

# **Disease-specific reference case extension: management of overweight and obesity in adults**

## **Appendix A: Workshop notes**

### **Clinical Expert and Patient Advocate Workshop**

Date: 4 June 2025

Chair: David Wonderling

Organised by: NICE

Platform: Zoom

#### **Purpose of the Workshop**

The workshop was convened to gather clinical expert and patient advocate input on the development of NICE's disease-specific reference case extension for obesity. The discussion focused on current service provision, comparator definitions, population stratification, modelling challenges, and future research priorities.

#### **Attendees**

Clinical experts from various disciplines participated, including specialists in bariatric surgery, pharmacotherapy, nutrition and primary care. A patient group representative was also in attendance. Each participant shared their experience and perspectives on obesity management, pharmacotherapy, and surgical interventions.

#### **Key Topics and Discussions**

##### **Current Service Provision and Standard Care**

Discussions highlighted the tiered structure of obesity services and the challenges in defining comparators across tiers. Experts noted the evolving role of pharmacotherapy in primary care and the limited capacity in Tier 3 services.

##### **Population Stratification – weight cut-offs**

Experts debated the use of BMI versus waist circumference, with consensus leaning towards BMI due to its clinical utility and data availability. Ethnic-specific BMI thresholds were suggested to improve stratification.

##### **Outcomes and Comorbidities**

Participants emphasized the importance of capturing cardiometabolic, structural, and musculoskeletal outcomes. Cancer, mental health, PCOS, IVF & fertility, CKD were also mentioned but that there was currently a lack of clinical trials for direct evidence

of treatment effect for these. Importance of focusing on outcomes that have been directly measured in trials or where there are validated risk equations highlighted. Real-world evidence and trial data were discussed as sources for modelling benefits and risks.

## **Subpopulations and Strata**

There was strong support for inclusive modelling using risk scores to identify patients most likely to benefit. They did not want sub-populations excluded from the reference case extension, for example people living with T2DM and obesity. Concerns were raised about outdated guidelines and the need for holistic approaches.

## **Predicting Risk of Future Events**

Experts discussed the limitations of risk equations and the need for trial data to validate predicted outcomes. Modelling challenges were acknowledged, especially for incretin agonists that have effects on certain outcomes that are independent of weight loss. It was noted that clinical data sets such as CPRD will not capture private prescriptions of these medicines. Furthermore, risk tools are largely based on white wealthier populations and there is a need for more tools tested in diverse groups.

## **Weight Change Over Time**

The chronic nature of obesity was emphasized, with long-term treatment and individualised care being key themes. Stopping rules and medication adherence were identified as important modelling considerations. The need for education on the value of nutrition was highlighted.

## **Quality of Life and Experience**

Stigma and patient experience were highlighted as critical factors. Experts advocated for consideration of societal impacts such as return to work.

## **Next Steps and Future Research**

Recommendations included modelling service delivery in primary care, researching access across ethnic groups, and prioritising treatments for those with greatest benefit potential.

## **Summary**

The workshop provided valuable clinical insights to inform the obesity reference case extension. There was consensus on the need to prioritise treatments for patients with the greatest potential benefit, and to ensure modelling reflects real-world service provision and patient diversity.

# Economic Modelling Workshop

Date: 3 July 2025

Chair: David Wonderling

Organised by: NICE

Platform: Zoom

## Purpose of the Workshop

This workshop was convened to gather expert input on economic modelling approaches for NICE's disease-specific reference case extension for obesity. The discussion focused on population stratification, comparator definitions, model structure, health states, risk prediction, treatment effects over time, and quality of life considerations.

## Attendees

Participants included health economists, statisticians and modelling specialists with experience in obesity, diabetes, and related comorbidities. The group brought diverse perspectives on modelling approaches, data sources, and the challenges of capturing real-world complexity in economic evaluations.

## Key Topics and Discussions

### Summary of Existing Models

No major models were identified as missing from the review. A participant noted that the DHSC Calorie Model, although primarily used for population-level calorie change, does have some functionality for modelling weight loss and weight regain.

### Population and Comparators

There was a strong consensus on the importance of stratifying by BMI, but also recognition that comorbidities may be more important determinants of risk and treatment benefit. Discussion on the limitations of simple BMI splits; preference for sampling across the full BMI distribution, especially in individual patient models. Real-world populations differ from clinical trial populations; models should reflect this.

Comparators should remain broad and flexible to accommodate evolving NHS services and new treatments. Minimum comparators should be specified for consistency, but future-proofing is essential.

### Model Structure and Health States

There was debate over the merits of individual patient simulation versus cohort Markov models. Individual patient models can better capture heterogeneity but are less transparent. Key comorbidities to prioritise: CVD, diabetes, sleep apnoea, kidney disease, and liver disease.

