AREA PRESCRIBING COMMITTEE MEETING
Birmingham, Sandwell, Solihull and environs
Minutes of the virtual meeting held on
Thursday 9th July 2020
Venue – Microsoft Teams

PRESENT:

Dr Paul Dudley	Birmingham and Solihull CCG (Chair)
Dr Lisa Brownell	BSMHFT
Liz Thomas	Birmingham and Solihull CCG
Nilima Rahman-Lais	Birmingham and Solihull CCG
Dr John Wilkinson	Birmingham and Solihull CCG
Dr Nashat Qamar	Birmingham and Solihull CCG
Jonathan Boyd	Sandwell and West Birmingham CCG
Dr Sonul Bathla	Sandwell and West Birmingham CCG
Satnaam Singh Nandra	Sandwell and West Birmingham CCG
Emily Horwill	Sandwell and West Birmingham NHST
Dr Angus Mackenzie	Sandwell and West Birmingham NHST
Dr Sangeeta Ambegaokar	Forward Thinking Birmingham Partnership
Alison Tennant	Birmingham Women's and Children's NHS FT
Melanie Dowden	Birmingham Community Healthcare NHS FT
Gurjit Sohal	UHB NHS FT
Carol Evans	UHB NHS FT/Birmingham and Solihull CCG
Prof Inderjit Singh	UHB NHS FT
Prof Jamie Coleman	UHB NHS FT
Dr Mark Pucci	UHB NHS FT
Jonathan Horgan	Midlands and Lancashire CSU
Kuldip Soora	Midlands and Lancashire CSU
Daya Singh	Midlands and Lancashire CSU

IN ATTENDANCE:

Dr Indhu Prabakar for item 0720/05	UHB NHS FT
Dr Kate Campbell for item 0720/05	UHB NHS FT

No.	Item	Action

0720/01 Apologies for absence were received from:

Nigel Barnes, BSMHFT
Dr Dhiraj Tripathi, UHB NHS FT (deputy attended)
Prof Mark DasGupta, Birmingham and Solihull CCG (deputy attended)

It was confirmed that the meeting was quorate.

0720/02 Items of business not on agenda (to be discussed under AOB)

- Antimicrobial guidance – Community acquired pneumonia
- Acetylcysteine on formulary
- Discontinuation of danazol
- Red drugs and COVID-19

0720/03 Declaration of Interest (DoI)

The Chair reminded members to submit their annual declarations of interest to the APC Secretariat.

0720/04 Welcome and Introductions

The Chair welcomed everyone to the meeting today.

The Chair reminded members, the meeting is digitally recorded for the purpose of accurate minute taking and once the minutes are approved, the recording is deleted by the APC secretary.

0720/05 Levonorgestrel IUS (Kyleena®) new drug application

The Chair welcomed Dr Indhu Prabakar, consultant in sexual and reproductive health, UHB NHS FT and Dr Kate Campbell, senior registrar, UHB NHS FT to the meeting. Introductions were carried out for the benefit of the attendees.

The Chair invited Dr Prabakar to present the application for the levonorgestrel intrauterine delivery system (LNG-IUS), Kyleena®.

Dr Prabakar presented a series of slides outlining the application for Kyleena®. Dr Prabakar began by stating Mirena® is the first version of LNG-IUS and has reached its 27th or 28th year on the market. Therefore, there is reasonable clinician experience with LNG-IUS.

Kyleena® was launched in January 2018 and was available in clinics in Birmingham shortly afterwards from June 2018. Jaydess® is licensed for contraception for up to 3 years. Kyleena® has the advantage of the license for contraception but for up to 5 years. Kyleena® is a smaller and thinner device compared to Mirena®. Total levonorgestrel content in Kyleena® is 19.5mg and the release rate is 12micrograms per 24 hours. Mirena® contains 52mg levonorgestrel and the average release rate is 20micrograms per 24 hours. Kyleena® therefore has less hormone loaded into the device and less released per day.

Kyleena® contains a silver ring for improved visibility in imaging studies. All LNG-IUS are inserted using a “single handed” technique.

