Betsi Cadwaladr University Health Board Drug and Therapeutics Group

Minutes of meeting held on Wednesday 7th February 2024 via Microsoft Teams

Present:	[redacted]
Agenda item	
24.001	**Welcome and Introduction**
24.002	**Apologies:** [redacted]
24.003	**Declaration of Interests** Nil declared.
24.004	**Minutes of the last meeting** The minutes of December's meeting were accepted as an accurate reflection of the meeting.
24.005	**Matters Arising** **Plenvu™ powder for oral solution as bowel preparation prior to endoscopy/diagnostics,** [redacted] We have been notified of a significant increase in contract price from 1st February for Moviprep™ sachets, the bowel preparation of choice prior to endoscopy, within BCU. BCU has previously supported the use of Plenvu™ as an alternative option during a shortage of Moviprep™ stock recently. Plenvu™ is very similar in use and licensing but with less volume for patients to administer. The cost is more efficient. Due to the need for a timely decision, the application was shared with the DTG executive members for out of committee approval so that our procurement team could prepare for the switch ahead of 1st February. The group approved the switch from the use of Moviprep™ to use Plenvu™ from 1st February 2024 as the BCU bowel cleansing preparation once all existing Movprep™ stock is used up. **Discussion**: • Endoscopy teams will capture and audit the bowel preparation score on their database system. • BCU has experience in using Plenvu™ during times of significant Moviprep™ shortage in the past year.

- The group considered the request from East to keep stock of both Plenvu™ and Moviprep™ but this was rejected as the use of Moviprep™ has now been superseded by Plenvu™. The tolerability of Plenvu™ is anticipated to be better.
- The results of the endoscopy audit are to be fed back to DTG members in due course.

Decision: **Approved to switch from Moviprep to Plenvu as bowel preparation of choice.**
BRAG status: Red

Trichloroacetic acid (TCA) for dermatology use, presented by [redacted], Dermatology Pharmacist (east)

Request to switch from using 90% TCA to 75% TCA was considered. Both strengths are unlicensed. From published evidence available and from experience, it is understood that 75% TCA is as effective and is less irritant than 90% TCA solution. The request considered was for a wholesale switch from using 90% to 75%. No cost impact– confirmed with pharmacy procurement team.

Discussion:

- The application is made from East and Central, but not West due to the lack of dermatologists in the West.
- Prescribing will all remain in secondary care.

Decision: Approved inclusion of trichloroacetic acid 75% on BCU formulary, making TCA 90% is non-formulary
BRAG status: Red

Naloxone SBAR, Presented by [redacted]

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The BCU Harm Reduction Team submitted a request for access to use the new formulation of naloxone as 1.26mg nasal spray pebble. It has been demonstrated to be equally as effective in reversing opioid overdose as the current formulations listed on the formulary. The North Wales Take Home Naloxone Programme currently has 2 naloxone preparations available. The programme, funded by Welsh Government, is a crucial part of the work to prevent and reduce drug related deaths. No cost impact. The SBAR presented is recommending to add the nasal spray pebble to the BCU formulary.

Decision: Approved pending financial approval
BRAG status: RED

Prescribing Dilemmas – private patients, Presented by [redacted]

All Wales Medicines Strategy Group has circulated, for consultation, a document to support prescribers when asked to prescribe a shared care treatment that has been initiated by a private healthcare provider. AWMSG are updating their Prescribing Dilemma document to make it more robust around this issue. It was shared for information and to raise awareness of this consultation.

Discussion:

- Shared care with private providers is widespread in field of mental health, e.g. ADHD, with patients seeking private consultation to gain a diagnosis, and asking GPs to continue the prescribing.

	• This document is welcomed to give an approach as to how NHS works with private health providers to provide safe care for our patients. • There is concern that private health providers may not be available to provide continual support long term. GP representatives didn't feel that the document currently helps GPs, as it list what they need to consider, but ultimately, the legal responsibility lies with the GP. • A private episode is a defined episode of care with an end point, whereas this document is for the shared care prescribing of a medication, where there is no end point and a need for continued care. • DTG members were informed that this is a document out for consultation, with a closing date of 14th February, if they are listed as part of the consultation process. Members who are not included on the list may share their comments with [redacted] before the closing date so that they can be shared with AWTTC. **Decision**: Document noted, any comments/feedback to be shared with [redacted] before the 14th February.
24.006	**MHRA Drug Safety Update** The MHRA Drug Safety Update for December 2023 and January 2024 were noted. **January's update included**: Valproate – new safety and educational materials to support regulatory measures in men and women under 55 years of age. Valproate must not be started in new patients (male or female) younger than 55 years, unless two specialists independently consider and document that there is no other effective or tolerated treatment, or there are compelling reasons that the reproductive risks do not apply. For the majority of patients, other effective treatment options are available. At their next annual specialist review, women of childbearing potential and girls receiving valproate should be reviewed using the revised valproate Annual Risk Acknowledgment Form. A second specialist signature will be needed if the patient is to continue on valproate, however subsequent annual reviews will only need one specialist. General practice and pharmacy teams should continue to prescribe and dispense valproate and if required offer patients a referral to a specialist to discuss their treatment options. Valproate should be dispensed in the manufacturer's original full pack. Fluoroquinolone antibiotics: must now only be prescribed when other commonly recommended antibiotics are inappropriate. Systemic fluoroquinolones can cause long-lasting, disabling and potentially irreversible side effects, sometimes affecting multiple body systems and senses. In the UK indications for systemic fluoroquinolones have been updates so they must only be used in situations when other antibiotics, that are commonly recommended for the infection, are inappropriate. Omega-3-acid ethyl ester medicine: dose-dependent increased risk of atrial fibrillation in patients with established cardiovascular diseases or cardiovascular risk factors. Atrial fibrillation is now listed as an adverse drug reaction with a "common" frequency (may affect up to 1 in 10 people) for medicines containing omega-3-acid ethyl esters licensed for the treatment of hypertriglyceridaemia. The observed risk was found to be highest with a dose of 4g/day. Advise patients taking omega-3-acid for the treatment of hypertriglyceridaemia to seek medical attention if they develop symptoms of atrial fibrillation. If a patient develops atrial fibrillation whilst taking these medicines for the treatment of hypertriglyceridaemia then the medicine

