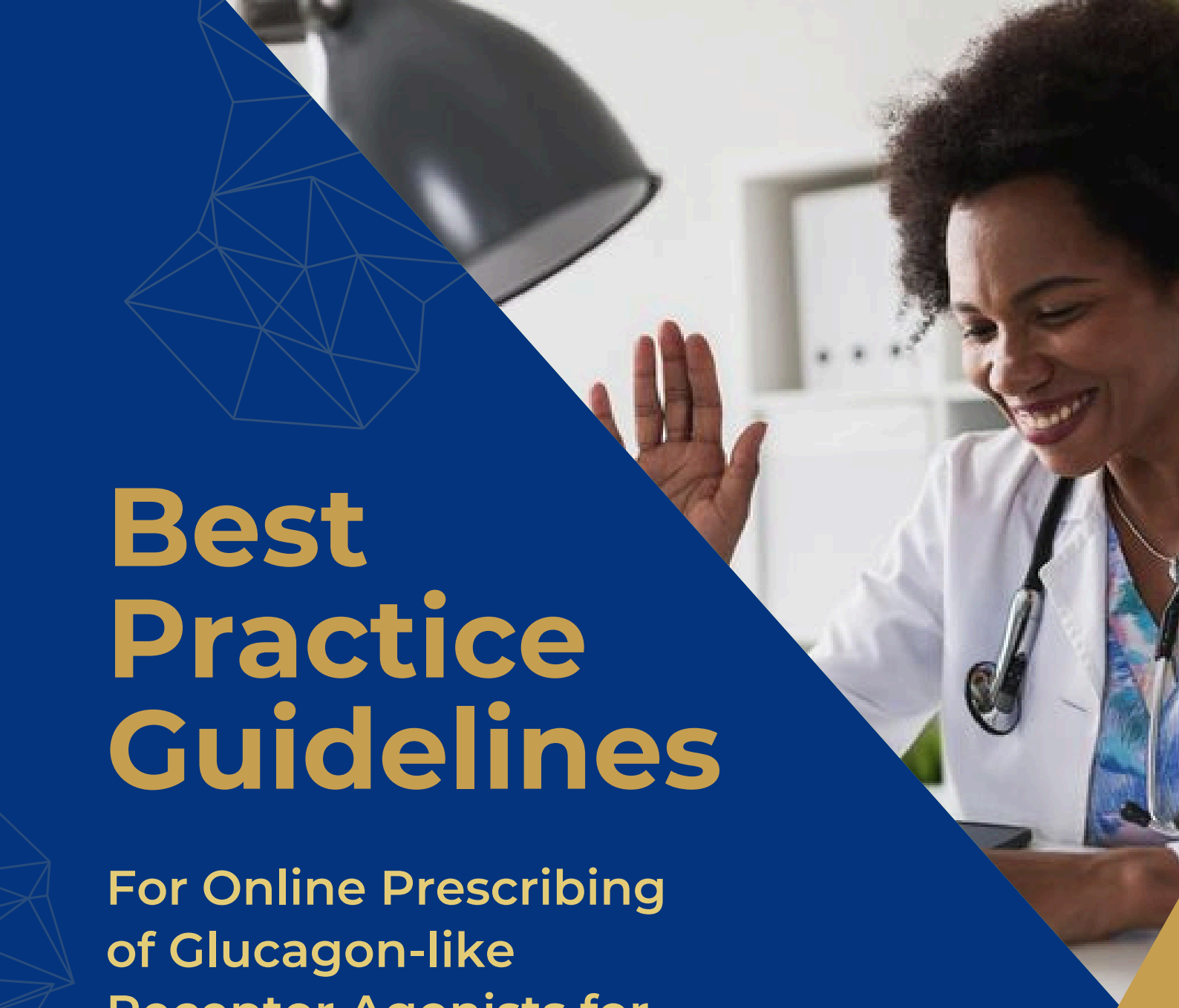

Best Practice Guidelines

For Online Prescribing of Glucagon-like Receptor Agonists for Weight Management in Adults

DiCE

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About this document

These Best Practice Guidelines (BPGs) are based on the collective experience of established online healthcare providers who participate in the Digital Clinical Excellence (DiCE) Forum. Working group virtual meetings were held between January and April 2024. The purpose of these meetings was to gather and review existing evidence and contemporary practices, and to form a consensus on a best practice approach to enhance the quality and safety of online / remote prescribing within the independent pharmacy sector.

