
- the company provides semaglutide according to the commercial arrangement.

Use lower BMI thresholds (usually reduced by 2.5 kg/m^2) for people from South Asian, Chinese, other Asian, Middle Eastern, Black African or African-Caribbean family backgrounds.

1.2 Consider stopping semaglutide if less than 5% of the initial weight has been lost after 6 months of treatment.

Decision making framework (DMF)

National guidance and priorities

The ICS has a legal obligation to commission this medicine in line with the NICE TA.

- This NICE TA has been assigned within 3 months of its date of publication or commercial availability of the product. Although the TA was published on the 8th March 2023, it only became commercially available to coincide with an update of the TA, on the 04th September 2023
- The implementation deadline is 4th December 2023 but with constrained supplies

Clinical effectiveness

Clinical trial evidence shows that people lose more weight with semaglutide alongside supervised weight management support than with the support alone. Mean weight loss in obese people without diabetes was 15% in several trials, sustained up to 2 years with continued use.

The company's model which informed the NICE TA, used risk equations to estimate the risk of long-term cardiovascular events such as an acute coronary event or stroke, and the risk of developing type 2 diabetes. These equations were based on surrogate outcomes from STEP 1 including BMI, systolic blood pressure, total cholesterol, high density lipoprotein and HbA1c levels. The NHS England representative explained that the risk equations used had not been validated by any data showing beneficial cardiovascular outcomes with weight loss in people without diabetes. They quoted a real-world, large UK study (with a follow up of up to 6 years) that did not show a reduction in cardiovascular events related to sustained weight loss alone. The clinical experts highlighted that a reduction in cardiovascular events has been shown with GLP-1 inhibitors (the same class of drug as semaglutide) in people with diabetes. However, they accepted this had not yet been shown in people without diabetes. The committee was also aware that risk equations were based on an assumption of a steady state. They were not designed for estimating long-term risk when using an intervention with a time-limited benefit (such as a 2-year treatment course; see section 3.12). Also, risk equations are not prognostic on an individual basis.

For people with diabetes, semaglutide has been shown to stabilise blood sugar levels (reduction in HbA1c) and weight loss at the doses approved for people with Type 2 diabetes and addressed in a separate NICE TA. Doses licensed for the management of diabetes are lower than those licensed for the treatment of obesity, and weight loss is lower, with a mean loss of 4.5Kg[11]. In trials using the higher doses for weight loss, patients with type 2 diabetes had a lower mean (SD) percentage weight loss at 3 and 6 months compared with those without type 2 diabetes: 3.9% (3.1%) vs 6.3% (3.7%) at 3 months (P = .001) and 7.2% (6.3%) vs 11.8% (5.3%) at 6 months (P = .005)[12]

Patient safety

- The product should be used within its product license.
- Semaglutide is a Black Triangle drug[1] – all suspected adverse reactions should be reported in order to identify rare adverse effects.
- National patient safety alert issued for GLP-1 receptor agonists: The alert warns healthcare providers not to switch between brands or double up on lower-dose preparations when the higher dose is unavailable[5]
- Falsified Ozempic (semaglutide) pens identified at two wholesalers in the UK[6]
    - Buying semaglutide from illegally trading online suppliers significantly increases the risk of getting a product which is either falsified or not licensed for use in the UK.
    - Products purchased in this way will not meet our strict quality and safety standards, and taking such medicines may put your health at risk

Patient factors

- There is a very high demand for weight loss medication. Consensus is that demand will vastly exceed capacity and current constrained supplies and access to Tier 3 services, or equivalent, which have been made on the basis of the original NICE costing template (April 2023)

Environmental impact

- The devices are single use, plastic, which will need to be discarded. Needles will also be used and will need to be discarded as sharps clinical waste.

Equality & diversity

From the NICE Technology appraisal[1]:

Commissioners and/or providers have a responsibility to provide the funding required to enable the guidance to be applied when individual health professionals and their patients wish to use it, in accordance with the NHS Constitution. They should do so in light of their duties to have due regard to the need to eliminate unlawful discrimination, to advance equality of opportunity and to reduce health inequalities. And:

3.22 The committee noted that people from some minority ethnic family backgrounds are at an equivalent risk of the consequences of obesity at a lower BMI than people from a White ethnic family background. Also, NICE's guideline on obesity recommends using lower BMI thresholds for South Asian, Chinese, other Asian,

Middle Eastern, Black African or African-Caribbean family backgrounds when identifying the risk of developing type 2 diabetes and providing interventions to prevent it. The committee agreed that a similar adjustment would be suitable when considering treatment with semaglutide.

