Budget impact minimisation approaches used across Europe, Brazil, and Japan in the reimbursement of obesity medications

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INTRODUCTION

- The market entry of effective obesity medications (OMs) offers promise to patients with obesity and obesity-related comorbidities
- However, the high prevalence of the disease, plus the cost of such medications raises affordability concerns amongst payers, particularly those in et-conscious HTA markets
- As such, novel approaches to et impact (BI) minimisation must be sought to enable access

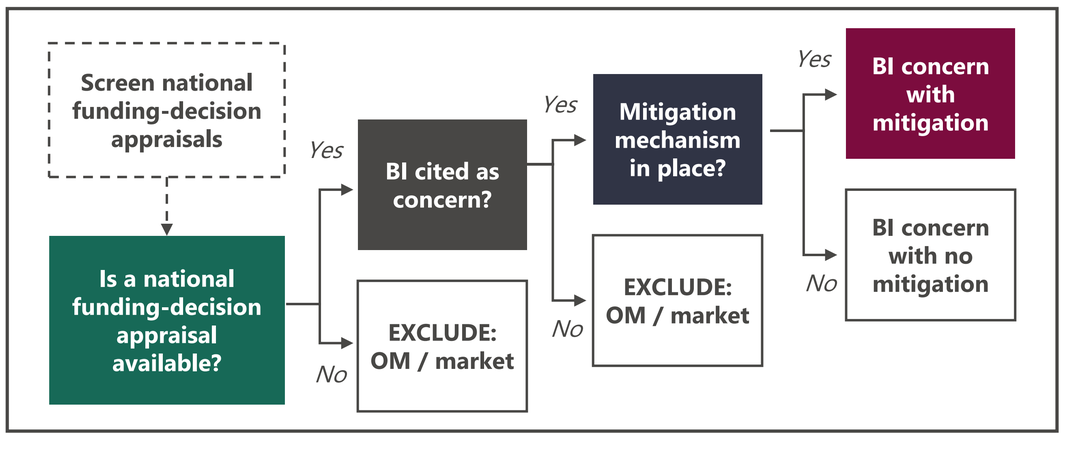
OBJECTIVE

- This analysis evaluates the extent to which HTA markets explicitly cite BI as a concern in the reimbursement of obesity medications
- Amongst markets which cite BI as a concern, we investigated what formal measures have been taken to manage the cost

METHODS

- We first assessed whether liraglutide, semaglutide, or tirzepatide had been reviewed by national HTA bodies during 2020–2025. The assessment covered markets where et impact is typically a factor in reimbursement decision-making: Brazil (CONITEC), Denmark (Danish Medicines Council), Italy (AIFA), Japan (MHLW), Spain (AEMPS), and the UK (NICE)
- We reviewed national funding-decision appraisals (including HTA reports, therapeutic positioning (IPT) reports, and administrative listings) plus supporting grey literature (e.g. formal meeting minutes, media reports, journal articles) for each assessed therapy. The analysis focused on identifying whether BI was cited as a consideration for reimbursement decision-making and, if so, whether it was explicitly referenced in national funding-decision appraisals.
- Amongst markets where BI was cited as a consideration, either explicitly or implicitly, further grey literature and HTA searches were conducted to explore if identified BI concerns were being addressed, and if so, what mechanisms are in place to mitigate them (**Figure 1**)

Figure 1. Research methodology



RESULTS

- Overall, we identified 12 national funding-decision appraisals (10 HTA/IPT reports and 2 administrative listings) assessing liraglutide, semaglutide, and/or tirzepatide across Brazil (BR), Denmark (DK), Italy (IT), Japan (JP), Spain (ES), and the UK (**Figure 2**)
- In the initial review of national funding decision appraisals, BI was explicitly cited as a reimbursement factor in 3/12 appraisals (BR: liraglutide[1] & semaglutide[2]; UK: tirzepatide[3])
- When evaluating grey literature, it was stated that BI is an influential factor in reimbursement decision-making for a further 2 appraisals (DK: semaglutide[4]; ES, semaglutide[5]), taking the total appraisal decisions influenced by BI to 5

MARKET-SPECIFIC INSIGHTS

- Formal cost-containment measures to mitigate the BI risk have been employed in 2/6 markets (DK, UK), or for 2/5 appraisals where et impact (**Figure 3**)
  - → **UK:** Tirzepatide was forecast to exceed the previous UK BI threshold of £20 million, prompting a 12-year staggered rollout period at launch. The aim of the rollout period is, in part, to mitigate the anticipated BI of tirzepatide[3]
  - → **DK:** Risk-sharing mechanisms were trialled to manage the BI risk of semaglutide to the public payer[6]
- BR, ES have cited BI as a concern formally or informally[1,2,5], but have agreed to no formal mitigation measures (**Figure 3**)
  - → Literature suggests that the extended price negotiation process between the CIPM and the manufacturer of semaglutide has consistently cited et impact as a cause for delayed reimbursement negotiations
- Neither IT not JP has cited BI as an explicit factor in reimbursement decision making (**Figure 3**)

