Scottish Government
Riaghaltas na h-Alba

NHS SCOTLAND

Consensus statement: national criteria for the prioritisation of glucagon-like peptide-1 receptor agonists (GLP-1 RAs) and GLP-1 RA/glucose-dependent insulinotropic polypeptide receptor agonists (GIP RAs) for the treatment of obesity in NHS Scotland

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Situation

Glucagon-like peptide-1 receptor agonists (GLP-1 RAs) are a class of medicines previously used exclusively for the treatment of type 2 diabetes. In recent years, research has expanded to better understand their use in obesity treatment and has led to the development of newer medicinesincluding the dual action GLP-1/GIP RAs. Clinical trials such as LEAD[1] STEP[2], SURPASS[3] and SURMOUNT[4] have demonstrated clinically significant weight loss outcomes and more recently the results of the SELECT[5] trial have shown statistically significant reductions in cardiovascular disease morbidity and mortality. The Scottish Medicines Consortium (SMC) has approved liraglutide (Saxenda®), semaglutide (Wegovy®) and tirzepatide (Mounjaro®) for restricted use in NHS in Scotland for weight management.

Engagement with Health Boards, Area Drugs and Therapeutic Committees, weight management specialists, dietitians, pharmacists, nurses and doctors and Scottish Government policy teams, indicated an enthusiasm to develop a 'Once for Scotland' clinical consensus to support and facilitate a phased implementation of SMC advice.

Background and Assessment

To support the NHS in Scotland in the implementation of the SMC recommendations for the use of these medicines for the treatment of obesity, a national short-life working group (SLWG) was established. The initial medicine in scope was semaglutide/Wegovy® but the SLWG agreed that the guidance could also be applied to future medicines for the same indication e.g. tirzepatide/Mounjaro®, now accepted for restricted access by the SMC. We have excluded liraglutide/Saxenda® from this guidance. The SLWG is chaired by the Professional Adviser in the Diet and Healthy Weight Team in the Scottish Government.

The SMC approved semaglutide/Wegovy® in October 2023 with the following advice:

"**Semaglutide (Wegovy®) is accepted for restricted use within NHSScotland.**

Indication under review: as an adjunct to a reduced-calorie diet and increased physical activity for weight management, including weight loss and weight maintenance, in adults with an initial Body Mass Index (BMI) of

- ≥30kg/m^2 (obesity), or
- ≥27kg/m^2 to <30kg/m^2 (overweight) in the presence of at least one weight-related comorbidity.

SMC restriction: BMI of ≥30kg/m^2* in the presence of at least one weight-related comorbidity. Patients should be treated in a specialist weight management service.

*a lower BMI cut-off may be more appropriate for members of minority ethnic groups known to be at equivalent risk of the consequences of obesity at a lower BMI than the white population.

In a phase III study, semaglutide, as an adjunct to diet and exercise, was associated with significant reduction in body weight compared with placebo in patients with a BMI ≥30kg/m² or ≥ 27kg/m² if they had at least one weight-related comorbidity.

This advice applies only in the context of an approved NHSScotland Patient Access Scheme (PAS) arrangement delivering the cost-effectiveness results upon which the decision was based, or a PAS/ list price that is equivalent or lower."

It is estimated that the number of adults in Scotland with a BMI>30 kg/m^2 is approximately 1 million[6]. Nationally validated data on the number of people in Scotland with obesity and more than one clinical condition associated with obesity is not available. It may be possible for boards to obtain more locally available data on BMI distribution with associated conditions from primary care systems which might assist with demand modelling.

When the SMC advice was issued, there was feedback at the time that:

1. Some Health Boards do not have a weight management service model that can support the implementation of the SMC advice.
2. The unresolved supply issues with GLP-1 RAs might make implementation problematic for this number of potential patients.
3. Uncertainty over the "real-world" GLP-1 and GLP-1/GIP RAs take-up rate can make service and financial planning challenging.

Following a cross-policy discussion within the Scottish Government between medicines, prescribing and primary care colleagues and further engagement with Health Boards, Area Drugs and Therapeutic Committees (ADTCs), weight management specialists, dietitians, pharmacists, nurses and doctors, the Scottish Government Diet and Healthy Weight Policy team established this SLWG, in collaboration with the ADTC Collaborative (hosted within Healthcare Improvement Scotland) to bring together national experts and clinicians to consider how to phase implementation of SMC advice, with the aim of trying to address or mitigate the delivery issues highlighted above.

Recommendations

The SLWG recognise that the SMC provides advice for NHS in Scotland on a 'Once for Scotland' basis regarding the clinical and cost effectiveness of new medicines. The SLWG unanimously support the SMC advice and agree that ideally these medicines should be offered to patients in line with their recommendations from the outset. However, the SLWG acknowledges the delivery challenges described above and have therefore advised a phased approach to implementation. This 'Once for Scotland' implementation guidance aims to prevent variation between Health Boards in access to these medicines.

The SLWG advises that the first phase of implementation should be those patients who have a:

- **BMI of ≥38kg/m^2 in the presence of at least one weight-related comorbidity**

The knowledge and expertise of the SLWG, drawing on clinical trial evidence and guidelines, along with health economic analysis contained within the SMC Wegovy Detailed Advice Document, supports this revised BMI.

To help guide clinicians as to what constitutes a 'weight-related comorbidity', please see Guidance Criteria (on the following page).

SMC advice for semaglutide (Wegovy®) includes the following restriction that "patients should be treated in a specialist weight management service".