The Weight Management steering group have identified that the number of people eligible to this treatment far exceeds current constrained supply, available pathways, and funding identified in the NICE TA costing template being much less than that required for actual eligible patients estimated as seeking treatment with semaglutide, and therefore the proposal is to identify groups of people identified as having the most urgent clinical need to enable fair access to the available supplies, and carrying out further evidence review and extend those groups as the current constraints are lifted. This will be the main option presented.

Place in therapy relative to available treatments

There is a large unmet need for many people living with obesity, and semaglutide is a new treatment option.
Diet and exercise are key treatments prior to and during treatment with semaglutide, but there is a very big cohort of patients in whom diet and exercise, on their own have failed:
Recent meta-analyses of new anti-obesity drugs and their weight-loss efficacy have shown that the overall placebo-subtracted weight reduction (%) for at least 12 months ranged from 2.9 to 6.8% for the following drugs: phentermine/topiramate (6.8%), liraglutide (5.4%), naltrexone/bupropion (4.0%), orlistat (2.9%)[7]
In the key semaglutide trial[8]: Once-Weekly Semaglutide in Adults with Overweight or Obesity: compare the effect of semaglutide s.c. 2.4 mg once-weekly versus semaglutide placebo as an adjunct to a reduced-calorie diet and increased physical activity in subjects with overweight or obesity on body weight, demonstrating the incremental benefit of semaglutide over diet and exercise alone. Lifestyle modifications can reduce the risk of developing cardiovascular complications, but patients do not easily maintain any accomplished weight loss[9].
The 'Two-year effects of semaglutide in adults with overweight or obesity: the STEP 5 trial'[10] showed that the mean change in body weight from baseline to week 104 was -15.2% in the semaglutide group (n = 152) versus -2.6% with placebo (n = 152), for an estimated treatment difference of -12.6 %-points (95% confidence interval, -15.3 to -9.8; P < 0.0001, and this supports the 2-year benefit of semaglutide over placebo in people complying with the diet and exercise requirements.
However the NICE evaluations indicate that Semaglutide is limited to 2 years because of restricted time in specialist weight management services and lack of evidence for longer use, and the costing
Semaglutide may improve cardiometabolic risk factors and reduce antihypertensive/lipid-lowering medication use versus placebo in adults with overweight/obesity without diabetes. These potential benefits were not maintained after treatment discontinuation[13]

Stakeholder views

The paper was developed in consultation with an Obesity Pathway Steering group, of which the members are listed on the Cover Sheet, although, due to time constraints, they will not have seen this complete paper before consultation.
It is then sent out for consultation and comments are listed on the front sheet.

Cost-effectiveness

For people who have at least 1 weight-related comorbidity and a BMI of at least 35 kg/m2 or a BMI of 30 kg/m2 to 34.9 kg/m2 and also meet the NICE criteria for referral to a specialist weight management service, the cost-effectiveness estimates for semaglutide are likely to be within what is normally considered a cost-effective use of NHS resources*
For these groups, semaglutide is recommended alongside lifestyle interventions in an appropriate multidisciplinary setting.

People from some minority ethnic family backgrounds have an equivalent risk from obesity at a lower BMI than people from a White ethnic family background
**Note: The cost efficacy calculations are based on an assumption provided by the company that 3 years after stopping semaglutide (with a 2-year treatment period), the weight advantage with semaglutide would be lost. This means the average weight for people taking semaglutide would be in line with what it would be in the average population in the diet and exercise treatment arm after 5 years[1]. New evidence indicates that One year after withdrawal of once-weekly subcutaneous semaglutide 2.4 mg and lifestyle intervention, participants regained two-thirds of their prior weight loss, with similar changes in cardiometabolic variables[4]. Findings confirm the chronicity of obesity and suggest ongoing treatment is required to maintain improvements in weight and health[4] This new data changes the cost efficacy calculations assumed by NICE and approximately doubles the cost per quality adjusted life year (QALY) from around £20,000 per QALY to £40,000 per QALY which is above the normally accepted upper threshold for NICE approval*

The drug cost per Place according to NICE resources greatly **exceeds** £100,000.

