NHS
South Yorkshire
Integrated Care Board

Minutes of the Meeting of the Sheffield Area Prescribing Group
16th November 2023

Present:

Dr Andrew McGinty.GP and joint Chair of APG, NHS South Yorkshire ICB
Heidi Taylor. Deputy Director, Medicines Optimisation Team. NHS South Yorkshire ICB
Sharron Kebell. Specialist Commissioning Pharmacist, NHS South Yorkshire ICB
Emily Parsons. Medicines Governance Pharmacist, NHS South Yorkshire ICB
Abiola Allinson. Chief Pharmacist. Sheffield Health & Social Care FT
Dr Jonathan Mitchell. Consultant representative, Sheffield Health & Social Care FT
Joanne Wragg. Director of Pharmacy, Sheffield Children's FT
Andrew Moore. Deputising for STHFT Chief Pharmacist.
Dr Laura Smy. GP and Representative of Local Medical Committee.
Dr Rhona Leadbetter. GP, NHS South Yorkshire ICB
Dr Trish Edney. Lay member. Healthwatch representative
Helen Taylor. Clinical Effectiveness Pharmacist, NHS South Yorkshire ICB
Thomas Bisset. Community Pharmacy South Yorkshire representative.

Absent

Dr Zak McMurray. Medical Director and joint Chair of APG, NHS South Yorkshire ICB
Barbara Obasi. Clinical Effectiveness Pharmacist, NHS South Yorkshire ICB
Mr Veeraraghavan Chidambaram-Nathan. Consultant representative STHFT
Helen Caley. PCN Pharmacist representative
Richard Crosby. Head of Practice Support, NHS South Yorkshire ICB

In Attendance:

Deborah Morris. Clinical Effectiveness Technician. NHS South Yorkshire ICB
Jill Rigby. Pharmacist, NHS South Yorkshire ICB
Mark Denial. DSN, Sheffield Children's FT
Hilde Storkes. Formulary Pharmacist, NHS South Yorkshire ICB
Charlotte Norman. Trainee Pharmacist
Alysha Robins. Trainee Pharmacist

		ACTION
1.	**Apologies for Absence**	
	Apologies for absence have been received from, Dr Z McMurray, Barbara Obasi, Helen Caley, Richard Crosby and Mr Nathan The chair welcomed Jill Rigby, Mark Denial, Hilde Storkes and trainee pharmacists Charlotte Norman and Alysha Robins who will be observing today. Richard Crosby will also now be joining the APG membership and Barbara Obasi has returned to work, though both have sent apologies for the meeting today. The Chair declared the meeting was quorate.	

2.	**Declarations of Interest**	
	JM advised, with reference to the prolactin agenda item today, that he is a specialist advisor to NICE on psychosis and was involved in writing NICE guidance relevant to that topic. AMcG stated that this should not preclude JM from contributing to that discussion.	
3.	**Minutes of the October Area Prescribing Group**	
	LS asked that the comment on page 4, *LS agree that it would be part of the diabetes annual review and added that medication would not be stopped in primary care, medication would be reauthorised.* Is reworded to read. *LS agree that it would be part of the diabetes annual review and added that medication would just be reauthorised.* With that amendment, the minutes were agreed as an accurate account of the meeting. The group had a discussion on how the APG papers would be sent out to the group and if resending the whole package of papers, on the morning of the meeting, was useful. The conclusion was that the papers would be sent on the day of the deadline and when unavoidable, late papers will follow when ready. AMcG as chair, would find it useful to have the papers re-sent on the morning of the meeting.	
4.	**Matters Arising**	
	Progesterone (Cyclogest®) pessaries for prevention of threatened miscarriages in patients at high risk, for up to 16-week gestation. SK updated the group on the idea of having a virtual ward and the associated use of SystmOne. STHFT are reviewing to see if this is a feasible option; other directorates are also looking into this. SK also informed the group that it would seem that STHFT have not been consistent in following the NICE clinical guideline in making this treatment available to patients. **APG will be updated when more is known.** **Semaglutide Red TLDL status and holding statement.** SK reminded the group that the Tier 3 weight management service was nearing fruition and it would seem that the TLDL classification would certainly be Red in relation to that service. Other plans for potential GP prescribing in this area has not yet been developed. **NFA for APG at this time.** **Melatonin on STHFT unlicensed medicines list (Produced by the medicines safety committee).** This was raised at the October APG when an item, raised in the Doncaster minutes, reported that prescribing for a patient, who was under the care of Sheffield ophthalmology, resulted in a request to a GP to take over the prescribing of melatonin, in an exceptional circumstance. AM confirmed that STHFT approval for off-label use of melatonin is for insomnia in patients with spinal injuries and for patients, under neurology,	SK