The potential risks of double-counting outcomes (e.g., cancer may already be accounted for in mortality ratios or mental health may be captured in BMI utility values) were highlighted. Mental health and IVF/fertility highlighted as important but challenging to incorporate into an obesity model. Suggested these should be captured qualitatively.

Prioritisation of outcomes should be based on evidence of direct treatment effects. It was noted that there are ongoing clinical trials of incretin agonists for the treatment of other obesity related comorbidities such as chronic low back pain.

Multi-morbidity and the type of comorbidities are critical; not all comorbidities carry equal weight in terms of risk and benefit.

## **Predicting the Risk of Future Events**

Challenges in using risk equations were highlighted, especially for time-varying effects and when evidence is limited for certain interventions (such as apps or lifestyle interventions). The use of risk equations was considered pragmatic. The importance of validating models with real-world data and considering both direct and indirect effects of treatments was highlighted. The participants discussed the potential benefit of a large individual patient data meta-analysis to estimate time paths and risk equations or asking manufacturers to harmonise analyses across trials to improve risk prediction of outcomes (e.g. CVD). The MedSci et al 2023 paper was noted by a number of participants as a useful reference: [Weight change and risk of obesity-related complications: A retrospective population-based cohort study of a UK primary care database.](#)

## **Treatment Effects Over Time**

Stopping rules included in previous models reflected NHS service constraints. Weight regain was highlighted as a key modelling consideration. Sensitivity analyses are needed to address uncertainties in long-term weight trajectories and treatment discontinuation. Difficult in relying on real-world evidence was noted as this is limited by data gaps and drug shortages.

The models should capture treatment effect over time rather than an end point as they will fluctuate and change and be affected by drop-outs.

## **Quality of Life, Resource Use, and Costs**

The risk of double-counting quality of life and cost was discussed. Multiplicative approaches to disutility for multiple morbidities are recommended (per NICE TSD12).

Generally, participants were wary of specifying treatment related adverse effects upfront.

It was noted that societal impacts, including employment and carer effects, are important but evidence is sparse. The reference case extension could include recommendations on what quality of life and societal outcomes should be measured in future trials.

## **Additional Considerations**

Can the reference case extension include guidance on minimum modelling principles (e.g., quality assurance, expert appraisal, transparent limitation)? Finally, there was discussion on whether NICE should supply a reference model to ensure consistency and reduce burden on manufacturers.

## **Summary**

The workshop provided valuable insights into the complexities of economic modelling for obesity interventions. There was consensus on the need for flexible, inclusive models that reflect real-world populations and evolving treatment landscapes. Prioritising key comorbidities, validating models with real-world data, and ensuring transparency in modelling approaches were identified as critical next steps. Recommendations for future research and data collection were also discussed to address current evidence gaps.

# Industry Workshop

Date: 17 September 2025

Chair: David Wonderling

Organised by: NICE

Platform: Zoom

## Purpose of the Workshop

The workshop was convened to present and discuss NICE's draft disease-specific reference case extension for obesity. The meeting served as an opportunity to gather feedback on the draft statements from industry stakeholders ahead of the formal consultation period scheduled for November–December 2025.

## Attendees

Industry experts with interest in obesity, ranging from pharmacological treatments and surgical interventions to health technology and glucose monitoring were in attendance.

## Key Topics and Discussions

### Introduction to the project

A presentation was provided on the rationale for developing a disease-specific reference case for obesity was provided. Clarification was provided that the extension will not be mandatory for current guidance under development but will inform future evaluations (with reference to the obesity reference case extension included in scopes and appraisal invitations).

### Population Stratification – weight cut-offs

A presentation was provided on the proposed stratification framework, capturing both weight categories and presence/absence of type 2 diabetes mellitus (T2DM) and atherosclerotic cardiovascular disease (ASCVD). NICE clarified that the stratification was intended for cost effectiveness analysis rather than budget impact. Concerns were raised about modelling diabetes within obesity frameworks, which could yield different results than dedicated diabetes models. Issues with data availability and feasibility of stratified modelling were noted by attendees.

### Comparators and Treatment Pathways

Comparators included in the reference case extension were discussed. An attendee noted a need to distinguish minimally invasive procedures from traditional bariatric surgery, whilst another highlighted the role of devices in behavioural interventions.

A query as to whether the bariatric surgery comparator addresses combined treatment of pharmacotherapy followed by bariatric surgery.

A participant noted the evolving NHS service landscape and asked how NICE would accommodate rapid changes in delivery models (a need for rapid review).

