

**Amber with Guidance (Amber-G)** = To be initiated by a specialist\* with follow up prescribing and monitoring by primary care clinicians.

\*Specialist is defined by IMOC as a clinician who has undertaken an appropriate formal qualification or recognised training programme, or who has the appropriate knowledge and competencies within the described area of practice.

**Tirzepatide (Mounjaro®) Kwikpen in adults 18 years and over with type 2 diabetes mellitus.** **(Note tirzepatide is also licensed for weight management, but this is not covered by this guideline).**

Tirzepatide is Amber G in the South Yorkshire traffic light list for the treatment of insufficiently controlled Type 2 diabetes in adults.

The details of side-effects, cautions, contraindications and interactions are not a complete list and the current BNF <https://bnf.nice.org.uk/drugs/tirzepatide/> and the SPC (<https://www.medicines.org.uk/emc/>) remain authoritative.

The SY ICB Medicines Optimisation Team will alert primary care prescribers if any significant changes in review or monitoring arrangements of Amber-G medicines they prescribe are recommended.

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| <p><b>Background Information</b></p>    | <p>Tirzepatide is a combined GLP-1 (Glucagon-like-peptide-1) agonist and GIP (Glucose-dependant insulinotropic polypeptide agonist).</p> <p>Tirzepatide should be initiated by a specialist who has undertaken formal training or equivalent in the specialist area including e.g. Secondary care prescriber, GPSI, Diabetes specialist nurse and specialist pharmacists or practice nurses who have undertaken specialist training. Once the response to treatment has been established and side effects tolerated, ongoing prescribing can transfer to primary care/ non- specialist care with a clear care plan to consider dose titration or stopping if changes in response are not seen (see monitoring section below).</p>  |
| <p><b>Indication</b></p>                | <p>Tirzepatide is indicated for the treatment of adults with insufficiently controlled type 2 diabetes mellitus as an adjunct to diet and exercise:</p> <ul style="list-style-type: none"> <li>• In addition to other medicinal products for the treatment of diabetes.</li> <li>• As monotherapy when metformin is considered inappropriate due to intolerance or contraindications. (Whilst tirzepatide is licensed for monotherapy, SY ICB promote the use of tirzepatide as outlined in the NICE <a href="#">TA 924</a> criteria).</li> </ul> <p><a href="#">NICE TA 924</a> Clinical Guideline for adults advises that tirzepatide may be used if:</p> <ul style="list-style-type: none"> <li>• triple therapy with metformin and two other oral antidiabetic drugs is ineffective, not tolerated or contraindicated, (consider triple therapy by switching one drug for a GLP-1 agonist or tirzepatide) <b>and</b></li> <li>• Patients must have a BMI of 35kg/m<sup>2</sup> or more, and specific psychological or other medical problems associated with obesity, <b>or</b></li> <li>• Have a BMI less than 35kg/m<sup>2</sup>, <b>and</b>:             <ul style="list-style-type: none"> <li>○ <b>For whom</b> insulin therapy would have significant occupational implications <b>or</b></li> <li>○ weight loss would benefit other significant obesity-related complications.</li> </ul> </li> </ul> <p>Use lower BMI thresholds (usually reduced by 2.5kg/m<sup>2</sup>) for people from South Asia, Chinese, other Asian, middle Eastern, Black African or African-Caribbean family backgrounds.</p> <p>Patients currently prescribed a DPP4 inhibitor should have their medication reviewed and the DPP4 stopped prior to commencing a GLP-1 inhibitor or tirzepatide. DPP4 inhibitors and GLP-1 agonists /tirzepatide should not be used in combination.</p> |
| <p><b>Dosage and administration</b></p> | <p>Tirzepatide solution for injection is provided as a prefilled oral solution Kwikpen (2.4ml) containing four doses of 0.6ml solution per dose (sufficient for 28 days' supply).</p>  |

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Tirzepatide solution for injection (Mounjaro®) is to be injected subcutaneously in the abdomen, thigh or upper arm.

The dose can be administered at any time of day, with or without meals.

Injection sites should be rotated with each dose. If a patient also injects insulin, they should inject tirzepatide solution for injection (Mounjaro®) into a different injection site. Patients/carers should be counselled on injection technique and administration sites for injection (thigh, abdomen or upper arm).