DiCE BPG aims to align with existing professional and regulatory standards, but also to broaden and strengthen them from an industry perspective. This is in recognition of the fact that rapidly progressing and expanding areas of care are often developing at a faster pace than professional or regulatory standards are published. BPGs are not intended to replace or contest any current professional or regulatory standards. Prescribers must always adhere to the standards set by regulatory bodies relevant to their profession, and any other relevant national guidance.

DiCE BPG applies only to prescribers and is not intended for use by healthcare practitioners operating under a Patient Group Direction. In addition, while DiCE BPG may be useful for prescribers operating outside of the United Kingdom, it is not written with this purpose in mind and some recommendations may not apply.

This guidance has been developed specifically for digital asynchronous prescribing of glucagon-like peptide-1 receptor agonists (GLP-1RA) for weight management in adults. Other types of prescribing of GLP-1RA fall outside the scope of this document. Recommendations are regularly reviewed and updated where necessary.

Professor James Kingsland OBE,
Clinical Lead & Chair
Digital Clinical Excellence 'DiCE'

DiCE Best Practice Guidelines are not intended to replace current prescribing information. Prescribers should always refer to the BNF and Summary of Product Characteristics, and any relevant national guidelines

About Digital Clinical Excellence 'DiCE'

DiCE was established in March 2019 to provide a collective voice and support to the growing community of UK digital healthcare providers. The network aims to drive excellence in digital care standards to support clinical care improvement and safety in digital healthcare. DiCE members are senior clinical leaders from online clinical service providers who ensure collective governance for DiCE. There is no commercial focus or activity within the network.

DiCE aims to work collaboratively within the industry and with relevant professional bodies and healthcare regulators to produce its Best Practice Guidance. However, these are industry produced and should not be regarded as being endorsed by any professional body or regulator, who have their own standards. Healthcare professionals are reminded that the only statutory standards that must be adhered to are those produced by the UK healthcare regulators. Established national guidance such as those produced by NICE, SIGN or other statutory bodies must also be followed.

DiCE is managed by Healthworks Ventures Ltd.

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About digital asynchronous prescribing

The term 'digital asynchronous prescribing' describes the process of online / remote prescribing of medicines using a form-based assessment, without a real-time conversation between prescriber and patient.

Digital asynchronous prescribing is subject to the same legal requirements and regulations as in-office primary care, including the Royal Pharmaceutical Society (RPS) competency framework for consultations and prescribing governance that applies to all prescribers in England and Wales [1].

In addition, registered online pharmacies and other prescribing platforms are required to follow guidance and professional standards set by relevant regulatory bodies, for example the General Medical Council (GMC) and the General Pharmaceutical Council (GPhC) [2-4]. In England, registered prescribing platforms employing doctors as part of the prescribing team also fall under the remit of the Care Quality Commission (CQC) [5].

When conducted in a well-regulated setting with good risk management systems, routine reviews to drive continuous learning improvement, and careful consideration of how information is provided to patients, asynchronous prescribing can be effective in replacing some in-office primary care visits, providing timely care and increased convenience for patients [6–11].

