South East London (SEL) glucagon-like peptide (GLP-1) analogue pathway for adults aged 18 years and over

Developed by the SEL Diabetes Medicines Working Group and lead obesity clinicians across SEL, on behalf of the South East London Integrated Medicines Optimisation Committee

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This guidance does NOT override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

South East London Integrated Medicines Optimisation Committee (SEL IMOC). A partnership between NHS organisations in South East London Integrated Care System: NHS South East London (covering the boroughs of Bexley/Bromley/Greenwich/ Lambeth/Lewisham and Southwark) and GSTFT/KCH /SLaM/ Oxleas NHS Foundation Trusts and Lewisham & Greenwich NHS Trust

A summary of current NICE guidance for glucagon-like peptide-1 (GLP-1) receptor agonists and tirzepatide (a dual glucose-dependent insulinotropic polypeptide (GIP) and GLP-1 receptor agonist), split by primary use, is given below. For people where there is more than 1 use for the medicine (for example, treating type 2 diabetes and obesity) or for people with more than 1 comorbidity (for example, type 2 diabetes with atherosclerotic cardiovascular disease and heart failure), compare the tables and rows to reach a decision with and for the person, taking into account their personal preferences. For further information see link.

Management of type 2 diabetes (T2DM)

(for glycaemic, cardiovascular and renal benefits)

If a person has more than one co-morbidity a shared decision should be made with them about which co-morbidity to prioritise when choosing medicine.

Primary care and diabetes specialist

Management of Obesity

Alongside a reduced-calorie diet and increased physical activity (Wraparound care)

Other indications

GLP-1 analogues are not currently licensed for any other indications in the UK. Consider alternative therapies. This guidance will be updated in due course to include Semaglutide for reducing CVD risk.

For guidance on managing weight loss and definitions of obesity, see NICE's guideline on overweight and obesity management

For further guidance on Type 2 diabetes, see CESEL Type 2 Diabetes Guidance.

If person co-prescribed insulin specialist team initiation only

Obesity (BMI ≥ 30*kg/m²)

Criteria for prescribing

Consider adding as further treatment (if not already taking):

- a GLP-1 receptor agonist or
- tirzepatide

after at least 3 months of treatment with metformin and an SGLT-2 inhibitor (or an SGLT-2 inhibitor if metformin is contraindicated or not tolerated) to help the person reach their individualised glycaemic target

Offer diet and other aspects of healthy living advice

Available GLP-1 analogue options:

GLP-1 receptor agonist:

- Ozempic® (injectable semaglutide) up to a dose of 1mg once a week
- Rybelsus® (oral semaglutide)
- Trulicity® (dulaglutide) injection
- Liraglutide (branded generics licensed for T2DM available) injection

- **Joint GLP-1 receptor agonist and GIP agonist option:** Mounjaro▼® (tirzepatide) injection

Stopping rule:

Stop the GLP-1 receptor agonist or tirzepatide if:

- The person becomes underweight (BMI < 18.5 kg/m²)
- They do not help the person reach their individualised glycaemic targets and they are not being taken for their cardiovascular benefits.

Tirzepatide can also be used for the management of Type 2 diabetes in line with NICE TA 924

Early onset T2DM (<40 years)

Criteria for prescribing

Consider

- a GLP-1 receptor agonist (for its cardiovascular, renal and glycaemic benefits) or
- tirzepatide (for its glycaemic benefit)

as initial treatment with metformin and an SGLT-2 inhibitor (or an SGLT-2 inhibitor if metformin is contraindicated or not tolerated)

Atherosclerotic cardiovascular disease** (ASCVD)

Criteria for prescribing:

Offer subcutaneous semaglutide (Ozempic) up to 1 mg once a week as initial treatment with metformin and an SGLT-2 inhibitor (or with an SGLT-2 inhibitor if metformin is contraindicated or not tolerated)

NHS England cohort 1 and 2

Primary care and SWMS

Criteria for prescribing :

BMI ≥ 35kg/m²* **and** 4 or more qualifying co-morbidities (see details of definitions) which include:

- ASCVD
- Hypertension
- Dyslipidaemia
- Obstructive sleep apnoea
- T2DM

For primary care see QOF OB005

Wraparound care:

- Initiation primary care: Referral to NHS Behavioural Support for Obesity Prescribing (BSOP) programme
- Initiation in SWMS: Behavioural support provided by SWMS

Available GLP-1 options:

- Primary care or SWMS: Mounjaro▼® (tirzepatide) injection
- SWMS only: Wegovy▼® (semaglutide) Injection in line with NICE TA 875

Stopping rule:

Consider stopping if less than 5% of the initial weight has been lost after 6 months on highest tolerated dose.

