Healthcare economics: cost risks and criteria models

Between lifestyle and guideline: the role of GLP-1 analogues in statutory health insurance (GKV) care for obesity

GLP-1 analogues such as Wegovy and Co. promise not only massive weight loss, but also preventive effects in diabetes, cardiovascular disease and Alzheimer's. Nevertheless, statutory health insurance funds (GKV) and the Joint Federal Committee (G-BA) in Germany have so far refused to cover the costs, citing in particular the high cost of treatment, the lack of long-term data and the classification as a "lifestyle drug". At the same time, political pressure is growing: parts of the FDP have already called for an extension of indications, while the GKV warns of a cost explosion and fraud risks. The article highlights the front lines of this debate, assesses medical opportunities and economic risks, and analyses whether Germany is facing a reorientation in obesity care.

>> They are called Ozempic, Wegovy, Mounjaro or Saxenda: the new GLP-1 analogues have made it from diabetology into the headlines. What was once considered a treatment option for type 2 diabetes is now being hailed by Hollywood stars and TikTok influencers as a miracle cure for weight loss. But behind the media hype lies a highly relevant medical and health policy issue: should statutory health insurance funds (GKV) cover the costs of GLP-1 analogues, even for people without diabetes? While some doctors see GLP-1 receptor agonists as a revolution in obesity treatment, critics warn of the medicalisation of lifestyle and an overload of the healthcare system.

What do weight loss injections really do? A look at effectiveness and risks

Obesity has a significant impact on health policy due to serious comorbidities (1). According to Blüher, 13 per cent of total mortality in Europe is currently attributable to overweight and obesity (2). The prevalence of obesity in the population is therefore posing new challenges for the healthcare system. While the number of obese children and adolescents worldwide has risen from 11 million in 1975 to 124 million in 2016 (3) over the last 40 years, there is growing pressure on politicians and the medical profession to develop a viable and sustainable concept for combating obesity. But is the weight-loss injection really the universal solution to combating obesity in society?

GLP-1 analogues (glucagon-like peptide-1 receptor agonists) are among the most innovative drugs of the last decade. This term refers to active ingredients such as semaglutide, tirzepatide and liraglutide, which mimic the body's own hormone GLP-1 – a key hormone in glucose and energy metabolism. Due to their GLP-1-like effect, these active ingredients lower blood sugar levels and slow down gastric emptying. In addition,

semaglutide increases control over eating behaviour, reduces the preference for fatty foods and the frequency of food cravings, which can result in significant weight loss (4). According to the SELECT study, the administration of semaglutide to overweight or obese patients (2.4 mg weekly) leads to a reduction in body weight of around 15 per cent after 33 months. The risk of heart attack, stroke or cardiovascular death can also be reduced by 20 per cent in patients with existing cardiovascular disease through treatment with semaglutide (5).

However, in reality, adherence to treatment after twelve and 36 months is only 65 per cent and 50 per cent, respectively (6). Since lifelong medication is necessary due to the well-known yo-yo effect, adherence could play a decisive role in the long-term effectiveness of the therapy in the future (7). Side effects such as nausea, vomiting and diarrhoea are seen as one of the reasons for poor adherence.

While the short-term efficacy of GLP-1 analogues is well documented, there is still a lack of reliable data on their safety and effectiveness when taken over several years, especially in people without diabetes. Although serious side effects are rare, they are potentially serious: the substances are suspected of increasing the risk of thyroid cancer in people with a predisposition to the disease (8). Individual cases of acute optic neuropathy (NAION) (9) have also been documented. In order to conclusively evaluate the benefits of weight loss injections, long-term clinical studies must be conducted and the results comprehensively analysed.

Based on the results of existing studies, weight loss injections can currently be classified as a new, promising drug for the treatment of obesity. But why then are the costs of the therapy not covered? Can our solidarity-based system not afford the weight loss injection?

Status quo of cost coverage in Germany

Currently, statutory health insurance funds in Germany cover the costs of GLP-1 analogues exclusively for the approved indication of treating type 2 diabetes, but not for obesity. The legal basis for cost coverage is the principle of economic efficiency: according to Section 12 of the German Social Code, Book V (SGB V), statutory health insurance funds are obliged to provide services that are sufficient, appropriate and economical and do not exceed the "necessary extent" (10).

The differences are based on the legal framework and assessments by the Joint Federal Committee (G-BA) and the health insurance funds. Diabetes is considered a "full-fledged chronic disease" with a high demand for care. Obesity, on the other hand, is medically recognised as a disease in Germany, but is not systematically classified as requiring treatment if there are no secondary diseases. GLP-1 analogues are currently considered non-reimbursable lifestyle drugs for weight loss alone, despite strong evidence for prevention (11).

What could the weight-loss injection cost in the future?

Statutory health insurance companies are warning of the potential costs of nationwide reimbursement of GLP-1 analogues for the treatment of obesity. The AOK Federal Association estimates costs of up to 45.8 billion euro per year (12). But how high would the actual expenditure be and how does it compare to the total healthcare expenditure currently spent by the

statutory health insurance system on medicines?

