NHS
Kent and Medway

Medicines Optimisation Newsletter [February 2024] (Issue No. 55)

Kent and Medway ICB Updates

Formulary and Guidance

Mounjaro®▼ (tirzepatide) KwikPen® solution for injection

Tirzepatide is approved for treating **type 2 diabetes in line with NICE TA924**:

- Tirzepatide is a long-acting dual glucose-dependent insulinotropic polypeptide (GIP) receptor and glucagon-like peptide-1 (GLP-1) receptor agonist, a new class of medicine, that increases insulin sensitivity and secretion, suppresses glucagon secretion, and slows gastric emptying. GLP-1 RAs are already well used in the management of type 2 diabetes, while the dual action on the GIP receptor is a new mechanism of action.
- In Kent and Medway, tirzepatide is on formulary as "**specialist initiation**" (specialist defined as secondary care prescribers, GPs, Specialist DSNs, specialist pharmacists or nurses in primary care (e.g. practice/spoke nurses) who have completed PITstop/equivalent training).
- Prescribing tirzepatide solely for **weight loss** (in the absence of a type 2 diabetes diagnosis) is **not** clinically supported or funded by Kent and Medway ICB until NICE have evaluated its use for this indication.

As of the 12th of February 2024, tirzepatide is **commercially available in the UK** (under the brand name Mounjaro®) and can be prescribed on the NHS in line with **NICE TA924:**

- Please note that the multi-dose Mounjaro® KwikPen® is the **only device/formulation** currently available in the UK.
- The BNF currently includes information for the autoinjector formulation, but not the KwikPen® formulation. For clinical information on the KwikPen®, please see the **SPC**.

It may take some time for Mounjaro®▼ (tirzepatide) KwikPen® to be uploaded onto EMIS (please ensure to update to the latest version of EMIS):

- While awaiting activation of digital prescribing, healthcare professionals can issue hand-written prescriptions as a last resort if a robust clinical audit trail is maintained.
- Before electronically prescribing Mounjaro® KwikPen®, please verify that EMIS has added the **correct formulation** before issuing a digital prescription:
  - **KwikPen®** (available in the UK): tirzepatide 5mg/0.6ml solution for injection 2.4ml pre-filled disposable devices

The following is the **incorrect** formulation:

  - Autoinjector (unavailable in the UK): tirzepatide 5mg/0.5ml solution for injection pre-filled disposable devices

(Pharmacies are not permitted to substitute KwikPen® for autoinjector prescriptions).

- Tirzepatide is **administered** by subcutaneous injection **once a week**. The Mounjaro®▼ (tirzepatide) KwikPen® (pre-filled pen) contains **4 doses** (**one pen = 4 weeks supply**).
- It may take some time for community pharmacies to obtain stock. Currently, only the **2.5mg and 5mg doses** are available for pharmacies to order in Great Britain. The higher doses will be made available over the coming months.
- Mounjaro® will be added onto either the March or April 2024 Drug Tariff. The NHS BSA has confirmed that before publication, Mounjaro® is still reimbursed by the NHS for the treatment of type 2 diabetes as per NICE TA924.
- As a new drug, Mounjaro®▼ (tirzepatide) is subject to additional monitoring, to quickly identify new safety information. Healthcare professionals are asked to **report any suspected adverse reactions** (minor or serious) to the Yellow Card Scheme.

The Kent and Medway ICB Medicines Optimisation team are developing a **prescribing factsheet** for Mounjaro®▼ (tirzepatide) KwikPen® to summarise the key information including dosing, administration, prescribing responsibilities, patient safety, monitoring, review, storage, disposal and links to further information and resources. This will be uploaded onto the **local formulary websites** in due course.

Wegovy® (semaglutide) solution for injection for Weight Management

Wegovy® (semaglutide) is for specialist prescribing only and is not for prescribing by primary care when used for weight management in line with the **NICE TA875**. For more information, and an update on the availability of Wegovy® (semaglutide) to support weight loss, please see **here** on the public facing NHS Kent and Medway website.

The Kent and Medway ICB Medicines Optimisation team are aware that **private providers** are prescribing Wegovy® for patients on private prescriptions. As a result, practices are often sent communication/letters from these private providers, informing practices that patients are being prescribed Wegovy®. This information should not be confused for requests for primary care/the practice to prescribe Wegovy® for the patient(s) on the private providers' recommendations.

