LIRAGLUTIDE (SAXENDA) AS AN ADJUNCT TO LIFESTYLE MEASURES IN WEIGHT MANAGEMENT

TARGET AUDIENCE	Primary and secondary care
PATIENT GROUP	Patients with prediabetes engaging with a Lanarkshire Weight Management Service (LWMS) intervention

Clinical Guidelines Summary

The SMC has accepted the use of Liraglutide 6mg/mL (Saxenda) for restricted use within NHS Scotland for those with a BMI of ≥35 kg/m^2, prediabetes and another cardiovascular risk factor who are treated by a specialist weight management service.[1]

	Prediabetes noted at point of referral
AROUND 12 WEEKS INTO LWMS INTERVENTION:	Discussion regarding suitability for Saxenda at multi-disciplinary team meeting
POTENTIAL SUITABILITY AGREED:	Appointment at LWMS consultant clinic for further assessment of suitability and counselling
DECISION TO TREAT:	Arrangements for prescription of Saxenda, consumables and education session made
FOLLOWING TITRATION AND 12 WEEKS AT 3 MG DOSE: (ONGOING MAINTENANCE PHASE OF LWMS INTERVENTION)	Review by LWMS specialist nurse/dietitian
LOSS OF 5% OR MORE FROM INTIAL BODY WEIGHT: (ONGOING MAINTENANCE PHASE OF LWMS INTERVENTION)	Ongoing treatment decision communicated to primary care with request for ongoing supply prescription of Saxenda and needles
AT ONE YEAR:	LWMS consultant review, consider discontinuation/further year of treatment

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Guideline Body

Content list

Medication name, formulation and licensed indication

Liraglutide 6mg/mL (Saxenda) is licensed as an adjunct to a reduced-calorie diet and increased physical activity for weight management in adult patients with an initial Body Mass Index (BMI) of ≥30kg/m² (obese), or ≥27kg/m² to <30kg/m² (overweight) in the presence of at least one weight-related comorbidity such as dysglycaemia (prediabetes or type 2 diabetes mellitus), hypertension, dyslipidaemia or obstructive sleep apnoea.

Treatment with Saxenda should be discontinued after 12 weeks on the 3.0mg/day dose if patients have not lost at least 5% of their initial body weight

Summary of National Guidance

On 9th May 2022 Liraglutide 6 mg/mL (Saxenda) was accepted by SMC for restricted use within NHS Scotland(1).

The submitting company requested that SMC considered Liraglutide with BMI ≥35kg/m^2 (a subset of population within marketing authorisation); hence the following restriction was applied:

BMI ≥35kg/m^{2*} (obesity class II and above) with:

- Non-diabetic hyperglycaemia (prediabetes) at high risk of type 2 diabetes which is defined as having either:
  - Fasting plasma glucose level of 5.5 to 6.9mmol/L or
  - HbA_{1c} of 6.0 to 6.4% (42 to 47mmol/mol), and
- High risk of cardiovascular disease (CVD):
  - Total cholesterol >5mmol/L, or
  - High-density lipoprotein (HDL) <1.0mmol/L for men and <1.3mmol/L for women, or
  - Systolic blood pressure (SBP) >140mmHg.

*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.

Patients should be treated in a specialist weight management service.

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<u>Patient Pathway</u> (see summary previously)

Prediabetes Noted at Point of Referral

Patients will be referred to the LWMS for support with weight management either with a pre-existing diagnosis of prediabetes or a new diagnosis of prediabetes which has been established as part of the referral process. The LWMS will vet the referral and offer the patient a choice of appropriate interventions. *It is important to note that patients should not be referred to the LWMS for Saxenda treatment specifically. The appropriateness of this treatment will be decided by the LWMS clinical team as below, and in line with SMC guidance*.

12 Weeks into LWMS Intervention - Discussion regarding suitability for Saxenda at multi-disciplinary team meeting

Each intervention has an active phase of around 12-16 weeks followed by a maintenance phase with less frequent LWMS input for the following 9 months. Once the patient has engaged with their intervention for most of the active phase, their case will be discussed at the multi-disciplinary team meeting. If Saxenda is agreed to be potentially of benefit, they will be appointed at the LWMS consultant clinic.

Potential Suitability Agreed - Appointment at LWMS consultant clinic for further assessment of suitability and counselling

All potential patients will then be reviewed at the LWMS consultant clinic.

- Baseline screening will be performed – height, weight, U&E, LFTs, HbA1c, fasting plasma glucose and lipids.
- A decision will be made regarding eligibility based on the inclusion and exclusion criteria (see Appendix A – Eligibility Criteria).
- The LWMS consultant will counsel the patient regarding Saxenda and its use.

