AREA PRESCRIBING COMMITTEE MEETING
Birmingham, Sandwell, Solihull and environs

Minutes of the virtual meeting held on
Thursday 8th October 2020
Venue – Microsoft Teams

PRESENT:

Dr Paul Dudley	Birmingham and Solihull CCG (Chair)
Prof Mark Dasgupta	Birmingham and Solihull CCG
Liz Thomas	Birmingham and Solihull CCG
Nilima Rahman-Lais	Birmingham and Solihull CCG
Dr Nashat Qamar	Birmingham and Solihull CCG
Dr John Wilkinson	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	Birmingham Women's and Children's NHS FT
Alison Tennant	Birmingham Women's and Children's NHS FT
Dr Neil Bugg	Birmingham Women's and Children's NHS FT
Melanie Dowden	Birmingham Community Healthcare NHS FT
Nigel Barnes	BSMHFT
Prof Jamie Coleman	UHB NHS FT
Dr Dhiraj Tripathi	UHB NHS FT
Dr Mark Pucci	UHB NHS FT
Gurjit Sohal	UHB NHS FT
Prof Inderjit Singh	UHB NHS FT
Maureen Milligan	The ROH NHS FT
Jonathan Horgan	Midlands and Lancashire CSU
Graham Reader	Midlands and Lancashire CSU
Daya Singh	Midlands and Lancashire CSU

IN ATTENDANCE:

Dr Marcus Mottershead, for item 1020/05	UHB NHS FT

No.	Item	Action

1020/01 **Apologies for absence were received from:**

Dr Lisa Brownell, BSMHFT
Carol Evans, UHB NHS FT/ Birmingham and Solihull CCG
Kuldip Soora, Midlands and Lancashire CSU

It was confirmed that the meeting was quorate.

1020/02 **Items of business not on agenda** (to be discussed under AOB)

No other items of business were discussed

1020/03 **Declaration of Interest (DoI)**

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

1020/04 **Welcome and Introductions**

The Chair welcomed everyone to the meeting.

The Chair reminded members, that 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.

1020/05 **Colesevelam (Cholestagel®) and Colestipol (Colestid®) new drug application**

The Chair welcomed Dr Marcus Mottershead consultant gastroenterologist, UHB NHS FT to the meeting

The Chair invited Dr Mottershead to present the application for colesevelam (Cholestagel®) and colestipol (Colestid®).

Dr Mottershead began by highlighting that the current first line option for treating bile malabsorption diarrhoea is colestyramine (Questran® light) and there are a number of patients who are intolerant to this. He highlighted that in studies that have shown patients who are started on Questran® light, only half of these patients are still taking the drug after 6 months and less than a quarter of patients after 12 months, primarily due to tolerance issues. Dr Mottershead explained that based on cost, colestyramine will remain as 1st line option, whilst colestipol would be 2nd line, with colesevelam as a 3rd line option.

Dr Mottershead explained that colestipol is available as 5g granule sachets and the usual dose is 1-2 times a day, maximum 30g in 24 hours. Dr Mottershead explained that there is not a comparative trial of colestipol vs colestyramine, however the adverse effects of colestipol are as expected. He added that colestipol is a safe medicine to use and does not interact with huge number of medications and would be a reasonable alternative to colestyramine as a 2nd line option. The price of colestipol is £15.05 for one sachet a day per patient per 28 days of treatment. Colestyramine is £8.41 for one sachet a day per patient per 28 days of treatment. Dr Mottershead highlighted colestipol would be reserved for patients that have failed first line treatments. He mentioned that loperamide has been used however there is a risk of patients treated with this, being

deficient in fat soluble vitamins A, D, E and K and therefore it is not a substitute for a bile acid sequestrants. It is expected that the estimated number of patients to be treated is up to 20 patients across the Trust.

Dr Mottershead presented the application for colesevelam. He proposed this as a 3rd line option, recognising that both colestipol and colesevelam are more expensive than colestyramine. He provided assurance that clinicians will carry out CAT scans for a definitive diagnosis before prescribing colestipol or colesevelam. Colesevelam is available as 625mg tablet and the usual dose is 1–6 tablets a day. In his experience, patients tend not to take more than two a day whilst most patients are on one tablet a day. Dr Mottershead explained that more data is available in terms of outcomes for the use of colesevelam, indicating that it is better tolerated than colestyramine. He stated colesevelam has a similar side effect profile to colestipol and colestyramine, however caution is needed for interactions with ciclosporin and further caution should be exercised when treating patients with triglyceride levels greater than 3.4 mmol/L due to the triglyceride increasing effect. The price of colesevelam is £19.22 for 1 tablet per day for 30 days. Dr Mottershead proposed that prescribing will be initiated by Consultants as third line treatment.

