Annex D: Implementation Proposal

1. In collaboration with national clinical advisors, NHS England (NHSE) has devised a template model for the safe and effective use of tirzepatide, based on the SURMOUNT-1 trial featured in Eli Lilly's submission to the National Institute of Health and Care Excellence (NICE) Committee. This model was shared with NICE on 19 February 2024 and the details of this model can be found in **Annex B**.

2. Using this model of care as a guide, NHSE, in conjunction with Integrated Care Boards (ICBs), is proposing an alternative implementation proposal (IP) that would allow for the steady and consistent expansion of service capacity to deliver a tirzepatide treatment pathway aligned to the treatment model outlined in **Annex B**.

IP

3. The IP requests an extension to the implementation period with a phased 'clinical priority' approach to full recommendation implementation.

4. The clinical prioritisation, informed by clinical expertise, begins with those patients with the highest clinical need. Over time, this scales to those at the lower bound of the committee's clinical recommendation. The IP provides granularity for how commissioners should approach introducing tirzepatide, setting ambitious targets based on the demographic data of the clinical cohorts.

5. The timing of the commencement of each clinical cohort is based not on calendar or financial year, but a clear plan for when capacity should become available for each cohort.

6. This IP has been developed so that the displacement of GP appointment capacity is limited, to manage the risk of health inequalities. [redacted] This will see steady, pressing growth in the use of tirzepatide while reducing the risk of destabilising GP services for other patients who do not use the medicine for weight management.

7. The clinical cohorts are based on a hierarchy of need and use the following qualifying diagnosed comorbidities only, matching those tracked through the SURMOUNT-1 trial.
   - Hypertension,
   - Dyslipidaemia,
   - Obstructive sleep apnea,
   - Cardiovascular disease.

8. Type 2 Diabetes, while an exclusion from the SURMOUNT-1 trial, has been added as a qualifying comorbidity for the IP.

Table 3: Proposed IP

FV cohort	Cohort length	Cohort definition		Cohort size	Cumulative patient access at cohort end
		BMI	Comorbidities		
Cohort I	18 months	≥ 40	≥3 ‘qualifying’ comorbidities	42,000	42,000
Cohort II	12 months	≥ 40	2 ‘qualifying’ comorbidities	95,000	137,000
Cohort III	14 months	≥ 40	2 ‘qualifying’ comorbidities (inc T2DM)	200,000	337,000
Cohort IV	39 months	≥ 40	1 'qualifying’ comorbidity (inc T2DM)	570,000	907,000
Cohort V	9 months	≬35 - 39.9	≥3 ‘qualifying’ comorbidities	100,000	1.007m
Cohort VI	20 months	≬35 - 39.9	2 ‘qualifying’ comorbidities	224,000	1.231m
Cohort VII	32 months	≬35 - 39.9	2 ‘qualifying’ comorbidities (inc T2DM)	370,000	1.601m
12 Years	**144 months**				**1.6M patients**

9. The cohorts above will be adjusted for ethnic differences related to the categorisation of obesity, in-keeping with the NICE recommendation for this medicine. This means that a lower BMI threshold will be applied in the IP for people with a South Asian, Chinese, other Asian, Middle Eastern, and Black African or African-Caribbean ethnicity. For these patients, the BMI threshold above will be reduced by 2.5 kg/m^2 for all cohorts. For example, the assumed BMI of ≥40 BMI will apply as a BMI of ≥37.5 for patients with the ethnicities listed above. This will help ensure equity of access to the medicine and support providing access by clinical prioritisation (black adults are recorded as the ethnic grouping with the highest rate of excess weight). However, to note: the cohorts listed in Table 2 do not include demographic data for those eligible for treatment under a lower BMI threshold (this is a weakness in the data, listed in paragraph 16).

10. Our IP starts with those with the greatest clinical need who will be most likely to require the support of these services, and it does this when NHS services are least prepared to provide this for them. This is why the initial cohorts are lower in number, allowing escalation of provision as services become online and treatment pathways become more established.