SEL Urgent Access Criteria

Specialist weight management services (SWMS) only

Criteria for prescribing :

BMI ≥ 35kg/m²* **and** 1 weight related comorbidity (not restricted to qualifying co-morbidities) **and** one of the below:

- Active malignancy and need for urgent weight loss for planned therapy e.g. radiotherapy/ surgery
- Urgent weight loss needed for organ transplant
- Idiopathic intracranial hypertension (IIH), needing frequent lumbar punctures and/or visual compromise
- Undergoing planned **time-sensitive** surgery for **life-limiting conditions**, where a high BMI is the main barrier to surgery
- Under the care of NHS fertility service and weight loss is needed for assisted conception
- Obesity hypoventilation syndrome (OHS)

Wraparound care:

- Initiation in SWMS: Behavioural support provided by SWMS

Available GLP-1 options:

- Mounjaro▼® (tirzepatide) injection
- Wegovy▼® (semaglutide) Injection

Stopping rule:

Consider stopping if less than 5% of the initial weight has been lost after 6 months of treatment.

Maximum treatment duration 2 years

Non-diabetic hyperglycaemia

SWMS only

Criteria for prescribing :

BMI ≥ 35kg/m²* **and** non-diabetic hyperglycaemia (HbA1c 42-47mmol/mol) **and** high risk of cardiovascular disease (based on risk factors such as hypertension and dyslipidaemia)

Wraparound care:

- Initiation in SWMS: Behavioural support provided by SWMS

Available GLP-1 options:

- Liraglutide (branded generics licensed for weight management)

Stopping rule:

Discontinue if less than 5% of the initial weight has been lost after 12 weeks of treatment on 3mg/day dose.

Maximum treatment duration 2 years

To note: *A lower body mass index threshold should be used (usually reduced by 2.5 kg/m²) for people from South Asian, Chinese, other Asian, Middle Eastern, Black African or African-Caribbean ethnic background

**Atherosclerotic cardiovascular disease definition as per NG28 includes: coronary artery disease such as myocardial infarction and unstable angina, cerebrovascular disease such as transient ischaemic attack and ischaemic stroke and peripheral arterial disease

- Medication should be added in a stepwise manner for full glycaemic control management pathway– see CESEL Type 2 diabetes guidance
- Specialist weight management services are abbreviated to SWMS throughout this document
- If weight reduction is primary aim and **not** glycaemic control see 'Management of Obesity' arm

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Initiation

Review investigations, bloods and examinations:
- For T2DM only : HbA1c (& glucose levels if relevant)
- Weight & body mass index (BMI). If BMI <35kg/m^2 waist to height ratio (WtHR) – record baseline
- Blood pressure (BP) & lipid profile
- Renal profile & liver function tests (LFTs)
- Thyroid profile if on levothyroxine and starting Rybelsus
- Review and correct any nutritional deficiencies prior to initiation if suspected

Review clinical suitability: see pages 3-6
- In BMI less than 25kg/m^2 consider suitability. For T2DM: exclude other forms of diabetes, seek specialist advice as needed

For weight management review :
- Weight trajectory, causes & weight gaining medication
- Ability to engage with behavioural support programme (BSOP) as a requirement of prescribing

Discuss with appropriate specialist team as needed, e.g. if:
- History of pancreatitis
- Significant gastro-intestinal issues such as inflammatory bowel disease, bile acid malabsorption, gastroparesis – discuss with usual team
- Heart failure (HF) III/IV (HF team)
- Serious Mental Illness (SMI) - there is limited data in SMI / those with complex psychiatric issues, ensure joined up care, assess if additional support is needed
- Severe liver disease – discuss with usual liver team, consider referral to appropriate specialist for initiation

Refer to specialist team if:
- Prescribed insulin (T2DM team or SWMS)
- Previous bariatric surgery (Tier 4 SWMS). Bariatric surgery need (Tier 4 SWMS, consider starting GLP-1 analogue, alongside referral)
- Active eating disorder, binge eating disorder or active concerns (SWMS)
- Chronic kidney disease stage 4 or 5 (T2DM team or SWMS)
- Assess & refer to services as needed e.g. social care, physio, mental health support (e.g. talking therapies)

Discuss with patient:
- Benefits, risks and side effects (see pages 5 & 7)
- Starting dose, titration plan and any adjustments to other medications
- Provide patient education (see page 8) and jointly agree therapy

Consider slow upward titration (every 8-12 weeks**) in:**
- Diabetic retinopathy (see page 6)
- Previous GLP-1 analogue use with tolerability/gastro-intestinal side-effects
- Older adults with concerns of muscle loss (see page 5)

Follow up:
- Issue prescription for GLP-1 analogue giving appropriate quantity.
- For injectable therapy, prescribe needles (see page 7) & sharps bin

Dose titration/tolerability review(s)