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

- A member wanted to confirm whether GPs are expected to continue the prescribing of both agents if approved onto the formulary. Dr Mottershead responded that a RICaD has been produced for this reason and that both agents are safe and well tolerated drugs. He went on to say that his vision is to start the medication in secondary care and once the patient is tolerating the drug and it is proving to be effective, then primary care will take over the prescribing.
- A CCG representative commented that they found the applications to be very good and comprehensive with a RICaD in place. The member agreed that a RICaD is appropriate rather than an ESCA.
- A member raised that with other clinical pathways, the APC usually take a 1st and 2nd line option approach and rarely go for a 3rd line option. It was asked that if the APC were to take the view of having just colestyramine and colestipol on formulary, would this be unsuitable for care of these patients. Dr Mottershead explained that this would not be inappropriate. The reason for colestipol being 2nd line option is that it is more cost effective. He further stated that he would have preferred colesevelam as 2nd line due to the evidence base and that the cost difference between colestipol and colesevelam is not much.
- It was asked whether there are any availability issues with either of these agents. Dr Mottershead responded that there was a short supply issue with Questran light® but is not able to comment on any availability issues of colestipol and colesevelam. A table of the stock availability of the drugs was then shared with the membership during the meeting. No further comments were made.
- A member asked what happens to the patients that drop out of treatment with colestyramine after 6 and 12 months. Dr Mottershead responded that he currently completes a NHS Trust chairman's action form for these patients which is a long process for all involved.
- A secondary care representative asked that as it is proposed to have three agents, is there any risk of wider use beyond the proposed patient pathway or is there a clear algorithm in place to apply 1st/2nd and 3rd line.

Dr Mottershead explained that they have governance in place as a CAT scan would be needed before prescribing colestipol or colesevelam.

The Chair thanked Dr Mottershead for attending the meeting, and 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:

- A member raised that they are worried about the risk of wider use beyond the planned pathway with the agents, as there is already an understanding that patients do not prefer the current 1st line option and the 2nd line option is not proven to be clinically better. A member responded that the APC have historically had conversations regarding the risk of 'creep' and fully acknowledge the point however systems, and processes are in place to monitor this. It was recognised that there is a risk.
- A member raised that if there is a medication available which is better for patients, then the APC should not be adverse to using it. As there is a set pathway then it is for the clinicians to understand and utilise that pathway. The proposed agents are more palatable for bile acid malabsorption and there is evidence for it to be used in 2nd and 3rd line following a CAT scan. The member went on to say that patients with bile acid malabsorption can be quite unsettled with their symptoms and if there is something that can be used to help them and if we have systems in place to prevent wider use beyond the pathway then we shouldn't be too concerned.
- A member commented that he is reassured by the fact that there is a clinical pathway which involves a consultant and a clinical test for the use of 2nd and 3rd line options.
- It was agreed that the RICaD should be amended so that it refers to the clinical pathway. This will help provide assurance to GPs that they will only be asked to continue the prescribing of the agents if the test has confirmed diagnosis and the consultant has signed it off. Currently the RICaD states 'A consultant Gastroenterologist will diagnose bile acid malabsorption diarrhoea and initiate as first line cholestyramine. Colesevelam is a 3rd line alternative for when cholestyramine is not tolerated, ineffective or not available.'
- A member raised that the RICaDs under the monitoring section states, 'blood test to check vitamin levels (A, D, E, K) and B12 after 3 months of treatment'. The member was concerned that the RICaD is not clear on who will be doing these blood tests and needs further clarity. Primary care colleagues agreed that they are not able to request vitamin A, D, E and K blood tests and many primary care colleagues would refer to secondary care if the results were outside the normal range.
- It was agreed that the RICaDs should note that the agents are being used for an unlicensed indication, however, this is appropriate.
- A member commented that GPs would only do tests that are within the product license.

The Chair directed the members to the Decision Support Tool for **colestipol (Colestid®)** for completion:

Patient Safety: No potential abuse, low risk of toxicity, interactions acceptable

Clinical effectiveness: Acceptable compared to colestyramine

Strength of evidence: Strong, equivalent to colestyramine

Patient factors: Improved acceptability compared to colestryamine

Cost effectiveness or resource impact: More costly

Place of therapy relevant to available treatments: 2nd line

National guidance and priorities: Nothing applicable

Local health priorities: No issues raised

Equity of access: No issues raised

Stakeholder views: None

Implementation requirements: ESCA not required. RICaD to specify established off- label use. RICaD needs to confirm vitamin testing carried out by secondary care (testing unavailable in primary care)

Prescribing data: n/a

Decision Summary: APC wish to support the addition of Colestid® on formulary with the status Amber Specialist Initiation supported by RICaD.