Whether the communication/letter from the private provider is for information only, or is a request for the practice to prescribe/continue the prescribing of Wegovy®, we kindly ask/remind practices:

- **not to prescribe** Wegovy®, but advise that prescribing should be retained by the private provider,

- that it should be **recorded** on patients' records that they are being prescribed Wegovy® for weight management from a private provider via private prescriptions,
- that if Wegovy® is being prescribed by a private provider then reviews, monitoring etc. should also remain the **responsibility of the private provider**, not the practice.

The following information on the public facing NHS Kent and Medway website may be useful, and patients who have had a prescription issued after a private consultation can be signposted to it, if necessary:

- Information on prescriptions issues after private consultation :: NHS Kent and Medway (icb.nhs.uk)
- Mixing private and NHS treatment :: NHS Kent and Medway (icb.nhs.uk)

We would also like to remind colleagues that the public should be made aware that there have been reports of **fake weight loss pens** being sold online. Please see the link to the MHRA warning here for more information.

Trurapi® (insulin aspart) 100units/ml solution for injection

Trurapi® is a **biosimilar insulin**. Trurapi® contains **insulin aspart**, a rapid-acting insulin, and is a biosimilar of the originator insulin, NovoRapid®. Trurapi® has been shown to be equivalent to NovoRapid®, which is already widely used, in its pharmacokinetic and pharmacodynamic properties.

Trurapi® is licensed, identically to the originator insulin (NovoRapid®), for the treatment of **type 1 and type 2 diabetes** mellitus in adults, adolescents and children aged 1 year and above. Trurapi is not licensed for children under 1 year old (exclusion).

It is administered by subcutaneous injection, subcutaneous infusion, or intravenous infusion, depending on the preparation/setting. All preparations of Trurapi® are now **on formulary** across Kent and Medway. Trurapi® is available as:

- Trurapi® **100 units/ml** solution for injection 10ml **vials**
- Trurapi® **100 units/ml** solution for injection 3ml **cartridges**
- Trurapi® **100 units/ml** solution for injection 3ml prefilled **SoloStar® pens**

Please see individual SPCs on the emc website for further details.

In Kent and Medway Trurapi® (insulin aspart) is now recommended as the **preferred/first-line brand** of the rapid-acting insulin aspart, in view of the cost to the NHS because of the potential cost savings from using Trurapi® instead of NovoRapid®. This is in line with NICE guidance, NHS England, and Kent and Medway PRGC Policy Recommendations in relation to biosimilar medicines.

New patients/new initiations should be started on Trurapi®, in place of NovoRapid®. Therefore, primary care may begin to see more patients initiated on/prescribed Trurapi® on the recommendations of specialists, on discharge from hospital etc.

Where clinically suitable, in line with NICE guidelines, on an individual patient basis, existing patients can be switched from the originator insulin (NovoRapid®) to the biosimilar insulin Trurapi® as a shared decision with the patient, with close glucose monitoring where this decision is made. When switching between NovoRapid® and Trurapi®, it is a unit:unit conversion. i.e. prescribe a 1:1 dose.

Local "Kent and Medway Guidance on Biosimilar Insulin Prescribing" and "Kent and Medway Guidance on Safe Insulin Prescribing" have been produced to summarise the biosimilar insulins available currently in the UK and to support healthcare professionals, within different healthcare settings, engaged in the care of patients with diabetes/using insulin, in the safe and appropriate prescribing and dispensing of insulins and biosimilar insulins (these documents can also be found on all local formulary websites).

Fezolinetant (Veoza®) – not for NHS prescribing

Fezolinetant (Veoza®) is a new non-hormonal oral medication, which was licensed by the MHRA on the 14th of December 2023 as a treatment option for vasomotor symptoms (hot flushes and night sweats) caused by the menopause. It is now available on private prescription, while the NHS launch is to follow. As of February 2024, fezolinetant is not yet listed in the Drug Tariff.

A NICE Technology Appraisal (TA) is in development (publication date to be confirmed) to review the clinical and cost effectiveness of fezolinetant. If recommended, it will be available to prescribe on the NHS. Until it has been reviewed by NICE, then assessed for use locally in Kent and Medway, **practices are asked not to prescribe fezolinetant, which is not currently available to prescribe on the NHS.** Further details regarding its prescribing position will be disseminated once it has been evaluated by NICE then through ICB governance processes.