For more general information on professional standards and guidance relevant to digital asynchronous prescribing, refer to the following documents developed by UK regulatory and professional bodies:

- Guidance for registered pharmacies providing pharmacy services at a distance, including on the internet (GPhC, 2022) [12]
- Good practice in prescribing and managing medicines and devices (GMC, 2021) [4]
- Policy for providing medicines online (RPS, 2019) [13]
- Is a remote consultation appropriate? (GMC, 2019) [14]
- Remote prescribing high-level principles (Joint statement by UK-wide healthcare regulators, royal colleges and faculties, 2019) [15]
- The state of care in independent online primary health services (CQC, 2018) [5]

1. Weight management in patients living with obesity

The UK has the third highest level of obesity in Europe [15]. In 2021/22, an estimated two-thirds of adults in England met the World Health Organization criteria for overweight (Body Mass Index [BMI] 25–30 kg m2) or obese (BMI >30 kg/m2) [16]. For many of those adults, weight management is a lifelong struggle that presents serious challenges to their mental and physical health. Obesity has been linked to over 200 complications, including cardiovascular disease, type 2 diabetes, cancer, osteoarthritis, depression and anxiety, and is estimated to be responsible for over 30,000 deaths each year in England alone [17].

The causes of obesity are complex, with many contributing factors including genetic, psychosocial, environmental and societal factors, in addition to lifestyle factors and behavioural patterns. Now widely recognised as a chronic disease that requires medical intervention, tackling obesity through evidence-based and long-term strategies is a priority for the UK-wide NHS [18].

In 2022/23, more than 1.2 million hospital admissions were recorded where obesity was the primary or secondary diagnosis [19]. By 2050, annual costs attributable to overweight and obesity are projected to reach £9.7 billion in the UK-wide NHS alone – an increase from the current estimate of £6.5 billion per year – with wider costs to society estimated to reach almost £50 billion per year [17].

Access to dedicated (Tier 3) weight management services is unevenly distributed across the UK population, and largely restricted to patients with chronic, complex obesity who are able to attend 12 months of face-to-face consultations. Bariatric surgery is effective for weight loss, but weight management continues to be a struggle for many patients post-surgery and waiting lists can be several months or years long [20,21].

Given the scale of the obesity problem, more flexible ways to access effective interventions for weight management are needed.

1.1 Glucagon-like peptide-1 receptor agonists (GLP-1RA) for weight management

For decades, effective drug therapy for weight management has been a ‘holy grail’ within the pharmaceutical industry. The use of GLP-1RA (also known as GLP-1 analogues) has been hailed as a “game changer” by obesity experts, with major implications for UK health policy [22].

Currently, there are three GLP-1RA licensed for weight management in the UK:

- Semaglutide (Wegovy) [23]
- Liraglutide (Saxenda) [24]
- Tirzepatide (Mounjaro [25], not yet licensed in Northern Ireland)

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*Tirzepatide has a dual mode of action, both as a GLP-1RA and as a glucose-dependent insulinotropic polypeptide receptor agonist (GIP-RA) [25]

Other branded semaglutide (Ozempic [26], Rybelsus [27]) and liraglutide (Victoza [28]) products are licensed for the treatment of type 2 diabetes, but not currently for weight management. An ongoing National Patient Safety Alert restricts off-label use of these medications, with supply issues expected to last until the end of 2024 [29].

In this fast-moving therapy area, additional options for weight management are likely to become available in the near future. DiCE Best Practice Guidance will be updated as and when the need arises.

2. Why is a best practice approach needed?

2.1 Providing a safe and trustworthy service

Weight loss and weight management are highly sensitive topics, as demonstrated by the high-profile media attention afforded to GLP-1RA, largely focusing on perceived negatives. Establishing a best practice approach is essential to reassure patients that their medication is coming from trustworthy pharmacies and clinicians who are aware of any risks and clear on their responsibility to protect patients.

Based on the real-world experience of members of the DiCE Working Group, the number of patients seeking GLP-1RA medications for weight management from independent online prescribers in the UK is estimated to exceed 200,000 per year. This estimate is derived from aggregated current activity within DiCE participant organisations through sharing of anonymised contact data.