Rationale: n/a

The Chair directed the members to the Decision Support Tool for **colesevelam (Cholestagel®)** for completion:

Patient Safety: No potential abuse, low risk of toxicity, interactions acceptable

Clinical effectiveness: Acceptable compared to colestyramine

Strength of evidence: Strong, equivalent to colestyramine

Patient factors: Improved acceptability compared to colestyramine

Cost effectiveness or resource impact: More costly

Place of therapy relevant to available treatments: 3rd line

National guidance and priorities: Nothing applicable

Local health priorities: No issues raised

Equity of access: No issues raised

Stakeholder views: None

Implementation requirements: ESCA not required. RICaD to specify established off- label use. RICaD needs to confirm vitamin testing carried out by secondary care (testing unavailable in primary care)

Prescribing data: n/a

Decision Summary: APC wish to support the addition of colesevelam on formulary with the status Amber Specialist Initiation supported by RICaD.

Rationale: n/a

ACTIONS: **APC Sec/UHB NHSFT**

- **Relay decision to applicants by Thursday 15th October 2020**
- **Amend RICaDs in line with comments outlined above**

1020/06 Chair nomination process

The Chair directed members to the enclosure for the chair nomination process and letter.

The APC secretariat introduced the chair nomination process to the members. The secretariat explained that the chair nomination process and letter is currently in its draft format. The intention is for member organisations to use the letter to engage their own organisations and employees to encourage applications for a chair role.

- It was agreed that the APC has benefited by a co Chair approach with primary and secondary representation and this should be the preferred approach.
- It was confirmed that the current co Chairs are able to apply to continue their roles but that this would be with wider applications as they are at the stage of 4 year chair re- selection.
- It was agreed that the qualifications can be amended to be a Health Care Professional and not restricted to medical professionals only.
- It was agreed that in the event of needing interviews the Secretariat will select a couple of members (covering primary and secondary care) to support these and they will ensure that there are no conflicts of interest such being from the same organisation.
- It was agreed for an anonymous vote to take place before an interview stage takes place. However, it was raised that the committee need to be clear on how the voting process will work.

ACTIONS:

- **It was confirmed that subject to the above amendments, the chair nomination process and letter can be circulated to the APC member organisations** **APC Sec**

1020/07 BSSE APC ESCA Denosumab

The Chair directed members to the denosumab ESCA. An action from the August 2020 meeting was to remove all reference to treatment in men in line with the NICE TA 204 for prevention of osteoporotic fractures in postmenopausal women. The APC secretariat explained that in addition to the required change, additional comments have been submitted by a member CCG following the August meeting. Changes suggested from the CCG was explained to the committee by the secretary. The Committee agreed to their addition.

- A member raised that point 3 in the ESCA states 'Ask the GP whether she is willing to participate in shared care….'. This should be corrected to state 'Ask the GP whether he or she is willing to participate in shared care…..'
- It was raised that a minor formatting change for the table on page 2 is needed.
- A member raised primary care colleagues have not supported shared care for this agent and the ESCA has been discussed for several times at APC.
- A member commented that the denosumab for primary care has been contentious issue and the APC are trying to minimise the risk of clinicians refusing to prescribe denosumab.

ACTIONS:

- **It was confirmed that subject to the above amendments, the denosumab ESCA can be uploaded and published to APC BSSE website.** **APC Sec**

1020/08 Lithium carbonate m/r tablets (Priadel®) switching guideline

The Chair directed members to the lithium carbonate switching guideline produced by BSMHFT to help with the withdrawal of lithium.

On 5th October 2020, notification was received that the Competition and Markets Authority (CMA) have opened an investigation into suspected anti-competitive practices and are now investigating Essential Pharma. As a result, they have now suspended their withdrawal of Priadel® and supplies will be available beyond March 2021. In light of this, clinicians across all healthcare settings are advised that there is no longer a need to implement system wide switching of patients from Priadel® tablets to an alternative lithium carbonate preparation until further notice.

It was agreed to approve the lithium carbonate switching guideline and hold it in reserve until further action is needed.

The APC committee wished to express thanks to the mental health trust for their hard work in producing the guideline.

