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HPR3

Lifestyle or disease? How EU HTA bodies frame obesity and the consequences for reimbursement of anti-obesity medicines

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BACKGROUND

Although WHO and the European Association for the Study of Obesity classify obesity as a chronic disease at BMI ≥30 kg/m², European HTA bodies frame it inconsistently. The lifestyle-versus-disease divide is well described; less understood is how that framing is operationalized into access restrictions. [1,2,3]

OBJECTIVE

To assess how selected European HTA bodies frame obesity and determine whether disease framing influences reimbursement criteria and access to anti-obesity medicines.

METHODS

This study was conducted in two steps, focusing on the definition and HTA assessment of overweight and obesity:

1. **Definition review**: we reviewed how overweight and obesity were defined across major international and national organizations, with particular attention to BMI thresholds, comorbidity criteria, and disease framing.

2. **HTA evidence review**: we reviewed HTA assessments published between 2017 and 2025 for anti-obesity medicines (AOMs) (liraglutide, semaglutide, tirzepatide, and naltrexone/bupropion) across eight HTA bodies (HAS, G-BA/IQWiG, NICE, SMC, AIFA, AEMPS, ZIN, and TLV). We extracted obesity framing statements, BMI thresholds, comorbidity and prior-treatment criteria, comparators, and ICERs, and analysed EMA §4.1/§5.1 sections handling of comorbidity indications.

RESULTS

A. Clinical definitions consistently frame obesity as a chronic disease

Across international and national clinical organisations, obesity was consistently recognised as **a chronic disease rather than a lifestyle choice. WHO and EASO use BMI ≥30 kg/m²** as the conventional threshold for obesity, while newer frameworks increasingly emphasise excess adiposity, fat distribution, organ dysfunction and obesity-related complications beyond BMI alone. ***(Table 1)***

B. HTA evidence review

Disease recognition did not ensure access

Nineteen assessment decisions were identified across 6 issuing bodies: HAS, NICE, SMC, AIFA, AEMPS, and ZIN; (G-BA excludes AOMs by statute, no relevant TLV reports were identified).

HAS recognised obesity as a disease but restricted tirzepatide to BMI ≥35 kg/m², age ≤65 years, and prior failure.

ZIN applied a hybrid framing with mixed outcomes, rejecting semaglutide, restricting liraglutide, and recommending naltrexone/bupropion within its full label.

AIFA classified key AOMs as non-reimbursed Class C medicines, while AEMPS rejected semaglutide across assessed subgroups.

NICE and SMC restrict reimbursement to BMI ≥30 with comorbidities and to BMI ≥35. ***(Table 2)***

BMI thresholds were a major restriction

Half of approved decisions **reimbursed only at BMI ≥35 despite disease defined at ≥30,** requiring prior deterioration. Some decisions required BMI ≥40 kg/m² or additional comorbidities criteria.

Cost-effectiveness alone was not sufficient to secure broad access

UK ICERs were generally around £9,000–17,000/QALY (some £21,000–30,000), yet most decisions were restricted or denied. It means that even when the medicines looked cost-effective by UK standards, this did not automatically translate into broad reimbursement.

Comorbidity expansion did not ensure broader access

Comorbidity expansion represented a strategic route to position AOMs beyond weight loss, particularly through evidence in OSA, HFpEF, cardiovascular risk.

However, while EMA SmPCs incorporated such evidence within §5.1 clinical-trial descriptions, this did not automatically generate separate indications or broader reimbursement eligibility. HTA continued to apply restrictive criteria limiting the access-expanding effect of these strategies.

Table 2. Reimbursement outcomes across 19 HTA assessments

	HAS	NICE	SMC	AIFA	AEMPS	ZIN
Liraglutide	-	**Restricted** BMI ≥35 + prediab. + CV risk	**Restricted** BMI ≥35 + prediabetic + CV risk	**Not recommended** Class C	-	**Restricted** BMI ≥35 + comorbidities or BMI ≥40
Semaglutide	-	**Restricted** BMI ≥35 or (30.0 to 34.9 kg/m2) + comorbidities	**Restricted** BMI ≥30 + comorbidities	**Not recommended** Class C	**Not recommended** BMI of ≥ 27 to < 30 + comorbidities **Not recommended** BMI ≥30 **Not recommended** adolescents ≥12 years with obesity (≥ 60 kg)	**Not recommended**
Tirzepatide	**Restricted** BMI ≥35, ≤65 y, prior failure (Re-evaluation-No change)	**Restricted** BMI ≥35 + comorbidities	**Restricted** BMI ≥30 + comorbidities	**Not recommended** Class C	-	-
Naltrexone/ bupropin	-	**Not recommended**	**Not recommended**	-	-	**Recommended** Full label