	with REM sleep issues. It would be impossible for STHFT pharmacy to know, for individual patients, the indication/reason for directorates making requests to GPs. In the case reported at Doncaster, STHFT had no knowledge of why that request had been made. AM has now looked at that patients record and found that the patient had experienced trauma and melatonin was prescribed for insomnia secondary to that and, the patient is under 55 years old, which also made it off-label use. HeiT agreed to feed this back to Doncaster and added that in the on-going work to produce a SY TLDL, nuances are becoming apparent. In the case of Doncaster, they have assigned a TLD classification for every drug that they have had an enquiry about, but for the SY TLDL, it has been agreed that a TLDL classification will be given for licensed indications and for unlicensed indications where there is guidance or recognised evidence to support its use. Anomalies, as described above, will be for primary care and the specialist to understand the evidence/reason why the request has been made and to go back to STHFT to inform them of the requests so that if common themes emerge it could, potentially, be considered at the Medicines Safety Committee and be added to the off-label use register. AM added that for one-off instances it would not go to the Medicines Safety Committee, it would only be for cohorts of 6 patients or more per year, advising that there is a backlog of unlicensed medicines (ULM) applications. LS asked if some work could be done to raise awareness with secondary care prescribers around communicating with primary care prescribers about ULM and the procedures which are in place. AM replied that it is not known what the level of understanding is about ULM and will contact Nicky Thomas, Pharmacy Healthcare Governance Manager at STHFT and a contact for the Medicines Safety Committee, for advice. HeiT added that EP could also raise this with the Medicines Safety Group, which Nicky Thomas is also a member of, to see if any further promotion could be done. APG will be updated via the Medicines Safety Group. **Timely Transfer of information on admission (SHSC)** AA explained that this is in relation to the work of the home treatment teams. SHSC do not currently have consistent access to summary care records (SCR), the EPR process, which will facilitate this, is still being rolled out. Requests for information is being made to general practice but it can take 2 – 3 days to receive a reply and APG are asked for suggestions on what could be done differently, pending the consistent access to the SCR, to support expediting, particularly for the service users who are in crisis. GP comment from the group suggested that a general practices admin email address might be one solution which may provide quicker responses than going through the regular channels. Another option, for those patients who have a smart phone, is to support them to access their GP records and so they could share the information needed. AA will look at this suggestion.	AM EP AA

	It may, however, require a phone call to the GP practice to ask a suitable member of the practice team to read out the information on the SCR. LS, as LMC representative, will pick up this conversation outside the meeting with AA to see if the LMC could send a message to practices asking to prioritise the requests from the home treatment teams. **NFA for APG at this time.** AA left the meeting temporarily.	LS/AA
8	**Prescribing Guidance**	
	Glucagon (Ogluo®) JR reminded the group that this proposal was taken to IMOC in May 2023 where Ogluo® was approved as Amber G (Amber with guidance) on the SY TLDL and that, for Sheffield patients, guidance would be developed. The proposal for this guidance is that all initiations will be made by SCFT alongside insulin treatment for children aged 2 years and above and that Ogluo® will be stopped at age 19 years. It will be first line for severe hypoglycaemia and would be used instead of GlucaGen Hypokit®. In May there was a serious shortage notification for GlucaGen Hypokit® and this has resulted in some Ogluo® already being in the system. The advantage of Ogluo® is that it is a 2-step process, as opposed to a 9-step process with the GlucaGen Hypokit® so the administration time is quicker. It is easier to train the patient/carer how to administer, it offers a fast and reliable method as no mixing involved. There is less stress involved in administration and the Ogluo® device has a hidden needle. The shelf life for Ogluo® is 30 months, where GlucaGen Hypokit® is 36 months. It is anticipated that there would be about 40 patients a year initiated on Ogluo® and it would be expected that one pen would be prescribed every 30 months, in line with expiry dates. There is a significant cost difference between Ogluo® at £73 and GlucaGen Hypokit® at £11.52. A question was raised about the SPC recommendation to supply 2 devices but the recommendation from SCFT is to supply one device as, if a second dose is needed, the ambulance crew would be able to deliver that second dose. However, if a child lives between parents, then it may be possible that 2 devices could be provided but, the advice is that the child should be carrying the device at all times. JR also pointed out that when the TLDL proposal was discussed at IMOC, Doncaster have decided that for children under 5 years of age Ogluo® should be the treatment of choice but for children over 5 years of age, it will only be available in special circumstances. JR summarised the guidance, highlighting the sections on dosage and administration and on cautions and contraindications, explaining that the Barnsley guidance template has been used. There was a question about side effects of hypoglycaemia, which are reported in the SPC at 42%	