According to the GEDA study, the prevalence of obesity (BMI ≥ 30$^{kg/m2}$) among adults in Germany is 19 per cent (13). Analyses by BARMER show that the proportion of obese people with manifest type 2 diabetes is around 35 per cent (14). These individuals are already entitled to have their GLP-1 therapy costs covered. According to current calculations, the price mix for GLP-1 therapy in 2027 will be £2,747 per year (15).

Based on this study, initial estimates can be made of future cost developments for the coverage of GLP-1 therapies for people with obesity without diabetes by the statutory health insurance system:

In summary, future costs will depend largely on the legal definition of the severity of obesity that determines the scope of services available to patients, as well as the prevalence of GLP-1 agonist treatment in Germany. The expected annual costs for undifferentiated coverage are therefore between €3.82 billion (15% treatment prevalence) and €19.09 billion (75% treatment prevalence), depending on the prevalence of treatment.

Anzahl der Patient:innen mit Adipositas nach Ausprägungsgrad				
Behandlungs-prävalenz	**Personen mit Adi-positas Grad 1 ohne Diabetes**	**Personen mit Adi-positas Grad 2 ohne Diabetes**	**Personen mit Adi-positas Grad 3 ohne Diabetes**	**Personen mit Adipositas ohne Diabetes gesamt**
Patientenzahl	6.435.000	1.950.000	877.750	9.262.750
15%	965.250	292.500	131.663	1.389.413
35%	2.252.250	682.500	307.213	3.241.963
50%	3.217.500	975.000	438.875	4.631.375
65%	5.182.750	1.267.500	570.538	6.020.788
75%	4826.250	1.462.500	658.313	6.947.063

Tab. 1: Anzahl der Patient:innen mit Adipositas nach Ausprägungsgrad (16). Eigene Darstellung.

If we compare the projected expenditure with the approximately £55 billion per year spent by the SHI on medicines (17), it is clear that general coverage of GLP-1 therapies could pose another enormous financial challenge for the SHI.

From a financial perspective alone, it can therefore be assumed that weight-loss injections alone will not be able to save us from the sharp rise in obesity prevalence in the future. Rather, a holistic concept is needed that combines pharmacological advances with preventive lifestyle changes to find effective and sustainable answers to an increasingly acute health policy challenge.

From pharmacology to prevention: an integrative model for the statutory health insurance system

The debate about the possible reimbursement of GLP-1 analogues for the treatment of obesity is currently dividing experts, politicians and society. It is a question of fairness in healthcare provision, system financing and social responsibility. While some see the possible reimbursement of costs as a milestone for public health, others warn of spiralling costs and the medicalisation of lifestyle problems.

Current studies show that remarkable progress has been made in the fight against obesity thanks to weight-loss injections. Nevertheless, it is important not to respond to the development of obesity prevalence solely by prescribing weight-loss injections across the board. This approach should be critically questioned not only for economic reasons, but also because it would counteract any efforts to make the necessary lifestyle changes.

In other words, the root causes of the sharp increase in obesity prevalence must be specifically addressed and sustainably targeted with appropriate measures as part of a national prevention strategy (18). Changes in the food market, the constant availability of energy-dense, sugar- and fat-rich foods, and the considerable lack of physical activity in everyday life (19) cannot be eliminated by pharmacological means alone.

Based on the current state of research, a step-by-step prerequisite model is therefore recommended, which promotes lifestyle changes in affected individuals with the help of evidence-based prevention programmes and at the same time enables access to the supportive potential of weight-loss injections.

The stages of the prerequisite model are defined as follows:

- Patients with grade 1 obesity (BMI 30–34.9$^{kg/m2}$): The costs of GLP-1 analogues are only covered if there are additional weight-related comorbidities, e.g. high blood pressure, dyslipidaemia, prediabetes or cardiovascular risk factors. A further prerequisite is regular participation in prevention courses and a demonstrable

If weight loss is less than five per cent at the end of the year, drug therapy can be covered from the beginning of the following year. Continued participation in prevention courses is a prerequisite.

- Patients with grade 2 obesity (BMI 35–39.9$^{kg/m2}$): Regular participation in prevention courses and an increase in physical activity over at least six months are required. If weight loss is less than two per cent, GLP-1 therapy will be covered from the beginning of the second half of the year. Here, too, ongoing participation in prevention measures is required.

- Patients with grade 3 obesity (BMI ≥ 40$^{kg/m²}$): GLP-1 therapy is covered for this degree of severity. Regular participation in prevention courses is still a prerequisite for coverage.

In line with the entitlement to tobacco cessation drugs defined by the G-BA (20), people with obesity should in future be entitled to coverage under the outlined eligibility model.

Citation

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The step-by-step prerequisite model is intended to prioritise the relevance of lifestyle adjustments and, if necessary, ensure a supportive pharmacological alternative. However, taking into account the cost analysis outlined above and the massive increase in the prevalence of obesity (21), it should be noted that without a change in social attitudes and a strong focus on prevention in the health and education sectors, the associated

costs will not remain sustainable in the future. <<

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Author declaration

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