BSW APC: BaNES, Swindon & Wiltshire (BSW) ICB, Avon & Wiltshire Mental Health Partnership NHS Trust (AWP), Royal United Hospitals Bath NHS Foundation Trust, Great Western Hospitals NHS Foundation Trust, Salisbury NHS Foundation Trust, HCRG Care Group, Swindon Community Health Services, Wiltshire Health & Care



BSW Prescribing Guidance for Oral Semaglutide

On 3rd Jan 24, DHSC/NHSE published a National Patient Safety Alert <u>NatPSA/2024/001/DHSC</u> on the ongoing shortages of GLP-1 receptor agonists (GLP-1 RAs) noting supply is not expected to return to normal until at least the end of 2024.

Summary of actions for clinicians and prescribers of GLP1-RAs until supply issues have resolved; to be completed as soon as possible and no later than 28 March 2024, material updates to actions in **bold**:

- 1. Only prescribe GLP-1 RAs for licensed indications.
- 2. Prescribe semaglutide (Rybelsus®) tablets for new initiations of a GLP-1 RA (in line with NICE NG28).
- 3. Identify patients prescribed exenatide (Byetta®) and liraglutide (Victoza®) injections and (in line with NICE NG28) switch to semaglutide (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:
 - discuss stopping GLP1-RA if patients have not achieved treatment goals as per NICE NG28
 - do not double up a lower dose preparation where a higher dose preparation of a GLP-1 RA is not available.
 - do not switch between strengths of a GLP-1 RA solely based on availability.
 - 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.

NHS BSW Prescribing guidance for Oral Semaglutide (Rybelsus® ▼)

Oral semaglutide is unique in that it is the first *oral* GLP1 receptor agonist.

- Like its subcutaneous formulation, oral semaglutide is indicated as an adjunct to diet and exercise for the treatment of adults with insufficiently controlled type 2 diabetes mellitus. Semaglutide should not be used in patients with type 1 diabetes mellitus or for the treatment of diabetic ketoacidosis.
- Oral semaglutide has a GREEN Traffic Light Status "appropriate for initiation in both primary and secondary care". If necessary to initiate or switch a patient to oral semaglutide (refer to actions 2 & 3 on p1), prescribers should counsel patient on dose titration schedule and administration instructions for Rybelsus® as given below.

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Dose titration schedule and administration information:

Rybelsus® dose titration schedule:

Inform patient that Rybelsus® requires dose titration over at least 3 months. Prescriptions should be issued monthly to ensure review and avoid wastage.

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.

Monitoring and patient review are broadly in line with injectable GLP1s. Due to highly variable absorption, the manufacturer estimates 2-4% of patients may not respond to oral semaglutide. To continue with treatment patients should demonstrate ≥3% weight loss/ ≥10 mmol ($^{\sim}$ 1%) HbA1c lowering at review at 3months, maintained at 6 months.

- Review after 4 weeks; if tolerated increase dose to 7mg
- Review after 8 weeks; if indicated consider maximising dose to 14mg
- Review after 12 weeks and again at 6 months to review patient weight and HbA1c and determine if continuation is appropriate.

How to take Rybelsus® tablets:

Take Rybelsus® tablets on an empty stomach at any time of the day. 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.

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.

Oral semaglutide should <u>not</u> be included in a 'dosette' box as the SPC states it should be stored in the original blister package to protect from light and moisture.

Adverse effects:

Gastro-intestinal adverse effects are common, especially in the first few weeks and may include nausea, vomiting, diarrhoea; patients should be advised to stay hydrated especially if they have kidney problems. Severe and on-going stomach pain could indicate acute pancreatitis and patients should seek immediate advice. As with injectable GLP1s, taking a sulfonylurea medicine or insulin with Rybelsus® might increase the risk of hypoglycaemia. See SPC for full list of adverse effects.

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Specialist contact information:

SFT Consultants/Nurse Specialists Contact via Secretaries		
Consultants' secretaries	Phone	01722-429229
Advice & Guidance	Email	shc-tr.diabetes@nhs.net
RUH Consultants/Nurse Specialists		
RUH consultants (immediate advice)	Phone	Consultant Connect
RUH consultants (1-2 day advice)	Email	ruh-tr.endocrinediabetes@nhs.net
BaNES DSNs (immediate advice)	Phone	07876 265064
BaNES DSNs (1-2 day advice)	Email	ruh-tr.communitydsn@nhs.net
Wiltshire DSNs (immediate advice)	Phone	01249 456483
Wiltshire DSNs (1-2 day advice)	Email	whc.diabetesnurses@nhs.net
GWH Consultants/Nurse Specialists		
GWH consultants (1-5 day response)	E-mail	Gwh.endocrinologyadvice@nhs.net
		<u>Gwh.diabetessecretaries@nhs.net</u>
Swindon Community DSNs (1-2 day response)	E-mail	bswccg.communitydiabetesservice@nhs.net
Swindon Community DSNs (same day advice)	Phone	01793 696621
Swindon Community DSNs (immediate advice)	Mobile	07979 119974/ 07917 084000

Additional information to support stock shortages:

Links to local resources Stock Shortages - Medicines (bswtogether.org.uk).

Refer to the public facing page on the SPS website for an overview of stock availability for all GLP-1 RAs https://www.sps.nhs.uk/articles/prescribing-available-glp-1-receptor-agonists/

National guidance to support clinicians in choosing suitable alternative glucose lowering therapies to GLP-1 RAs during this period of national shortage. <u>Clinical Guidance</u> from the Primary Care Diabetes Society (PCDS) and Association of British Clinical Diabetologists (ABCD) should be used in conjunction with NICE <u>NG28 Type 2 Diabetes in Adults: choosing medicines</u>.