	however, this was observed in clinical trials but not considered in relation to the glucagon. All patients would have hypoglycaemia, or they wouldn't require Ogluo®. JR added that SCFT reduce insulin dose following a major hypo. Families are told about side-effects, and it is explained that if the hypo results in the need to give Ogluo® that the body releases all its stores of glycogen and that hypos can happen 24 – 48 hours afterwards. JR explained that should the patient be attended by ambulance the DSN would like to follow up, in order to investigate why the patient has had a hypo, considering too, that many of these patients will have a CGM. JR also raised the comments received about the references that have been used for the guidance and that there is no outcome data on the trials referenced; JR is not aware of any data on patient harm and available evidence is anecdotal. MD added that the anecdotal evidence is around that the water, rather than the mixed preparation, been given. There have also been incidents where the carer has panicked and did not administer treatment until the ambulance arrived. Other information received is that parents, due to panic, have tried to administer crushed Gluco Tabs or GlucoGel to an unconscious child. MD also commented that it is a struggle to get data as the ambulance service do not inform SCFT when they have attended a patient. MD informed the group that schools will not give GlucaGen Hypokit® because they are not trained, and it is not used regularly enough to gain experience but, as Ogluo® is an auto-injector, schools are willing to receive training and administer. This is also the case for children's clubs e.g., sports and scouts. TB informed the group that Ogluo® is available from the national wholesalers but with Alliance, as it uses a central store, it would take 1 – 3 days to arrive at the community pharmacy. Patients should be made aware that Ogluo® will not be routinely stocked in community pharmacy, it will need to be ordered. MD replied that patients are told to mark the Ogluo® packaging with a date one month ahead of the expiry date as a reminder to order a new device. For patients that have used their device, this may cause a problem, though MD commented that he hasn't seen a severe second hypo in the many years he has been a DSN. TB added that community pharmacy may be able to offer a service, in the future, a path of care service, adding Ogluo® as stock items to one or two community pharmacies in each ICB place but that would be dependent on a commissioning decision. HeiT asked if CGM has reduced the need for use of glucagon, MD replied that in some respect CGM has but, parents are over treating hypos. HeiT also suggested that, as patients who have had a hypo will use the more accurate blood glucose monitoring, if the monitoring section could be expanded to clarify this and link to patient care plans. HeiT also asked what is used in the children under 2 years old. MD replied	JR/MD

	that the glucagon is used and reconstituted to use a smaller dose. HeiT suggests that 'Glucagon' is added to the title and the background information section includes that Ogluo® is a prefilled auto-injector. There is some repetition within the guideline that could be removed, e.g., refer to local guideline; HeiT will share the detail with JR after the meeting. With regard to being inequitable across SY ICB, as described above, Doncaster have restricted the use of Ogluo® for children under 5 years old, and to be cognisant of this. LS commented that the Amber G classification indicates that follow-up prescriptions and monitoring is carried out by primary care and doesn't consider that the monitoring would be carried out by primary care clinicians, this will be done, appropriately, by the diabetes teams, therefore, Ogluo® doesn't fit the Amber G criteria and so it would be welcomed to include the Sheffield decision on patient cohort choice. LS asked that, with the risk of further hypos in the 24-to-48-hour window, and the issues around the potential time-lag in community pharmacy obtaining Ogluo®, is prescribing and dispensing in community the right thing to do and could SCFT keep an accessible small stock of devices. LS added that, as reported on the proposal document, the primary care opinions have all expressed concerns about the costing and if it is appropriate to prescribe Ogluo® in primary care. Finally, LS ask if SCFT will be actively stopping Ogluo® when the child reaches age 19. MD responded, with regard to stopping Ogluo®, that there are joint transition clinics where the adult diabetes team attend, and this will be discussed with the patient when nearing the end of transition to the adult service. TE asked about the training for schools to give Ogluo®, and who provides that training. MD confirmed that it is the children's DSNs that give that training. RL asked about the transition phase and raised concern that the Ogluo® will not be stopped and asked for confirmation on how Ogluo® will be stopped. MD confirmed that the transition clinics start when the child is 14 or 15 years of age so that transition will be over a period of 4 – 5 years which allows a number of years to adjust. AMcG added that it has been confirmed that the adult diabetes team have said that they will not support the use of Ogluo® in adults. JW commented on the point about the inequity across SY ICB and that this inequity is caused by Doncaster's stance on restricting to under 5-year-olds. JW also asked if the replacement Ogluo®, following use could be given by the DSNs, MD agreed that it could, if the hypo happened during the day but most hypos are experienced during the late evening, overnight or early morning and therefore the child would be attended by the ambulance service. It would only be if the parent contacted SCHFT that they would be aware.	JR/MD HeiT/JR JR/MD