Section 1: cost of the technology

a. Annual cost per patient (or complete course if shorter)

   These costs are not publicly available. Semaglutide used at much lower doses for the treatment of people with Type 2 diabetes costs £952.25 per patient per year (based on Drug tariff price of £73.25 flat rate for 0.25mg, 0.5mg and 0.75mg doses (November 2023),

b. Availability of CAP/PAS price:
   Yes

c. Price relative to comparable medicines:
   If semaglutide is used to treat those patients eligible for treatment with liraglutide in line with NICE TA664, which is targeted to people with obesity and pre-diabetes, there is a relatively small price increase.
   Where semaglutide is to be prescribed for patients who meet this TA thresholds but not those for liraglutide in obesity, this will be a new cost. The semaglutide TA will have many more eligible patients than the liraglutide TA.

Section 2: NICE resource impact statement and template
Number of patients Year 1 and Year 5:

Potential patient numbers per 100,000:

a. NICE resource impact statement
   April 2023: 379 patients – Surrey Heartlands (46 per 100,000)
   October 2023 13,500 patients – Surrey Heartlands (1654 per 100,000)
   Steering group estimates 60,000 patients – Surrey Heartlands (7336 per 100,000). This number was based on a single GP practice where an extensive audit was carried out which demonstrated that the estimated adults identified in the NICE TA as being eligible to treatment was realistic with regards to their local population, noting that this practice is in an area of lower deprivation. Feedback from several clinicians in the steering group was that they estimated that almost all patients referred to specialist treatment had previously tried diet and exercise and they estimated that around 80% of the eligible patients would be requesting treatment with semaglutide. This is not an accurate number, however it is not possible to be more accurate at this time.

Factors affecting these numbers:

The NICE TA template from April 2023 estimated that, in Surrey Heartlands, out of an adult population of 817,850, **77,748** Adults would be eligible to treatment with semaglutide within the NICE TA thresholds. The steering group, with special feedback from a GP who carried out an internal audit on her patients, and where those results were extrapolated to the Surrey Heartlands population agreed that this number was in the right magnitude for our population. Where the steering group disagreed with the NICE resource template, was that this calculator estimated that the vast majority of those patients, when referred to an appropriate treatment centre would choose diet and exercise, and 379 patients would choose semaglutide. The steering group agreed that patients will all have been trying diet and exercise for years before asking to be referred for further treatment. The steering group estimated that around 80% of eligible patients would choose semaglutide, representing **60,000 patients**, noting that these are the obese patients who have been identified in the NICE TA. The actual number of obese adults in Surrey is much higher:
The Health Survey for England 2021 estimates that 25.9% of adults in England are obese and a further 37.9% are overweight but not obese. Obesity is usually defined as having a body mass index (BMI) of 30 or above. BMI between 25 and 30 is classified as 'overweight'[14] .This represents over 210,000 patients who are obese in Surrey.

b. NICE resource impact template

The cost impact exceeds the £100,000 per threshold, even at the lowest estimate of 379 patients per year. Costs are confidential and will be provided to the Surrey Heartlands Director of Pharmacy and Medicines Optimisation

Even when restricting access to Tier 3 services, as per most recent guidance, the steering group highlighted that there has already been a very sharp increase in the request for referrals from eligible patients, once they are aware of the option of this new treatment. The current pathway is therefore insufficient to meet the demand and additional pathways would need to be commissioned.
NICE have approved 4 digital resources in October 2023, and further resources will be available in 2024 which will be able to increase capacity, but these will have an additional cost, and will still be limited by constrained supplies of semaglutide.

Commentary:

The number of patients who will be able to be treated in the near future will be:

- constrained supplies of semaglutide for the treatment of obesity there are no described number of patients who will be guaranteed treatment in Surrey Heatlands, however the steering group has been given an estimate.
- a bottleneck resulting from limited existing capacity which can be redirected for this therapy
- time required to develop and commission new pathways

This will create a large number of people who will be disappointed with lack of access to a treatment they are entitled to as described by a NICE technology appraisal.
The Area Prescribing Committee will therefore be asked to

- consider whether it is appropriate to adopt a phasing in approach for Wegovy due to constrained supplies, treating patients in line with guidelines published by Clinical Colleges. At a time of this meeting a draft is available and has been shared OR
- consider whether all eligible patients should be treated on a first come/ first served basis.