Dr Prabakar presented a table of Pearl Indices demonstrating contraceptive efficacies. The Pearl Index for Mirena® is between approximately 0.2 to 0.5 over a 5-year duration. The Pearl Index for Kyleena® is 0.33, mirroring Mirena®.

The slide demonstrating bleeding patterns shows Mirena® gives near total amenorrhea. Kyleena® data shows a likely similar result to Mirena®; Kyleena® averages 12micrograms per day and this is likely to be even lower by the fifth year. From the data, Dr Prabakar concluded a third of women are likely to experience amenorrhea after 5 years and the remaining will experience minimal spotting with Kyleena®. This is deemed acceptable by patients and clinicians.

Dr Prabakar presented Phase III study results. Investigators rated placement of Kyleena® and Jaydess® as 'easy' and subjects rated the placement as less painful compared with the Mirena® group and these results are statistically significant.

In conclusion, Dr Prabakar outlined the reasons for adding Kyleena® to the formulary. Kyleena exposes patients to the lowest dose of hormone over a 5-year period. Progesterone carries a risk of side effects such as hair loss and ovarian cysts and a lower exposure will reassure patients and clinicians alike. Kyleena® costs approximately £76 compared to Mirena which costs approximately £98. Kyleena® demonstrates similar bleeding patterns to the alternatives available. There are favourable clinician and patient factors with Kyleena® as discussed. Availability of Kyleena® extends patient choice. Dr Prabakar added Kyleena® is recommended as the first line LNG-IUS for ages 15-40 years in some areas of the UK.

<u>The Chair invited questions or comments from members. Discussion points/concerns raised included:</u>

- A member queried if Jaydess® could be removed from the formulary as it is licensed for contraception for up to 3 years and is less cost effective than Kyleena® which is licensed for contraception for up to 5 years. Dr Prabakar confirmed that she had heard from the manufacturer that Jaydess® is likely to be discontinued. She added Mirena® is licensed for other gynaecological indications and in practice, Dr Prabakar prefers Mirena® for women over 40 years old.
- A member asked if patients are likely to prefer a device providing contraception for up to a fewer number of years for example if they were planning pregnancy. Dr Prabakar explained Kyleena® may be removed after 3 years as opposed to 5 years if required.
- A member queried if clinicians are required to attend a separate training event on insertion of Kyleena® or is the same method used. Dr Prabakar confirmed the insertion technique is the same for all LNG-IUS, however it may be easier with Kyleena® as it is a thinner device.
- A member queried if Kyleena® can be used for other gynaecological indications like Mirena®; Kyleena contains a lower amount of hormone. Dr Prabakar explained longer duration studies are required to show if Kyleena® is as effective in other indications such as the treatment of heavy bleeding. Kyleena® is not licensed for other indications.
- A member raised the Scottish Medicines Consortium (SMC) paper shows a higher incidence of ovarian cysts with Kyleena®. Dr Prabakar explained cystic ovaries (cysts less than 5cm) are part of the normal

functioning of the ovaries. The studies for Kyleena® have not shown any large cysts or ovarian cyst related incidents i.e. burst cysts or ovarian torsions requiring intervention. In practice, patients are counselled on the potential of cystic ovaries with all LNG-IUS.

- A member queried the place in therapy. Dr Prabakar confirmed Jaydess® is likely to be discontinued soon. There is an ongoing place for Mirena® and Kyleena® within tertiary clinic settings and choosing a first line device is advantageous in tertiary clinics where more complex cases are seen. Within primary care settings Dr Prabakar is willing to provide the necessary information/recommendations if required by the APC.

The Chair thanked Dr Prabakar and Dr Campbell for attending the meeting, for answering all the questions from the APC members and advised them that the decision would be relayed within 5 working days, in line with APC policy.

Further discussion points in the absence of the representatives included:

- The Chair raised that Levosert®, Umbrella's first line LNG-IUS is not on the APC formulary. A UHB NHS FT representative confirmed the Trust specialist pharmacist can work with Umbrella to bring recommendations for primary care to the APC.
- A member highlighted that the incidence of side effects and the pregnancy rate was slightly higher with Kyleena® compared to other LNG-IUS. A member highlighted the evidence of harm was not found to be statistically significant. A member added as the hormone within the devices is the same, it is likely to have similar side effect profile to other LNG-IUS.
- A member queried the commissioning arrangements between Umbrella and GPs. This was deemed outside of APC remit and would be considered by commissioners outside of APC.