	AMcG asked that wording in the section on when 2 devices may be required is strengthened and to clarify that it would only be by exception not the norm, and to describe some examples of those exceptions. AMcG asked how many under 2-year-olds are diagnosed, and if the situation could be confusing with switching to Ogluo® at 2 years then back again at 19 years. MD replied that the figure for under 2-year-olds being diagnosed was not known but would be few patients, as those patients diagnosed under 5 years old account for about 20% of all children. JW made the point that the cohort on Ogluo® will be in school for the majority of those years and, as said previously, if they were issued a GlucaGen Hypokit®, the school would not administer. **With the above amendments, APG approve the guideline.** JR and MD left the meeting. **Dapagliflozin▼ and Empagliflozin▼ in Heart Failure with Reduced Ejection Fraction (HFrEF) in patients with and without Diabetes Mellitus: guidance for primary care** HS is presenting the updates to this proposal on behalf of Riz Iqbal (RI) and reminded the group that it was agreed, when NICE TA773 was published, that empagliflozin would be classified as Amber and the existing guideline for *Dapagliflozin▼ in Heart Failure with Reduced Ejection Fraction (HFrEF) in patients with and without Diabetes Mellitus: guidance for primary care*, would be updated to include empagliflozin. There were, however, two points on the guideline that were sticking points when APG previously discussed this updated guideline, which related to the heart failure specialist nurses who were not prescribers and therefore unable to write the first prescription. The specialist nurses would counsel the patient on the use of the SGLT2 inhibitor and obtain the patients consent following review by the heart failure MDT, the specialist nurses would then ask the GP to prescribe the first prescription. It is the writing of the first prescription that the LMC and APG GP members, found inappropriate and added additional responsibility on the primary care clinician on what is a specialist area of initiation and so this has been removed. There were further discussions between the LMC and Professor Al-Mohammad, to find a solution to the issue of the first prescription. There has now been approval of a project, funded by NHSE, where a prescribing pharmacist, with an expertise in heart failure, is to support the heart failure specialist nurse clinic and would be able to write the first prescription. Professor Al-Mohammad has reported that there is an unacceptable delay in appointments for the clinic and for the non-prescribing specialist nurses to find a prescriber to write the first prescription is introducing a further delay. The project will be supported by RI, and it is hoped to find other prescribing pharmacists, with appropriate expertise, to review patients who have been discussed at the MDT. This new project has	JR/MD

	not been included in the proposal as it is a 12-month project, and it is hoped that this would give time to allow the specialist nurses to obtain the prescribing qualification. HS added that there was some ambiguity about the renal monitoring section on when the SGLT2 inhibitor should be stopped. This came about because of the difference between the prescribing practice in secondary care and the SPC. The wording in the SPC doesn't refer to ongoing prescriptions and at what eGFR level they should be stopped, the SPC only states at what eGFR level that treatment can be initiated. Page 1 of the guideline has been simplified, which has the initiation criteria, and the ongoing monitoring section now advises to refer back to the advice on page 1, which has been hyperlinked. With regard to when the SGLT2 inhibitor should be stopped, when RI discussed this with Professor Al-Mohammad, he has the view that the other nephrotoxic drugs that the patient is on should be looked at to see if they can be adjusted, to allow the patient to continue to receive the SGLT2 inhibitor. RI considered that this would not be an appropriate action for primary care and therefore those patients should be discussed with the heart failure specialist or the renal physician. HS commented also that there may be a cause of confusion as there is a guideline for dapagliflozin and empagliflozin for HFrEF and a separate one for CKD and, some patients will have both conditions. The decision on where those patients would be best managed would be made by the heart failure and renal specialists. LS commented on diabetic patients on insulin or a sulphonylurea, who attend the heart failure clinic, who are then deemed appropriate for an SGLT2 inhibitor. This needs to be discussed with the diabetes specialist nurses (DSNs) and cannot see why the GP needs to be involved in that communication. HS replied that this is in the original, approved, dapagliflozin HFrEF guidance. When that guidance was discussed at APG it was agreed, after discussion with the heart failure specialists, that there is a better referral pathway from the GP to the DSNs than from the heart failure specialist. There has been no feedback on any problems with this arrangement since the approval of the dapagliflozin HFrEF guidance and it seems to be working. AMcG asked about the eGFR threshold for initiating patients. The guideline states that a drop in eGFR is expected within a month of initiation and likely to stabilise after 3 months and is there a sense of how much of a drop is expected. HS replied that, as looked at with the STHFT combined guidelines that APG reviewed in connection with the CKD guidance, that a 30 – 40% drop is quoted. HS has asked the specialist to clarify that if, particularly with initiating empagliflozin, the eGFR is just above 20, inevitably you will be below at 3 months, but no explanation has been offered. Pragmatically, if a patient is close to eGFR 20ml/min/1.73m^2 they wouldn't be started on treatment and input from a renal specialist would be sought. HS added that for dapagliflozin, the reason for a higher threshold, eGFR ≥30 ml/min/1.73m^2, is because in the clinical trial there were very few	