Online prescribers have a duty to provide a safe service for all patients seeking treatment with a GLP-1RA, and to follow the professional standards set by the regulatory body relevant to their profession [2–4]. For example, the GMC professional standards state that medicines should only be prescriber if the prescriber feels that they have adequate knowledge of the patient's health, and are satisfied that the medicines serve the patient's needs [4]. These principles are closely aligned with those of the GPhC [2].

It is expected that all prescribers using asynchronous form-based assessments have undertaken a comprehensive risk assessment of the service being provided, in line with current statutory guidance and standards [2,4,12].

Best practice in digital asynchronous prescribing requires that appropriate screening, prescribing and monitoring is undertaken by professionals meeting the requirements of the RPS competency framework [1]. Monitoring is especially important for black-triangle medicines (e.g. Wegovy [23] and Mounjaro [25]), which are subject to additional monitoring of real-life experiences to allow quick identification of new safety information. Online prescribers should be active participants in the reporting of side effects for these medications (see section 4.3).

To ensure high-quality provision of care, online prescribers should proactively audit and review the quality and safety of their weight management service. This includes analysing prescribing trends to be able to identify any inappropriate prescribing and supply.

In addition, consideration should be given to providing pharmacy teams with training on weight management medicines, as well as pharmacists having access to a prescriber of appropriate seniority who can provide further advice and support.

2.2 Information sharing and patient consent

Current professional and regulatory standards recommend that online prescribers request patient consent to share their treatment details with their other healthcare professionals involved in their care (for example, their GP) before prescribing prescription-only medicines [2,4].

Patients requesting GLP-1RA treatment should be asked to consent to GP notification. If a patient refuses consent, the prescriber should record their reasons for refusing (for example, concerns about privacy). They should also inform the patient about the importance of sharing information between healthcare providers to ensure continuity of care, and the potential risks of not sharing this information. Prescribers should keep a clear written record of treatment decisions made based on the information provided by the patient, particularly if a GLP-1RA is prescribed without obtaining consent for GP notification. This is in line with current professional and regulatory standards [2,4].

In cases where failing to share information could pose a risk to patient safety, the prescriber should inform the patient that they cannot prescribe and signpost the patient to appropriate alternative services.

2.3 Patients with eating disorders

Weight management medications may be subject to misuse, for example by patients who misrepresent their height, weight and past medical history during the screening process. This may include patients with one or more diagnosed or undiagnosed eating disorders. Some prescribers currently include eating disorder screening questions (e.g. the SCOFF questionnaire [30]) in their form-based assessments as a precaution. Other tools are signposted, along with information on recognising signs and symptoms, as part of the NICE Clinical Knowledge Summary on assessing patients for eating disorders [31].

Notably, although participants in the DiCE Working Group have had instances where patients with eating disorders sought a GLP-1RA prescription, aggregated anonymised contact data suggest that this group accounts for only a very small percentage of the total number of consultations for GLP-1RA. This suggests that GLP-1RA medications are not currently in high demand among people with eating disorders. However, participants in the DiCE Working Group recognise that this is a potentially high-risk area. If a patient's responses to the form-based assessment suggests that they may have an eating disorder, it is recommended that prescribers follow-up with the patient via telephone or video call (or other two-way communication method), before making a prescribing decision.

For patients with binge eating disorder, there is limited evidence to suggest that GLP-1RA medications may have beneficial effects on weight management [32,33]. However, this amounts to off-label use and should not be encouraged [23–25,33]. Although patients who have recovered from past eating disorder(s) may still be eligible for treatment with a GLP-1RA for weight management, this should be a specialist decision (see section 4.3).

2.4 Patient BMI verification

It is the consensus of the DiCE Working Group that there is no completely foolproof way to safeguard against wilful misuse of GLP-1RA in the context of digital asynchronous prescribing. However, comprehensively risk-assessed patient verification steps should be taken to identify patients suitable for treatment.