	should be discontinued permanently. Suspected adverse drug reactions associated with omega-3-acid ethyl ester medicines should be reported via the yellow card scheme. .**December's update included**: Aripiprazole: risk of pathological gambling. There has been an increase in the number of yellow card reports of gambling disorder and pathological gambling associated with aripiprazole use; concerns have also been raised about lack of awareness of this issue. In the UK, reports occurred in patients with and without a prior history of gambling disorder and the majority were reported to resolve upon reduction of dose or stopping treatment. Vitamin B12: cobalt sensitivity reactions typically present with cutaneous symptoms of chronic or subacute allergic contact dermatitis. Infrequent, cobalt allergy may trigger erythema multiforme-like reaction. Symptom onset may be immediate or delayed up to 72 hours post administration. Cobalt allergy is estimated to affect 1 to 3% of the population. **ACTION: circulate details of the Drug Safety Update to the relevant clinical teams and include link on the DTG Newsletter.**
24.007	**New medicine requests**
24.007.01	**Hybrid Closed Loop systems for managing blood glucose levels in type 1 diabetes (NICE TA 943)** **Presented by [redacted], Lead Diabetes Nurse (BCU), [redacted], Consultant Endocrinologist (East), [redacted], Diabetes Specialist Nurse and pump expert (East).** Disclosure: [redacted] is currently the lead diabetes nurse for Wales sitting on the All Wales Diabetes Strategic network and working with other clinical leads across Wales in reviewing the NICE TA for Hybrid Closed Loop (HCL) systems. The hybrid closed loop (HCL) systems are technology device insulin pump with continuous glucose monitoring which allows automated insulin delivery. HCL systems are recommended as an option for managing blood glucose levels in type 1 diabetes for adults who have an HbA1c of 58mmol/mol (7.5%) or more, or have disabling hypoglycaemia despite best possible management with at least 1 of the following: - Continuous subcutaneous insulin infusion (CSII) - Real-time continuous glucose monitoring - Intermittently scanned continuous glucose monitoring. HCL systems are recommended as an option for managing blood glucose levels in children and young people. HCL systems are recommended as an option for managing blood glucose levels in type 1 diabetes for women, trans men and non-binary people who are pregnant or planning to become pregnant. Only use HCL systems with the support of a trained MDT experienced in CSII and continuous glucose monitoring in type 1 diabetes. Only use HCL systems if the person or their carer is able to use them. The clinical and cost effectiveness is well documented and reviewed within the NICE TA 943. The application has been taken through the NICE impact assessment group prior to presenting to DTG today. In normal circumstances, a NICE TA has a defined period of time for implementation. The Welsh Government have asked for a derogation of that, so that we have a 5 year phasing in plan of adoption of HCL services in Wales. In North Wales there are around 4,000 individuals

with type 1 diabetes, and in adult services, there are around 20 new patients presenting with type 1 diabetes into adult services every year.
The NHS Executives through the Strategic Diabetes Network in Wales have been asked to propose an implementation plan and this will be the first phase. Our priorities will be children and young people, women planning for pregnancy or who are pregnant, and the largest proportion will be those who have been diagnosed with type 1 diabetes within the first year, taking back to 2020 to account for the fact there may have been poor access to the usual support that we would have given due to COVID.
The anticipated number have been derived from those with type 1 diabetes, with 2/3rd probably having HbA1c over 58 mmol/mol, then looking at the priority groups, of which from clinical practice and experience, physicians are estimating around 50% of those who have been offered have taken it up.
In adult services, clinical staff are developing experience in this and currently have a number of adults across the 3 sites already using HCL systems. Pump expertise is limited to a couple of members of the team at each site which does limit the capacity. A business plan is being worked with team members and finance which is factoring the growth in activity and the impact of this on the sessions offered to adults with type 1 diabetes from the specialist teams.
From experience, the patients that have been started on HCL systems are doing exceptionally well with much improved HbA1c, better quality of life and having to think a lot less about their diabetes.

Children services within BCU are already offering HCL systems. They are prioritising the pre-school age group and are also making sure as much as possible that children and young people that are coming through to adult services are also offered this technology in adult services.