	patients who had an eGFR <25 ml/min/1.73m^2, as stated in the SPC and locally they would not start unless the eGFR ≥30 ml/min/1.73m^2. A note has been added to the guideline to advise that local recommendation differs from the SPC. HS added that, as with any guideline, there will be patients that will not fit exactly, adding that there is also concern that there are currently no guidelines for empagliflozin in HFrEF. RL asked that in the box *Additional patient counselling & advice for DIABETIC patients ONLY,* if more information is needed on *Caution- Patients can present with euglycaemic DKA when treated with SGLT2 inhibitors.* HS responded that this was an MHRA warning a few years ago and thought it may be well known, but a link to the MHRA alert will be added. LS asked that in the green, initiation boxes, to make it clear that it is to initiate, **counsel** and prescribe the initial supply. **APG approve the guideline.** HS and JW left the meeting. AA re-joined the meeting.	HS/RI HS/RI
5.	**Medicines Management Safety Issues**	
	Medicines Safety update EP updated the group on the request made to ask if a warning/reminder could be added to ICE to prompt HCPs to ask about **biotin as it may interfere with thyroid immunoassays**. This is currently being looked at. Richard Oliver has asked if it could be added to the Amiodarone SCP, which EP will recommend for when that SCP is updated, and it will also be added to Chapter 20: Common Blood Monitoring Schedules. EP highlighted a report from the **Isotretinoin Implementation Advisory Expert Working Group,** isotretinoin is Red on the TLDL and there is no prescribing in primary care however, the report recommends that patients are given information including the risks and benefits at the time of referral to the specialists so that they have time to read, digest and think about them before seeing the specialist. There is a request to share more than is currently shared on referral and a recommendation to take bloods before or at referral and consider contraception for patients of childbearing age. There is a recommendation to consider that primary clinicians can be used as a second approved named HCP for patients under 18 years old. The MOT dermatology lead attended the North Trent dermatology meeting last week and it was, at this stage, decided not to use primary care clinicians in SY and Chesterfield areas in this capacity. On the patient reminder card for isotretinoin, which is an MHRA document, it mentions that concerns with mental health can be raised with the	

	dermatology team or GP, who should be a key partner in the pathway for managing any mental health problems. Actions for Sheffield following this report would be to record as a 'Specialist Issued Drug' on primary care clinical systems for all patients prescribed it in secondary care. That primary care HCPs should be aware of and alert to the risks of treatment and how to manage these. The Acne Clinical Guideline has information on when to refer to secondary care but not how to refer, and this was discussed at the North Trent dermatology meeting; there may be a proposal to use the Association of Dermatology referral proforma which has been produced for use in primary care. EP has recommended a consultation with GPs or the CRG, as this changes the referral process. AMcG commented that the suggestions and recommendations are impractical and shifts workload to primary care. The assumption seems to be that the GP is referring for isotretinoin treatment when in fact the referral is for an expert assessment which may or may not consider isotretinoin as appropriate treatment. There is concern that the GP may be the second approved HCP as, this should be for specialists only. LS added that the specialist may be doing themselves a disservice with the notion that primary care is qualified to engage in this way. EP agreed that this is useful feedback and has already suggested that the North Trent group would benefit from having GP and LMC involvement and EP confirms that this groups comments will be shared. HeiT added that when the MHRA alert was published about the insulin passports, Sheffield did a risk assessment and adopted a slightly different route and as long as a robust risk assessment is in place, something similar may be consider for this alert. It was **Meds Safety week**, last week, which was promoted in the Practice Bulletin, at the APG learning lunch and the ICB promoted on social networks. **Valproate,** should now be dispensed as full original packs, which helps to ensure that patients will always receive the PIL and warnings on the packaging. TB added that there may be a delay in this being consistent as there are different pack sizes still on shelves, so it may take a while to settle down. **Azathioprine.** There are now 2 new strengths, 75mg and 100mg.	
6.	**Pharmacy and Prescribing Commissioning Group Feedback**	
	HeiT informed the group that there was an acknowledgement of the **CGM policy that IMOC approved**. The CGM policy now includes prescribing for Type 2 diabetic patients.	