Review investigations, bloods and examinations:
- For T2DM only :HbA1c (3 monthly- 6 monthly until HbA1c stable on unchanging therapy and then 6 monthly to continue) & glucose levels if relevant
- Weight, BMI & if required WtHR – record weight change
- Renal profile 3-6 months after initiation (see Box 1 below)
- Re-check thyroid function if taking levothyroxine & Rybelsus 6-8 weeks after initiation
- Nutritional deficiencies if suspected

Review clinical suitability: see pages 3-6
- Tolerability & gastro-intestinal side effects
- Assessment of adequate nutritional intake, protein intake, hydration (see page 5) .
- Weight change
  (If substantial, unexpected weight loss, investigate further to rule out underlying pathology)
- Blood pressure

For T2DM, review:
- Glyceamic control and assess need for further adjustment of other glucose lowering therapies (see page 5)

For weight management review:
- Engagement with BSOP, noting requirement to engage with as part of Mounjaro▼® prescribing
- Review weight related co-morbidities as needed

Discuss with appropriate specialist team as needed (examples outlined in initiation section (blue box)

Discuss with patient:
- Adherence – if breaks in treatment (longer than 4 weeks) consider dose re-titration if higher doses prescribed, taking into account reason for break, side-effects and tolerability during titration and previous doses prescribed.
- Dose titration
- Medication review and adjustments if needed, including changes to other glucose lowering therapies are needed (see page 5).
- Refresh patient education (see page 8)

Follow up:
- Issue prescription for GLP-1 analogue giving appropriate quantity and relevant consumables (see page 7)

If GLP-1 analogue is prescribed for indications that do not meet agreed criteria, prescribing will remain with the initiating team.

6 month

Review as per Dose titration/tolerability review (purple box)

For weight management:
- Assess stopping rule (see page 2 for criteria specific stopping rule)
- If unable to tolerate or despite max tolerated dose does not meet weight loss required to continue therapy or would benefit from alternative intervention – refer to SWMS.

Ongoing /Annual review

Review investigations, bloods and examinations
- For T2DM only: HbA1c (3 monthly- 6 monthly until HbA1c stable on unchanging therapy and then 6 monthly to continue)
- Weight, BMI & if required WtHR
- Renal profile & LFT's
- Check thyroid function if taking levothyroxine & Rybelsus or significant weight loss with any GLP-1 analogue prescribed
- Blood pressure
- Nutritional deficiencies if suspected

Reassess clinical suitability: pages 3-6

Discuss with appropriate specialist team as needed
(examples outlined in initiation section (blue box)

Discuss with patient:
- Adherence
- Dose titration
- Medication review and adjustments if needed, including changes to other glucose lowering therapies are needed (see page 5), medications where weight impacts use e.g. BP medications and weight-based dosing
- Refresh patient education (see page 8)
- For weight management: document completion of BSOP programme at first annual review

At any stage of treatment

- Stop GLP-1 analogue if BMI <18.5 kg/m^2 (underweight).
- For T2DM: Stop GLP-1 analogue if they do not help to reach individualised glycaemic targets and they are not being taken for cardiovascular benefit.
- Refer to appropriate specialist team as needed

If GLP-1 analogue not suitable refer to:
- CESEL guide for T2DM
- Local obesity pathway for weight management

Box 1: renal function advice –read in conjunction with renal advice on page 5:
- If eGFR drop >10ml/min, review eGFR trend prior to initiation. Discuss with appropriate clinician. Consider other causes, re-check profile within 4 weeks.
- If eGFR drop 5-10ml/min, re-check at 6 months and if stable check and review at 12 months. If not stable discuss with appropriate clinician.
- If eGFR drop <5ml/min, re-check at 6 & 12 months. Discuss with appropriate clinician if not stable

Contra-indications, cautions and recommendations***

Contra-indications
- Hypersensitivity to active substance or excipients

Not recommended
- Acute pancreatitis
- Pregnancy or breast feeding or those considering pregnancy (see advice below)
- For treatment of diabetic ketoacidosis (DKA)
- Type 1 diabetes
- Severe gastrointestinal (GI) disease e.g. IBD, gastroparesis (tirzepatide to be used with caution)
- No experience in those with heart failure New York Heart Association (NYHA) class IV, for semaglutide and liraglutide, not recommended
- Higher rate of cholelithiasis and cholecystitis compared to placebo. Inform patients of characteristics symptoms of cholelithiasis and cholecystitis and do not start in active cholelithiasis and cholecystitis.