It is not the intention of this guidance to mandate one method of weight and BMI assessment over another. Strategies currently used by members of the DiCE Working Group include:

- Patient selfies to verify BMI +/- photo of scales as weight verification
- Video call to verify BMI
- In-person collection of prescriptions to verify BMI
- Cross-referencing clinical and demographic information from NHS Summary Care Records

Each of these strategies has some limitations (see section 5), and there may be other patient verification strategies in use. To ensure the robustness of the screening process, it is recommended that prescribers should use a combination of strategies and make a decision based on all the available information.

3. Considering the patient journey

People seeking a prescription for a GLP-1RA may have struggled with their weight for decades, and are likely to have tried losing weight through other methods such as calorie restriction, exercise and weight loss support groups [34]. They may have experienced stigmatisation, bias and discrimination from healthcare professionals and society at large, and have low self-esteem [35].

A recent survey of 440 patients prescribed weight management medication within one UK pharmacy group (a participant in the DiCE Working Group) found that 20% were concerned about receiving fake medication [34]. The same survey found that patients were more committed to making lifestyle changes when paying for weight management medication privately [34].

Provision of GLP-1RA injections via the online space is under great scrutiny from the media and regulators, so it is vital that providers give strong consideration to robust patient verification and to provide as much information and support as possible to help patients get the maximum benefit from the treatment. This should include information and resources around diet and exercise – this is also a requirement of the product licenses for these medicines [23–25].

4. Recommendations from the DiCE Working Group

4.1 Who should follow these recommendations?

The following recommendations are intended as best practice guidance for developing form-based assessments to allow online providers to safely prescribe GLP-1RA for weight management in adults. Although some GLP1-RA are licensed for weight management in adolescents, participants in the DiCE Working Group do not currently prescribe GLP-1RA in people under 18 years of age.

They are not intended to be overly restrictive, since this may drive patients to obtain GLP-1RA from unregulated sources, causing potential harm. Nor are they intended to be comprehensive of all possible considerations, or to impose a universal screening process across all providers. For example, some providers may include further considerations (e.g. SCOFF eating disorder screening questions [30]) in the screening process.

These recommendations are intended to complement current prescribing information for GLP-1RA licensed for weight management in adults. Online providers should always refer to the BNF and Summary of Product Characteristics before prescribing a GLP-1RA in patients seeking treatment. Relevant NICE, SIGN and other national guidelines produced by statutory bodies should also be followed.

4.2 Recommendations for initial consultation and prescribing

A patient may be eligible for a GLP-1RA for weight management:

– If their age falls within the eligible range for a licensed GLP-1RA

- For example, Wegovy has been evaluated in patients up to 75 years of age [23] while Mounjaro has been evaluated in patients up to 85 years of age [25].

– **If they have a BMI of 30 kg/m2 or above, or 27 kg/m2 or above plus at least one weight-related comorbidity (adults)**

- Weight-related comorbidities include (but are not limited to) hypertension, dyslipidaemia, obstructive sleep apnoea, cardiovascular disease, prediabetes, or type 2 diabetes mellitus [23–25].
- Lower BMI thresholds of overweight (≥23 kg/m2) and obesity (27.5 kg/m2) are recommended for people from South Asian, Chinese, other Asian, Middle Eastern, Black African or African-Caribbean family backgrounds [36].
- BMI should be interpreted with caution in adults with high muscle mass and in people aged 65 and over [36].

– If they are otherwise considered eligible for treatment

- Some patients may not meet the BMI criteria when starting treatment, for example due to breaks in treatment due to surgery or financial hardship, or when restarting treatment if it has been interrupted (e.g. due to stock issues).
- Patients may be considered eligible for treatment provided that:
  - their initial starting point met the eligibility criteria, and
  - the prescriber is satisfied that GLP-1RA treatment still meets the patient's needs at the time of the assessment.
- Generally, where a medication is licensed for weight maintenance, breaks in treatment may not necessarily be a barrier to restarting medication.
- All treatment decisions should be made on a case-by-case basis.