Patients should be advised to carefully read the instructions for use and the package leaflet for the pre-filled KwikPen before administering the medicinal product.

The starting dose of tirzepatide is 2.5mg once weekly for 4 weeks. The specialist initiating tirzepatide should prescribe for the first 4 weeks (minimum) and review the patient before increasing the dose to 5mg.

The patient should be maintained on a dose of 5mg until the patient is reviewed and the patient's weight and HbA1c checked (3-6 months after tirzepatide initiation). Patients should be on a dose for a minimum of 4 weeks before any dose increase is considered. The usual maintenance doses are 5mg, 10mg or 15mg, with 15mg weekly being the maximum dose.

If at the 6-month review, the patient is not meeting the following treatment targets:

- Reduction in HbA1c of at least 11mmol/mol AND
- Weight loss of at least 3% of initial body weight in 6 months.

A review of tirzepatide prescribing should be conducted and \*tirzepatide prescribing stopped if clinically appropriate (\*This is not covered in [NICE TA924](#) for tirzepatide but is recommended for GLP-1 agonists. To reduce the risk of treatment inertia NICE guidance should be followed).

[NICE TA924](#) states that in clinical trials the reduction of HbA1c was a flatter response curve and that increasing the dose did not significantly reduce the HbA1c. Higher doses do however, produce a statistically significant increase in weight loss. For those patients requiring further weight loss, an increase in dose may be considered. It is advised that the dose be increased to 7.5mg for 4 weeks, then 10mg until the next HbA1c/weight loss review.

#### Missed dose.

If a dose is missed, it should be administered as soon as possible within 4 days after the missed dose. If more than 4 days have passed, skip the missed dose and administer the next dose on the regular scheduled day. In each case, the patient should resume their regular once weekly dosing schedule (e.g. Patient usually administers on Saturday but goes away for the weekend and forgets to take the medication with them, they may administer on Sunday, Monday or Tuesday on their return. Should they return later than this then they should administer their next dose on Saturday and skip the missed dose).

#### Changing the dose schedule

The day of weekly administration can be changed, if necessary, as long as the time between two doses is at least 3 days.

#### Adding tirzepatide to existing metformin and/or SGLT2 inhibitor therapy

Current dose of metformin and/or SGLT2 inhibitor may be continued

#### Adding tirzepatide to existing sulphonylurea and/or insulin therapy

Patients taking a sulphonylurea or insulin in combination with tirzepatide are at an increased risk of hypoglycaemia. A reduction in the dose of sulphonylurea or insulin may be considered to reduce the risk of hypoglycaemia. Blood glucose self-monitoring is necessary to adjust the dose of sulphonylurea and insulin. A stepwise approach to insulin reduction is recommended. As the responses will be variable it is suggested that patients on these medications be given guidance by specialists with the knowledge to safely titrate sulphonylureas / insulin.