ACTIONS: **APC Sec**

- **Express thanks to BSMHFT in producing the switching guideline**

1020/09 NPSA alert - Steroid Emergency Card

The Chair directed members to the enclosure for the NPSA alert – Steroid Emergency Card.

The NPSA alert asks providers to ensure all eligible patients are issued with a Steroid Emergency Card and to ensure processes are in place to check if a patient has a Steroid Emergency Card ahead of any emergency treatment, elective surgery, or other invasive procedures.

- A Trust member raised that the steroid card is for adults only and it has been escalated that it does not include paediatrics. The Trust are looking at what should be in place for children.
- A member raised that the West Midlands MSO group have written to the authors of the alert to seek clarification on the cohort of patients the alert should be given too.
- Another Trust representative commented that they have a working group looking at all the measures and guidelines that need to be put in place because of the alert.

1020/10 Trust DtPs and DTC non-formulary approvals

- A member commented that the APC should adopt a standardised template for recording Decline to Prescribes and non-formulary approvals for the ease of analysis. It was agreed that UHB NHSFT will circulate their template for all to use.

ACTIONS:

- **Circulate UHB NHSFT template for Decline to Prescribe and non-formulary approvals** **APC Sec**

1020/11 H2-antagonists – alternatives to ranitidine

The Chair directed members to the email enclosure from a member Trust organisation regarding the ongoing supply issues for H2 antagonists.

A Trust representative stated that the Trust are finding it difficult to treat patients on a narrow range of H2 antagonists following the removal of oral ranitidine from the UK market in its entirety. The alternative agents are nizatidine, famotidine and cimetidine, however all three agents are currently non-formulary and due to this, a large number of decline to prescribe forms are being received from GPs.

- A member raised that there are current supply issues with these other agents and rather than putting all agents on the formulary, it is important to give guidance to GPs.
- A member suggested the website is updated *'The supply disruption recommendations relating to H2As as a result of the issues around ranitidine are likely to remain prevalent for the foreseeable future. Where a patient has previously been prescribed ranitidine, the most likely course of action will be to step up to PPIs or down to antacids/alginates. H2As should be reserved as an option of last resort for patients who do not respond to other treatments and combinations. Please reserve H2As for exceptional cases in order to preserve supplies. Where an H2A is indicated, please use the lowest dose of the least costly agent available in your locality. You will need to liaise with local community pharmacists to establish availability in your area as national availability will not necessarily translate to local availability'*
- It was asked whether all three drugs based on cost should be mentioned in the formulary amendment. A member responded there is a significant cost difference between famotidine and nizatidine and

there are some pharmacies that are unable to obtain any of the three agents.
- It was agreed to add an addendum to the formulary to assist clinicians and to link the Supply Disruption Alert.

ACTIONS:
- **Add addendum to ranitidine entry with proposed wording and link the Supply Disruption Alert (SDA)**

1020/12 Declines by Trust DTC

None were reported

1020/13 RMOC recommendations

There were no RMOC recommendations released in September 2020.

1020/14 SNOMED codes – dementia ESCA

The APC secretariat raised that a request has come in from a CCG to add SNOMED codes to the dementia ESCA.

- A CCG representative raised whether SNOMED codes will be incorporated for all ESCAs. It was clarified that SNOMED codes will be incorporated into ESCAs going forwards as part of the review process. Currently some practices use either READ or SNOMED codes or both.

ACTIONS:
- **Incorporate SNOMED codes into dementia ESCA and republish onto APC website**

1020/15 Minutes of the meeting held on Thursday 10th September 2020 – for ratification

The minutes of the meeting held on Thursday 10th September 2020 were discussed for accuracy.

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

1020/16 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:

- 0719/06 - BSSE Away day documents - Trusts to develop report on LMWH prescribing. In progress. Update: Update action table with December 2020 due date to produce the LMWH report.

- 0619/AOB - Azathioprine for haemolytic anaemia - Produce Azathioprine ESCA for haemolytic anaemia. In progress.

1020/17 NICE Technological Appraisals (TAs)

In September 2020, there were 7 TAs published; 2 are NHSE commissioned, 1 is CCG commissioned and 4 are not recommended.

The CCG commissioned NICE TA is:

- Naldemedine for treating opioid-induced constipation [TA651]

Green status agreed for CCG commissioned

Red status agreed for NHSE commissioned

Naloxegol is already green on formulary, designation of naldemedine follows that precedent.

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

Any other business:

None was discussed

The Chair thanked the members for their input today. The meeting closed at 15:30.

Date of next meeting: Thursday 12th November 2020 via Microsoft Teams