Discussion:

- This is a revolution in diabetes, and has potential to be life changing for so many patients. The diabetes technology group will need to co-ordinate reviewing the various HCL available, to ensure choice for patients.
- Review of patients started on HCL systems will be undertaken by the specialist teams. The specialist would encourage active repatriation into secondary specialist services for any adults with type 1 diabetes who maybe lost to follow up in the past as we need to ensure that everyone who is eligible gets an opportunity to be offered the HCL systems.
- The business case will be completed in the next couple of months. It is important to get the business case approved to ensure that we will be in a position to offer the service to the degree that we would wish to do according to the planned phase approach.
- The technology (i.e. pump and continuous glucose monitoring (CGM)) are mostly all within the All Wales framework, therefore procured, not prescribed; although some of the CGMs available on prescription will have capability for HCL systems. The technology is rapidly changing but also to acknowledge that change and competition will drive down the costs in future.
- Primary care will continue to need to prescribe insulin for the pumps and also basal insulin and short acting insulin in the event of system failure. Back up supplies of blood glucose testing strips and also blood ketone testing strips will also need to be prescribed for use during acute illness to make sure they do not develop DKA.
- Concern that some aspect of prescribing is missed in primary care, for example when insulin has not been ordered for a long period, and then taken off repeat, when patients are on CSII and suggestion that information needs to be sent out to colleagues in primary care. A newsletter is being produced by [redacted], if anyone has any further contributions to contact [redacted] directly.

Decision: Approved pending financial approval from Senior Leadership Team.

	BRAG status: RED
24.007.02	**Semaglutide for managing overweight and obesity (NICE TA 875)** **Presented by [redacted], Service Lead Weight Management Service (level 3) BCU, [redacted], Consultant Lead for Weight Management Service BCU.** **Background:** This application is for use of semaglutide (Wegovy) within BCU level 3 weight management service. BCU has a small level 3 service and team covering North Wales. NICE TA 875 Semaglutide is recommended as an option for weight management, including weight loss and weight maintenance, alongside a reduced calorie diet and increased physical activity in adults, only if: it is used for a maximum of 2 years, and within a specialist weight management service providing MDT management of overweight or obesity (including tier 3 and 4), and they have at least 1 weight-related comorbidity and: a BMI of at least 35kg/m2 or a BMI of 30.0kg/m2 to 34.9kg/m2 and meet the criteria for referral to specialist weight management services in NICE guideline on obesity: identification, assessment and management. Due to the capacity of the BCU team, the service will be tighter and will specifically be patients with BMI more than 45kg/m2 and co-morbidities, BMI over 60kg/m2 who cannot be listed for bariatric surgery until their BMI is below 60 and those that need to specifically lose weight prior to surgery e.g. joint surgery. From the data, lifestyle changes can provide 5-10% weight loss, but with semaglutide alongside this, they can achieve 15% weight loss. Prescribing semaglutide will be integrated within the current service, so patients considered for this would receive a 3 month lifestyle support in readiness to starting semaglutide as there is a recognised need for lifestyle support alongside the medication. Once patient has managed to lose the weight or hit plateau state of weight loss, the semaglutide would be stopped and the weight management team would be ready to engage the patient to the next stage of their weight management programme. Discussion: • The BCU approach will be tighter than NICE guidance, therefore not compliant with NICE TA 875 due to staffing capacity in the weight management service within BCU. The BCU level 3 weight service will only see patients with BMI over 45kg/m2, whereas NICE specifies tier 3 to be over 35kg/m2. The capacity/staffing issue has been escalated and is on the BCU risk register. • A business case was rejected when the application for liraglutide was presented at DTG – however, there is no plan to re-submit this at present. • Semaglutide will replace liraglutide as the GLP-1 of choice in weight management. Liraglutide has been unavailable and therefore not been used within BCU. • If, following treating the niche/tighter group of patients, and capacity available, it was raised whether more patients, as per NICE TA criteria could be considered however, the team do not anticipate that they will be able to give access to more than the proposed tighter group of patients at present. • Semaglutide will only be prescribed for this indication within the weight management service. **Decision: Approved pending financial agreement from Senior Leadership Team** **BRAG status: RED**

24.007.02	**Ryaltris™ for treatment of moderate to severe nasal symptoms associated with allergic rhinitis.** **Presented by: [redacted], ENT Consultant, Central IHC** Ryaltris™ (olopatadine and mometasone) is indicated for adults and adolescents 12 years and older for the treatment of moderate to severe nasal symptoms associated with allergic rhinitis. This application would be in addition to Dymista™ currently on the formulary. Ryaltris™ contains mometasone as steroid component. Proposal is for this to be used as another 3rd line option following antihistamines and nasal steroid/antihistamine and avoiding allergen. From clinical evidence, it appears that mometasone is more effective for management of nasal obstruction compared to fluticasone. **Discussion**: • Queried whether need Dymista™ to remain on the formulary. Team feel that both Dymista™ and Ryaltris™ are still required as although both are similar, there are some differences which may benefit patients. If patient has conjunctivitis/itchy eye symptoms, Dymista™ would be preferred however if nasal obstruction is the main symptom, Ryaltris™ would be the best option. • Ryaltris™ is a fine mist, and does not shoot to the back of the throat, and seems better tolerated, may improve compliance with no taste/smell. **Decision: Approved pending finance approval from Senior Leadership Team** **BRAG status: Green**
24.007.03	**Labinic acid (Probiotic) oral drops in neonates** **Presented by [redacted], Advanced Neonatal Nurse Practitioner, Central IHC.** This applications was made on behalf of BCU for inclusion of probiotics on the formulary for babies that fit into a specific gestational model. This will be used in neonates only, and for infants born before 32 weeks gestation or any preterm with very low birth weight (i.e. birth weight of less than 1.5kg and born between 32 and 36 weeks gestation). Use of probiotics improve patterns of gut colonisation and reduce risk of gut condition necrotizing enterocolitis (NEC) and death. It is a food supplement, and therefore not classified as a medicine in the UK/EU. Supplementation will continue until 34 weeks corrected gestational age or until discharge. Discharge is likely to be at or slightly before 40 weeks corrected gestational age. This treatment will not need to be continued following the babies discharge from the neonatal unit, and therefore no requirements for GPs to continue prescribing. Discussion: • BCU Microbiologists are in support of this application. • Currently, when babies are being transferred back to BCU from England, the neonatal teams are having to stop probiotic prescriptions. • A guideline has been discussed at the last MPPP meeting to support the use of labinic drops within the health board. This was based on an All-Wales guideline. **Decision: Approved pending financial agreement from Senior Leadership Team** **BRAG status: RED**

