

**Minutes from the meeting held on Thursday 14th July 2022 at 2pm
via Microsoft Teams**

Minutes

Present:

Dr Richard Chudleigh (RC), Consultant Physician, Diabetes (CHAIR),
Judith Vincent (JV), Clinical Director, Pharmacy & Medicines Management,
Alan Clatworthy (AC), Clinical Effectiveness Pharmacist,
[REDACTED] Principal Pharmacist – Head of Operational Services (Deputy Chief Pharmacist),
[REDACTED] Head of Prescribing and Medicines Management,
[REDACTED] Pharmacy Manager, Cefn Coed,
[REDACTED] Senior Pharmacist - Analytics & Logistics,
Helen Griffiths (HG), Corporate Head of Nursing,
[REDACTED] Consultant Physician, Diabetes,
[REDACTED] Advanced Nurse Practitioner (NMP Representative),
[REDACTED] GP,
[REDACTED] Pharmacy & Medicines Management (Notes).

In attendance for agenda item 25/22:

[REDACTED] ThinkGlucose Lead/Diabetes Specialist Nurse,
[REDACTED] Education & Training Pharmacist.

25/22 Self-Management of Insulin Policy:

This work has been completed jointly with Diabetes & Pharmacy & Medicines Management. [REDACTED] summarised the presentation that had been circulated 'Insulin / Glucagon-Like Peptide-1 Receptor Agonist Self-Management Policy for Adult Inpatients'.

MMOB were asked to support the following recommendations:

- Review documents, providing comments and feedback.
- Provide final sign off and approval of the policy once reviewed.
- Approve roll out across the Health Board.
- Endorse implementation of the policy for adults.

There was a general discussion and some suggested changes to some of the wording in the policy:

- The booklet suggests that needles, lancets and blood glucose strips will not be supplied. This needs amending as the needles and lancets would be supplied if required. Not practical to supply the glucose strips as there are many different machines.
- Some sections of the policy need to be clearer on what would be self-administration vs self-management in the context of GLP-1 RA use.
- The Self-Management diary needs to include ability to record which insulin the patient is self-administering (not just dose).

MMOB were happy to approve the policy pending the above amendments. [REDACTED] agreed to make the relevant changes to the documentation. **Action:** [REDACTED]

26/22 Apologies for absences:

Dr Anjula Mehta, [REDACTED], [REDACTED] & Dr Owen Pearson.

27/22 Minutes of previous meeting: The minutes of the meeting held on the 26th May 2022, were accepted as a true record of the meeting.

28/22 Matters Arising:

Tc99m – PSMA (21/22f) – following the last meeting the document was circulated for review and any comments giving a deadline of a week. No comments were received so the request was approved and the authors informed.

Mexiletine (21/22d) – Primary Care prescribing of this drug was discussed in PCPAG. The group felt that prescribing needs to remain in Secondary Care as this is such a specialist area and needs sufficient monitoring. MMOB supported this decision and prescribing will remain in Secondary Care.

Action: Alan Clatworthy

Ryeqo (21/22g) – this was discussed in PCPAG and there were concerns around the Dexa scan requirements. They emphasised the importance of ensuring that the Dexa scan reviews are included in the Secondary Care requirement. Once the Dexa scan has been completed at year 1, the Primary Care team would be happy to continue the prescribing.

There was a general discussion on the potential patient numbers and the importance on ensuring that the Dexa scan is carried out 12 months after starting treatment. To discuss with the Dexa Scan Clinic so they are aware of this patient group and can clarify access/waiting times. **Action: Alan Clatworthy**

29/22 New Product Requests & Formulary Amendments

- a) **Cariprazine (Reagila®) implementation plan** – is an atypical oral antipsychotic, and is licenced for treatment of schizophrenia.

Cariprazine is recommended as an option for restricted use within NHS Wales.

Cariprazine (Reagila®) should be restricted for use in the following subpopulation within its licensed indication for the treatment of schizophrenia in adults:

- for use as a second-line therapy in people with schizophrenia where predominantly negative symptoms have been identified.

Cariprazine (Reagila®) is not recommended for use within NHS Wales outside of this subpopulation”

Will be an additional antipsychotic available on the formulary

Place in therapy: AWMSG recommend use as second-line therapy in people with schizophrenia where predominantly negative symptoms have been identified. Restricted to Consultant Psychiatrist initiation and completion the requisition form.

MMOB approved the implementation plan. **Action:** [REDACTED]

- b) **Teduglutide (Revestive) implementation plan** - is recommended, within its marketing authorisation, as an option for treating short bowel syndrome (SBS) in people 1 year and above. People should be stable following a period of intestinal adaptation after surgery before having teduglutide. Teduglutide is recommended only if the company provides it according to the commercial arrangement.