For more information on fezolinetant, including mechanism of action, the British Menopause Society (BMS) has an update on fezolinetant following its licensing by the MHRA which can be found here.

Prescribing of Armour Thyroid and other unlicensed desiccated thyroid extract (DTE) products

We would like to remind practices that Armour Thyroid and other unlicensed desiccated thyroid extract (DTE) products are **NOT recommended** for prescribing on FP10 in Kent and Medway.

Patients currently being prescribed Armour Thyroid or other desiccated thyroid extract products should be reviewed by an NHS Consultant Endocrinologist and a switch to levothyroxine considered. The withdrawal or adjustment of treatment should only be undertaken by, or with oversight of, an NHS consultant endocrinologist.

NHS England guidance on items which should not routinely be prescribed in primary care lists Armour Thyroid (a DTE product). It is listed because of the clinical concerns, cost, and lack of evidence of superiority of DTE over levothyroxine.
Advice for prescribers on liothyronine use in the NHS, lists thyroid extract products (e.g. Armour thyroid and ERFA Thyroid) as not recommended. This is because their safety, quality and efficacy cannot be assured.

NICE guidance on the assessment and management of thyroid disease states there is not enough evidence that DTE products offer benefit over levothyroxine and advised that its long-term adverse effects are uncertain.

Actions for prescribers in primary care:
Requests for DTE products
When patients request DTE products

- Follow position statement on prescribing of DTE products
- Do not initiate DTE products for management of hypothyroidism
- Explain the clinical concerns around DTE to patients who ask about it

Switching from DTE products
When patients are already taking DTE products

- Consider referring these patients to a consultant NHS endocrinologist who will consider switching to levothyroxine where clinically appropriate

Please see SPS for more information. Avoid prescribing desiccated (natural) thyroid extract – SPS - Specialist Pharmacy Service – The first stop for professional medicines advice

For Kent and Medway Joint Prescribing Committee Position Statement ARMOUR THYROID and other unlicensed desiccated thyroid extract products see link below

km-position-statement-armour-thyroid-and-dessicated-thyroid-extract_.pdf (medwayswaleformulary.co.uk)

Gluten Free Prescribing in Kent and Medway

We would like to remind practices that in NHS Kent and Medway **only bread and mixes** are allowed to be prescribed on FP10 prescriptions;

- Bread includes fresh, long life and part-baked loaves and rolls.
- Mixes include bread and flour mixes.

Gluten Free (GF) products should only be prescribed for the Advisory Committee on Borderline Substances (ACBS) indications for patients with a confirmed documented diagnosis. Any prescribing not in line with an ACBS approved indication should be discontinued and patients should be advised to purchase until a confirmed diagnosis is given.

Only patients who meet ACBS indications are entitled to Gluten-free foods on FP10 i.e.

- Gluten-sensitive enteropathies including steatorrhoea due to gluten sensitivity;
- Coeliac Disease; proven by biopsy;
- Dermatitis herpetiformis.

Examples of items **NOT** to be prescribed on NHS prescription (list not exhaustive). E.g Crackers, all biscuits, crisp bread, breakfast cereals, oats, pasta, pizza bases.

Patients with a confirmed diagnosis of phenylketonuria (PKU) will be allowed to be prescribed low protein food on prescription (which is not freely available at supermarkets).

An FAQ document has been produced to answer common questions which can be found here. For any further queries please contact your local medicines optimisation teams.

issue-55-faq-gluten-free-guidance-dec-2024v2.pdf (medwayswaleformulary.co.uk)

Reducing OTC Prescriptions in Primary Care

NHS England has published guidance on reducing the amount of OTC medication provided on prescription. NHS England » Guidance on conditions for which over the counter items should not routinely be prescribed in primary care.

To help implement this guidance consistently across the county, the ICB's medicines optimisation team has prepared a briefing and position statement (attached) and set up an OTC phone line (details found in the briefing statement).

The briefing document outlines several resources to help reduce this cost, including a support line for patient or prescriber queries, and patient messaging. The position statement clarifies under which limited circumstances a patient should be eligible for an OTC prescription.