24.007.04	**Ferric maltol as 2nd line treatment option for mild-moderate IBD patients with iron deficiency anaemia (AWMSG)** **Presented by [redacted]. Gastroenterology Specialist Pharmacist, East.** Ferric maltol has been approved by AWMSG as an option for restricted use within NHS Wales. Ferric maltol is restricted for use in adult patients with inflammatory bowel disease (IBD) who have mild-moderate iron deficiency anaemia (IDA) and have failed on, or are intolerant to, standard oral iron products and are considered suitable for intravenous iron. It is licensed for the treatment of iron deficiency in adults, however, this formulary application is only for IBD patients as per AWMSG recommendation. 1st line treatment would be standard iron preparations (such as ferrous sulphate/fumarate), however approximately 60% of IBD patients will fail on these as not able to tolerate or it has not had the desired effect. Currently, these patients would then be offered IV iron, however, ferric maltol could be a second line option alongside IV iron. It will not always be the second line option, e.g. patients who need to replace their iron stores quickly will need to have IV iron. Ferric maltol brings up the iron stores slowly. Ferric maltol is an oral preparation, and therefore will reduce the need for some patients to go to the IV suites for IV iron administration. It has been difficult obtaining appointments for some patients recently, therefore this will relieve appointments and avoid using IV suites in some cases. Suggested that 12 weeks treatment is required, however can be carried on life-long. The benefit of treatment would be reviewed after 12 weeks and adjusted according to response/blood tests. No dose adjustments required for renal or liver impairment. Discussion: • IBD patients notoriously struggle to absorb oral iron, and with the capacity issues at all sites for appointments for IV iron, this would be a beneficial other oral option. • This application is for IBD only patients. BCU will restrict this for IBD only patients, to gain experience in using ferric maltol. • A BCU Iron Deficiency Guideline is being drafted which could support prescribing of standard oral iron preparations – Ferric maltol will be included for IBD patients only. • Cost – more expensive than standard iron preparations, however cheaper than IV iron administration. • Prescribing will stay within secondary care. For IBD patients, if disease is well-controlled, unlikely to require this long-term, but patients will be managed by the Gastro team. **Decision: Approved pending financial agreement from Senior Leadership Team** **BRAG status: RED**
24.007.05	**Rimegepant for preventing episodic migraine in adults (NICE TA 906)** **Presented [redacted]** The Walton Centre Drug & Therapeutics Committee has approved the use of rimegepant in line with NICE as an option for preventing episodic migraine in adults who have at least 4 and

	fewer than 15 migraine attacks per month, only if at least 3 preventative treatments have not work. The alternative is either subcutaneous injections given every 4 weeks (via homecare), or IV infusion given every 12 weeks at the Walton Centre. Walton have approved a protocol, which stipulates that they would provide the first 12 weeks of treatment, they would then reassess the patient, determine if they are benefitting from treatment and provide a further 2 months' supply. They are then requesting primary care to take over the prescribing – this is the stance they have taken in Merseyside. This application will bring us in-line with the Walton Centre and their protocol. This has been discussed at the BRAG group who supported it being AMBER Retained, with prescribing by primary care, and an annual review of the patient at the Walton Centre. Discussion: • Confirmation of funding – the first year funding will come from New Treatment Fund, however the cost pressure will then be in primary care as this will bypass secondary care. • There are no monitoring requirements for primary care. • There are ongoing discussions for the use of rimegepant for the treatment of migraine (NICE TA 919). **Decision: Approved pending financial agreement from Senior Leadership Team** **BRAG status: AMBER Retained**
24.008	**NICE and AWMSG Impact Assessments** **Selpercatinib for treating RET fusion positive advanced non-small cell lung cancer in adults (NICE TA 911, July 2023)** Selpercatinib, an oral treatment, dosing weight based and is taken until disease progression. From study, it identified that patients remained on treatment for approximately 25 months. There is a PAS price in place. The comparator here is platinum therapy in combination with pembrolizumab. The evidence considered by NICE gives some uncertainty in terms of outcome benefits and the longevity of treatment, therefore there is some uncertainty in relation to the cost-effectiveness. There is a commercial access agreement in place which makes it affordable to the NHS and the BCU oncology team are keen to use selpercatinib and have it available as an option for their patients with this specific mutation. **Decision: Approved pending financial agreement from Senior Leadership Team** **BRAG status: RED** **Daratumumab in combination with lenalidomide and dexamethasone for untreated multiple myeloma (NICE TA 917, October 2023)** Daratumumab is a subcutaneous injection given with lenalidomide and dexamethasone both oral treatments. The median duration of treatment in the trials was 25 months. It has a cost per QALY of £20k to £30k. It is given continuously until disease progression or unacceptable toxicity. Previously, patients would have had combination of lenalidomide with dexamethasone only, therefore addition of this s/c treatment has identified a potential pressure for cancer service. The potential staffing issue is being looked at within the cancer services, however it was recognised that due to limited treatment options they wanted access to daratumumab as it demonstrated an increased benefit for those patients who received it on top of the oral therapy. **Decision: Approved pending financial agreement from Senior Leadership Team.**