People reading this document will also notice that there is a very big affordability of the gap between

- the cost estimated in the original NICE costing template which would be assumed was that considered for NHS funding
- the cost estimated in the new costing template, and

- the number of patients estimated to be the actual number requesting treatment in practice

And an affordability gap between the assumption that a 2 year course of treatment will have long term benefit to patients, and the recent evidence that weight is rapidly regained after cessation of treatment.

- The TA does not state that previously treated patients could not be retreated (nor should it as it is based on a wrong assumption)
- There are several other treatments, some demonstrating greater benefit, such that sequential use of these treatments is expected creating exponential growth of costs as these will be cumulative over a life-time and not the 2 years described.

The Surrey Heartlands Director of Pharmacy and Medicines Optimisation has delegated authority to enable the Committee to be a decision-making committee providing the impact of any single decision does not exceed £100,000 within an individual Place per annum. Decisions with a cost impact of over £100,000 within an individual Place per annum require authorisation from Surrey Heartlands Health & Care Professionals Committee at their next meeting. Exception to this will be for any decision made in relation to a NICE Technology Appraisal (which are subject to requiring mandatory funding by commissioners) and other urgent items. The exceptions will be taken to the next Executive Meeting (which meets weekly) for authorisation.

Traffic light recommendation to APC

NHS Payment Scheme (NHSPS) excluded high-cost drug: see NHS England » 2023-25 NHS Payment Scheme

No but Tier 3 services are commissioned by CCGs and therefore the price will need to reflect the cost of these treatments.

Recommended traffic light status and rationale:

RED – For Ashford and St. Peter's Hospital Tier 3 service only. NICE have approved alternative digital solutions which need to be considered in the future.

Note: this service also delivers most of the provision for Frimley ICB. Their population is approximately 30% smaller than Surrey Heartlands, so the numbers described above should be considered within the context of the capacity of the service. The author has not investigated differences in obesity rates between the two ICBs

PAD definitions, available at: Traffic Light Status (res-systems.net)

Implementation

NICE TA implementation must be within 3 months of its date of publication or commercial availability of the product.

The NICE TA states that Commissioners and/or providers have a responsibility to provide the funding required to enable the guidance to be applied when individual health professionals and their patients wish to use it, in accordance with the NHS Constitution. They should do so in light of their duties to have due regard to the need to eliminate unlawful discrimination, to advance equality of opportunity and to reduce health inequalities.

Actions to implement:

a. Primary care

- The supply of semaglutide (Wegovy®) for managing overweight and obesity, for NHS patients, is currently very tightly restricted to approved specialist services. The preparations of semaglutide available for the management of people with type 2 diabetes (Ozempic®) should not be prescribed for this indication.
- Novo have committed a separate supply for NHS patients than for private patients. Primary Care Prescribers are not able to prescribe Wegovy® for people who initiated treatment privately, even if they meet NICE thresholds.
- A very high demand for this treatment has been experienced in Primary Care.

b. Secondary care

Only specifically commissioned Obesity services with a Tier 3 or equivalent service, will be able to provide the education, training and medicines associated in the NICE Technology appraisal
Further cost calculations will need to be made to establish the cost efficacy of providing the medicines through homecare.

c. ICS

- This technology is commissioned by integrated care systems.
    - There is insufficient capacity to meet the demand of eligible patients, and this will need to be considered in the future.
    - The ICS needs to understand the potential cost impact of implementation of this NICE Technology appraisal.

d. PAD and Joint Formulary
- **RED** traffic light classification for Specialist Tier 3 services or equivalent
- Phasing groups if this is the option selected

Proposed tick box forms

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Declaration of interest:

	Name	Role	Date	Declaration of interests (please give details below)
Prepared by	Carina Joanes	Medicines Resource Unit (MRU) Lead Pharmacist (Clinical) Surrey Heartlands Integrated Care System	5th Nov. 2023	Personal
Supported by	Will King	Will King NHS LTP Prevention Programme Manager Surrey County Council	3rd Nov 2023	
	Dr. Katherine Mccullough	Consultant Physician in Acute Medicine, Diabetes and Endocrinology and Bariatric Medicine Royal Surrey Hospital NHS Trust NHS England Regional (South East) Advisor for Acute Medicine		
	Dr. Ruchika Gupta	Clinical Director for Long Term Planning Delivery Surrey Heartlands Integrated Care System		