Cautions
- History of pancreatitis –discuss with specialist team
- Risk factors for pancreatitis e.g. high alcohol intake, gall bladder or biliary disease, high triglycerides
- Limited/very limited experience in those aged ≥75 years (See SPC for further information).
- Diabetic retinopathy: rapid improvement in glucose control (e.g. with insulin and GLP-1 analogues) has been associated with temporary worsening of diabetic retinopathy. See page 6 for further information
- DKA has been reported in association with some GLP-1 analogues, particularly after discontinuation or reduction of concomitant insulin. If insulin dose is to be reduced, undertake in a stepwise manner with blood glucose self-monitoring. Discuss risk factors for and signs & symptoms of DKA & advise to seek immediate medical advice if these develop – refer to specialist team for initiation if prescribed insulin
- Cases of pulmonary aspiration have been reported in patients receiving GLP-1 analogue undergoing general anaesthesia or deep sedation. Therefore, the increased risk of residual gastric content due to delayed gastric emptying should be considered prior to performing procedures with general anaesthesia or deep sedation.
- Pre-clinical studies in rats/mice showed an increase in thyroid c-cell tumours, human relevance is considered low but cannot be excluded. Avoid in personal or family history of medullary thyroid carcinoma and in those with multiple endocrine neoplasia syndrome type 2 (MEN 2).

Additional GLP-1 specific recommendations:

All GLP-1 analogues:
- Monitor heart rate (HR) at regular intervals (increase noted in trials). Discuss symptoms of increased HR. If clinically relevant sustained increase in resting HR, review treatment.
- For weight management: safety and efficacy has not been established with other weight management treatments (e.g. use of more than one GLP-1 analogue at a time, use with Orlistat or in those with bariatric surgery)

Liraglutide:
- Use with caution in those with thyroid disease
- Therapeutic experience in patients ≥ 75 years of age is limited and use in these patients is not recommended

Mounjaro▼®:
- Preparation contains benzyl alcohol. May cause allergic reactions. People with hepatic or renal impairment should be informed of the potential risk of metabolic acidosis due to accumulation of benzyl alcohol over time
- Very limited data in people aged ≥85 years

Ozempic®, Rybelsus® & Wegovy▼® (Semaglutide):
- **Rybelsus® :** Review administration instructions if treatment response lower than expected
- **Wegovy▼® :** Limited experience in those aged 85 years or more

Pregnancy, planning pregnancy, contraception and hormone replacement therapy

GLP-1 analogues are not recommended during pregnancy because of limited safety data. Women of childbearing potential are recommended to use adequate contraception while prescribed GLP-1 analogues.

Inform all individuals of child-bearing potential (who are able to become pregnant):
- Weight loss may improve fertility
- Effective contraception must be used while taking the medicine, see below oral contraceptive advice with Mounjaro▼®.
- That if they want to become pregnant, they should stop GLP-1 analogue for a period of time before becoming pregnant (washout period) and should continue to use adequate contraception during that time.
- If a person reports that they are pregnant when taking GLP-1 analogue, tell them to stop taking it immediately. The healthcare professional should report any exposure to the UK Teratology Information Service.

Stopping GLP-1 analogue prior to pregnancy:

Washout period is dependent on the individual GLP-1 analogue:
- For Wegovy▼®, Ozempic® and Rybelsus® (semaglutide) – stop 2 months before pregnancy
- For Mounjaro▼® – stop 1 month (4 weeks) before pregnancy
- For Liraglutide (branded generics licensed for weight management) – stop just before trying to become pregnant

Oral contraceptives:

Individuals using tirzepatide and oral contraception should switch to a non-oral contraceptive method, or add a barrier method of contraception, for four weeks after initiation and for four weeks after each dose increase.

For further information see: The Faculty of Sexual & Reproductive Healthcare statement: GLP-1 analogue and oral contraception and patient information leaflet

Hormone replacement therapy:

The impact of these medications on efficacy of co-prescribed oral hormone medications within HRT are unknown.

For further information see: British Menopause Society guidance: Use of incretin-based therapies in women using hormone replacement therapy (HRT)

***Please note:** information is not exhaustive, please see Summary of Product Characteristics (SPC) at www.medicines.org.uk for more information including details of interaction with other medicinal products.

Side-effects***

Inform individuals of side effect management prior to initiation and review tolerability during treatment

- **Gastrointestinal (GI) effects**: Inform patient nausea, vomiting, diarrhoea, constipation, abdominal pain are listed as very common/common. Nausea is likely at initiation and/or dose titrations but likely to decrease over time.

To minimise GI effects, give side-effect minimisation advice:

- Reduce portion size
- Respond to feeling of fullness and stop eating
- Avoid overly fatty or fried foods
- Maintain adequate fluid intake – Drink ~2L per day (unless fluid restricted)
- Reassure that symptoms are often mild and transient

If higher doses not tolerated consider slow upward titration (every 8-12 weeks) or reduce to tolerated dose.
Caution with dehydration and renal function decline – advise on potential for dehydration and take precautions to avoid fluid depletion.
See patient information leaflet for dietary advice while on weight loss medications and for diabetes treatment.