Posters and digital screen displays can be found on the following link under over-the-counter medicines campaign https://www.kentandmedway.icb.nhs.uk/your-health/local-services/general-practice-services/general-practice-communication-and-engagement-resources

There is a monthly OTC focus with resources sent to all GP practices across Kent and Medway. So far to date we have provided resources on several topics including: Hayfever and sunscreens, constipation, diarrhoea, heartburn and indigestion and most recently vitamins and minerals. If for any reason you haven't received these please contact your local medicines optimisation teams.

By helping to support this piece of work, you will help reduce the cost to the NHS and free up practice and pharmacy time that would otherwise be spent processing OTC prescriptions.

issue-55-km-otc-briefing-statement.pdf (medwayswaleformulary.co.uk)

issue-55-km-otc-position-statement.pdf (medwayswaleformulary.co.uk)

HCP Specific Newsletter Updates

East Kent HCP – KCHFT pilot: mucolytic drug holiday initiative

Starting on 1st March 2024, the KCHFT respiratory team will be piloting a mucolytic drug holiday initiative. The evidence of efficacy for mucolytic medication for patients with COPD is limited, yet 24% of our COPD population are currently taking carbocisteine. Mucolytics are often started during an inpatient stay and the efficacy of this medication should be reviewed regularly and only continued if cough and sputum production has been reduced. This is often not made clear on discharge summaries, and patients remain on mucolytic therapy long term. Carbocisteine is taken as one capsule four times a day as a maintenance dose and contributes to a patients pill burden.

The pilot will focus on the patients currently being managed by the community respiratory team and will result in either the patient stopping mucolytic therapy or being switched to a once daily Acetylcysteine tablet. Acetylcysteine, as an effervescent tablet, is contraindicated in patients requiring a low sodium diet (and those using regular GTN), so it is likely that a few patients may remain on carbocisteine. The intention is to study the results of this pilot and roll out this pilot more widely in primary care. We would really appreciate your support with any patients that may query this rationale in primary care, and we look forward to sharing the results with you when the pilot concludes.

National Updates

MHRA Press Release – Pioneering genetic biobank to start recruiting patients on stroke prevention medicines

On 13th February 2024 the MHRA published a press release stating that the pioneering Yellow Card Biobank, a pilot launched by the Medicines and Healthcare products Regulatory Agency (MHRA) and Genomics England, will today start investigating Direct Oral Anticoagulants.

The Yellow Card Biobank aims to help understand how a patient's genetic makeup can impact the safety of their medicines and forms part of a long-term vision for more personalised medicine approaches. Approved scientists will use the genetic information in the Biobank to investigate whether a side effect from a medicine was caused by a specific genetic trait. This would in turn enable healthcare professionals to personalise prescriptions using rapid screening tests, so patients across the UK will receive the safest medication for them, based on their genetic makeup.

Direct Oral Anticoagulants have been linked to severe bleeding, which can be potentially serious and life threatening. The Yellow Card Biobank is exploring whether some people are at a higher risk of severe bleeding due to their genetic makeup, with the overall aim of reducing the occurrence of serious side effects. See their press release for more information.

Healthcare professionals can help by submitting a Yellow Card report using the Yellow Card website , providing as much information as possible about the patient's side effect. The Yellow Card Biobank may contact you directly to discuss the case further and may ask you to contact the patient on their behalf to ask if they will participate in the Yellow Card Biobank. It will be that patient's choice to take part in the Biobank.

If you have already submitted a Yellow Card report in the past relating to either of the two topics, severe bleeding after taking a direct oral anticoagulant or a severe skin reaction (SJS, TEN or DRESS) after taking allopurinol, they may also contact you directly in the coming months to discuss the case further.

MHRA Drug Safety Update – January 2024

The latest MHRA Drug Safety Updates can be accessed at Drug Safety Update - GOV.UK (www.gov.uk). This includes links to alerts, recalls and safety information and to the monthly Drug Safety Update PDF newsletter.

The January 2024 Drug Safety Update includes:

Valproate (Belvo, Convulex, Depakote, Dyzantil, Epilim, Epilim Chrono or Chronosphere, Episenta, Epival, and Syonell▼): new safety and educational materials to support regulatory measures in men and women under 55 years of age - GOV.UK (www.gov.uk)

New safety and educational materials have been introduced for men and women and healthcare professionals to reduce the harms from valproate, including the significant risk of serious harm to the baby if taken during pregnancy and the risk of impaired fertility in males.