[redacted]

Table 1: Demands of existing primary care capacity without variation (%)

	Year				
	1	2	3	4	5
GP appointments	20.2	8.1	3.3	2.9	2.5
Dietitian sessions	74.8	116.8*	102.8*	39.1	<1^
Psychological support sessions	27.6	28.3	23.3	10.7	<1^

Based on 2.8 million eligible patients. The numbers above include cumulative growth in patient numbers.

*Over 100% of existing NHS capacity.

^This scenario does not assume that some elements of ongoing clinical support will be required. If all patients are treated in earlier years, medium term, demand for dietetic and psychological support will return to low levels following the initial wave of demand.

Table 2: Demands of existing primary care capacity with variation (%)

	Year				
	1	2	3	4	5
GP appointments	0.22	0.52	1.14	1.77	2.05
Dietitian sessions	0.80	2.83	7.03	12.76	17.80
Psychological support sessions	0.29	0.89	2.13	3.68	4.88

Based on 2.8 million eligible patients. The numbers above include cumulative growth in patient numbers.

IP data assumptions

12. While the best care has been taken to produce the most accurate data upon which to base this FV, some assumptions have been made when compiling this cohort data for the IP.

- Uptake: it is assumed that over the length of a cohort, 100% of the cohort will present for pre-screening for the treatment.
- Presentation: Of these, 70% of the cohort will be willing and found clinically eligible to initiate treatment. This figure is informed by clinical advice.
- Drop-out: it is assumed 5% patient drop-off every six-months, leading to a full churn in patients using the medicine after ten years. As there is no stopping rule on this medication, we do not yet know the average length of treatment.
- Restart: it is feasible that a patient could initiate, cease and then re-initiate treatment before expansion of eligibility under the FV (a patient remains eligible for the treatment if in an eligible cohort and there is no restriction on restarting treatment if a patient is in an eligible cohort). We do not know how many patients may reinitiate treatment after stopping and so no allowance is made for the number of patients who may do this.
- Upper age limit: the cohorts are based on demographic data that has an upper bound of 75 years. Therefore, our cohort sizes may underestimate the actual cohort size and qualifying patients over the age of 75 are not in this count. While there are circumstances specific to this age group which may prohibit the use of a weight-loss medication The intention is that those over 75 years old will still be eligible to receive tirzepatide if clinically recommended; there is no upper age limit from NICE for its use.
- Patient population: this model assumes a static and location-blind patient population. Eligible patients in other settings, such as those detained and imprisoned, are included in the general population figures used for the cohorts. No factor has been applied to anticipate either rises or falls in the percentage of people with a relevant BMI, nor any factor has been applied to account for population growth or degrowth.
- Patient ethnicity: the estimated cohort sizes do not make any allowance for patients for some ethnicities who would be eligible for the access to the treatment at a lower BMI threshold. This is because the cohort sizes are not based upon patient level data. Therefore, we would expect that the actual cohort sizes are larger than listed here, to account for the patients eligible at lower BMI thresholds.