Use caution when prescribing a GLP-1RA for weight management:

– If the patient is already taking other medication(s) for weight management

- Inform the patient that concomitant use of GLP-1RA and other weight management medications has not been evaluated [23–25].
- Patients should stop taking other weight management medicines before starting a GLP1-RA.

– If the patient has experienced severe gastrointestinal side effects from previous treatment with a GLP-1RA

- The patient may benefit from a lower dose of GLP-1RA medication [23–25].
- Patients should be advised of signs of dehydration and red flag symptoms that indicate they should pause or discontinue treatment, e.g. dark urine, blood in stool or vomit, diarrhoea lasting longer than 72 hours, or being unable to keep food down without vomiting/diarrhoea [23–25].

– If the patient reports a history of severe liver or kidney disease during screening

- Advise the patient to consult their GP or private doctor for further investigation before prescribing.
- If further investigation indicates severe liver or kidney disease, GLP-1RA should not be prescribed. The effect of severe liver disease on the pharmacokinetics of GLP-1RA has not been studied [23–25].

Consider not prescribing a GLP-1RA for weight management:

– If the patient is being treated for type 2 diabetes with insulin or other anti-diabetic medications associated with risk of hypoglycaemia (e.g. sulfonylurea)

- Careful consideration should be given to risk management in this scenario, since monitoring of these patients in the asynchronous setting may not be adequate to ensure that their blood glucose levels are well controlled [23–25].
- Treatment with anti-diabetic medications not likely to cause hypoglycaemia (e.g. metformin) should not be considered a contraindication to use of GLP-1RA for weight management [36,37].

– If the patient has type 1 diabetes

- Diabetic ketoacidosis has been reported in insulin-dependent patients who had rapid discontinuation or dose reduction of insulin when starting treatment with a GLP-1RA [23–25].

– If the patient has diabetic retinopathy

- An increased risk of developing diabetic retinopathy complications has been observed in patients treated with certain GLP-1RA and insulin [23–25].

– If a patient has been on treatment for the evaluation period recommended by the manufacturer, and has not achieved the minimum weight loss objective (e.g. a 5% reduction from starting weight within 3 [24] or 6 months [23])

- The patient may benefit from other options for weight loss or a clinical examination [23–25].

– If the patient reports a history of inflammatory bowel disease or gastroparesis

- With some GLP-1RA, gastrointestinal side effects (e.g. nausea, vomiting and diarrhoea) are common and may worsen or exacerbate existing bowel disease [23–25].

– If the patient has symptomatic gallbladder issues or has had their gallbladder removed within the past 3 months

- There is evidence of an increased risk of gallbladder or biliary diseases with some GLP-1RA licensed for weight management, especially when used at higher doses and for longer durations [38].
- Patients with asymptomatic gall stones or who have had their gallbladder removedmore than 3 months prior to screening may still be eligible for GLP-1RA treatment.

Do not prescribe a GLP-1RA for weight management:

– If the patient is already taking another GLP-1RA

- For example, for type 2 diabetes [23–25].

– If the patient reports a history of eating disorder(s), e.g. anorexia, bulimia or binge eating disorder

- Although patients who have recovered from past eating disorder(s) may still be eligible for treatment with a GLP-1RA for weight management, this should be a specialist decision.
- Advise the patient to ask their GP or private doctor for a referral to an appropriate alternative service.

– If the patient has a history of pancreatitis

- Acute pancreatitis has been observed with the use of GLP-1RA [23–25].

– If the patient reports a history or family history of medullary thyroid cancer or multiple endocrine neoplasia type 2

- Preclinical studies suggest that GLP-1RA could potentially increase the risk of thyroid tumour, in particular medullary thyroid cancer [23–25].
- This risk is increased if there is a personal or family history of specific thyroid cancers.

– If the patient has severe congestive heart failure

- GLP-1 receptors are expressed in the heart and increased heart rate has been observed during treatment with GLP-1RA [23–25].
- GLP-1RA have not been studied in patients with severe congestive heart failure (New York Heart Association Class IV) and treatment is not recommended [23–25].

