Annex B: Template treatment model for tirzepatide

1. The proposed clinical service and associated costs are mapped to the SURMOUNT-1 trial, the main evidence source in the Eli Lilly evidence submission to the Health Technology Appraisal (HTA) committee. It is noted that the trial population excluded large groups of patients with co-morbidities, and therefore the generalisability of the findings of the trial needs to be interpreted with this in mind. This proposed service model was provided to the NICE tirzepatide appraisal committee for its meeting (4 June 2024) and was accepted by the committee as a reasonable interpretation of the treatment model and a fair approximation of their financial costs.

2. NHSE is aware that patients with obesity have a high burden of psychological issues, such as but not restricted to mood disturbance and low self-esteem. NHSE notes that the SURMOUNT-Trial applied the following exclusion criteria (Jastreboff et al NEJM 2022;387:205-216 Supplementary Appendix). Potential participants were excluded if they:
   - *Have a history of significant active or unstable Major Depressive Disorder (MDD) or other severe psychiatric disorder (for example, schizophrenia, bipolar disorder, or other serious mood or anxiety disorder) within the last 2 years Note: Patients with MDD or generalized anxiety disorder whose disease state is considered stable and expected to remain stable throughout the course of the study, in the opinion of the investigator, may be considered for inclusion if they are not on excluded medications*
   - *Have any lifetime history of a suicide attempt*
   - *Have a Patient Health Questionnaire-9 (PHQ-9) score of 15 or more at Visit 1 or 3, prior to randomization*

3. NHSE interpretation of the trial protocol is that a PHQ-9 score of 15 or more (moderate to severe depression) was an independent exclusion criterion. NHSE therefore questions the generalisability of the SURMOUNT-1 trial to patients in the NHS who may have significant psychiatric issues or have moderate to severe depression. NHSE recognises that this group of patients will need psychological support if they were to be treated with tirzepatide.

Template treatment model

4. The proposed service model does not currently exist in the NHS. The costs associated with the proposed service are therefore new costs as a direct consequence of the new availability of tirzepatide.

5. The patient pathway can be segmented into three stages:
   i. Stage 1 is patient assessment, counselling and training. Assessment includes both eligibility criteria, exclusion criteria (as per the SURMOUNT-1 trial) and clinical safety checks. Counselling includes dietary and physical activity education, as well as the benefits and risks of tirzepatide. If patients consent, then training on how to self-inject tirzepatide will be given.

   ii. Stage 2 is dose titration to the maximum tolerated dose of tirzepatide as in the SURMOUNT-1 trial. The number of visits reflects the SURMOUNT-1 trial. NHSE is aware that gastrointestinal adverse effects are common, and that some patients may need slower dose titration than others, which may require more visits to reach the maximum tolerated dose. NHSE is also aware of the need to monitor for safety given that tirzepatide is a new treatment in the

NHS, and to help maximise adherence to treatment and reinforce dietary and physical activity education.

iii. Stage 3 is maintenance of treatment in responders for whom there will be on-going associated costs for as long as they are treated with tirzepatide. The frequency of visits reflects the SURMOUNT-1 trial with additional MDT overview of progress and prescribing.

6. Based on this need and using evidence from patients who are screened for bariatric surgery, NHSE estimates that all patients will need some level of initial psychological assessment prior to commencement of tirzepatide, and some level of routine screening for psychological issues arising during the course of treatment. Based on experience with bariatric services and clinical opinion we estimate that 1 in 3 patients will need ongoing psychological support. Clinical opinion is that majority of these patients (estimated at 70%), could be managed by Talking Therapies and the remainder would need more intensive psychological input. NHSE has costed psychological intervention according to these estimates.

7. While the services and the staffing to provide this treatment pathway do not exist, this model has a theoretical annual cost of up to £1.6bn by 2026/27.

8. A full breakdown of the treatment model is shown in the table below:

Table 1: Breakdown of appointment slots within the treatment model, including costs

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**

9. *To note in the table above*: total number of Year 1 GP slots does not equate to 21 appointments. There will be fewer appointments but some will be required to last 20 or 30 minutes. Therefore additional '10 minute' appointment slots have been used to represent this cost.

Implications for the wider obesity pathway

10. The creation of the new primary care weight management pathway for tirzepatide will necessitate wider changes to weight management care pathways.

[redacted]A new clinical pathway for weight management, aligned with the latest NICE guidance, will require to be established to offer GPs an easier referral process and options for patient management. With the growing complexity of local and national face-to-face and digital services, alongside new pharmaceutical therapies, demand is likely to exceed current service capacities. [redacted]

Fig 1: Draft new weight management pathway using the 'Hub' model

Redacted

Fig 2: Draft referral pathway using the 'Hub' model

Redacted