SMOB recommendations for prioritization of 2.4 mg Semaglutide therapy in patients with complicated overweight or obesity

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Background

The current limited availability of the GLP-1 receptor agonist (GLP-1 RA) product Wegovy® (2.4 mg semaglutide) demands a prioritization by means of which patient-group should be treated first, second, etc. To support health care providers to make reasonable and (as much as possible) evidence-based clinical decisions, we provide the following recommendations for the prioritization process.

General recommendations:

1. All patients with complicated overweight or obesity should receive multimodal, individual lifestyle counseling, delivered by a dietitian or a qualified health care professional, to help adhering to a healthy, balanced diet and at least 150 minutes of physical activity per week.

2. All patients with a BMI ≥35 kg/m^2 or a BMI ≥30 kg/m^2 with uncontrolled type 2 diabetes (T2DM) defined by HbA1c ≥ 8% for ≥ 12 month and who formally qualify for bariatric surgery according to the SMOB guidelines (1) must be offered bariatric surgery and referral to a surgeon specialized in bariatric-metabolic surgery to receive surgery-specific information.

3. Patients with T2DM should be treated according to the SGED guidelines (2) that include the use of GLP-1 RA at an early stage of the disease. However, we acknowledge that the weight reducing efficacy of the reimbursed maximal semaglutide dose for T2DM treatment, i.e. Ozempic® 1 mg s.c. per week and its oral form of 14 mg Rybelsus®, is lower than the weight reducing efficacy of 2.4 mg s.c. per week (Wegovy®) and thus, does not provide the full benefit in regard of weight reduction. For patients with overweight/obesity and T2DM, tirzepatide (Mounjaro®) represents the most effective pharmacotherapeutic option to effectively reduce body weight and to improve glycemic control (3). However, to date treatment of patients with T2DM with Mounjaro® is not yet reimbursed by the regular health insurance. Moreover, in contrast to semaglutide, there are currently no cardiovascular outcome data reported for patients with T2DM upon tirzepatide treatment.

4. All patients for whom a GLP-1 RA pharmacotherapy for overweight/obesity management according to Swissmedic approved indication is considered must be informed about the following:
    1. Due to the chronicity of the disease the medication needs be continued over a long period of time, since stopping it will most likely result in a regain of body weight and worsening of related health conditions (4–6).

2. Due to the current time-limited cost coverage of Wegovy® treatment for complicated overweight and obesity by the regular health insurance, the costs for long-term treatment with the medication must be covered by the patient.

5. Patients that are already successfully treated with a GLP-1 RA-based drug, including those on Saxenda® (which will not be available for adults anymore in the near future) and those on an “off label” treatment with Ozempic® or Rybelsus® within the Swissmedic-approved indication for Wegovy® at the start of the respective pharmacotherapy, should receive a continued treatment and be switched to Wegovy® at first place.

6. The indication for the body weight management drug Wegovy® should be in line with the Swissmedic approved indication that includes patients with a BMI ≥27 kg/m^2 with at least one overweight-related disease. However, the limited availability of 2.4 mg semaglutide (Wegovy®) necessitates a treatment prioritisation within this patient-group. Therefore, we here recommend three different levels of prioritization categories.

Specific recommendations:

Prioritization category	Characteristics	EOSS*
1	a) The highest priority should be given to patients with an established cardiovascular disease according to the SELECT trial (7). These include patients with ≥1 of the following: history of myocardial infarction, stroke, or symptomatic peripheral arterial disease in combination with a BMI ≥27 kg/m^2. We suggest to also include patients who had a coronary revascularization (PCI/Bypass) procedure without prior myocardial infarction in this category. b) Any patient whose excess weight/obesity prevents him/her from undergoing a necessary surgical procedure (organ transplant, heart surgery, orthopaedic surgery, etc).	3
2	The second highest priority group includes patients a) with a BMI ≥27 kg/m^2 along with at least one severe comorbidity, i.e. osteoarthritis of the lower limb, sleep apnea, metabolic dysfunction-associated steatohepatitis (MASH), or obesity-related mental health impairment. Or b) with a BMI ≥27 kg/m^2 along with ≥ 2 overweight/obesity-related cardiovascular risk factors including hypertension, dyslipidaemia, prediabetes, metabolic dysfunction-associated fatty liver disease (MAFLD) Or c) with a BMI ≥30 kg/m^2 and heart failure with preserved ejection fraction (HFpEF), in line with the patient population studied in the STEP-HFpEF trial (8)	1-2
3	The lowest priority group includes patients with a BMI ≥ 27 kg/m^2 and only <u>one</u> overweight-related cardiovascular risk factor.	1

* Edmonton Obesity Staging System (9)

Outlook:

As the availability of 2.4 mg semaglutide (Wegovy®) is assumed to continuously increase, we suggest and support that with time also patients within a lower prioritization category can receive specific pharmacological treatment.

Concluding statements:

We appeal to all medical health care professional to consider our prioritization recommendations, to allow allocating the limited resources of semaglutide (Wegovy®) to the patients who likely benefit most from this pharmacotherapy and who display the best benefit/risk ratio according to the presently available evidence.

Overweight and obesity are chronic, relapsing, multifactorial diseases. On this background, we demand that pharmacotherapy of complicated overweight and obesity must not depend on individual financial resources. Thus, the cost coverage of time-wise unrestricted anti-obesity pharmacotherapy is an important goal for the future and urgently warrants clear regulations.

We underline that bariatric-metabolic surgery remains a fundamental component of severe obesity therapy, as it is still the most effective and sustainable treatment option available.

We are convinced that the future of weight management in obesity will, in addition to individual behavioral and nutritional counseling, be most likely a modular approach with the optimal use or even combination of pharmacotherapy and bariatric surgery based on individual patients' pathophysiological circumstances, comorbidities and personal preferences.

Lastly, independent of the utilized therapeutic intervention, all treated patients should be provided with continuous support by a qualified care team.

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