– If the patient is pregnant or trying to conceive

- There are limited data on the use of GLP-1RA in pregnant women, and studies in animals have shown reproductive toxicity [23–25].
- As a risk to the foetus cannot be excluded, if a patient treated with a GLP-1RA wishes to become pregnant, or pregnancy occurs, treatment should be discontinued, ideally at least 2 months before a planned pregnancy due to the long half-lives of these medications [23–25].

– If the patient is breastfeeding

- As a risk to breastfed children cannot be excluded, GLP-1RA are not recommended for use during breastfeeding [23–25].

– If the patient has a known hypersensitivity

- GLP-1RA should not be prescribed to patients with hypersensitivity to the active drug or to any of the other substances listed in the SmPC [23–25].

4.3. Recommendations for monitoring and review

The consensus among participants in the DiCE Working Group is that monitoring should take place within 3 months of starting treatment and at the time of prescription refill (repeat supply).

Providers should ensure that patients are able to contact them to report any treatment-emergent side effects while taking GLP-1RA medications, especially for black-triangle medications.

Recommendations

In addition to the product's patient information leaflet, online prescribers should provide patients with:

- Advice around maintaining a reduced calorie diet and increasing physical activity, and any resources available to help patients make lasting changes to their lifestyle.
- Advice about stopping treatment if they develop symptoms of acute pancreatitis, a sustained increase in heart rate, or any other potentially serious side effect of GLP-1RA medications (as specified in the prescribing information), and how they can seek help.
- Contraceptive advice, where appropriate (e.g. when prescribing Mounjaro [25]).
- Advice on how to self-report side effects of treatment to the MHRA using the Yellow Card online reporting tool for patients, with an emphasis on the importance of side effect reporting for black-triangle products.

Monitor patients within 3 months of starting treatment and at time of prescription refill

- At each monitoring assessment, prescribers should obtain all the necessary information to make a safe prescribing decision about continue a patient's GLP-1RA treatment.
- Patients should be encouraged to report any side effects, in addition to any that they may have reported to the MHRA.

Assess response to treatment:

- For some GLP-1RA medications, treatment response is defined in the prescribing information as a 5% weight loss or greater from baseline after an initial evaluation period [23,24].
  - Refer to the product licence of the GLP-1RA medicine being prescribed for specific details on when the assessment of treatment response should be made.
- If a patient does not achieve the response as specified in the product licence, in exceptional cases a decision may be taken to continue GLP-1RA treatment beyond the initial evaluation period.
  - This decision should be informed by a comprehensive risk vs. benefit assessment, including some evaluation of the patient's lifestyle changes since starting GLP-1RA treatment.
  - The decision of when to stop treatment should be made on a case-by-case basis and agreed with the patient.
- Prescribers should keep a clear written record of their discussions with the patient, including justification for treatment decisions made.
- Treatment decisions should also be mindful of the maximum treatment duration recommended by NICE (e.g. up to 2 years with Wegovy [39]).
- If, at any time, continuing treatment constitutes an off-label use of GLP-1RA medication, the implications of this should be clearly communicated to the patient.

5. Appendix: Further considerations for patient verification

The patient verification methods outlined in section 2.4 are effective as part of a risk-assessed asynchronous consultation for prescribing GLP-1RA for weight management, as demonstrated by the extensive real-world experience of the DiCE Working Group.

When deciding which verification methods to implement, online providers should consider the emotional burden on patients living with obesity asked to provide full-body selfies or to appear on video. Asking them to show their bodies in such a manner may lead to feelings of embarrassment, shame, or discomfort.

Clinicians involved in assessing the verification provided should have the necessary expertise to reliably estimate a patient's BMI from a still or moving image, and to flag any suspected manipulation of those images. They should also be aware that a patient's Summary Care Record, if they have one, may not have up-to-date readings for height and weight.

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