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|  | <p><u><b>Adding tirzepatide to gliptin therapy</b></u></p> <p>Adding tirzepatide therapy to gliptin therapy is not recommended as it has not been studied by the manufacturer. Tirzepatide and gliptins use similar pathways in the body by affecting incretin. It is thought that using them together may increase side effects such as acute pancreatitis</p>   |
| <p><b>Precautions for use</b></p>            | <p>When adding tirzepatide to existing metformin and/or sodium-glucose co-transporter 2 inhibitor (SGLT2i) therapy see the information contained in the dosage section <a href="#">above</a>.</p> <p>When tirzepatide is added to existing therapy of a sulphonylurea and/or insulin therapy see the information contained in the dosage section <a href="#">above</a>.</p> <p>No dose adjustment is needed based on age, gender, race, ethnicity or body weight.</p> <p>Patients of childbearing potential taking the oral contraceptive pill are advised to use an additional or alternate form of contraception on initiation of tirzepatide and at any tirzepatide dose increase (for a minimum of 4 weeks). This is in case vomiting or malabsorption occurs.</p> <p>Patients should be provided with suitable needles from the formulary and a Sharpsguard yellow sharps bin 5L for safe disposal of used needles. The yellow sharps bins should be disposed of through agreed place-based arrangements.</p> <p>Patients currently taking orlistat should be reviewed prior to tirzepatide initiation and the orlistat stopped for the duration of tirzepatide treatment.</p>   |
| <p><b>Cautions and Contraindications</b></p> | <p><b><u>This list is not exhaustive, see BNF and SPC for full details.</u></b></p> <p><b><u>Contraindications</u></b></p> <ul style="list-style-type: none"> <li>• Hypersensitivity to the active substances or any of the excipients. Cases of anaphylactic reaction and angioedema have been rarely reported with tirzepatide during post-marketing surveillance.</li> </ul> <p><b><u>Cautions</u></b></p> <p><b><u>Acute pancreatitis</u></b></p> <p>Tirzepatide has not been studied in patients with a history of pancreatitis. Avoid using in patients with a history of pancreatitis unless there is clear evidence that the precipitating cause is no longer cause for concern, in which it could be used with caution if benefits are thought to outweigh risks.</p> <p>Acute pancreatitis has been reported in patients treated with tirzepatide. Patients should be informed of the symptoms of acute pancreatitis. Common symptoms include:</p> <ul style="list-style-type: none"> <li>• suddenly getting severe pain in the centre of your tummy (abdomen) that does not go away, and may radiate to your back</li> <li>• feeling or being sick</li> <li>• a high temperature of 38°C or more (fever)</li> </ul> <p>If pancreatitis is suspected, tirzepatide should be discontinued. If the diagnosis of pancreatitis is confirmed, tirzepatide should not be restarted. In the absence of other signs and symptoms of acute pancreatitis, elevations in pancreatic enzymes alone are not predictive of acute pancreatitis (see section 4.8 of the <a href="#">SPC</a>). .</p> <p>At the time of writing, Yellow Card Biobank is investigating whether the risk of acute pancreatitis from GLP-1 injections for weight loss and type 2 diabetes may be influenced by an individual's genes. Healthcare professionals are also being asked to help recruit for the study by reporting <a href="#">Yellow Cards</a> on behalf of patients experiencing acute pancreatitis while taking GLP-1 medicines</p> |

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### Hypoglycaemia in patients with type 2 diabetes mellitus

Patients receiving tirzepatide in combination with an insulin secretagogue (for example, a sulphonylurea) or insulin may have an increased risk of hypoglycaemia. The risk of hypoglycaemia may be lowered by a reduction in the dose of the insulin secretagogue or insulin (see sections 4.2 and 4.8 of the [SPC](#)). Clinically significant hypoglycaemia (blood glucose < 3.0 mmol/L (< 54 mg/dL) or severe hypoglycaemia (requiring the assistance of another person) occurred in 10 to 14 % (0.14 to 0.16 events/patient year) of patients when tirzepatide was added to sulphonylurea and in 14 to 19 % (0.43 to 0.64 events/patient year) of patients when tirzepatide was added to basal insulin.

### Gastrointestinal effects

Tirzepatide has been associated with gastrointestinal adverse reactions, which include nausea, vomiting, and diarrhoea (see section 4.8 of the [SPC](#)). These adverse reactions may lead to dehydration, which could lead to a deterioration in renal function including acute renal failure. Patients treated with tirzepatide should be advised of the potential risk of dehydration, due to the gastrointestinal adverse reactions and take precautions to avoid fluid depletion and electrolyte disturbances. This should particularly be considered in the elderly, who may be more susceptible to such complications.

### Severe gastrointestinal disease

Tirzepatide has not been studied in patients with severe gastrointestinal disease, including severe gastroparesis, and should be used with caution in these patients.

### Diabetic retinopathy

Tirzepatide has not been studied in patients with non-proliferative diabetic retinopathy requiring acute therapy, proliferative diabetic retinopathy or diabetic macular oedema, and should be used with caution in these patients with appropriate monitoring.

Rapid improvement in glucose control (from range of means) has been associated with a worsening of diabetic retinopathy.

The clinical trials to date have excluded patients with retinopathy so there is a lack of clear clinical evidence on the topic.

While clinical experience is gained and in the absence of a UK/international consensus guidelines, the [British Association of Clinical Diabetologists and the Primary Care Diabetes Society](#) suggest the following for initiation of Mounjaro® (tirzepatide). See [Appendix 1](#) for flow chart).