The Chair directed the members to the Decision Support Tool for completion:

Patient Safety: Similar side effect profile to other available LNG-IUS

Clinical effectiveness: Established. Contraceptive effectiveness is comparable to other available LNG-IUS

Strength of evidence: Robust

Patient factors: Placement rated as 'easy', less pain than Mirena®

Cost effectiveness or resource impact: Cost effective compared to alternatives

Place of therapy relevant to available treatments: 2nd line in tertiary centres

National guidance and priorities: SMC approved

Local health priorities: CCGs supportive

Equity of access: N/A

Stakeholder views: N/A

Implementation requirements: Not required

Prescribing data: Not required

Decision Summary: Green

ACTIONS:

- **Add Kyleena® to APC formulary as Green** — **APC sec**
- **Relay decision to Dr Prabakar by Thursday 16th July 2020** — **APC sec**
- **Request a review of the contraceptives chapter for the APC formulary** — **UHB NHSFT/APC sec**

0720/06 Apomorphine solution for infusion (Dacepton®) cost comparison

Following the application to the APC for Dacepton® in February 2020, the APC requested further cost information from the applicant with regards to the solution for infusion and ancillary devices.

The Chair informed members that the manufacturers of Dacepton® have subsequently provided further information to commissioners regarding a commercial arrangement and the details were outlined to members. The details of this arrangement are not recorded in the minutes due to commercial confidentiality.

The Chair invited questions or comments from members. Discussion points/concerns raised included:

- The members agreed to add Dacepton® solution for infusion to the formulary.
- A member queried if Apo-Go® is still required on the formulary, now that Dacepton® has been approved and is deemed more cost-effective.
- There was a discussion surrounding if Dacepton® would be used for all newly diagnosed patients. Members agreed to request applicant's comments on this matter.

ACTIONS:

- **Add Dacepton® solution for infusion to APC formulary as Amber Specialist Recommendation** — **APC sec**
- **Relay decision to Dr Wright by Thursday 16th July 2020** — **APC sec**
- **Confirm place in therapy for Apo-Go®** — **APC sec**

0720/07 BSSE APC Management/development Meeting

The APC secretary outlined the decisions from the APC Management/development meeting held on Thursday 11th June 2020.

- The APC will be held monthly via virtual meetings for the foreseeable future
- Consultations with member organisations which were paused due to COVID-19 will resume – supporting documentation (ESCAs/RICaDs) and drug applications
- The development of the APC and potential oversight on safety is being considered by CCGs and MLCSU

The APC secretary highlighted APC approved medicines requiring review:

- The Red recommendation for budesonide orodispersible tablets (Jorveza®) approved in June 2019 was to be reviewed by APC when the NICE TA is published. The NICE TA was due to be published in October 2019 however this schedule has been affected by COVID-19 and there is currently no timeline in place. Remain Red.
- Within the last 12 months the following medicines were identified as requiring a review of their prescribing data: Betamethasone valerate plasters (Betesil®) approved in January 2020, Fixapost® eye drops (preservative-free preparations) and Dacepton® pen device and cartridges approved in February 2020.

The following items were approved due to supply issues with the alternatives and requiring review:

- Bromfenac (Yellox®) was accepted in January 2019 as an interim measure in place of ketorolac (Acular®). The manufacturer of Acular® have confirmed the product is now available. Bromfenac® will be made non-formulary.
- Clindamycin 1% gel (Zindaclin®) was accepted in April 2018 due to supply issues with clindamycin 1% solution (Dalacin T®). The manufacturer has confirmed clindamycin 1% solution is currently available. Clindamycin gel will be made non-formulary.
- Budesonide foam enema (Budenofalk®) was accepted due to supply issues with hydrocortisone foam enema (Colifoam®) and prednisolone foam enema (Predfoam®). Colifoam® manufacturers were contacted and state there is no active supply chain so it will not be available in future. Predfoam® has been discontinued and the generic version is less cost-effective than Budenofalk®. Budenofalk® to remain on formulary.