	The Tier 3 weight management service. As there is now a NICE TA for semaglutide (Wegovy®) which is now available. The patients that qualify for being offered this therapy is greater in number so, there is a question on how many patients the Tier 3 weight management service contract will cover. A paper will go to SPEC and what has been agreed should be apparent in the next couple of weeks. HeiTs final report of the meeting was that confirmation is still awaited from NHSE about **DOACs** and that generic apixaban is now the most cost effective DOAC, though the volume of availability is not known. The rebate for edoxaban is still in place and once official communication from NHSE is received, the suggestion is likely to be that apixaban, where appropriate, would be first line for new initiations but, for patients on edoxaban a switch to apixaban would not be made; **APG confirmed that they are supportive of that approach.**	
7.	**Formulary Sub-group**	
	Draft minutes of the November meeting were received. HelT updated the group with the discussions at FSG on the following. **Amiodarone SCP.** The SCP, which is due for review, has been updated and presented on the national template. It is yet to be confirmed if this SCP needs to next be discussed at APG or IMOC. The intention, when writing the updated document, was for Sheffield place. LS commented, as mentioned in the minutes, that an audit would be helpful if capacity allows. Regarding the patient responsibilities, LS asked if patients were ever given that list and if not, could this be looked at. **Methotrexate SCG.** This guidance was also due review and has been presented on the national template. This guideline has been to IMOC but due to the SY places having different commissioning arrangements, it was decided that the guideline would be for Sheffield place only. It is expected to come to APG in January 2024. LS commented that GPs may not be in agreement to have the ophthalmology indications included. **Rimegepant** was discussed as the NICE TA 919 was published last month which relates to treating migraine, the NICE TA906 for prevention of migraine was published in July. The headache clinic has, so far, only put an application to MMTG for prevention and IMOC has agreed a current TLD classification as Red. It was discussed at FSG that for treatment, primary care would possibly be best placed though as it is a new drug, it was considered that it should remain as Red for 6 months for both treatment and prevention. LS also commented on the proposal for a TLDL classification for use of **Ezetimibe in Children**, which FSG commented on ahead of it being presented at IMOC. The proposal was originally for Green but now is for an Amber classification. LS made the point that Green would not have been supported by the LMC. **Matters approved by FSG under delegated authority (for information):**	

	Shared Care Protocol for The Treatment of Children with Recombinant Human Growth Hormone- and the inclusion of Ngenla®. This has been approved for Sheffield but Ngenla® needs adding to the TLDL as Amber, and so requires further discussion on who will make this decision. **Chapter 6: 6.4.1.2. Progestogens.** Updated to include Gepretix® and the removal of the discontinued Climanor® brand of medroxyprogesterone acetate. **High-cost drugs advice to prescribers.** This was approved to retire and remove from the Intranet under delegated authority of APG as the advice has changed. **Riluzole supply issues advice,** minor amendment. **Matters approved by virtual agreement under delegated authority (for information):** **Sheffield Formulary Introduction.** **Matters for APG approval:** **Hyperprolactinemia -Management of prolactin in adults when antipsychotics are prescribed.** This is new guidance for the management of prolactin in adults when antipsychotics are prescribed. The basis for the production of this new guidance is that over the years there has been concern regarding the high number of requests for prolactin levels, without taking into consideration any pre-disposing reasoning. JM informed the group that this guidance is in line with the NICE psychosis guidance, which does not recommend prolactin monitoring, though not in line with NICE CKS, which advised to monitor prolactin every 6 months, but does not say what to do with the results. HelT had a number of comments/questions including that, the title could be clarified to read Monitoring and Management of Hyperprolactinemia when prescribing Antipsychotic Medication. In the top left-hand box of the pathway, where it states: *Avoid drugs known to cause hyperprolactinaemia in patient >25 years* should read. *Avoid drugs known to cause hyperprolactinaemia in patient* ***<25 years.*** In the top right-hand box, it states *Aripiprazole, clozapine, quetiapine, or olanzapine (less than 20 mg daily) - these are known not to raise prolactin levels,* but should this be reworded, to mirror the advice given at the top of page 2, to read *Aripiprazole, clozapine, quetiapine, or olanzapine (less than 20 mg daily) - these are* ***a rare risk*** *to raising prolactin levels.* Where it states that the drug review is by the psychiatrist team, bottom left-hand box on page 1, to make it clear that the medication will be initiated by the psychiatrist and to add a hyperlink to the detail on page 2.	AA AA AA AA