- **HbA1c less than 86mmol/mol (10%) with normal eye screening (R0M0) or background changes (R1) in the last two years** can continue with usual interval for eye screening. Discuss/educate person about risks, including asking them to report significant visual changes prior to initiation of treatment, and prompt importance of continued attendance for eye screening.
- **Significantly elevated HbA1c, e.g. 86mmol/mol (10%) or higher, in a person with normal eye screening (R0M0) in the last 2 years** - discuss/educate person about risks, including asking them to report significant visual changes prior to initiation of treatment, and prompt importance of continued attendance for eye screening.
- **Significantly elevated HbA1c, e.g. 86mmol/mol (10%) or higher, in a person with established background retinopathy (R1)** - consider discussion (or Advice & Guidance) with local diabetes team prior to initiation of treatment.
- **Active eye disease (R2/R3 or M1), under specialist ophthalmology services** - should be discussed with their specialist team prior to initiation to allow an individualised risk/benefit approach to treatment and monitoring to be formulated.

For South Yorkshire patients, please seek diabetes specialist advice in the first instance for patients with active eye disease. The diabetes team can then liaise with ophthalmology if they feel that starting tirzepatide is appropriate.

### Elderly

Only very limited data are available from patients aged ≥ 85 years.

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|                                     | <p><u>Sodium content</u></p> <p>This medicinal product contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially 'sodium-free'.</p> <p><u>Benzyl Alcohol [E1519]</u></p> <p>This medicine contains 5.4 mg Benzyl Alcohol [E1519] in each 0.6 ml dose.</p> <p>Benzyl alcohol may cause allergic reactions.</p> <p>Patients with hepatic or renal impairment should be informed of the potential risk of metabolic acidosis due to accumulation of benzyl alcohol over time.</p> <p><u>Mounjaro® safety summary<sup>9</sup> from USA. The MHRA have not classified this warning in the SPC or BNF for the UK. This summary is for information only.<sup>9</sup></u></p> <p>Mounjaro® may cause tumours in the thyroid, including thyroid cancer. Watch for possible symptoms, such as a lump or swelling in the neck, hoarseness, trouble swallowing, or shortness of breath.</p> <p>Advise patients if they have any of the above symptoms, tell the health care provider (GP, Nurse, Pharmacist etc).</p>   |
| <b>Renal and Hepatic impairment</b> | <p><u>Renal impairment</u></p> <p>No dose adjustment is required for patients with renal impairment including end stage renal disease (ESRD). Experience with the use of tirzepatide in patients with severe renal impairment and ESRD is limited. Caution should be exercised when treating these patients with tirzepatide.</p> <p><u>Hepatic impairment</u></p> <p>No dose adjustment is required for patients with hepatic impairment. Experience with the use of tirzepatide in patients with severe hepatic impairment is limited. Caution should be exercised when treating these patients with tirzepatide.</p>   |
| <b>Pregnancy and breast feeding</b> | <p><u>Pregnancy</u></p> <p>There are no or a limited amount of data from the use of tirzepatide in pregnant women. Studies in animals have shown reproductive toxicity (see section 5.3 <a href="#">SPC</a>). Tirzepatide is not recommended during pregnancy and in women of childbearing potential not using contraception.</p> <p>If a patient wishes to become pregnant, tirzepatide should be discontinued at least 1 month (but preferably at least 3 months) before a planned pregnancy due to the long half-life of tirzepatide. Tirzepatide should not be used during pregnancy Alternative methods of controlling blood glucose levels should be discussed and initiated.</p> <p><u>Breast feeding</u></p> <p>It is unknown whether tirzepatide is excreted in human milk. A risk to the newborn/infant cannot be excluded.</p> <p>A decision must be made whether to discontinue breast-feeding or to discontinue/abstain from tirzepatide therapy taking into account the benefit of breast-feeding for the child and the benefit of therapy for the woman.</p> <p><u>Fertility</u></p> <p>The effect of tirzepatide on fertility in humans is unknown.</p> |
| <b>Adverse Drug Reactions</b>       | <p><b>This list is not exhaustive, see <a href="#">BNF</a> and <a href="#">SPC</a> for full details.</b></p> <p><u>Very Common</u></p> <ul style="list-style-type: none"> <li>• Hypoglycaemia when used with sulphonylureas or insulin</li> <li>• Nausea, diarrhoea, vomiting, constipation</li> </ul> <p><u>Common</u></p> <ul style="list-style-type: none"> <li>• Hypersensitivity reactions and injection site reactions</li> </ul>   |