Place in therapy: Patients with high parenteral therapy need requirements or in whom parenteral therapy is failing or problematic. Decision to initiate therapy would be through SBS specialists.

MMOB approved the implementation plan. **Action: Alan Clatworthy**

- c) **Fenfluramine (Fintepla) implementation plan** - is recommended as an add-on to other antiepileptic medicines for treating seizures associated with Dravet syndrome in people aged 2 years and older, only if:
- it is an add-on to 2 other antiepileptic medicines

- the frequency of convulsive seizures is checked every 6 months, and fenfluramine is stopped if it has not fallen by at least 30% compared with the 6 months before starting treatment
- the company provides fenfluramine according to the commercial arrangement

Provides an alternative treatment option as an add-in therapy. Patient numbers are expected to be less than 10 in total. In practice, there has been relatively low uptake of cannabidiol for Dravet syndrome.

Place in therapy: Would likely be used for patients with inadequate response to cannabidiol. Fenfluramine is taken orally. It can be used with or without stiripentol. Because of how fenfluramine is metabolised, the recommended maintenance dose after titration is 0.7 mg/kg/day (maximum 26 mg/day) for people not taking stiripentol, and 0.4 mg/kg/day for people taking stiripentol (maximum 17 mg/day).

MMOB approved the implementation plan. **Action: Alan Clatworthy**

d) Respiratory biologics for Severe Asthma implementation plan -

NICE TA751 Dupilumab for treating severe asthma with type 2 inflammation.

NICE TA671 Mepolizumab for treating severe eosinophilic asthma.

NICE TA479 Reslizumab for treating severe eosinophilic asthma.

NICE TA565 Benralizumab for treating severe eosinophilic asthma.

NICE TA278 Omalizumab for treating severe persistent allergic asthma.

AWMSG draft Biological medicines for severe eosinophilic asthma.

Place in therapy: The All Wales Adult Asthma Management and Prescribing Guideline places treatment with biological medicines towards the end of the treatment pathway, for consideration in patients with severe difficult to treat asthma. The Guideline states that any patients receiving two or more courses of oral steroids in a 12-month period, despite adherence with optimised therapy, should be referred to secondary care specialists.

The severe asthma service estimates that the required additional infrastructure to deliver a safe and effective service is an additional consultant time of 3 days per week; and 1 WTE asthma nurse specialist band 7. This was discussed in the last NICE/High Cost Drugs meeting and the group approved the infrastructure financial request.

MMOB ratified the NICE/High Cost Drug decision for infrastructure funding and approved the implementation plan. **Action: Alan Clatworthy**

e) Bevacizumab implementation plan - is recommended as an option for restricted use within NHS Wales for use in combination with paclitaxel and cisplatin for the treatment of adult patients with persistent, recurrent, or metastatic carcinoma of the cervix.

Bevacizumab is not recommended for use within NHS Wales for use in combination with paclitaxel and topotecan in patients who cannot receive platinum therapy, for the treatment of adult patients with persistent, recurrent, or metastatic carcinoma of the cervix.

This recommendation applies only in circumstances where the approved Patient Access Scheme (PAS) is utilised or where the list/contract price is equivalent to or lower than the PAS price

Place in therapy: First line for the treatment of adult patients with persistent, recurrent, or metastatic carcinoma of the cervix.

Bevacizumab is licensed, in combination with paclitaxel and cisplatin or, alternatively, paclitaxel and topotecan in patients who cannot receive platinum therapy, is indicated for the treatment of adult patients with persistent, recurrent, or metastatic carcinoma of the cervix.

The company submission to AWMSG did not include the combination of bevacizumab, topotecan and paclitaxel (so this was not approved for use within NHS Wales).

Clinical practice in Wales (including SBUHB) is currently to use carboplatin (rather than cisplatin) in combination with paclitaxel for this indication as it does not require iv fluid hydration before therapy and has superior adverse effect profile. Addition of bevacizumab to carboplatin and paclitaxel is outside of UK license. It is requested that MMB approves the use outside of license for this combination to provide clinical governance for SBUHB clinicians.

MMOB noted and approved the unlicensed requirements and approved the implementation plan.

Action: Alan Clatworthy

f) **Icosapent ethyl (Vazkepa)** - is recommended as an option for reducing the risk of cardiovascular events in adults. It is recommended if they have a high risk of cardiovascular events and raised fasting triglycerides (1.7 mmol/litre or above) and are taking statins, but only if they have:

- established cardiovascular disease (secondary prevention), defined as a history of any of the following: – acute coronary syndrome (such as myocardial infarction or unstable angina needing hospitalisation) – coronary or other arterial revascularisation procedures – coronary heart disease – ischaemic stroke – peripheral arterial disease, **and**
- low-density lipoprotein cholesterol (LDL-C) levels above 1.04 mmol/litre and below or equal to 2.60 mmol/litre.

