AREA PRESCRIBING COMMITTEE MEETING
Birmingham, Sandwell, Solihull and environs
Minutes of the meeting held on
Thursday 12th January 2017
Venue – Birmingham Research Park, Vincent Drive,
Birmingham B15 2SQ – Conference Room A

PRESENT:

Dr Paul Dudley	PD	Birmingham CrossCity CCG (Chair)
Dr Sangeeta Ambegaokar	SA	Birmingham Children's Hospital NHS FT
Dr Neil Bugg	NB	Birmingham Children's Hospital NHS FT
Mark DasGupta	MD	Birmingham CrossCity CCG
Satnaam Singh Nandra	SSN	Birmingham CrossCity CCG
Alima Batchelor	AB	Birmingham South Central CCG
Shabana Ali	SA	Sandwell & West Birmingham CCG
Jeff Aston	JA	Birmingham Women's NHS FT
Tania Carruthers	TC	HoE NHS FT
Dr Timothy Priest	TP	HoE NHS FT
Carol Evans	CE	HoE NHS FT/ Solihull CCG
David Harris	DH	Birmingham Community Healthcare NHS FT
Prof Robin Ferner	RF	SWB Hospitals NHST
Inderjit Singh	IS	UHB NHS FT
Maureen Milligan	MM	The Royal Orthopaedic NHST
Ravinder Kalkat	RK	Midlands & Lancashire CSU
Isabelle Hipkiss	IH	Midlands & Lancashire CSU

IN ATTENDANCE:

Natasha Jacques	HoE NHS FT (observer)
Neena Vadher	Sandwell & West Birmingham CCG for item 0117/05
Adrian Tomlinson	Solihull CCG for item 0117/05
Denise Owen	SWB Hospitals NHST for item 0117/05
Paula Noakes	SWB Hospitals NHST for item 0117/05
Fran Harries	UHB NHS FT for item 0117/05

No.	Item	Action

0117/01 Apologies for absence were received from:

- Kate Arnold Solihull CCG
- Dr John Wilkinson Solihull CCG
- Dr Lisa Brownell BSMHFT
- Dr Waris Ahmad BSC CCG
- Jonathan Horgan Midlands & Lancashire CSU

It was confirmed that the meeting was quorate.

0117/02 Items of business not on agenda (to be discussed under AOB)

- Alfentanil use across interface- issues with palliative care discharges
- Dantrolene; proposed ESCA
- Update of COPD guidelines

0117/03 Declaration of Interest (DoI)

It was confirmed that DoI forms have been received for all members attending the meeting. There were no new interests to declare relating to items on the agenda.

It was confirmed that interests relating to events older than 3 years did not need to be declared.

0117/04 Welcome and Introductions

The Chair welcomed everyone to the meeting today.

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.

0117/05 Urinary incontinence appliances review

The Chair welcomed the representatives from the sub-group tasked with harmonising and reviewing the urinary incontinence formulary across Birmingham, Sandwell and Solihull.

A brief introduction was made outlining the objectives of the sub-group's review:

- To harmonise the formulary approach to these appliances across Birmingham, Sandwell and Solihull.
- To provide GPs and other healthcare professionals with information on prescription for continence products (e.g. appropriate quantities to prescribe per month, indications etc.) with the aim of reducing over ordering, wastage, poor communication and inappropriate use.

The sub-group comprised of local continence specialist nurses from the 3 acute Trusts, the Community Healthcare Trust and pharmacists from the 4 CCGs.

The process undertaken to get to this document was outlined: all existing formularies were pooled together but in the absence of a formulary, the

organisations provided a list of incontinence products used within their respective trusts. The information on products used was collated and variances identified. Products on PrescQIPP® Stoma and Incontinence toolkit were used as a starting point; the specialists agreed on choices based on their experience, quality and costs; cost-effectiveness was checked by the pharmacists.

The PrescQIPP® document was adapted with agreed choices and circulated to the group members for comments.