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|                            | <ul style="list-style-type: none"> <li>• Hypoglycaemia when used with metformin and SGLT2</li> <li>• Decreased appetite</li> <li>• Abdominal pain, dyspepsia, flatulence, GORD</li> <li>• Hair loss</li> <li>• Fatigue</li> </ul> <p><b>Report side effect to the MHRA via the yellow card reporting site. Available at: <a href="https://yellowcard.mhra.gov.uk/">https://yellowcard.mhra.gov.uk/</a></b></p> <p>The 7 completed phase 3 trial using tirzepatide alone or in combination with other glucose lowering medication showed that the most frequently reported adverse reactions were gastrointestinal disorders (nausea, constipation, diarrhoea and vomiting). In general, these reactions were mostly mild or moderate in severity and occurred more often during dose escalation and decreased over time.</p>   |
| <p><b>Monitoring</b></p>   | <p>Tirzepatide should be initiated by a specialist who has undertaken formal training or equivalent in the specialist area including e.g. Secondary care prescriber, GPSI, Diabetes specialist nurse and specialist pharmacists or practice nurses who have undertaken specialist training.</p> <p><u>Baseline monitoring (initiating specialist/clinician)</u></p> <ul style="list-style-type: none"> <li>• Weight</li> <li>• HbA1c (in appropriate patients)</li> </ul> <p><u>Initial monitoring (initiating specialist/clinician)</u></p> <ul style="list-style-type: none"> <li>• Review treatment after 4 weeks. Ensure the patient is rotating injection site, injecting correctly and any side effects are tolerable prior to increasing the dose to 5mg. This review should be undertaken by the initiating specialist/clinician.</li> </ul> <p><u>Primary care monitoring</u></p> <ul style="list-style-type: none"> <li>• Review patient and check HbA1c and weight every 3-6 months. See <a href="#">dosage section</a> above for further information/consideration of dose titration.</li> <li>• Dose escalation may be considered after discussion with initiating specialist. If a dose increase is appropriate the patient should be reviewed every 4 weeks whilst the dose is increasing.</li> <li>• If the patient is not meeting the reduction in HbA1c of at least 11mmol/mol AND Weight loss of at least 3% of initial body weight at each of the 6 monthly reviews, then stopping tirzepatide may be considered. This may be discussed with a specialist from the list above (either primary or secondary care) prior to stopping.</li> </ul> |
| <p><b>Interactions</b></p> | <p><b>This list is not exhaustive, see BNF and SPC for full details.</b></p> <p>Tirzepatide delays gastric emptying. MHRA drug safety alert January 2025 advises that delaying gastric emptying may increase the risk of residual gastric contents despite pre-operative fasting, leading to the potential risk of pulmonary aspiration.</p> <p>Delayed gastric emptying also has the potential to impact the rate of absorption of concomitantly administered oral medicinal products. This effect, resulting in decreased Cmax and a delayed Tmax, is most pronounced at the time of tirzepatide treatment initiation.</p> <p><u>Drugs with a narrow therapeutic index</u><br/>Monitor all patients on oral medicinal products with a narrow therapeutic index (e.g. warfarin, digoxin) especially on initiation of tirzepatide treatment.</p> <p><u>Paracetamol</u><br/>No dosage adjustment necessary. Following a 5mg single dose of tirzepatide the max plasma concentration of paracetamol was reduced by 50% and median was delayed by 1 hour.</p> <p><u>Oral contraceptives</u><br/>No dose adjustments required in patients with a normal BMI. One of the most common side effects of tirzepatide initiation is vomiting. Hence, it is advisable to switch to a non-oral contraceptive method or add a barrier method of contraception upon initiating</p>   |