- **Acute Pancreatitis:** Inform patient of symptoms and action to take, see NHS webpage on acute pancreatitis. Patient to discontinue treatment and contact healthcare professional immediately if symptoms occur. See MHRA update for further advice.
- **Non-arteritic anterior ischemic optic neuropathy (NAION) –** increased risk during treatment with semaglutide. There is no identified time interval for when NAION may develop. If sudden loss of vision (including partial loss), urgently attend eye casualty. If confirmed, discontinue semaglutide, see MHRA update for further advice.
- **Aspiration in association with general anesthesia or deep sedation –** ensure surgical team aware patient is taking GLP-1 prior to surgery. See MHRA update for further advice
- **Hypoglycaemia:** consider dose reduction of concomitant medications to prevent hypoglycaemia (in particular sulfonylurea and insulin) see page 5 for dose adjustment advice.
- **Diabetic retinopathy complications**: Advise patients to immediately report any symptoms of worsening retinopathy e.g. worsening vision (gradual or sudden), sudden vision loss, shapes floating in the field of vision (floaters), blurred or patchy vision, or eye pain. See page 6 for retinopathy advice
- **Loss of muscle mass:** During weight loss, patients may lose muscle mass which may impact patients' strength, physical function and daily movement. Those at risk include older adults, chronic disease, those with a history of falls, frailty or weakness. Follow national physical exercise guidance prioritise strengthening exercise twice a week – see Strength exercises – NHS for examples. Ensure adequate protein intake. Investigate any loss of physical function. Refer to physio if needed. Consider slow upward titration.

Note: For established medicines, report all serious suspected adverse drug reactions (ADRs) even if effect is well recognised. For black triangle drugs (▼), report all suspected ADRs. Report to https://yellowcard.mhra.gov.uk/

Medication Review***

Review medication prior to in GLP-1 analogue initiation and throughout treatment

Sulfonylureas, repaglinide and insulin: Consider dose reduction of sulfonylureas/repaglinide and/or insulin to prevent hypoglycaemia at initiation and dose titration.

Hypoglycaemia risk higher when:

- HbA1c or glucose levels are near target levels or patient has history of recent/recurrent hypoglycaemia
- Frailty
- Renal impairment

Advise patient to monitor additional glucose levels pre-breakfast (fasting) and pre-evening meal for first few weeks when GLP-1 analogue started and after each dose titration. Review HbA1c on initiation and 3 monthly OR at each dose titration. Refresh hypoglycaemia advice – see hypoglycaemia patient information leaflet. Advise on sick day rules. Arrange appropriate follow up to review glucose levels.

Insulin: For initiation or dose titration of GLP-1 analogue for any patient on insulin, seek advice through advice and guidance or refer to specialist service (diabetes or specialist weight management service).

Sulfonylureas or repaglinide: Adjust dose according to table below. If unsure of dose reduction seek advice prior to initiation using advice and guidance routes. Ensure sulfonylureas/repaglinide are taken with meals containing carbohydrates.

Monitoring parameter	Action for sulfonylureas or repaglinide
HbA1c less than or equal to 58mmol/mol **Or** near individualised HbA1c/glucose target, **Or** having hypoglycaemia **Or** glucose levels predominantly less than 9 mmol/L	Stop sulfonylurea/repaglinide. Monitor glucose levels as above and adjust further as necessary
HbA1c 59mmol/mol – 86 mmol/mol**** **Or** glucose levels predominantly 9 -13 mmol/L***	Reduce sulfonylurea/repaglinide dose by 50%. Consider further dose reduction or stop sulfonylurea/repaglinide in those at higher risk of hypoglycaemia (see notes above) or when at lower doses. Monitor glucose levels as above and adjust further as necessary.
HbA1c >86mmol/mol**** **Or** glucose levels predominantly ≥13 mmol/L***	Continue sulfonylurea/repaglinide initially and review glucose as GLP-1 analogue takes effect and at each dose titration.

****Adjust accordingly if individualised HbA1c is more than 58mmol/mol**

DPP-4 inhibitors: Do not offer both GLP-1 and DPP-4 inhibitor together due to acting on the same incretin pathway.

Weight gaining medicines - Review medicines for any that may cause weight gain. Examples include corticosteroids, hormones, antipsychotics, antidiabetics, antidepressants. Review if any can be stopped, reduced or changed to an alternative. Liaise with specialists when needed. It may not be possible to adjust or stop concomitant medicines that cause weight gain.

Potential to delay gastric emptying & impact rate of absorption of concomitantly administered: Monitor those on oral medicines with narrow therapeutic index (e.g. warfarin, digoxin) especially at initiation and dose increase. Risk of delayed effect to be considered for oral medicines with rapid GI absorption or prolonged release - potential of altered medicinal product exposure.

Possible changes to international normalised ratio (INR) in patients on warfarin or coumarin derivatives. More frequent monitoring recommended e.g. at initiation, dose change and cessation of liraglutide, semaglutide and tirzepatide.