Fluoroquinolone antibiotics: must now only be prescribed when other commonly recommended antibiotics are inappropriate - GOV.UK (www.gov.uk)

Systemic fluoroquinolones must now only be prescribed when other commonly recommended antibiotics are inappropriate. This follows a review by the MHRA which looked at the effectiveness of current measures to reduce the identified risk of disabling and potentially long-lasting or irreversible side effects. Where prescribing is unavoidable, always counsel the patient about side effects, provide them with the MHRA Patient Information leaflet and document this in the notes.

Omega-3-acid ethyl ester medicines (Omacor/Teromeg 1000mg capsules): dose-dependent increased risk of atrial fibrillation in patients with established cardiovascular diseases or cardiovascular risk factors - GOV.UK (www.gov.uk)

Systematic reviews and meta-analyses of randomised controlled trials have highlighted a dose-dependent increased risk of atrial fibrillation in patients with established cardiovascular diseases or cardiovascular risk factors treated with omega-3-acid ethyl ester medicines compared to placebo. Please see the full alert for information and advice for healthcare professionals.

Letters and medicine recalls sent to healthcare professionals in December 2023 - GOV.UK (www.gov.uk)

Please follow the links in the titles above for more information and resources.

NATIONAL CAS ALERTS (National Patient Safety Alerts and CMO Messages):
The MHRA Central Alerting System alerts can be accessed at https://www.cas.mhra.gov.uk/Home.aspx

Shortage of GLP-1 receptor agonists (GLP-1 RA) update 3rd Jan 2024

The ICB MO Team have contacted practices directly by email during the second week in January and included an item in the GP update on 4th January, to support practices with implementing this NatPSA. Please ensure that all members of staff especially those involved in the management of type 2 diabetes and prescription management are aware of this update.

NICE News – February 2024

Please find the NICE News for February 2024 attached.

recent-nice-publications-feb-2024.pdf (medwayswaleformulary.co.uk)

Shortages

Shortages Summary

From February 2024 onwards, the monthly Medicines Optimisation newsletter will no longer contain the medicines shortages update document, which was compiled each month from the shortages listed on the SPS (Specialist Pharmacy Services) Medicines Supply tool. The information published on the SPS Medicines Supply tool is provided by DHSC and NHSEI Medicines Supply Teams and was not formally reviewed by the NHS Kent and Medway Medicines Optimisation team.

During the time that the shortages update was compiled and included in the Medicines Optimisation newsletter, practices and healthcare professionals were still encouraged to **register for free access to the** SPS website and to **access the SPS Medicines Supply tool directly** in real time, to have access to the most up-to-date and complete information and advice available. Now that the shortages update will no longer be compiled by the Medicines Optimisation team for inclusion in the newsletter, healthcare professionals will be required to access the SPS Medicines Supply tool to access information on the latest shortages. Serious Shortage Protocols (SPPs) can be found on the NHS BSA website here.

It is a requirement of the **Kent & Medway Medicines Optimisation Scheme 2023-24** "Effective Management of Medicines Supply and Shortages" project for practices to develop a policy for managing stock shortages. This includes having access to the SPS Medicines Supply tool. It is expected that this will have been actioned as practices are required to submit the required reporting template for this project, section A and B, by the 28th of February 2024.

Shortage of Tegretol 200mg and 400mg prolonged release tablets

A Medicines Supply Notification (MSN) was issued on 10th January 2024 advising that stock Tegretol 200mg and 400mg prolonged release tablets should be available from 29/01/2024. However, we are aware that Tegretol appears out of stock with wholesalers and have received reports that patients experiencing significant difficulty obtaining their prescriptions in the community.

Novartis report that they are not experiencing supply issues with Tegretol 200mg and 400mg prolonged release tablets.

Novartis advise pharmacies continuing to experience difficulties obtaining Tegretol PR from your usual wholesalers to contact Novartis Customer Care directly on 0845 741 9442 or via email at novartis.customercare@novartis.com

The full MSN can be found here:
MSN_2024_004_Carbamazepine_Tegretol_200mg_and_400mg_PR_tablets.pdf (cpsc.org.uk)

ADHD medication availability and supply disruption update

The Department of Health and Social Care (DHSC) issued a National Patient Safety Alert on supply disruptions affecting various strengths of the following medications for the treatment of attention deficit hyperactivity disorder (ADHD) in September 2023. Please find further updated information attached below and updated re-supply dates.

issue-55-adhd-update.pdf (medwayswaleformulary.co.uk)

Not all drugs and strengths are impacted, therefore the individual patient's medication and quantity should be reviewed before signposting.

