Rybelsus® (oral semaglutide) tablets

The supply of glucagon-like peptide (GLP-1) receptor agonists (RA) continues to be limited, with supply not expected to return to normal until at least end of 2024. The BLMK Area Prescribing Committee (APC) Formulary Sub-Group has approved a temporary amendment to the GLP-1 RA formulary designations during the period of national shortage. These changes are based on recommendations included in the recent National Patient Safety Alert - NatPSA 2024- GLP-1 receptor agonists.

- **First-line option**: Rybelsus® (oral semaglutide) tablets for new initiations of GLP-1 RA treatment in adults with Type 2 diabetes (T2DM) where clinically appropriate and in line with NICE NG28.

- **Second-line options**: subcutaneous (SC) injection preparations (***We expect all new initiations where clinically appropriate will be oral, but some patients may not be eligible or compliant with the administration for Rybelsus)***
  - Dulaglutide (Trulicity®) once weekly
  - Semaglutide (Ozempic®) once weekly

Byetta® (exenatide) 5mcg/0,02ml and 10mcg/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.

BLMK ICB recommends that existing patients prescribed Byetta® and Victoza® injections (in line with NICE NG28) should be identified and switched to Rybelsus® tablets. Patients should be counselled on any changes in drug, formulation, and dose regimen where appropriate.

Switching Advice

Byetta (exenatide BD) to Rybelsus (oral semaglutide OD) - The 1st dose of Rybelsus should be given the next day after stopping exenatide.

- Exenatide (5mcg and 10mcg) switch to 3mg Rybelsus and then titrate up to 7mg after 1 month. Dose can be titrated again after 1 month to a 14mg maintenance dose to further improve glycaemic control.

Victoza (liraglutide OD) to Rybelsus (oral semaglutide OD) - The 1st dose of Rybelsus should be given the next day after stopping Victoza.

- Victoza 0.6mg switch to 3mg Rybelsus and titrate up to 7mg after 1 month.
- Victoza 1.2mg switch to 7mg Rybelsus and titrate up to 14mg after 1 month.
- Victoza 1.8mg switch to 7mg Rybelsus and titrate up to 14mg after 1 month.

The maximum recommended single daily dose of semaglutide is 14 mg. Taking two 7 mg tablets to achieve the effect of a 14 mg dose has not been studied and is therefore not recommended.

Counselling

Tablets should be taken whole on an empty stomach, with a sip of water (up to half a glass, equivalent to 120 mL). Patients should wait at least 30 minutes after a dose before eating, drinking,

or taking other oral medicines—intake with food or large volumes of water decreases the absorption of semaglutide.

Monitoring and Follow-up for new initiations

After initiation the patient should be monitored/followed up at the following intervals as per local guidance:

- At 3 months – review compliance and discuss any possible side-effects. Check HbA1c and weight.
- At 6 months – Check efficacy of treatment by checking HbA1c and weight. Compare measurements with those taken at baseline and confirm whether patient meets NICE continuation criteria.
- At 12 months - Consider discontinuing treatment if the response at 6 months is not maintained, taking into consideration the progressive nature of T2DM.

Note

As a result of limited supplies of GLP-1 agonists, BLMK ICB recommends that GLP-1 RAs licensed for T2DM should **NOT** be prescribed 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. For any switching information outside those recommended in the NatPSA 2024- GLP-1 receptor agonists, please seek advice and guidance from the community Diabetes Specialist teams.