Costs

13. The table below sets out the costs associated with the first three years of the IP:

Table 4: Draft IP, activity, and cost impact

		Activity Year					Impact on current service levels Year					Cost Year				
		1	2	3	4	5	1	2	3	4	5	1	2	3	4	5
Patient inflow		30,000	60,000	130,000	180,000	180,000										
GP appointments		344,585	827,840	1,827,120	2,830,881	3,285,366	0.22%	0.52%	1.14%	1.77%	2.05%	£14m	£34m	£75m	£116m	£135m
Blood tests		30,000	60,000	130,000	180,000	180,000						£m	£1m	£2m	£3m	£3m
Dietitian sessions		54,156	192,877	478,275	868,633	1,211,646	0.80%	2.83%	7.03%	12.76%	17.80%	£1m	£5m	£13m	£24m	£33m
Psychological support sessions		22,306	67,469	161,193	279,165	369,815	0.29%	0.89%	2.13%	3.68%	4.88%	£1m	£2m	£5m	£9m	£13m
GP Practice nurse appointments		59,365	183,821	444,009	800,716	1,132,566	0.08%	0.25%	0.61%	1.09%	1.55%	£1m	£3m	£8m	£15m	£21m
GP HCA appts		20,596	41,596	90,058	125,327	126,000	0.07%	0.13%	0.29%	0.41%	0.41%	£m	£m	£1m	£1m	£1m
Clinical Pharmacist appointments		16,113	96,469	254,888	537,529	867,966						£m	£1m	£3m	£6m	£10m
Off boarding/onward care		-	-	-	-	-						£m	£m	£m	£m	£m
Treatment Cost												£15m	£61m	£154m	£302m	£462m
Sharps		129,413	511,350	1,291,063	2,519,125	3,834,075						£m	£1m	£1m	£3m	£4m
Patient referrals for treatment	70%	21,000	42,000	91,000	126,000	126,000						£18m	£48m	£108m	£176m	£218m
												£33m	£108m	£262m	£478m	£680m
												45%	56%	59%	63%	68%

Progressing to removing the FV

14. The FV IP consists of a proposal lasting 12 years and six months. This duration consists of:
    a) An additional 90-days before any requirement to fund the medicine, providing a 180-day implementation period.
    b) Following the 180-days, a period of three years whereby the NHS increases its capacity to deliver for three cohorts of patients, leading to a service with the capacity for treating around 233,000 patients at the end of these three years.
    c) A further period of nine years during which Cohorts IV to VIII would be initiated, growing access from 233,000 to 1.6m patients, with the ambition to reduce the length of the IP as circumstances allow.
    d) Following the conclusion of Cohort VII, the complete withdrawal of the FV and the IP, leading to full implementation of the NICE recommendation for all patients within its scope (with an increase of a further 1.2m patients on full repeal).

15. However, this is the maximum length of the mitigations resulting from the FV and it may be possible to reduce the length of the FV if real-world use generates evidence that allows providers to streamline or make efficiencies in the treatment delivery that either release additional resource to treat more patients or, while maintaining patient safety and treatment efficacy, allow the service to be offered in a more light touch manner. However, due to the level of uncertainty in so many aspects of this technology, combined with the single opportunity to enter a FV, NHSE has proposed a FV IP that would support the NHS to deliver its commitment under our existing knowledge of the required treatment pathway.

16. It is intended for a review to take place at the points of three years of patient access, to allow all relevant parties to reappraise the situation based on the first three years of use by the NHS[1]. By this point, the NHS will have much better intelligence on demand for the medicine, the services required, and the costs incurred.
    a. We will know how quickly new services have been mobilised and how well the service is being delivered.
    b. We will know the knock-on impact on other weight management treatments and services.
    c. The proposed feasibility studies on alternative service models will have generated evidence to consider.
    d. We will have real-world evidence on treatment use, including longevity of demand for patients initialised.

Service models

17. To assess the correct configuration of services for the size and needs of the NHS patient cohort and support the cohort progression of the IP, the NHS intends to test multiple different models of delivery and support the roll-out of best practice learned.

[1] Regulation 7 of the NICE Regulations provides that *"(13) NICE must keep under review and may revise as it considers appropriate a technology appraisal recommendation".*
We consider this encompasses the ability to amend an FV since it is an integral part of a technology appraisal recommendation.

18. NHSE has identified five different delivery models, conceptualised in partnership with ICBs, which will be proposed to ICBs as options for meeting their commissioning responsibilities.

19. [redacted]

20. [redacted]
    - [redacted]
    - [redacted]
    - [redacted]
    - [redacted]

21. [redacted]
    i. [redacted]
    ii. [redacted]
    iii. [redacted]
    iv. [redacted]

[redacted]

22. [redacted]

[redacted]

23. [redacted]

24. [redacted]

25. [redacted]

Table 6: ICB Operating models of care

Redacted.

Fig 1: ICB delivery models – illustrative Redacted.

[redacted]

26. [redacted]

27. [redacted]