National Patient Safety Alert

Department of Health & Social Care

NHS England

Shortage of GLP-1 receptor agonists (GLP-1 RA) update

Date of issue:	3-Jan-24	Reference no:	NatPSA/2024/001/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 and those working in the Health and Justice sector.

Explanation of identified safety issue:

This NatPSA supersedes NatPSA/2023/008/DHSC.

The supply of glucagon-like peptide-1 receptor agonists (GLP-1 RAs) continue to be limited, with supply not expected to return to normal until at least the end of 2024.[NOTE A] The supply issues have been caused by an increase in demand for these products for licensed and off-label indications.

- Rybelsus® (semaglutide) tablets are now available in sufficient quantities to support initiation of GLP-1 RA treatment in people with type 2 diabetes (T2DM) in whom new initiation of GLP-1 RA therapy would be clinically appropriate.
- Byetta® (exenatide) 5micrograms/0.02ml and 10micrograms/0.04ml solution for injection 1.2ml pre-filled pens will be discontinued in March 2024.
- Victoza® (liraglutide) continues to be out of stock and further stock is not expected until end of 2024.
- Saxenda® (liraglutide) and Wegovy® (semaglutide) remain available on the NHS via specialist weight management services.

Do not prescribe GLP-1 RAs licensed for T2DM for off-label indications. Existing stock must be conserved for patients with T2DM to mitigate the risk of impaired access to treatment and increased risk in diabetes related complications.

Please refer to the public facing page on the SPS website for an overview of stock availability for all GLP-1 RAs.

Supplies of insulin remain good, however any surge in demand caused by patients requiring an escalation of treatment in the absence of GLP-1 RA stock may affect supplies.

Actions required

Actions to be completed as soon as possible and no later than 28 March 2024

*Material updates to actions in **bold**

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

1. Only prescribe GLP-1 RAs for licensed indications.
2. **Prescribe Rybelsus® tablets for new initiations of a GLP-1 RA** (in line with NICE NG28)**.**
3. **Identify patients prescribed Byetta® and Victoza® injections and** (in line with NICE NG28) **switch to Rybelsus® tablets.**
4. **Counsel patients on any changes in drug, formulation, and dose regimen where appropriate (see additional information below).**
5. Engage with patients established on affected GLP-1 RAs and consider prioritising for review:
   a. discuss stopping GLP1-RA if patients have not achieved treatment goals as per NICE NG28/CG189
   b. do not double up a lower dose preparation where a higher dose preparation of a GLP-1 RA is not available.
   c. do not switch between strengths of a GLP-1 RA solely based on availability.
   d. do not prescribe excessive quantities; limit prescribing to minimise risk to the supply chain whilst acknowledging the needs of the patients.
6. Use the principles of shared decision making where an alternative agent needs to be considered, as per NICE guidelines and in conjunction with the clinical guidance.
7. Support patients to access structured education and weight management programmes where available.

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

Additional information:

Clinical information

If necessary to initiate or switch a patient to Rybelsus® (refer to actions 2 & 3), prescribers should counsel their patient on the following dose titration schedule and administration instructions for Rybelsus®:

Rybelsus® dose: Initially 3mg once daily for 1 month, then increased to 7mg once daily for at least 1 month, then increased if necessary to 14mg once daily. The maintenance dose is 7mg or 14mg once daily, where the 14mg dose of Rybelsus® is advised, this should be achieved by prescribing one 14mg tablet. Do not use two 7mg tablets to achieve the 14mg dose.

How to take Rybelsus® tablets:

1. Take Rybelsus® tablets on an empty stomach at any time of the day.
2. Swallow Rybelsus® tablets whole with no more than half a glass of water (up to 120 ml). **Do not split, crush, or chew the tablet, as it is not known if it affects absorption of semaglutide.**
3. After taking Rybelsus® tablets wait at least 30 minutes before having the first meal or drink of the day or taking other oral medicines. **Waiting less than 30 minutes lowers the absorption of semaglutide.**

Guidance is available 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 NICE CG189 Obesity: identification, assessment and management.

NOTE A: **GLP-1 RAs affected.**
Refer to the public facing page on the SPS website for an up-to-date supply stock overview.

Semaglutide injection:

- Ozempic® 0.25 mg, 0.5mg and 1mg solution for injection in pre-filled pen

Dulaglutide:

- Trulicity® 0.75mg, 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

References:

1. Specialist Pharmacy Service: Prescribing available GLP-1 receptor agonist
2. Specialist Pharmacy Service: Prescribing available insulins
3. SPCs Semaglutide Products
4. SPCs Liraglutide Products
5. SPCs Dulaglutide Products
6. SPCs Exenatide Products
7. BNF: Type 2 diabetes

Stakeholder engagement:
The following stakeholders have been engaged in the management and consulted in the drafting of this alert: NHS Specialist Pharmacy Service Medicine Advice, Medicine Shortage Response Group, NHS England, national clinical experts in Diabetes, 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 straightforward National Patient Safety Alert. In response to CHT/2019/001 and CHT/2023/002 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 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.