***Please note:** information is not exhaustive, please see Summary of Product Characteristics (SPC) at www.medicines.org.uk for more information including details of interaction with other medicinal products.

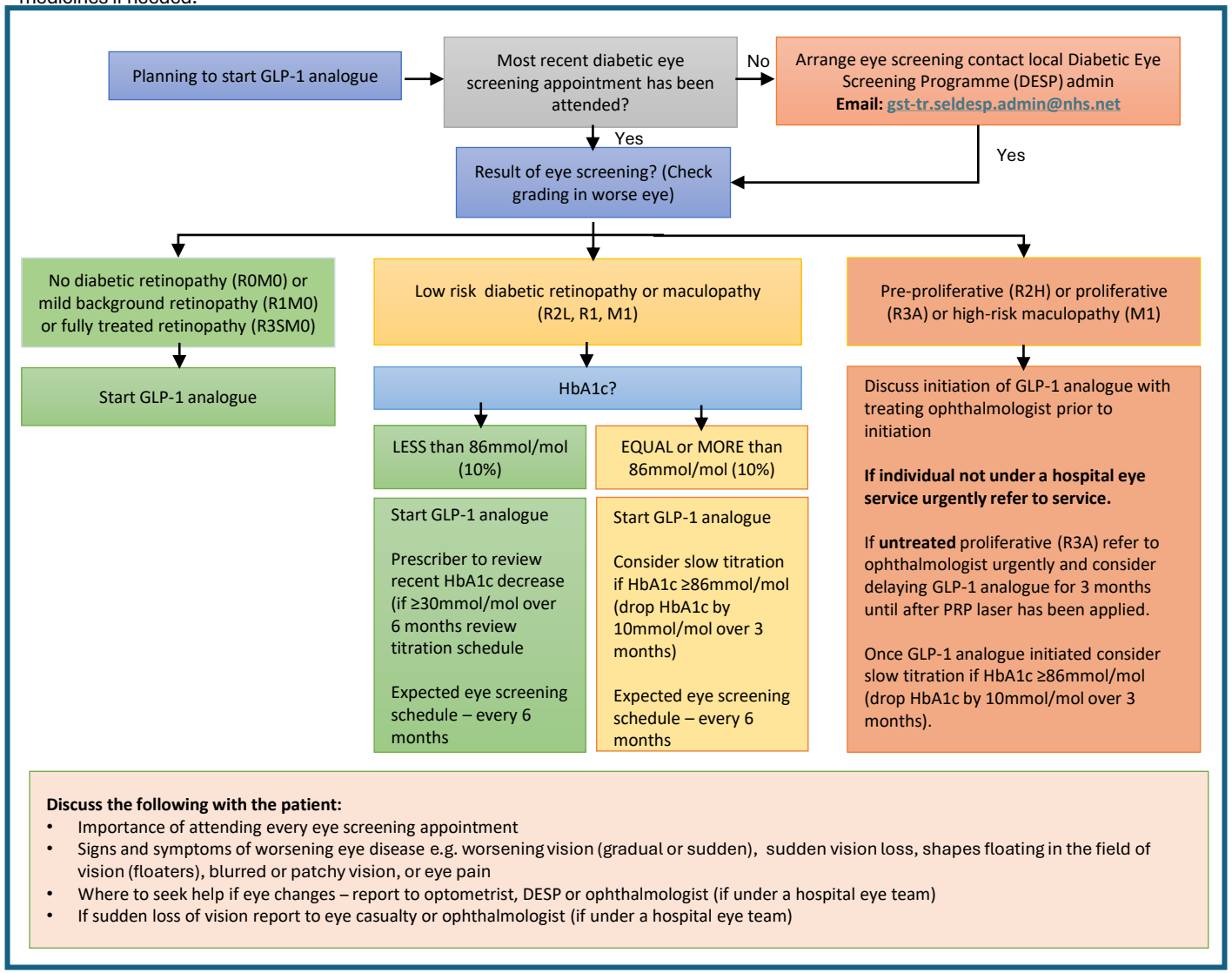
Renal and hepatic review***

	HEPATIC IMPAIRMENT	RENAL IMPAIRMENT
Liraglutide injection (branded generics licensed for T2DM and weight management)	**For use in T2DM:** **Mild or moderate:** No dose adjustment. **Severe**: Not recommended **For use in weight management:** **Mild or moderate:** No dose adjustment, use with caution **Severe**: Not recommended	**For use in T2DM:** **Mild, moderate or severe:** No dose adjustment **End stage renal disease (ESRD) (<15ml/min):** Not recommended **For use in weight management:** **Mild or moderate:** No dose adjustment **Severe (≥15ml/min to <30ml/min) and ESRD (<15ml/min):** Not recommended
Trulicity® (dulaglutide) **injection**	No dose adjustment required in hepatic impairment.	**Mild or moderate or severe renal impairment:** No dose adjustment **ERSD (<15ml/min):** Not recommended
Ozempic® (semaglutide) **injection**	**Mild or moderate:** No dose adjustment **Severe:** Limited experience, exercise caution if used	**Mild or moderate:** No dose adjustment **Severe:** No dose adjustment, experience limited
Wegovy® ▼ (semaglutide) **injection**	**Mild or moderate:** No dose adjustment **Severe:** Limited experience, exercise caution if used	**Mild or moderate:** No dose adjustment **Severe:** No dose adjustment, experience limited **ERSD (<15ml/min):** Not recommended
Rybelsus® (semaglutide) **oral tablet**	No dose adjustment in hepatic impairment **Severe:** Limited experience, exercise caution if used	**Mild or moderate:** No dose adjustment **Severe:** No dose adjustment, experience limited **ERSD (<15ml/min):** Experience limited.