	HelT also asked if Maudsley should be added as a reference; AA thought that it was not needed for this guideline. On the dose of up to 5mg of aripiprazole, HelT asked if initiation would be on a lower dose? AA replied that 5mg is usually the starting dose. LS asked what happens with men over 65 years old and women over 50 years old. Also, why it suggests that primary care may be asked to recheck bloods after a month; this doesn't make sense as the results would be needed by the specialist not the GP. AA replied that at FSG, it was discussed where the most appropriate place for rechecking bloods would be and that the results would be available on ICE, but AA will take this comment back for further consideration, LS added that primary care is not commissioned to carry out the request to recheck bloods at one month and does not have the capacity to do so. With regard to the age threshold, AA commented that management of prolactin would depend on symptoms and will contact STHFT endocrinologists on this point and will look to expand the information on this. AMcG commented, unless patients are exhibiting symptoms of hyperprolactinemia towards general practice, GPs would not be doing prolactin levels on anyone on antipsychotics as part of their routine monitoring. Most practices in Sheffield now have Ardens aligned to their clinical systems which will tell practices to do prolactin levels on review. It might be worth a conversation with IT to see if there is a solution as it may be difficult to amend Ardens for local use. RL asked, is the advice that, unless clinically concerned to not check prolactin or should prolactin be checked if the patient is on any antipsychotic, other than those 4 listed on the guideline. JM responded that most people on antipsychotics will have a raised prolactin and so a routine blood test will show raised prolactin, NICE suggested to do a base line prolactin and on retesting you would know, at that point, if it is raised, which can be dealt with but, you would then not have to investigate every instance of raised prolactin after the base line test. Prolactin testing has been written into the Sheffield mental health SMI template because the Bradford template was adopted and Bradford had written prolactin into the template, so now, people on an antipsychotic are getting an annual prolactin level, which comes back raised and GPs are asking if further investigation is needed, and this guidance seeks to avoid this occurring. There are some theoretical long-term risks of raised prolactin with antipsychotics, but the evidence base is conflicting. To treat a patient's symptoms of raised prolactin will involve options to reduce the antipsychotic dose, which will increase the risk of relapse or to add aripiprazole which increases the risks of combination antipsychotic drug burden and side effects.	AA AA AA/AmCG /HeiT

	JM would not test for prolactin routinely; if a patient has prolactin related side effects the test will prove if related to prolactin but there will still be the question of what action to take, which then comes back to specialist involvement. **Subject to the above amendments, AA, AMcG and HeiT will agree the final draft and APG will approve the guideline.**	
9.	**Integrated Medicines Optimisation Committee (IMOC)**	
	Minutes The October meeting approved the **Self-Care guidance** for SY ICB document which is now on the SY ICB Internet. The November meeting, the **CGM policy**, about the principle of prescribing in line with NICE, a supporting document, to give guidance will be available in time, was approved. Efmody®, a SCP to support use, was approved. With regard to the TLDL, **memantine orodispersible** was added as Grey, this is based on cost. The oral solution has been advised as a cost-effective alternative.	
10.	**NICE Guidance**	
	NICE summary for November APG The following items were noted. **Bimekizumab for treating active psoriatic arthritis, TA916**, a Blueteq form will be developed for this indication and has been classified as Red on the SY TLDL and the same applies to **Bimekizumab for treating axial spondyloarthritis, TA918.** **Rimegepant for treating migraine TA919** as referenced earlier, HeiT commented that this is a new indication, the difference between this TA and the one for prevention is the criteria for offering which is much broader for this TA. The problem might lie in whether these patients would fit the criteria for seeing a specialist. It is indicated for patients for whom 2 triptans have failed or are contraindicated and for patients who have 4 migraines a month, in which case the patient would be referred to the specialist service for chronic use. There is a concern that the NICE costing template underestimates the number of patients who are potentially eligible. Currently the TLDL status is Red. LS commented that the LMC have concerns about new drugs with limited experience in use, going to Green on the TLDL, and it may be worth further discussion at an early stage. **Tofacitinib for treating active ankylosing spondylitis, TA920.** SK will be developing a Blueteq for this indication. **Daridorexant for treating long-term insomnia TA922.** This is a drug which works in a different way to typical drugs for insomnia and reportedly doesn't have the same withdrawal and dependency effects. It is recommended for use following CBTI, but CBTI is not specifically	

	commissioned in any of the 4 places in SY ICB, but commissioning is exploring if CBTI could be an option. This has not yet been added to the TLDL as it is not yet available and there needs to be a greater understanding of ICB partners views and thoughts. LS asked about the **KardiaMobile 6L for measuring cardiac QT interval in adults having antipsychotic medication** and if there is any progress. JM responded that the guidance was looked at and it seems that it cannot be used on 'at risk' patients, so would have to use an ECG anyway. NICE have a number of conditions for the manufacturer about trial evidence and demonstrating that it is equivalent, and it needs to meet certain criteria around settings and who should be doing the monitoring. It was not thought, at this stage, to be useful.	
11.	**APG Mailbox.**	
	No communications received this month.	
12.	**Reports from Neighbouring Committees**	
	Doncaster & Bassetlaw action log Sept 23 LS commented that ivabradine is traffic lighted for angina and Sheffield have if for heart failure. HeiT added that this is historic, as Doncaster will traffic light for every indication. Going forward the SY TLDL will traffic light the drug and the status is the same for all indications the chemical level of the drug will be listed. RL asked for clarity on what Grey means on the SY TLDL, HeiT responded that it is Black and the rationale with the explanations are published on the SY ICB Internet.	
13.	**Never Events and Sis.**	
	None reported.	
14.	**Any Other Business**	
	AM and AA left the meeting. TE asked what is happening with the **chicken pox vaccine**, SK replied that this is still being looked at. Healthwatch have asked TE to raise the ongoing issues about the **inflexibility of some general practices to accommodate repeat prescription requests**; patients are being told that this must be done on-line, but this is not an option for all patients. HeiT and AMcG will pick this up with the primary care team. TB informed the group that PCS are running the **COVID medicines unit** from next week. There is also the news about the **Pharmacy 1st service**; but this is yet to be finalised. There will be seven common conditions, where patients can access, through the community pharmacy consultation service or as walk-ins. The contraception service will also change, where	HeiT/AMcG