A gentle reminder that community pharmacies will only be able to dispense what is written on the prescription, therefore new prescriptions will be needed for changes to the drug, dose or strength. This is a legal requirement, please bear this in mind. A phone call to local pharmacies to understand stock levels prior to prescribing is recommended.

We appreciate that the supply disruption will cause anxiety for patients and their families. NHS Kent and Medway has set up a non-clinical helpline for patients who would like more information on the supply disruption (01634 335095 option 3 then option 3, ADHD medicine shortages). This may help you to support the messaging for patients.

Riluzole availability

We have received reports that some patients have experienced difficulties obtaining Riluzole from community pharmacies. We have checked with the manufacturers and confirmed that the generic tablets are available (see below).

We also understand the availability of these tablets may be impacted by the reimbursement costs; whereby the acquisition costs are much higher for community pharmacies – this issue has been escalated to the NHSBSA.

The current stock status of Riluzole tablets is shown below:

Manufacturer	Drug	Brand name	Stock status	Return date/information from manufacturer
Zambon UK ltd	Riluzole 50mg orodispersible film	Emylif	All wholesalers should be able to obtain-in stock	_
Sun Pharma (Ranbaxy uk)	Riluzole 50mg tablets	Generic	OOS	Tentative eta of end of march
Sanofi	Riluzole 50mg tablets	Rilutek	Discontinued	_
Glenmark	Riluzole 50mg tablets	Generic	In stock	Available to purchase through their commercial channel and have recently sold to the following wholesalers: • Alliance Healthcare Ltd • OTC Direct Ltd • Trident Pharmaceuticals • Laxmico Ltd • AAH Pharmaceuticals Ltd • Sigma Pharmaceuticals Ltd

Martindale (Ethypharm group company)	Riluzole 5mg/ml oral suspension	Teglutik	Currently OOS	Expected 5.4.24 but please note due date is subject to change

Please ensure all staff are aware of the pathway to follow for reporting any medicines stock /price issues via Community Pharmacy England.
The link to the reporting page is below:
https://cpe.org.uk/dispensing-and-supply/supply-chain/problems-with-obtaining-a-generic-medicine/

Contractors should continue to use CPE's online reporting form to share details of drugs unavailable at Drug Tariff listed prices. As stock levels and prices can vary across the country, we rely on these contractor reports which help feed into the market surveillance and inform discussions with DHSC. The reports help to demonstrate the scale of the problems to DHSC and support escalations on particular lines, as needed. In certain circumstances, DHSC may request wholesaler invoices showing actual purchase prices as evidence to help CPE make further representations to the DHSC for an improved concessionary price.

Whilst CPE will continue to work to mitigate the overarching issues, there are some practical steps that pharmacy contractors and their teams can take to help manage the situation:

- Try contacting a range of different wholesalers and suppliers to locate stock at or lower than Drug Tariff price;
- Report issues where the product can only be obtained at a price higher than the Drug Tariff listed price using CPE's **online form**;
- Check for any known supply issues in the **Medicines Supply Tool** hosted on the Specialist Pharmacy Service (SPS) website (any new shortages can be reported to CPE **here).** Access to the Medicines Supply Tool requires **registration** with an NHS email address.
- Report any new medicine shortages not listed on the SPS website using **CPE's online reporting form**.
- Check for any current **Serious Shortage Protocols (SSPs)** that may allow alternatives to be given without needing to go back to the prescriber;
- Provide affected patients with a copy of this **medicines supply factsheet**; and
- Liaise with the GP to see if an alternative treatment can be provided.
- If you face verbal abuse from patients due to medicine supply issues, please don't feel like you have to tolerate it. The pharmacy regulations say that if a contractor or their staff (or other people at the premises) are threatened with violence, a contractor may refuse to dispense a prescription. This also applies if the person threatens to commit a criminal offence. Obviously, refusal is also an option if any of those threats are carried out.