Place in therapy: People must be taking a statin to have icosapent ethyl. Patients with a high risk of cardiovascular events and raised fasting triglycerides (1.7 mmol/litre or above) and are taking statins with established cardiovascular disease (defined as a history of any of the following: – acute coronary syndrome (such as myocardial infarction or unstable angina needing hospitalisation) – coronary or other arterial revascularisation procedures – coronary heart disease – ischaemic stroke – peripheral arterial disease, **and** low-density lipoprotein cholesterol (LDL-C) levels above 1.04 mmol/litre and below or equal to 2.60 mmol/litre.

Locally patients presenting to acute services (post stroke, MI or for revascularisation procedures) would be prioritised in first year of implementation.

This was discussed in the last NICE/High Cost Drugs and as part of a managed entry approach, it was agreed that for the first 12 months this treatment would be initiated by specialists within Secondary Care (cardiology, stroke services, lipid clinics) with continuation in primary care, this can then be reviewed regarding potential for Primary Care initiation of treatment in specified cohorts. It was noted that over next 12 months the Clinicians may be able to better define a prescribing pathway, which in turn would assist primary care prescribing decisions. [redacted] agreed to produce a one-page summary document for Primary & Secondary Care, giving information on the drug, what specific cohorts it will be used for, the common side effects, what prescribers need to consider etc. One drafted this will be shared with PCPAG and MMOB.

MMOB approved the implementation plan. **Action: Alan Clatworthy**

30/22 Policies for agreement and ratification:

a) **Patient Group Directions:** – a list of current agreed protocols were noted. A copy of all PGD's can be found at: <http://howis.wales.nhs.uk/sites3/page.cfm?orgid=988&pid=48028>

[redacted] will follow up on the expired Integrated Sexual Health PGDs. **Action:** [redacted]
Post meeting note: Diamorphine - not required at the moment due to the out of stock situation.

b) **Intravenous Iron – a complete guide** – this was deferred from the last meeting pending some consent issues within the document that needed to be discussed.
The document has now been updated and the relevant Specialities have been included in the conversations. AC summarised the changes to the document, the main changes are around the counselling section.

MMOB approved the guide. **Action: Alan Clatworthy.**

31/22 Any Other Business:

- a) **Switch of first-line low molecular weight heparin for thromboprophylaxis within SBU to Tinzaparin** – [REDACTED] provided some context and a summary of the paper that was circulated.

MMOB were asked to support and approve the switch back to tinzaparin as the first-line LMWH choice for thromboprophylaxis across all specialties where clinically appropriate.

It was noted that the Renal Dosing LMWH on COIN has expired and [REDACTED] will follow this up with the team. **Action:** [REDACTED]

MMOB supported this request. **Action:** [REDACTED]

- b) **GP Feedback/Decision on Analgesic Prescription Recommendation from Specialist Care** – this is an annotation of an existing form. The Pain Team and GPs have been involved in the update and is a more specialised form for their requirements.

MMOB approved the form. **Action:** [REDACTED]

32/22 Date and time of next meeting:

Thursday 22nd September 2022 at 2pm via Microsoft Teams

Medicines Management Operational Board

Agenda item	Action Required	Person Responsible
25/22	Self-Management of Insulin Policy - MMOB were happy to approve the policy pending the above amendments. CC/JJ agreed to make the relevant changes to the documentation	CC/JJ
27/22	Minutes from 26 th May 2022 – Approved to be added to the website.	KD
28/22	<ul style="list-style-type: none"> Mexiletine (21/22d) - MMOB supported this decision and prescribing will remain in Secondary Care. Ryeqo (21/22g) – need to discuss the Dexa scan requirements 	AC AC
29/22	a) Cariprazine (Reagila®) implementation plan – approved, to be added to the formulary b) Teduglutide (Revestive) implementation plan – approved, to be added to the formulary c) Fenfluramine (Fintepla) implementation plan – approved, to be added to the formulary d) Respiratory biologics for Severe Asthma implementation plan – approved, to be added to the formulary e) Bevacizumab implementation plan – approved, to be added to the formulary f) Icosapent ethyl (Vazkepa) implementation plan – approved, to be added to the formulary	AC
30/22	Policies for agreement & ratification: b) PGD List – Follow up on the expired Integrated Sexual Health PGDs c) Intravenous Iron – a complete guide – approved, author to be informed.	AJ AC
31/22	a) Switch of first-line low molecular weight heparin for thromboprophylaxis within SBU to Tinzaparin – approved, author to be informed. Renal Dosing LMWH on COIN has expired and OW will follow this up with the team. b) GP Feedback/Decision on Analgesic Prescription Recommendation from Specialist Care – approved, author to be informed.	OW OW OW