	Dr.Sarah Steely	PGCDiabetes Principal GP The Wall House Surgery, Reigate Clinical Lead for Diabetes Surrey Heartlands Integrated Care System		
	Theresa Kirkham	Theresa Kirkham Service Manager, Bariatrics & Upper GI Ashford & St Peter's Hospitals Foundation Trust		
	Sharmeen Ajaz	Acting Formulary Pharmacist, Lead Education and Training Pharmacist Ashford & St Peter's Hospitals Foundation Trust		
	Dr. Negin Sarafraz-Shekary (PhD)	Public Health Principal Surrey County Council		
	Jenn Smith	Senior Public Health Lead Surrey County Council		
	Dr. Liz Saunders	Consultant in Public Health Surrey County Council		
	Peter Dawson	Senior Public Health Lead Surrey County Council		
	Elizabeth Rahim	Director of Acute and Collaborative Contracts Surrey Heartlands CCG / NEL CSU		
	Rajni Cairns	Frimley Representative at the Obesity Steering Group Frimley ICB		
	Nketia Obed-Arthur	Divisional Lead Pharmacist for General and Specialist Medicine (SAMS, Frailty, Respiratory and Palliative Care) St. Peter's Hospital		
	Helen Marlow	Lead Respiratory Specialist Pharmacist and NICE Medicines and Prescribing Associate Surrey Heartlands ICB		
Reviewed by				

Explanation of declaration of interest:
None.

Version control sheet:

Version	Date	Author	Status	Comment
1	17/11/2023	Carina Joanes	Draft	Out for consultation
2	01/12/2023	Carina Joanes	Final	APC final papers

Blueteq® form:

Appendix 1 – Comparison between License, and NICE TA for Semaglutide (Wegovy®), and Criteria for Tier 3 Obesity service (Ashford and St. Peter's Hospital)

Licensed indication	NICE TA (March 2023)	Tier 3 and 4
https://www.medicines.org.uk/emc/product/13799/smpc	https://www.nice.org.uk/guidance/ta875/resources/semaglutide-for-managing-overweight-and-obesity-pdf-82613674831813	
Adults Wegovy is indicated as an adjunct to a reduced-calorie diet and increased physical activity for weight management, including weight loss and weight maintenance, **in adults** with an initial Body Mass Index (BMI) of • ≥30 kg/m2 (obesity), or • ≥27 kg/m2 to <30 kg/m2 (overweight) in the presence of at least one weight-related comorbidity. Adolescents (≥12 years) Wegovy is indicated as an adjunct to a reduced-calorie diet and increased physical activity for weight management in adolescents ages 12 years and above with	• it is used for a maximum of 2 years, and within a specialist weight management service providing multidisciplinary management of overweight or obesity (including but not limited to tiers 3 and 4), and • they have at least 1 weight-related comorbidity and: • a body mass index (BMI) of at least 35.0 kg/m^2, or • a BMI of 30.0 kg/m^2 to 34.9 kg/m^2 and meet the criteria for referral to specialist weight management services in NICE's guideline on obesity: identification, assessment and management. • the company provides semaglutide according to the commercial arrangement. Use lower BMI thresholds (usually reduced by 2.5 kg/m^2) for people from	BMI 35> and one weight related co-morbidity BMI 30-35 (CG189 criteria): the person has complex disease states or needs that cannot be adequately managed in Tier 2 (LD, for example) Must be used in conjunction with a specialist weight management programme for a period of 2 years Eligibility BMI 40> or 35-40 a significant co-morbidity BMI 30-35 (CG189 criteria): the person has complex disease states or needs that cannot be adequately managed in Tier 2 (LD, for example) OR Conventional treatment has been unsuccessful

• obesity* and • body weight above 60 kg. Treatment with Wegovy should be discontinued and re-evaluated if adolescent patients have not reduced their BMI by at least 5% after 12 weeks on the 2.4 mg or maximum tolerated dose.	South Asian, Chinese, other Asian, Middle Eastern, Black African or African-Caribbean family backgrounds. 1.2 Consider stopping semaglutide if less than 5% of the initial weight has been lost after 6 months of treatment.	