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England

Focus on: Tirzepatide (Mounjaro) for weight management in General Practice

Overview: What is Tirzepatide and how is it used?

Tirzepatide (brand name *Mounjaro*) is a glucagon-like peptide-1 (GLP-1) receptor agonist and a gastric inhibitory polypeptide (GIP), which makes it more effective for insulin resistance. Initially developed and licensed for type 2 diabetes, it has received MHRA approval for use in weight management in adults with obesity or overweight with weight-related comorbidities. Its mechanism of action is through enhanced insulin secretion, delayed gastric emptying, and increased satiety.

Licensed use in obesity:

Approved as an adjunct to a reduced-calorie diet and increased physical activity in adults with:

- a BMI ≥30 kg/m², or
- BMI ≥27 kg/m² with at least one weight-related comorbidity (e.g. hypertension, dyslipidaemia, cardiovascular disease, type 2 diabetes, pre-diabetes or obstructive sleep apnoea)

Dosage:

Once-weekly subcutaneous injection, with 4-weekly titration from 2.5 mg to a maximum of 15 mg, based on tolerance and clinical response. No dose adjustments are required for age, weight, ethnicity, renal impairment or liver impairment. The aim is to achieve a 5% drop in body weight by six months. Unlike other GLP-1 analogues for weight management, there is no time limit for the duration of Tirzepatide.

Contraindications:

- Personal or family history of medullary thyroid carcinoma
- Acute kidney injury
- Acute pancreatitis (caution with history of pancreatitis)
- Gastroparesis
- Diabetic retinopathy (caution)

Common side effects: (this is a black triangle medication/report adverse events)

- Gastrointestinal: nausea, diarrhoea, vomiting, constipation, abdominal pain, dyspepsia
- Hypoglycaemia (especially in combination with sulphonylureas or insulin)
- Injection site reactions
- Hair loss
- Lethargy
- Rarer side effects: pancreatitis, cholelithiasis, allergic reactions

Drug interactions:

- Slows gastric emptying, which may affect absorption of oral medications, particularly:
 - Oral <u>contraceptives</u> (switch to LARC or use barrier method for four weeks at initiation and after each dose escalation)
 - HRT (higher dose or non-oral progesterone advised)
 - o Narrow therapeutic index drugs (e.g. warfarin, digoxin)

2. Commissioning of Tirzepatide by NHS England

NICE has approved Tirzepatide with the following eligibility criteria:

- BMI ≥ 35 (reduced in Asian/black people by 2.5) and
- At least one weight related comorbidity
- Aim for at least 5% reduction body weight after 6 months

NHSE Interim Commissioning Guidance states that Tirzepatide must be implemented in primary care (practices, federations, or community specialist clinics) by 23 June 2025, and the responsibility for this has been delegated to ICBs. The funding for this is based on population obesity levels and is separated into drug costs and primary care management costs. Tirzepatide prescribing must be accompanied by wrap around support consisting of psychological, nutritional and exercise advice, and this will be delivered separately through a centrally funded digital package in the first year.

The target population for Tirzepatide will be risk stratified into cohorts and the first year will focus on the highest end; those with a BMI \geq 40 and at least four comorbidities. Subsequent years will expand this cohort so that the complete target population is treated by the end of year twelve.

3. Commissioning into General Practice: Monitoring, time and cost when pricing up a locally commissioned service

Set-up requirements

- Training costs: two-to-three-hour training session for at least two prescribers: 6 hours
- Establish patient register and recall system
- Establish safety net mechanisms for non-compliance
- Develop patient communication

Monitoring requirements:

- Baseline assessment (eligibility, consent, bloods, referral to wrap around care): x1 thirty-minute appointment by either GP or specialist prescriber
- Monthly review for first five months (check side effects, titrate dose): x4 fifteen-minute appointments by either GP or specialist prescriber
- Six-month review (check if 5% body weight lost, decision on continuation): x1 twenty-minute appointment by either GP or specialist prescriber
- Annual review (monitoring, compliance with medication and wrap around care): x1 twentyminute appointment by GP or specialist prescriber

Estimated time commitment:

- Set up phase: 6 hours clinician time (1.5 sessions), 2-3 hours administration time (non-recurrent)
- Initiation and titration phase: 110 minutes clinician time
- Maintenance phase: 20 minutes clinician time

It is recommended that the above time commitment is used as a guide for any practice or LMC costing toolkit, to determine if an enhanced service offer is cost effective.

4. Responding to information requests from private providers

Tirzepatide, and other GLP-1 analogues, are increasingly being initiated in the private sector for weight loss and practices are often asked to provide clinical information to private providers.

<u>GMC</u> regulations state that medicines must only be prescribed if there is sufficient knowledge to prescribe safely, which includes access to a patient's medical records and verification of information through examination. The General Pharmaceutical Council has issued <u>guidance</u> for pharmacies providing on-line services, outlining the necessary safeguards required for safe prescribing, which include independent verification of body mass index and medical history.

The BMA recognises that supplying information to third parties for the issuing of private medication is not an essential service or understood to be within GMS. Instead, it is recommended that private providers encourage patients to share their on-line records with them to obtain a full medical history, including observations. A <u>template letter</u> for practices has been developed for this purpose, which can be embedded into the electronic medical record system.

Any medications prescribed outside of the practice should be added to a patient's medication record as an 'external prescription', so that drug interactions and safety alerts may be triggered.

Separate from requests for information, if a patient has already been started on a GLP-1 analogue by a private provider, and there are existing drug interactions or contraindications, it is a <u>GMC</u> obligation to act upon this, in the interests of patient safety.

Practices may also wish to consider sending out a bulk text message to all women of childbearing age, to highlight the importance of a medication review if they are started on GLP-1 analogues in the private sector. Enquiries regarding any medication received from a private provider should also form part of an annual medication review for women on HRT or contraception.

Conclusion

Tirzepatide represents a new therapy for weight management which can be delivered in primary care, but requires structured implementation, appropriate monitoring, and clarity around responsibilities. GPs should engage in prescribing where clinically appropriate and safely resourced to do so.

References

Special Product Characteristics Tirzepatide
NICE TA 1026 Tirzepatide
Faculty of Sexual and Reproductive Health
British Menopause Society
Primary Care Women's Health Society