	BRAG status: RED **Durvalumab with gemcitabine and cisplatin for treatment of unresectable or advanced biliary tract cancer (NICE TA 944, January 2024)** The comparator to this treatment is gemcitabine and cisplatin alone. The drugs are given in combination for 8 cycles and then durvalumab would be continued alone until disease progression. Durvalumab is an infusion that is administered every 28 days. Topaz trial data determined the median duration was 7.3 months but this ranged from 0.1 to 24 months in the study. This will have an impact on staffing within the cancer service, assessment of which is being compiled within the service. **Decision: Approved pending financial agreement from Senior Leadership Team.** **BRAG status: RED** **Olaparib for previously treated BRCA mutation positive hormone relapsed metastatic prostate cancer (NICE TA 887, May 2023)** This has been considered previously, however there was an issue in relation to the provision of the BRCA testing for patients with prostate cancer. This issue has now been resolved by Welsh Government for all health boards at the start of this year. It is therefore possible to make this treatment choice available to all patients residing in Wales. Olaparib is an oral treatment and given until disease progression; the trial data identified that patients typically have 9 cycles of treatment. The comparator is IV cabazitaxel, therefore there will be benefit in terms of staffing capacity as olaparib is an oral treatment. **Decision: Approved pending financial agreement from Senior Leadership Team.** **BRAG status: RED** **Zanubrutinib for the treatment of chronic lymphocytic leukaemia (NICE TA 931, November 2023).** Zanubrutinib is recommended as an option for treating CLL if it is untreated and there is a 17p deletion or tumour protein 53 (TP53) mutation or there is no 17p deletion or TP53 mutation and fludarabine + cyclophosphamide + rituximab or bendamustine + rituximab is unsuitable, or the disease is relapsed or refractory. This was considered, but the haematologists have subsequently concluded that they have suitable alternatives that they would prefer to remain with as they have knowledge and understanding of their benefits and complexities of management of patients taking those treatments. They are opting to keep this as a purple option. **Decision: Approved to remain as Purple option** **BRAG status: PURPLE**
24.009	**New Treatment Fund** The New Treatment Fund spreadsheet was noted. **Update on pathway for signing off new drug applications ([redacted]).** The pathway to approve new medication applications and who has the ability to approve certain levels of financial instructions within the health board has been approved and a paper is being submitted to the Senior Leadership Team this month for agreement. The process for future DTG applications (NICE approved or non-NICE approved) will ensure that executives are sighted of all output from this group and the subsequent impact on the IHC and the Pan-BCU services, be that in year one to year five as a consequences of the decisions made by this

	group. This process will give greater assurance and response in terms of the approval of the decisions made at DTG by executives in future.
24.010	**NICE Technology Appraisals, ratified AWMSG Decisions** **<u>NICE Technology Appraisals:</u>** Foslevodopa-foscarbidopa is recommended as an option for treating advanced levodopa-responsive Parkinson's in adults whose symptoms include severe motor fluctuations and hyperkinesia or dyskinesia, when available medicines are not working well enough, only if they cannot have apomorphine or deep brain stimulation, or these treatments no longer control symptoms. (NICE TA 934, November 2023). Secukinumab is recommended as an option for treating active moderate to severe hidradenitis suppurativa (acne inversa) in adults when it has not responded well enough to conventional systemic treatment, only if adalimumab is not suitable, did not work, or has stopped working. (NICE TA 935, December 2023). Pembrolizumab plus chemotherapy with or without bevacizumab is recommended as an option for treating persistent, recurrent or metastatic cervical cancer in adults whose tumours express PD-L1 with a combined positive score of at least 1. It is recommended only if pembrolizumab is stopped at 2 years of uninterrupted treatment, or earlier if the cancer progresses. (NICE TA 939, November 2023). Velmanse alfa is recommended as an option for treating the non-neurological signs and symptoms of mild to moderate alpha-mannosidosis, only if treatment is started in people under 18 years (it can be continued in people who turn 18 while on treatment). (NICE HST 29, December 2023). Empagliflozin is recommended as an option for treating chronic kidney disease (CKD) in adults, only if: it is an add-on to optimised standard care including highest tolerated licensed dose of ACE inhibitors or angiotensin-receptor blockers, unless these are contra-indicated, and people have an eGFR of 20mL/min/1.73m2 to less than 45mL/min/1.73m2 or 45mL/min/1.73m2 to 90mL/min/1.73m2 and either a urine albumin-creatinine ratio of 22.6mg/mmol or more OR type 2 diabetes. (NICE TA942, December 2023). Targeted-release budesonide is recommended as an option for treating primary immunoglobulin A nephropathy (IgAN) when there is a risk of rapid disease progression in adults with a urine protein-to-creatinine ratio of 1.5g/g or more. Targeted release budesonide is recommended only if it is an add-on to optimised standard care including highest tolerated licensed dose of ACE inhibitors or angiotensin-receptor blockers, unless these are contraindicated. (NICE 937, December 2023) Sebelipase alfa is recommended as an option for long-term enzyme replacement therapy in Wolman disease (rapidly progressive lysosomal acid lipase deficiency (LAL-D), only if people are 2 years or under when treatment starts. (NICE HST 30, January 2024). Olaparib with bevacizumab is recommended, within its marketing authorisation, for maintenance treatment of high-grade epithelial ovarian, fallopian tube or primary peritoneal cancer in adults whose cancer has completely or partially responded after 1st line platinum-

based chemotherapy with bevacizumab, is advanced (FIGO stages 3 and 4), is homologous recombination deficiency positive (defined as having either a BRCA1 or BRCA 2 mutation, or genomic instability. (NICE TA 946, January 2024).