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|                            | <p>tirzepatide therapy (for 4 weeks), or after each dose increase (for 4 weeks). Further information can be accessed in the <a href="#">Faculty of Sexual &amp; Reproductive Health statement</a>.</p> <p><b>Hormone Replacement Therapy</b><br/>Tirzepatide delays gastric emptying and therefore may reduce the absorption of any oral component of HRT. Women taking oral HRT may be advised to switch to a non-oral therapy whilst using tirzepatide (Patch, IUD, vaginal and for a minimum of 4 weeks after stopping tirzepatide. Further information is available in the <a href="#">British Menopause Society tools for clinicians</a> document.</p>  |
| <b>Patient information</b> | <p>Patients should be counselled by the initiating prescriber on:</p> <ul style="list-style-type: none"> <li>• Priming of the device: Each Kwikpen contains 4 doses. To prime the device, slowly turn the knob until two clicks are heard. Hold the pen with the needle pointing up and tap cartridge gently to collect air bubbles at the top. Release some medicine by pushing the dose knob until it stops. Count to 5 whilst holding the knob. The dose window should now read zero.</li> <li>• Injecting: Dial the dose by turning the knob until it stops at '1'. This is equivalent to a dose of 0.6ml.</li> <li>• Correct injection technique</li> <li>• Injection site use and rotation of injection site</li> <li>• Tirzepatide (Mounjaro®) may be removed from fridge 30min prior to injecting to help reduce stinging at injection site on administration of injection.</li> <li>• Drinking enough water (Minimum 6-8 glasses per day).</li> </ul> <p>Please provide patient with a patient information leaflet. Available at: <a href="https://www.medicines.org.uk/emc/product/15481/pil">https://www.medicines.org.uk/emc/product/15481/pil</a>. The patient may also wish to follow the 'How to use Mounjaro® Kwikpen® step by step instructions online. Available at: <a href="https://medical.lilly.com/uk/products/answers/how-to-use-the-mounjaro-tirzepatide-kwikpen-219072">https://medical.lilly.com/uk/products/answers/how-to-use-the-mounjaro-tirzepatide-kwikpen-219072</a></p> |

## **Contact names and details**

| <b>Contact Details</b> | <b>Email</b>  |
|------------------------|---|
| Sheffield              | <a href="mailto:jackie.elliott6@nhs.net">jackie.elliott6@nhs.net</a><br>Or contact the local diabetes specialist nurses or community specialist diabetes nurses   |
| Rotherham              | <a href="mailto:diabetes.specialistnursing@nhs.net">diabetes.specialistnursing@nhs.net</a>  |
| Doncaster              | Secondary care secretaries<br><a href="mailto:dbth.diabsec@nhs.net">dbth.diabsec@nhs.net</a><br>Primary care diabetes specialist nurse team<br><a href="mailto:RDASH.DiabetesYASReferrals@nhs.net">RDASH.DiabetesYASReferrals@nhs.net</a>                   |
| Barnsley               | Secondary care secretaries:<br><a href="mailto:bdgtr.endodiab.secretaries@nhs.net">bdgtr.endodiab.secretaries@nhs.net</a><br>Primary care diabetes specialist nurse team:<br><a href="mailto:barnsleydiabetes.spa@nhs.net">barnsleydiabetes.spa@nhs.net</a> |

This guidance has been reviewed by Dr Jackie Elliott clinical lead for diabetes Sheffield Teaching Hospital.

## **Equality and diversity**

[NICE TA 924](#) advises using lower BMI thresholds (usually reduced by 2.5kg/m<sup>2</sup>) for people from South Asia, Chinese, other Asian, middle Eastern, Black African or African-Caribbean family backgrounds. Further information regarding BMI can be accessed via the [indication](#) section of the document.

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Amber G guideline tirzepatide (Mounjaro ®)

Date Approved: by IMOC February 2025 V2.1

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**Appendix 1 - British Association of Clinical Diabetologists and the Primary Care Diabetes Society** suggest the following for initiation of Mounjaro® (tirzepatide)



Association of  
**British Clinical  
Diabetologists**

**PCDS**

Primary Care Diabetes Society

Figure 1. Suggested Pathway for Diabetic Eye Disease

### Suggested pathway for diabetic eye disease when starting Rybelsus® or Mounjaro®