## **Model structure and health states**

An overview of the modelling requirements was presented. An attendee questioned why CKD was included as a state for T2DM and ASCVD populations only and if inflammatory conditions such as arthritis should be included. Participants discussed whether mental health should be included as a health state, they noted the importance but also the challenges of including it including weak trial data and the risk of double counting. They suggested that impact on mental health could be captured qualitatively. Finally, concerns with the lack of nuance in the definition of bariatric surgery as an outcome was raised (that is no distinction between minimally invasive and invasive surgery, which will have different costs and consequences).

## **Clinical parameters and variables: treatment effects and risk prediction**

The presentation highlighted the recommendations relating to modelling treatment effects and risk prediction, as well as modelling treatment waning and weight regain. A participant emphasised that clinical parameters (e.g., glycaemic control) may not revert at the same rate as weight regain. Treatment duration and weight regain are areas of uncertainty, as more data becomes available, will NICE allow for rapid update of products that have been appraised on older assumptions.

A question was also raised about whether the models would factor in waiting times for surgery and include the provision of other treatment in that time.

The different sources of real-world evidence were discussed including registries and NHS data.

It was clarified that an NMA for each stratum should be conducted if data is available. If insufficient data, then transferring between strata could be considered.

Finally, it was explained that rationales for the reference case extension statements will be provided with references in the final document.

## **Measuring and valuing health effects, cost and healthcare resource use**

A summary of the approach to capturing quality of life, resource use and costs was presented. Concerns were raised about generalising the resource use data from specific subgroups (e.g., tirzepatide implementation cohort) for other subgroups.

## **Equality and other considerations**

A discussion was held on how to address health inequalities in modelling. Distributional cost effectiveness analysis was suggested. The importance of considering productivity impacts and access for children and adolescents was

highlighted. Further clarity was requested on the distinction between required and recommended elements of the reference case.

## Summary

NICE will consider this feedback when revising the draft reference case extension. A formal public consultation will be held in November–December 2025. Final publication is expected by March 2026.

# NHS Commissioners Workshop

Date: 9 October 2025

Chair: David Wonderling

Organised by: NICE

Platform: Zoom

## Purpose of the Workshop

This workshop was convened to engage NHS commissioners in the development of NICE's draft disease-specific reference case extension for obesity.

## Attendees

Participants included representatives from NICE and NHS commissioning bodies. Attendees brought perspectives from commissioning, service delivery, pharmacy, and clinical leadership, with a shared interest in obesity treatment pathways and health economics.

## Key Topics and Discussions

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#### Introduction to the Project

Commissioners were introduced to the rationale and objectives of the reference case extension, including an overview of health economic modelling components. Key concerns raised included the tension between affordability and cost-effectiveness, with emphasis on the need for models to reflect real-world budget constraints and opportunity costs. Tirzepatide was cited as an example of a high-cost intervention with implementation challenges due to broad eligibility and limited resources.

#### Population Stratification

The proposed stratification approach included weight categories and presence/absence of T2DM and ASCVD. Commissioners highlighted the need to distinguish drug effects from weight loss outcomes and to consider functional disability (e.g. osteoarthritis) as a key comorbidity. Socioeconomic factors and preventative strategies were emphasised. They noted the need to stratify interventions by clinical need and comorbidity complexity. suggestions to use tools like the Charlson Comorbidity Index and criteria from the Society of Endocrinology's joint statement to stratify populations.

## **Service Provision and Comparators**

Discussions focused on the evolving nature of obesity services and the importance of including bariatric surgery as a comparator due to its long-term cost-effectiveness. Commissioners noted inconsistencies in access to pharmacotherapy and the growing impact of private prescribing on NHS affordability and data quality. Concerns were raised about wraparound care ending prematurely, leading to weight regain. Hidden costs (e.g. cold storage, waste disposal) and commercial pricing implications were identified as important modelling considerations. The limited long-term evidence for new therapies was highlighted, including the need for real-world data. Finally, they noted the potential role of medicines to provide short-term weight loss to enable people to access other treatments (e.g. organ transplant)

## **Outcomes and Treatment Assumptions**

Commissioners advocated for inclusion of broader health impacts such as weight-related cancers, CKD, mental health conditions, and return-to-work outcomes. Emotional wellbeing and sustainability of prescribing models were highlighted, with calls for deprescribing strategies and long-term support. Real-world data was preferred over trial data for modelling resource use, with triangulation across datasets (e.g. Eclipse) suggested. Safety concerns related to unsupervised GLP-1 use were noted, and a stepped prescribing model was proposed—starting with injectables followed by oral alternatives.

## **Equality and Broader Considerations**

The importance of addressing health inequalities was emphasised, particularly for underserved groups including individuals with severe mental illness, learning disabilities, and autism.

## **Summary**

NICE will incorporate commissioner feedback into the draft reference case extension. A formal public consultation is scheduled for November–December 2025, with final publication expected by March 2026.