G-BA automatically excludes AOMs by statute, TLV no report available

Future EU HTA: JCA Policy Outlook

The EU JCA framework is **clinically neutral and does not label obesity as disease or lifestyle**. However, future PICO scoping may indirectly shape how AOMs are assessed by defining eligible populations, comparators, outcomes and subgroups. While reimbursement decisions remain national, **AOMs may become increasingly relevant from 2030**, when JCA expands to all new centrally authorized medicines.

CONCLUSIONS

- **Clinical disease recognition did not ensure broad AOM reimbursement; only a minority of decisions reimbursed AOMs at BMI ≥30 kg/m² without additional restrictions.**
- **HTA bodies restricted access without necessarily challenging obesity's disease status, relying instead on BMI thresholds, comorbidity gates, prior treatment failure, age limits, service restrictions, and budget controls.**
- **Favourable ICERs and comorbidity evidence did not consistently expand access.**
- **A persistent gap remains between clinical obesity definitions and reimbursed eligibility thresholds.**

Table 1. Obesity Definitions Across International and National Organisations

Organizations	Definition of overweight and obesity
WHO	Obesity is a **chronic, relapsing disease** characterised by abnormal or excessive fat accumulation that poses a health risk, in adults with **BMI ≥30 kg/m²**
EASO	An adiposity-based **chronic, relapsing with multifactorial causes disease** characterized by the function, total amount and distribution of adipose tissue. **BMI ≥25 kg/m² indicates overweight and ≥30 kg/m² indicates obesity.**
World Obesity Federation	Obesity is a **chronic, relapsing, progressive disease process** characterised by excessive body fat accumulation with multiple organ-specific consequences
NICE guideline	Overweight and obesity are **chronic health conditions**
German guideline	Obesity is a **chronic disease** that requires long-term, often lifelong treatment

REFERENCES

1. WHO, *Obesity and overweight*, 2025. **2.** EASO, *Definition of Obesity*; Bowman-Busato et al., *International Journal of Obesity*, 2024. **3.** World Obesity Federation, *Obesity: a chronic relapsing progressive disease process – A position statement*. **4.** NICE, *NG246: Overweight and obesity management*, 2025; updated 2026. **5.** DAG-led S3 Guideline on the Prevention and Treatment of Obesity, updated 2024. **6.** Scottish Medicines Consortium.(SMC) **7.** National institute for health and care excellence (NICE) **8.** French national authority for health (HAS) **9.**National health care institute (ZIN) **10.** Italian medicines agency (AIFA) **11.** Spanish Agency for Medicines and Healthcare Products (AEMPS)

ABBREVIATIONS

***EU**: European Union; **HTA**: Health Technology Assessment; **AOM(s)**: Anti-obesity medicine(s); **WHO**: World Health Organization; **EASO**: European Association for the Study of Obesity; **BMI**: Body Mass Index; **G-BA**: Federal Joint Committee; **IQWIG**: Institute for Quality and Efficiency in Health Care; **TLV**: Dental and Pharmaceutical Benefits Agency; **HAS**: French National Authority for Health; **ZIN**: National Health Care Institute; **AIFA**: Italian Medicines Agency; **AEMPS**: Spanish Agency for Medicines and Healthcare Products; **NICE**: National Institute for Health and Care Excellence; **SMC**: Scottish Medicines Consortium; **CV**: Cardiovascular; **UK**: United Kingdom; **ICER**: Incremental Cost-Effectiveness Ratio; **QALY**: Quality-Adjusted Life Year; **EMA**: European Medicines Agency; **SmPC**: Summary of Product Characteristics; **OSA**: Obstructive Sleep Apnoea; **HFpEF**: Heart Failure with Preserved Ejection Fraction; **JCA**: Joint Clinical Assessment; **PICO**: Population, Intervention, Comparator and Outcomes.*

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