Mounjaro® ▼ (tirzepatide) **injection**	No dose adjustment in hepatic impairment **Severe:** Limited experience, exercise caution if used	**Mild or moderate:** No dose adjustment **Severe: (≥15ml/min to <30ml/min) and ERSD (<15ml/min):** No dose adjustment needed. Experience is limited – exercise caution if used

***Please note:** information is not exhaustive, please see Summary of Product Characteristics (SPC) at www.medicines.org.uk for more information including details of interaction with other medicinal products.

Diabetic Retinopathy

Diabetic retinopathy (DR) complications: rapid improvement in glucose control (e.g. with insulin and GLP-1 analogues) has been associated with temporary worsening of diabetic retinopathy.
Semaglutide: An increased risk of DR complications was observed in trials in those treated with insulin and semaglutide.
Mounjaro▼®: has not been studied in those with non-proliferative DR, proliferative DR or diabetic macular oedema.
Use with caution & monitor, see flow diagram below to review DR prior to initiation of GLP-1 analogue and adjust titration of diabetes medicines if needed.



Discuss the following with the patient:
- Importance of attending every eye screening appointment
- Signs and symptoms of worsening eye disease e.g. worsening vision (gradual or sudden), sudden vision loss, shapes floating in the field of vision (floaters), blurred or patchy vision, or eye pain
- Where to seek help if eye changes – report to optometrist, DESP or ophthalmologist (if under a hospital eye team)
- If sudden loss of vision report to eye casualty or ophthalmologist (if under a hospital eye team)