	community pharmacy will be able to initiate prescribing. This is expected to start next year. TB highlighted that a community pharmacy had received a request to supply an expensive, specialist issued drug which is Red on the TLDL, and asked if this and any other such incidents should be reported through APG. It was decided that this will be considered and discussed outside of this meeting. AMcG advised the group that **SystmOne has changed the CrCl calculator**, it now gives CrCl on ideal weight, actual weight and adjusted weight. It will be worth the MOT looking at this further.	
15.	**Date of the next meeting:** 18th January 2024, 1:30PM. Virtual meeting	

Summary Points and Recommendations

November 2023

IMOC approvals	• Efmody® SCP
IMOC TLDL approvals	See appendix 1.
Shared care/Prescribing Guidelines	• Shared Care Protocol for The Treatment of Children with Recombinant Human Growth Hormone- – Approved under delegated authority of APG. • Glucagon (Ogluo®) – Approved. • Dapagliflozin▼ and Empagliflozin ▼ in Heart Failure with Reduced Ejection Fraction (HFrEF) in patients with and without Diabetes Mellitus: guidance for primary care – Approved.
Sheffield Formulary Updates	• Chapter 6: 6.4.1.2. Progestogens – Approved under delegated authority of APG. • Sheffield Formulary Introduction - Approved, virtually, by FSG under delegated authority of APG. • High-cost drugs advice to prescribed – Approved to retire and remove from the Intranet.
Other	• Riluzole supply issues advice – Amendment approved by FSG under delegated authority of APG

Appendix 1 IMOC TLDL approvals

Drug/Product	**Brand/name**	**Indication**	**Agreed TLS**
Andusomeran (Spikevax XBB.1.5	Spikevax® XBB.1.5	Covid-19 vaccine	Green
Raxtozinameran Comirnaty® Omicron XBB.1.5	Comirnaty® Omicron XBB.1.5	Covid-19 vaccine >12 years	Green
Raxtozinameran Comirnaty® Omicron XBB.1.5 [***)***	Comirnaty® Omicron XBB.1.5	Covid-19 vaccine for children aged 5-11years	Green
Raxtozinameran Comirnaty® Omicron XBB.1.5	*Comirnaty® Omicron XBB.1.5 [3 micrograms/dose]*	Covid-19 vaccine for children 6months>4 years	Green
Daridorexant	*Quviviq*®	Treatment of adults with insomnia characterised by symptoms present for ≥3 months and considerable impact on daytime functioning	Do not traffic light yet
Memantine orodispersible tablets		Moderate to severe dementia in Alzheimer's disease & Oscillopsia in multiple sclerosis	Grey 4 – with a note to suggest solution more cost effective option
Methocarbamol		Short-term symptomatic relief of muscle spasm	Grey 1
Methylnaltrexone bromide injection		Opioid-induced constipation	Grey 2

Telmisartan & Hydrochlorothiazide	Micardis Plus®	Hypertension	Grey 4
Minocycline		Acne Vulgaris and Acne Rosacea	Grey 1
Modafinil		Narcolepsy	Amber
Mosunetuzumab		Follicular lymphoma	Grey 2
Ofatumumab		In line with positive NICE TA recommendations	Red 1
Natalizumab		In line with positive NICE TA recommendations	Red 1
Necitumumab		lung cancer	Grey 2
Olmesartan and amlodipine		Hypertension	Grey 4
Osilodrostat		Endogenous Cushing's syndrome	Grey 1,7
Oxerutins		Oedema associated with chronic venous insufficiency	Grey 3
Ozanimod		In line with positive NICE TA recommendations	Red 1
Pegunigalsidase alfa		Fabry disease	Red 1,6
Bimekizumab		In line with positive NICE TAs	Red 1
Rimegepant		For prevention	Red
Tofacitinib		In line with positive NICE TAs	Red 1
Ruxolitinib		Polycythaemia vera	Red 1,6

Daridoxrexant		For long-term insomnia	Do not traffic light yet
Tabelecleucel		treating post-transplant lymphoproliferative disorder caused by the Epstein-Barr virus	Grey 2
Glofitamab		Relapsed or refractory diffuse large B-cell lymphoma after 2 or more systemic treatments	Red 1,6