NICE Technology Appraisals – Not recommended

Lutetium-177 vipivotide tetraxetan is not recommended, within its marketing authorisation, for treating prostate-specific membrane antigen-positive hormone-relapsed prostate cancer in adults. (NICE TA 930)

Cabozantinib is not recommended, within its marketing authorisation, for treating locally advanced or metastatic differentiated thyroid cancer (DTC) that is unsuitable for or refractory to radioactive iodine, and that has progressed after systemic treatment, in adults (NICE TA 928)

NICE Technology Appraisals – Terminated

NICE TA 932, November 2023 – Decitabine-cedazuridine.
NICE is unable to make a recommendation on decitabine-cedazuridine (Inaqovi) for untreated acute myeloid leukaemia in adults when intensive chemotherapy is unsuitable. This is because Otsuka pharmaceuticals did not provide an evidence submission.

NICE TA933, November 2023 – Tisenlecleucel.
NICE is unable to make a recommendation on tisagenlecleucel (Kymriah) for treating relapsed or refractory diffuse large B-cell lymphoma in adults after 2 or more systemic therapies. This is because Novartis did not provide a complete evidence submission.

NICE TA 936, November 2023 – Idecabtagene vicleucel
NICE is unable to make a recommendation on idecabtagene vicleucel (Abecma) for treating relapsed or refractory multiple myeloma after 3 or more treatments in adults. This is because BMS did not provide an evidence submission.

NICE TA 938, December 2023 – Dupilumab
NICE is unable to make a recommendation on dupilumab (Dupixent) for treating eosinophilic oesophagitis in people 12 years and older. This is because Sanofi did not provide an evidence submission.

NICE TA 941, December 2023 – Ravulizumab
NICE is unable to make a recommendation on ravulizumab (Ultomiris) for treating AQP4 antibody-positive neuromyelitis optics spectrum disorder in adults. This is because Alexion Pharma UK withdrew its evidence submission.

NICE TA 940, December 2023 – Ravulizumab
NICE is unable to make a recommendation on ravulizumab (Ultomiris) for treating generalised myasthenia gravis in adults. This is because Alexion Pharma UK withdrew its evidence submission.

AWMSG recommendations

Nil

One Wales Interim Commissioning Decisions

Nil

	NICE Evidence Summaries Nil **Health Technology Wales Guidance** Nil
24.011	**Reports back (from new medicine applications)** Nothing to report back.
24.012	**Formulary updates** **<u>Request to add Gadobutrol and gadoxetate disodium – gadolinium based (contrasts used in diagnostics) onto the formulary</u>** Based on historic use as per new PGD booklet. This booklet replace three PGDs – PGD 257, 261 and 262. The PGD was presented at MPPP for a periodic review. These contrasts are currently not listed on formulary. Request to add to reflect current practice and PGD. **Decision: Approved** **BRAG status: RED** **<u>Request to add Dental Lignospan (lidocaine 2% and adrenaline 1:80,000 strength) onto the formulary</u>** Based on historic use as per PGD 186. The PGD was presented at MPPP for a periodic review. Not currently listed on formulary. Request to add to reflect current practice and PGD. **Decision: Approved** **BRAG status: RED** **<u>Procurement Sitrep – November 2023</u>** The sitrep from procurement team was noted by the group.
24.013	**DTG Decision Newsletter** DTG newsletter was deferred pending the financial approval of decisions.
24.014	**IPFR Decisions** IPFRs **SUPPORTED** by DTG executive members and IPFR panel:

Medicine requested	Indication
Amivantamab	Non-small cell lung cancer
Pembrolizumab	Lung cancer
Anakinra	Recurrent pleuritic
Lanreotide	Polycystic liver and kidney disease
Guanfacine	ADHD
Sotrovimab	Urticaria
Baricitinib	Dermatomyositis
Obinutuzumab	AAV-microscopic polyangitis

Copal G&V bone cement	Infected joint replacement surgery
Rituximab	Systemic Lupus Erythematosus
Varicella vaccine	Immunisation ahead of methotrexate initiation
Pregabalin	Reducing regimen for pregabalin misues
Infliximab	Hidradenitis Suppurativa
Agomelatine	Recurrent depression
Varicella vaccine	Immunisation ahead of methotrexate initiation
Boric acid pessaries	Candida glabrata infection
Anakinra	Refractory gout
Dosulepin	Recurrent depression
Bendamustine	Hodgkin lymphoma
Guanfacine	ADHD and tics
Cenobamate	Refractory epilepsy

IPFRs **DECLINED** by DTG executive members and IPFR panel:

Medicine requested	**Indication**
Baricitinib	Alopecia universalis
Baricitinib	Alopecia universalis
Pembrolizumab	Nasap polyp carcinoma
Abemaciclib	Localised breast cancer

IPFRs **WITHDRAWN:**

Medicine requested	**Indication**
Abiraterone	Adenocarcinoma prostate
Panitumumab	Metastatic sigmoid cancer