Dose information***

GLP-1 analogue	Licensed use	Approved doses (SEL)	Initiating dose	Dose titration	Average weight loss & HbA1c reduction	No. doses in single pen	No. pens required each month	Pen needles in pack?	Patient material links
Liraglutide (branded generics for T2DM) injection	T2DM	0.6mg 1.2mg 1.8mg	Start 0.6mg daily.	After at least one week, increase the dose to1.2mg daily. Dose may be increased to 1.8mg after a further week to improve glycaemic control. Dose over 1.8mg is not recommended	LEAD-3: 1.8mg daily: After 52 weeks, HbA1c reduction 1.14%, weight reduction 2.45kg	30 doses of 0.6mg 15 doses of 1.2mg 10 doses of 1.8mg	Between 1-3 pens dependent on dose (30 days)	No	Not available
Trulicity® (dulaglutide) injection	T2DM	1.5mg 3mg 4.5mg	1.5mg once weekly as part of add on therapy	If needed, the dose can be increased to 3mg once weekly after at least 4 weeks and after a further 4 weeks to 4.5mg to improve glycaemic control.	AWARD-3: 1.5mg dose: After 26 weeks, HbA1c reduction 0.78% , weight reduction 2.29kg	Single weekly dose	4 pens (28 days supply)	Yes – pre-attached, auto-retracts	Not available
Ozempic® (semaglutide) injection	T2DM	0.25mg 0.5mg 1mg	0.25mg once weekly	Increase the dose to 0.5mg weekly after 4 weeks. After at least a further 4 weeks, the dose can be increased to 1mg weekly to further improve glycaemic control	SUSTAIN-1: 1mg dose: At 30 weeks, HbA1c reduction1.55%, weight reduction 4.53kg	4 doses	1 pen (28 days supply)	Yes – 4 needles	See link
Rybelsus® (semaglutide) oral tablets	T2DM	1.5mg 4mg 9mg	1.5mg daily	Increase dose to 4mg daily after 1 month. After at least a further 1 month the dose can be increased to 9mg daily to further improve glycaemic control. Maximum dose is 9 mg daily. Take once daily on an empty stomach after a recommended fasting period of at least 8 hours. Swallow tablet whole with a sip of water (up to half a glass of water equivalent to 120 ml). Wait at least 30 minutes before eating or drinking or taking other oral medicinal products to ensure full absorption. Rybelsus should always be taken as one tablet per day.	PIONEER-1, 14mg daily dose (equivalent to 9mg daily dose): HbA1c reduction 1.1%, weight reduction 2.4kg at 26 weeks	Not applicable	Not applicable	Not applicable	See link
Mounjaro®▼ (tirzepatide) injection	T2DM & Weight management	2.5mg 5mg 7.5mg 10mg 12.5mg 15mg	2.5mg once weekly	Increase the dose to 5mg once weekly after 4 weeks as maintenance dose. The majority of glucose lowering effect (HbA1c reduction) is seen at the 5mg dose. If HbA1c target not achieved or further weight reduction required further dose increases can be made in 2.5 mg increments after a minimum of 4 weeks on the current dose. Maximum dose is 15mg once a week. The recommended maintenance doses are 5, 10 and 15mg.	SURPASS-1: (T2DM) HbA1c reduction 2.11%, weight reduction 8.8kg at 40 weeks SURMOUNT-1 (without diabetes) 15mg dose: 22.1% after 72 weeks SURMOUNT 2 (with diabetes): 15mg dose: 15.7% after 72 weeks	4 doses	1 pen (28 days supply)	No	T2DM: See link Obesity: See link
Wegovy®▼ (semaglutide) injection **Specialist weight management services only**	Weight management	0.25mg 0.5mg 1mg 1.7mg 2.4mg	0.25mg once weekly	Increase the dose to 0.5mg weekly after 4 weeks. After at least a further 4 weeks, the dose can be increased to 1mg weekly, then after a further 4 weeks to 1.7mg weekly and then after a further 4 weeks to a maximum dose of 2.4mg weekly.	STEP-1 (without diabetes) 2.4mg dose: weight reduction of 14.9% (−15.3 kg) after 68 weeks STEP-2 (with diabetes) 2.4mg dose: weight 9.6% (-9.7kg) after 68 weeks	4 doses	1 pen (28 days supply)	Yes – 4 needles	See link
Liraglutide (branded generics for weight management) injection **Specialist weight management services only**	Weight management	0.6mg 1.2mg 1.8mg 2.4mg 3.0mg	Start 0.6mg daily.	The dose should be increased to 3.0 mg once daily in increments of 0.6 mg with at least one-week intervals to improve gastro-intestinal tolerability. If escalation to the next dose step is not tolerated for two consecutive weeks, consider discontinuing treatment. Daily doses higher than 3.0 mg are not recommended.	SCALE (without diabetes): 3.0mg dose: 8% (-8.4kg) after 56 week SCALE Diabetes: 3.0mg dose: 6% (-6.4kg) after 56 week	30 doses of 0.6mg 15 doses of 1.2mg 10 doses of 1.8mg 7 doses of 2.4mg 6 doses of 3.0mg	Between 1-5 pens dependent on dose (30 days supply)	No	Not available

***Please note:** information is not exhaustive, please see Summary of Product Characteristics (SPC) at www.medicines.org.uk for more information including details of interaction with other medicinal products.

Patient education

Discuss with all patient prior to initiation:

- ❑ Treatment goals
- ❑ Benefits, risks and side-effects
- ❑ Medicine administration - including dosing, time of dose and missed doses
  - ❑ For injections – how to use the device and administer, how to store and handle sharps disposal and provide compatible needles where needed.
  - ❑ For Rybelsus® tablets – specific administration advice to aid absorption (see page 7)
- ❑ Side-effect minimisation advice (see page 5)
- ❑ Pregnancy/planning pregnancy (including washout period advice)
- ❑ Adequate contraception
- ❑ Medication adjustment advice (see page 5)
- ❑ Healthy living advice including diet and physical exercise
- ❑ Follow up frequency and next appointment date, including contact details for the team
- ❑ Provision of written educational material where relevant

For T2DM:

- ❑ Sick day rules guidance
- ❑ Blood glucose monitoring requirements (including driving in line with Driver and Vehicle Licensing Agency (DVLA) guidance)
- ❑ Hypoglycaemia risk and actions to be taken e.g., dose reduction of concomitant medications (in particular insulin & sulfonylureas (SU)). Refresh hypoglycaemia prevention and management.
- ❑ For those with existing diabetic retinopathy, the patient is aware/has been informed of the risks of diabetic retinopathy complications, the symptoms of worsening retinopathy and action to be taken if this occurs.

For weight management

- ❑ Requirement to engage with behavioural support as part of Mounjaro▼® prescribing –Inform patient about BSOP program and make referral (if not appropriate for BSOP program to refer to SWMS).
- ❑ Expected weight loss trajectories and stopping rule
- ❑ Vitamin and mineral supplementation (to purchase appropriate Multivitamin A-Z over the counter)
- ❑ To prevent muscle loss: Adequate protein intake and physical exercise advice (see page 5)

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