As there are different configurations of weight management services in different Health Boards, the SLWG advises that:

Patients can be treated in any healthcare setting where evidence-based and appropriate lifestyle advice can be delivered. This could be:

- **A tier 2 or tier 3 weight management service depending on the complexity of the individual's needs**
- **Primary and community care, consistent with long term condition management of associated condition e.g. hypertension**
- **Secondary care as part of specialist treatment for associated conditions e.g. diabetes, chronic kidney disease (CKD)**

This advice does not override the individual responsibility of health professionals to make decisions, exercising their clinical judgement, based on the circumstances of an individual patient, in a shared-decision making consultation. All Health Boards have Medicines Access routes for patients that fall out with 'advice'.

To evaluate this first phase, prescribing data and outcomes will be monitored throughout implementation to understand "real-world" demand which will inform further engagement on progression to Phase 2. The SLWG has proposed what Phase 2 and Phase 3 of eligibility and implementation could rather look like but there are no timescales at present.

Guidance criteria for the prioritisation of use of GLP-1 RAs and GLP-1/GIP RAs in the treatment of obesity in NHS Scotland

Treatment with these medicines is not intended to be an alternative to evidence based dietary advice and support in the treatment of obesity but should be used as an adjunct.

SMC advice includes the following restriction that “patients should be treated in a specialist weight management service”. As there are different configurations of weight management services in different Health Boards, the SLWG advises that:

Patients can be treated in any healthcare setting where evidence-based and appropriate lifestyle advice can be delivered. This could be:

- **A tier 2 or tier 3 weight management service depending on the complexity of the individual’s needs**
- **Primary and community care, consistent with long term condition management of associated condition e.g. hypertension**
- **Secondary care as part of specialist treatment for associated conditions e.g. diabetes, CKD**

It is for managing clinicians to ensure essential advice and support on the need for a reduced energy diet (calorie deficit) and increased physical activity is available to individual patients.
Key points:

- Prescribing should be initiated by an appropriately trained healthcare professional who has a full knowledge of the patient’s physical, mental and social health, and of all concurrent treatments and their interactions, with a plan in place to monitor the response to treatment.
- Treatment should be withdrawn if weight loss is under 5% at six months.
- Dose escalation should be stopped at the lowest effective dose.

Priority criteria for Phase 1 are listed below:

Phase 1:

GLP-1 RA and GLP-1/GIP RAs should be used as an adjunct to a reduced-calorie diet and increased physical activity for weight management including weight maintenance, in adults with an initial BMI of:

- ≥38kg/m^2 (≥35kg/m^2 for members of minority ethnic groups known to be at equivalent risk of the consequences of obesity at a lower BMI than the white population)

AND

- One or more obesity-related clinical conditions (see below)

OR

- Edmonton Score of 3 or 4 EOSS - Edmonton Obesity Staging System (ottawahospital.on.ca)

Prescribing below this BMI cut-off, or for other diseases mediated by obesity, will only be in clinical scenarios where BMI criteria is a clinical requirement for access to essential treatment, for example, life-saving surgery, in-vitro fertilisation. All Health Boards have medicines access routes and non-formulary processes that can be used for individuals that fall outwith the stated criteria.

Obesity-related clinical conditions*

- Chronic kidney disease (stages 3 or 4)
- Pre-existing cardiovascular disease
- Type 2 diabetes
- Hypertension
- Idiopathic intracranial hypertension
- Metabolic dysfunction-associated steatotic liver disease (MASLD/NAFLD)
- Obstructive sleep apnoea
- Polycystic ovary syndrome (PCOS)
- Prediabetes
- Dyslipidaemia
- Significant psychological distress related to obesity

*for the purpose of this consensus statement the expert group preferred the term 'obesity-related clinical condition' rather than 'weight-related comorbidity' which was the term used by the pharmaceutical company within their application for a licence. Within our phased prescribing guidance, we have therefore used our preferred term, however the conditions listed are the same.

These conditions will remain under review as the evidence base evolves and outcomes from implementation of Phase 1 are evaluated.

Proposed Phase 2:

GLP-1 RA and GLP-1/GIP RAs used as an adjunct to a reduced-calorie diet and increased physical activity for weight management including weight maintenance, in adults with an initial BMI of:

- ≥35kg/m^2 (≥32kg/m^2 for members of minority ethnic groups known to be at equivalent risk of the consequences of obesity at a lower BMI than the white population)

AND

- One or more obesity-related clinical conditions

Phase 3:

GLP-1 RA and GLP-1/GIP RAs used as an adjunct to a reduced-calorie diet and increased physical activity for weight management including weight maintenance, in adults with an initial BMI of:

- ≥30kg/m^2 (≥27kg/m^2 for members of minority ethnic groups known to be at equivalent risk of the consequences of obesity at a lower BMI than the white population)

AND

- One or more obesity-related clinical conditions

References

1. A Randomized, Controlled Trial of 3.0 mg of Liraglutide in Weight Management | NEJM
2. Once-Weekly Semaglutide in Adults with Overweight or Obesity | NEJM
3. Tirzepatide versus Semaglutide Once Weekly in Patients with Type 2 Diabetes | NEJM
4. Tirzepatide Once Weekly for the Treatment of Obesity | NEJM
5. Semaglutide and Cardiovascular Outcomes in Obesity without Diabetes | NEJM
6. The Scottish Health Survey 2022 – volume 1: main report - gov.scot (www.gov.scot)

For any queries related to this document, please contact DietPolicy@gov.scot .