IPFR **feedback forms** received:

Medicine requested	**Indication**	**Outcome**	**Request for ongoing treatment**
Adalimumab	Palmoplantar psoriasis	No improvement	No
Adalimumab (high dose)	Hidradenitis suppurativa	No improvement	No
Agomelatine	Recurrent depression	No improvement	No
Bendamustine	Hodgkin lymphoma	Partial response	Yes for further 2 cycles

24.015	**National Drug Related Publications** **National Prescribing Indicators – Analysis data to September 2023.** The national prescribing indicators analysis data were noted by DTG members.
24.016	**Medicines Value Improvement Group (MVIG)** This group has not met.
24.017	**DTG Sub Groups**
24.017.01	**Medicines Policies, Procedures and PGDs** **<u>For approval:</u>** Updated MMPGD 286 Zostavax - UKHSA have extended the expiry date of Shingles vaccine (Zostavax) – extended from 30 June 2024 to 31 October 2024. This is noted within the PGD. Minor update to the intravenous immunoglobulin charts (IVIg) in line with the updated clinical guideline. Minor update MM03 Independent Prescribing Protocol. A minor change in section 11.3 due to change in legislation which now allows paramedics to prescribe certain CD and they requested that this was updated in line with this change. Therapeutic radiology can also prescribe CDs, but there are discussions ongoing with their professional leads before they are added to the policy. **<u>For noting</u>**: MM61 Guideline for the Management of Dry Eyes in Adults. A footnote has been added to refer back to the patient safety message from UKHSA: Avoid all carbomer containing eye gels patients with cystic fibrosis, patients being cared for in critical care settings, or who are severely immunocompromised and in hospital, and for patients awaiting lung transplantation. This is precautionary measures due to the potential contamination of Burkholderia cenocepacia. **<u>Documents approved by MPPP (pending some minor amendments):</u>** **<u>Written Controlled Documents:</u>** Clinical guideline: Management of Spontaneous Intracerebral Haemorrhage. Approved with minor amendments. Document submitted retrospectively as already approved by CEG in December 2023 due to urgent need. MM33 Guideline for the safe use of Phenytoin. This is based on The Walton Centre's guideline, adapted for use within BCU. Approved with minor amendments. Probiotics in Preterm and Very Low Birth Weight Infants. Guideline to accompany the DTG application discussed in item 24.007.04. Guideline is based on All Wales document. Approved with minor suggestions for author to consider.

	Scabies treatment options. Ivermectin was approved for care home residents only on dermatology or microbiology advice only. Approved with minor amendments. **Medicines Management Policy/Procedures/Protocols:** MM34 Antimicrobial Restriction and Protection Policy. Updated Policy approved with minor amendments. Policy approved prior to MPPP by ASG. **Prescription Chart** Nil **Standard Operating Procedures:** MM89 Medicines Management in Domiciliary Settings in North Wales. Updated review of current guideline. Approved but escalating the need to review section 16: Transcription of Medications. Group are concerned that there is a need for care workers to write an interim MAR chart if not provided by a community pharmacy. This is current practice but work is needed to review this and utilise medication label or copy of discharge prescription to minimise the risk of transcription. **Patient Group Directions:** MMPGD 258: PGD for the administration of Sodium Chloride 0.9% by Registered Radiographers for CT and MRI imaging investigations or procedures working within radiology services in BCUHB. Updated PGD, approved with minor amendments. MMPGF 260: Administration of hyoscine butylbromide injection by registered radiographers for CT and MRI imaging investigations. Updated PGD approved with minor amendments. PGD booklet – intravenous administration of gadolinium based contrast media, by registered radiographers for MRI imaging investigations and procedures working within radiology services in BCUHB. Updated PGD approved with minor amendments. PGD 186 Dental Lignospan. Updated PGD approved with minor amendments. PGD 187 Dental Articaine. Updated PGD approved with minor amendments. PGD Dental Durophat. Updated PGD approved with minor amendments. **Decision: DTG endorsed the above documents and decisions.**
24.017.02	**Wound Management Steering Group** A meeting was held on the 6th February chaired by [redacted]. This sub group will be re-instated and will be meeting quarterly. They have agreed to share minutes/agenda/chair's actions with DTG. **Decision: DTG supported the resurrection of this group.**
23.017.03	**BRAG** The BRAG group have met twice in the last month. The key items discussed includes: • Request for BRAG status of rimegepant to be be AMBER Retained as discussed in item 23.007.06