<u>The Chair invited questions or comments from members. Discussion points/concerns raised included:</u>

- A member queried if the APC has had sight of the Terms of Reference for the management/development subgroup. MLCSU will bring a ToR to a future APC meeting
- Members agreed to review prescribing data of the medicines highlighted after a further 6 months.

ACTIONS:

- **Update the formulary with decisions outlined above** — **APC sec**
- **Review and bring ToR for the management/development subgroup to a future APC meeting** — **APC sec**

0720/08 RMOC recommendations

There were no RMOC recommendations released in April, May and June 2020.

0720/09 Minutes of the meeting held on Thursday 9th June 2020 – for ratification

The minutes of the meeting held on Thursday 9th June 2020 were discussed for accuracy.

It was confirmed the minutes are approved, can be uploaded to the APC website and the recording deleted.

0720/10 Matters Arising

The Chair moved onto the action table for comments and updates:
(See separate document attachment for updated version). Consider actions closed if not discussed.

The outstanding actions include:

- 0220/08 BSSE APC ESCAs/RICaDs Clarify arrangements for DXA scan with denosumab treatment
- 1219/07 BSSE APC RICaDs aliskiren and amiodarone – Amend amiodarone RICaD as discussed.
- 1119/07 - BSSE APC Anti-dementia treatments ESCA - Inform APC of changes to the commissioning of anti-dementia medicines
- 0719/06 - BSSE Away day documents - Trusts to develop report on LMWH prescribing.
- 0619/AOB - Azathioprine for haemolytic anaemia - Produce Azathioprine ESCA for haemolytic anaemia.

0720/11 NICE Technological Appraisals (TAs)

In April 2020, there was 1 TA published and it is NHSE commissioned.

In May 2020, there were 3 TAs published and all are NHSE commissioned.

In June 2020, there were 9 TAs published; 2 are NHSE commissioned, 3 are CCG commissioned and 4 are not recommended.

The CCG commissioned NICE TAs are:

- TA631: Fremanezumab for preventing migraine
- TA633: Ustekinumab for treating moderately to severely active ulcerative colitis
- TA626: Avatrombopag for treating thrombocytopenia in people with chronic liver disease needing a planned invasive procedure

Red status agreed

ACTION: Update APC formulary with decisions on NICE TAs. **APC sec**

Any other business:

1. **Antimicrobial guidance**

The Birmingham Antimicrobial Advisory Group (BAAG) have requested the addition of an interim statement to their primary care antimicrobial guidance

stating the NICE COVID-19 rapid guideline NG165 *managing suspected or confirmed pneumonia in adults in the community* supersedes the NICE guidance NG128 for community-acquired pneumonia. The BAAG guidance will be updated with these most current recommendations. There are no changes to recommendations in children.

ACTION: Update formulary with the BAAG interim statement **APC sec**

2. Acetylcysteine on formulary

Acetylcysteine sachets are recommended as Red on formulary and are licensed as mucolytic agent. A member highlighted acetylcysteine capsules and effervescent tablets are now available and licensed for the same indication. This section of the formulary therefore requires rationalising.

ACTION: Consult with respiratory specialists and bring comments to a future APC meeting **UHB NHSFT/APC sec**

3. Danazol discontinuation

Danazol is recommended as Amber for hereditary angioedema (off label use). A member raised that both strengths of danazol have been discontinued.
A Trust representative advised that members clinicians within secondary care have been notified and there is a small cohort of patients where use is historical and there is an ongoing need to supply. New initiations will be supplied by the Trust.

ACTION: Amend danazol status to Red for new initiations until a licensed product is launched in the UK **APC sec**

4. Red drugs and COVID-19

A primary care representative highlighted the potential for increased requests for Red rated drugs from GPs due to reduced access to services during COVID-19.

A Trust representative highlighted the opposite issue where specialists were being requested to supply medicines that the GPs would ordinarily supply. The representative explained that this had been sorted out by communicating with the CCG representatives to ensure the supply came from the correct route as per the formulary.

Members agreed open communication between sectors would resolve any ‘inappropriate’ requests.

The Chair thanked the members for their input today. The meeting closed at 15:45.

Date of next meeting: Thursday 13th August 2020 via Microsoft Teams