National Patient Safety Alert

Department of Health & Social Care

NHS England

Shortage of GLP-1 receptor agonists

Date of issue:	18-Jul-23	Reference no:	NatPSA/2023/008/DHSC

This alert is for action by: All organisations involved in prescribing and dispensing GLP1-RA medicines

This is a safety critical and complex National Patient Safety Alert. Implementation should be co-ordinated by an executive lead (or equivalent role in organisations without executive boards) and supported by clinical leaders in diabetes, GP practices, pharmacy services in all sectors , weight loss clinics, private healthcare providers, those working in the Health and Justice Sector.

Explanation of identified safety issue:

There are very limited, intermittent supplies of all glucagon-like peptide-1 receptor agonists (GLP-1 RAs) NOTE A.

Supplies are not expected to stabilise to meet full market demand until at least mid-2024.

The supply issues have been caused by an increase in demand for these products for licensed and off-label indications.

The off-label use of these agents for the management of obesity is strongly discouraged. Existing stock must be conserved for use in patients with diabetes. These shortages have serious clinical implications in the management of patients with type 2 diabetes. The clinical implications include erratic blood glucose control, with the potential to increase diabetes-related complications, including the risk of future cardiovascular events and diabatic ketoacidosis

Patients established on GLP-1 RA products may not be able to access products which could result in treatment failure and/or a loss of blood glucose control. Some patients established on GLP-1 RA therapy for type 2 diabetes may need to be switched to alternative treatments including insulin. Initiating insulin therapy requires training and education alongside a potential need for enhanced glucose monitoring to ensure patients are aware of how to recognise and manage hypoglycaemic events.

Saxenda (liraglutide), a GLP-1 RA licensed for weight loss is unavailable until mid-2024.

Actions required

Actions to be completed as soon as possible, and not later than 18/10/2023

Actions for clinicians and prescribers of GLP-1 RAs until supply issues have resolved.

1. Only prescribe GLP-1 RAs for their licensed indications.
2. Do not initiate new patients on GLP-1 RAs for the duration of the shortage.
3. Proactively identify patients established on affected GLP-1 RAs and consider prioritising for review based on the criteria set out in the clinical guidance and
   i. discuss stopping treatment with patients who have not achieved treatment targets as per NICE NG28 or NICE CG189
   ii. do not switch between brands of GLP-1 RAs, including between injectable and oral forms.
   iii. do not double up a lower dose preparation where a higher dose preparation of GLP-1 RA is not available.
   iv. do not prescribe excessive quantities; limit prescribing to minimise risk to the supply chain whilst acknowledging the needs of the patient.
4. Use the principles of shared decision making where an alternative agent needs to be considered, as per NICE guidelines[3] and in conjunction with the clinical guidance.[2,4]
5. Support patients to access structured education and weight management programmes where available.
6. For type 2 diabetics; If switching a patient on to insulin, please ensure an insulin is chosen as per information on the SPS page on prescribing available insulins as not all suppliers are able to manage an uplift in demand.[4]

For further detail, resources and supporting materials see: Enter specific webpage provided by alert issuer

For any enquiries about this alert contact: DHSCmedicinesupplyteam@dhsc.gov.uk

Failure to take the actions required under this National Patient Safety Alert may lead to CQC taking regulatory action

Additional information:

Notes

A. GLP-1 RAs affected[6]

Semaglutide injection and tablets:

- Ozempic® 0.25 mg, 0.5mg and 1mg solution for injection in pre-filled pen
- Rybelsus® 3mg, 7mg and 14mg tablets

Dulaglutide:

- Trulicity® 0.75 mg, 1.5mg, 3mg and 4.5mg solution for injection in pre-filled pens

Liraglutide:

- Victoza® 6mg/ml solution for injection in prefilled pen
- Saxenda® 6mg/ml solution for injection in prefilled pen

Exenatide:

- Byetta® 5micrograms/0.02ml and 10micrograms/0.04ml solution for injection 1.2ml pre-filled pens
- Bydureon® 2mg/0.85ml prolonged-release suspension for injection 1.2ml pre-filled pens

Clinical Guidance

This guidance aims to support clinicians in choosing suitable alternative glucose lowering therapies to GLP-1 RAs during this period of national shortage.

Clinical Guidance from the Primary Care Diabetes Society (PCDS) and Association of British Clinical Diabetologists (ABCD) should be used in conjunction with NICE NG28 Type 2 Diabetes in Adults: choosing medicines.

For alternative weight loss management guidance see CG189 Obesity: identification, assessment and management (nice.org.uk)

References

1. NICE Type 2 diabetes in adults: choosing medicines https://www.nice.org.uk/guidance/ng28/resources/visual-summary-full-version-choosing-medicines-for-firstline-and-further-treatment-pdf-10956472093
2. Joint PCDS and ABCD guidance: GLP-1 receptor agonist national shortage https://www.pcdsociety.org/pcds-abcd-guidance-glp1-shortage
3. NICE Shared decision making (NG197) https://www.nice.org.uk/guidance/ng197
4. NICE Obesity: identification, assessment and management (nice.org.uk) CG189
5. Specialist Pharmacy Service Prescribing available insulins https://www.sps.nhs.uk/articles/prescribing-available-insulins/
6. Specialist Pharmacy Service Prescribing available GLP-1 receptor agonists https://www.sps.nhs.uk/articles/prescribing-available-glp-1-receptor-agonists/
7. emc Summary of Product Characteristics https://www.medicines.org.uk/emc
8. BNF Type 2 diabetes https://bnf.nice.org.uk/treatment-summaries/type-2-diabetes/

Stakeholder engagement

The following stakeholders have been engaged in the management and consulted in the drafting of this alert: Specialist Pharmacy Service Medicines Advice, Medicine Shortage Response Group, NHS England, national clinical directors for Diabetes, national clinical experts in Diabetes, NHS England Patient Safety, Medicines and Healthcare products Regulatory Agency and the Devolved Governments.

Advice for Central Alerting System (CAS) officers and risk managers

This is a safety critical and complex National Patient Safety Alert. In response to CHT/2019/001 your organisation should have developed new processes to ensure appropriate oversight and co-ordination of all National Patient Safety Alerts. CAS officers should send this Alert to the executive lead nominated in their new process to coordinate implementation of safety critical and complex National Patient Safety Alerts, copying in the leads identified on page 1.