	• A re-draft of the previous shared care agreement for hydroxychloroquine in rheumatological conditions in adults was reviewed. The SCA was in place until Royal College of Ophthalmology concluded that there was no need for ongoing ophthalmology monitoring in 2011. However, the Royal College has revised their guidance and have reinstated the need for ongoing monitoring with the frequency dependant on patients circumstances. The updated SCA is supported by rheumatology and was approved by BRAG. The SCA will be put back in place, and BRAG status of hydroxychloroquine changed to AMBER with SCA for these conditions. • A request for review of BRAG status for gonadorelins (goserelin,leuprorelin, triptorelin, degarelix). These were listed historically as AMBER, however with the revision of AMBER status they became AMBER Retained. There is a local enhanced service for the provision of these treatments. The administration of these treatments in primary care clinicians in specialist service had raised concerns that they did not have capacity within their service to provide the first dose. Request to review from AMBER Retained to AMBER Advise. The BRAG group supported this request as many felt they were providing the first dose currently and therefore support the BRAG status change. • There was a request from specialties to revise the wording in the AMBER Retained communication document. It had been extracted from the response letter that sits in the shared care agreement. The wording has been revised and now specifies that “I have given your patient at least one month supply of treatment and I’ve reviewed the patient and they are now stable, if you’re in agreement, please continue to prescribe the treatment”. This has been shared with the specialists and the BRAG group accepted the revised wording. • A request from oncology to review the BRAG status of the hormone treatments for breast cancer and the management of drugs such as anastrozole, letrozole, tamoxifen and exemestane to revise those from AMBER Retained to AMBER Initiate. Following discussion with the oncology team around the long term treatment plan for these patient and the follow up DEXA scans, the BRAG group supported that change from AMBER Retained to AMBER Initiate for all those drugs. • An updated version of the Amiodarone SCA in arrhythmias in adults. This was an existing document that has been in place for a number of years that was up for revision. Upon minor amendments, the document was approved for further use. • A request to review the heart failure drugs that had been considered at DTG in December, where an application had been submitted for GREEN formulary BRAG status however the applicant in DTG meeting opted for AMBER Initiate and the BRAG group after a long discussion endorsed this decision of AMBER Initiate and did not consider GREEN as sufficient for this group of medicines and therefore did not support this BRAG revision. • A revised SCA for denosumab following the removal of the need for routine Vitamin D monitoring from the SPC, the SCA was updated to remove Vitamin D monitoring and this was supported by the bone unit specialist and the BRAG group. • The SCA for methylphenidate in adults with ADHD was discussed. There was an objection raised in relation to the level of payment that practitioners are eligible to claim for the work required for General Practice for management and ongoing prescribing of ADHD treatments in adults, this will be discussed at a primary care contract management committee later this month.

	• A draft guideline was reviewed for the management of DVT in high risk patients who are travelling. This was at the request of haematology service and the draft was supported by BRAG group and will be taken to MPPP next as part of the approval process. • We reviewed a number of mental health medicines management guidelines • MM50 Medicines Management Guideline for the Adult Mental Health Home Treatment Teams – this was supported by the BRAG group with no comments • MM35 Prescribing for cognitive symptoms in people diagnosed with Dementia – approved by the BRAG group with no comments. • MM52 Prescribing Antipsychotics in Dementia. There was extensive discussion about this document. The group did not support the document as it currently stand, the comments have been fed back to the authors and they have been invited to attend the next BRAG meeting to discuss. • Testim, a formulation of testosterone, which has been discontinued, so we requested the revision of the BRAG status from AMBER to BLUE. • A revised SCA for azithromycin in adults was discussed, with a minor amendment to the monitoring requirement as there is no longer the need for U&Es and the frequency of LFT testing had changed from 3 monthly to 6 monthly in-line with the BTS guidelines. **Decision**: **DTG endorsed the above decisions**
24.017.04	**NICE and AWMSG Impact Assessments Group** The group has met, there was nothing in addition to what was already discussed to report back to the group..
24.017.05	**Approved Prescribable Medical Devices** The group has not met.
24.018	**Minutes from Medicines Management Groups**
24.018.01	**Mental Health and Learning Disabilities** The minutes of this group were noted. The key items for noting include: • Valproate prescribing – the team are coming up with a procedure for all new patients initiated on valproate and will also be looking at the database as per MHRA guidance. • There will be another audit in primary care on rapid tranquilisation in the next month.
24.018.02	**Cancer, Haematology, and Palliative Care** Feedback by [redacted]. Key items for noting: • The All Wales Guideline for the management of hydration during cisplatin therapy has been adopted and also the prevention and management of tumour lysis syndrome. • Following a death of a patient taking herbal remedies in combination with their cancer treatment, as part of the inquiry, there was a request for a development of a herbal patient information leaflet. This has been drafted for BCU use. There is also an All-

	Wales version being drafted, however the BCU leaflet will be used until the All-Wales document is being approved.
24.018.03	**North Wales Neuroscience Medicines Management Meeting** This group has not met.
24.018.04	**Respiratory Medicines Management Group** The group has not met
24.018.05	**HMP Berwyn Medicines Management Group** The documents were noted. A question raised at the last DTG group regarding discharge prescriptions from the prison. The number of days of discharge for men leaving custody in HMP Berwyn is 7 days, so a minimum of 7 days is given; if they were in possession when they were in prison they may have more, but if they were not in possession, for safety or risk of harm to themselves, they will only be given 7 days supply on discharge.
24.019	**Controlled Drug Local Intelligence Network** No representative present at DTG.
24.020	**Safer Medicines Steering Group** Feedback from [redacted], Documents noted. The group has been busy working on patient safety alerts – including hyperkalaemia, valproate in terms of dispensing and as discussed in item 24.018.01. This is our current piece of work and there will be more feedback from this task and finish group and this will also be fed back to the patient safety group.
24.021	**Minutes from Antimicrobial Stewardship Group (ASG)** Presented by [redacted]. Concern raised again regarding lack of amikacin therapeutic monitoring still not available within biochemistry, which is a risk. There is still an issue with teicoplanin being recorded as virology other leading to clinicians missing the therapeutic drug monitoring level. These are 2 items for escalation **Decision: Noted for escalation to CEG.**
24.022	**Any other business**
24.023	**Matters of significance** Nil

24.024	**Date of the Next Meeting** Wednesday 6th March 2024