Decision to Treat - Arrangements for prescription of Saxenda, consumables and education session made

Following a decision to commence treatment with Saxenda

- The LWMS consultant will correspond with the patient, their primary care provider and the LWMS specialist nurse, with the following information: dosing schedule, advice regarding needle disposal, points of contact (the LWMS physician via their secretary or the LWMS specialist nurse).
- The LWMS consultant will send a prescription for Saxenda to the hospital pharmacy, specifying the brand name. This will be for the 4 week titration period and the first 3 months at maintenance dose.

- The LWMS consultant will write to the primary care prescriber requesting a prescription for adequate needles for this period (either BD Viva or Mylife Penfine Classic needles, both which are available on the local formulary).
- As Saxenda is administered by daily subcutaneous injection the LWMS specialist nurse will arrange an education appointment with the patient.

Following Titration and 12 weeks at Maintenance dose (with ongoing maintenance phase of LWMS intervention running concurrently) – Review by LWMS specialist nurse/team

- Following dose titration and 12 weeks at maintenance dose, a review appointment will be conducted by the LWMS specialist nurse or another team member. They will record the patient's weight, and inform the LWMS consultant.

Loss of 5% or More Body Weight - Ongoing treatment decision communicated to primary care with request for ongoing supply prescription of Saxenda and needles (with ongoing maintenance phase of LWMS intervention running concurrently)

- If the patient has not lost 5% or more of their body weight no further prescription will be issued. If the patient has lost 5% or more of their body weight the LWMS consultant will send a recommendation to the primary care prescriber asking for their prescription for Saxenda and needles to be continued in primary care for a further 9 months.

One Year - LWMS consultant review, consider discontinuation/further year of treatment

- A review appointment with the LWMS consultant will be arranged a year after commencement of maintenance dose and a decision made about further continuation. At present treatment duration is thought likely to be 1-2 years based on real world studies submitted to the SMC by the manufacturer.

Appendix A – Eligibility Criteria

Inclusion criteria:

- Age between 18 and 75
- BMI 35kg/m^2 (obesity class 2 and above), with prediabetes and high risk of cardiovascular disease defined either as high total cholesterol (>5mmol/L), low HDL (<1.0mmol/L for men and 1.3mmol/L for women), or high systolic blood pressure (>140mmHg)
- Have completed at least 12 weeks of their weight management Intervention
- No contraindications to Liraglutide 6mg/mL (Saxenda)

Exclusion criteria:

- Patients who do not fit the inclusion criteria
- Pregnancy
- Breast-feeding
- Severe renal impairment, including end stage renal disease (eGFR <30mL/min)
- Severe hepatic impairment
- Known active gallbladder disease
- Pancreatitis
- Type 1 diabetes mellitus
- Congestive heart failure (NYHA class IV)
- Ongoing use of other weight management products
- Eating disorders
- Endocrinological causes of obesity
- Hypersensitivity to Liraglutide or excipients

References/Evidence

1. Scottish Medical Consortium. (2022). *Liraglutide (Saxenda) Advice*. [online] Available at: https://www.scottishmedicines.org.uk/medicines-advice/liraglutide-saxenda-resub-smc2455/

Appendices

1. Governance information for Guidance document

Lead Author(s):	I Howat
Endorsing Body:	NHSL Area Drug & Therapeutics Committee
Version Number:	V1.2
Approval date	
Review Date:	
Responsible Person (if different from lead author)	

CONSULTATION AND DISTRIBUTION RECORD	
Contributing Author / Authors	C. Payne, Lanarkshire Weight Management Specialist Nurse
Consultation Process / Stakeholders:	• Discussion and agreement of pathway at LWMS clinical MDT, including the LWMS lead consultant, lead GP, specialist nurse, psychologist, dietitians and diabetes dietitians. • Circulated to the local LMC and GP subcommittee for review and comment. • UHM head of pharmacy and deputy lead pharmacist Prescribing Management asked for advice regarding appropriate needles.

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Distribution	Lanarkshire Weight Management Service Team All GPs in NHS Lanarkshire NHSL Lanarkshire formulary

CHANGE RECORD

Date	Lead Author	Change	Version No.
19/10/2022	I Howat	Correction of typos, type of needle. Clarification of appropriate action if eGFR deteriorates whilst on treatment. Change of title.	1
			2
			3
		.	4
			5

2.You can include additional appendices with complimentary information that doesn't fit into the main text of your guideline, but is crucial and supports its understanding.

e.g. supporting documents for implementation of guideline, patient information, specific monitoring requirements for secondary and primary care clinicians, dosing regimen/considerations according to weight and/or creatinine clearance

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Lead Author	**I Howat**	**Date approved**	**October 2022 by ADTC**
Version	**V1.1**	**Review Date**	**October 2025**