Figure 2. HTA status of obesity medications across markets under study

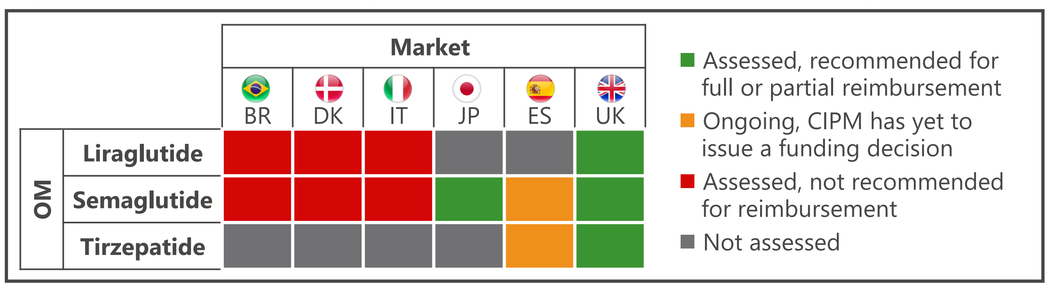


Figure 3. Cross-market overview of BI consideration and formal mitigation measures

Market	BI cited as factor	Formal mitigation measures	Type of measure
UK			12-year staggered rollout (tirzepatide)
DK			Risk-sharing mechanism (semaglutide)
BR			Concern noted in appraisals, no formal mitigation
ES			BI cited in extended price negotiations
IT			Not cited as explicit factor
JP			Not cited as explicit factor

CONCLUSIONS

To mitigate BI uncertainty, collaboration between manufacturers and payers is essential

1. **Despite the marked unmet need for obesity medications, few products are reimbursed.** Only the UK and JP currently reimburse OMs, yet all 6 markets have assessed at least one OM. Final decisions from Spain's CIPM on semaglutide and tirzepatide are still pending
2. **Multiple markets cite BI as a concern; however, this is not always formalised** in official appraisals - only two of the five assessments that flagged BI subsequently introduced formal cost-containment measures
3. **Uncertainty around BI can cause delays** in reimbursement and/or price negotiations and may therefore hinder timely patient access
4. **To mitigate these delays,** early and transparent collaboration between manufacturers and payers is essential to address BI concerns and design mitigation measures (e.g., staggered roll-outs, risk-sharing agreements, price : volume caps) that balance patient access and financial sustainability

References: [1]CONITEC, Liraglutide for obesity recommendation report, 2023. https://www.gov.br/conitec/pt-br/midias/consultas/relatorios/2023/20230511_relatorio_liraglutida_cp_17_2023.pdf. Accessed October 16 2025; [2]CONITEC, Semaglutide for obesity recommendation report. Relatório preliminar - Semaglutida para o tratamento de pacientes com obesidade graus II e III, sem diabetes, com idade a partir de 45 anos e com doença cardiovascular. Accessed October 16 2025; [3]NICE. Tirzepatide for managing overweight and obesity, 2025. https://www.nice.org.uk/guidance/ta1026. Accessed October 16 2025; [4]Medicintilskudsnævnet (Danish reimbursement Board). The Danish Reimbursement Board's recommendation – Wegovy. https://laegemiddelstyrelsen.dk/da/tilskud/generelle-tilskud/~/media/32CBD17CE86C4E77905B70DF41D029B8.ashx. Accessed October 16 2025; [5]elEconomista. Health to delay funding for Novo Nordisk's obesity therapy until 2025. https://www.eleconomista.es/salud-bienestar/empresas/noticias/12998516/09/24/sanidad-retrasara-la-financiacion-de-la-terapia-contra-la-obesidad-de-novo-nordisk-hasta-2025.html. Accessed October 16 2025; [6]Medwatch. Novo Nordisk ready to share Wegovy reimbursement risk. https://medwatch.com/News/Pharma__Biotech/article16973629.ece. Accessed October 16 2025; [7]Reuters. Denmark could help more patients with Wegovy cost if Novo pays too - minister. https://www.reuters.com/business/healthcare-pharmaceuticals/denmark-could-help-more-patients-with-wegovy-cost-if-novo-pays-too-minister-2023-12-01/#:~:text=In%20Denmark%2C%20where%20Novo%20Nordisk,over%2030%20and%20co%2Dmorbidities. Accessed October 16 2025.

Abbreviations: AEMPS: Agencia Española de Medicamentos y Productos Sanitarios; AIFA: Agenzia Italiana del Farmaco; BI: et impact; BR: Brazil; CIPM: Comisión Interministerial de Precios de los Medicamentos; DK: Denmark; ES: Spain; HTA: Health technology assessment; IPP: Therapeutic positioning; JP: Japan; MHLW: Ministry of Health, Labour and Welfare; NICE: National Institute for Health and Care Excellence; OMs: Obesity medications; UK: United Kingdom

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