The limitations of this review were highlighted: Secondary care organisations have a limited range of urinary incontinence products based on their procurement arrangements. There is limited evidence base for incontinence appliances and newer products have entered the market since the formulary choices were agreed.

It was reiterated that bowel products are not covered in this formulary.

The proposed RAG rating was outlined:

- Red: Catheter trays
- Amber (on advice of urology or specialist continence teams): Catheter maintenance solutions and silver coated catheters

All other products (except the items listed in Red and Amber above) would be Green.

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

- It was confirmed that all the Trusts were contacted to provide contact details of relevant clinicians to involve in this review. The names of the specialists involved are listed in the document.
- A member highlighted two recent Cochrane reviews on short term and long term use of catheters which included silver coated catheters that concluded that there wasno statically significant reduction in symptomatic catheter associated urinary tract infections (UTIs).
- The specialist nurses concurred that the issue of silver coated catheters had caused a lot of discussion and that these were no longer used on the wards or by community nurses at Sandwell and other Trusts. However, these were still recommended by the Urologists at City hospital, hence why they were still listed on the formulary but as Amber.
- The member representing SWB Hospitals NHS Trust proposed to remove these from the formulary and agreed to speak to the Urologists at City hospital to convey the APC's decision.
- It was highlighted that this area of prescribing in primary care was prone to over ordering or blanket ordering of everything listed rather than a more selective process, and resulted in significant waste. A Medicines Management representative confirmed that audits have been piloted in Solihull, and it was proposed that once the formulary and supporting guidance were approved by the APC, this could be used as an audit tool across the member CCGs. It was proposed that the supporting guidance would also be used as an education resource for the community nurses.
- It was highlighted that the barrier creams proposed on this formulary were in line with those already approved on Chapter 13 (Skin) with the addition of LPF barrier cream. The rationale for proposing this barrier cream was the need for a water-based barrier cream to be used in catheterised

patients using pads for bowel problems as Sudocrem® was not appropriate.

- It was highlighted that although the proposed RAG status was explained in the presentation, this was not clear in the formulary document. This will be rectified by one of the pharmacists from the sub-group.
- A member requested clarification on the Specialist Continence Team referred to several times in the document on who it included and what was the process for contacting them. The specialist continence nurses confirmed that there were established teams in Sandwell and Birmingham. It was therefore suggested to include the contact details for these teams in the document.
- A member questioned the statement on page 11 of the document which read: Routine use of prophylactic antibiotics should be avoided on grounds of cost, potential side-effects, and the danger of encouraging antibiotic resistance. It was confirmed that cost is not an issue in this context and may confuse the issue. It was therefore requested to remove reference to cost in this sentence.
- Another member questioned the choice of anaesthetic lubricant (lidocaine 2% and Chlorhexidine gel, Instillagel®) which is listed in the drug tariff as a medicinal product when there is an appliance/medical device which is identical in composition but has a lower acquisition cost (Optilube Active®). The incontinence nurses stated that whilst they were able to use the equivalent appliance in the hospital setting as they have access to a doctor in the case of an adverse reaction, they would not be covered in the same way in the community/patient's home because in a community setting they can only use a medicinal product. It was confirmed that both products are prescribable on FP10 prescriptions.

  A number of points were raised which need further investigation and clarification:
  - Is the issue around the status of the prescriber and restrictions i.e. nurse prescriber or non-medical independent prescriber?
  - Is it around authority to administer?
  - Is it a product the community nurses are expected to keep in stock or obtain via a prescription for the individual patient?

  It was agreed to look into these issues further and bring back to the committee any relevant findings.
- It was confirmed that all the products included in the proposed formulary were already listed in the previous Trusts' version and that no new products had been introduced. A revision was already planned in six months' time to consider the new products that have entered the market since this list was produced. Any new product would need a new application to be considered at the APC, and the principle of one new product to replace an existing product was reinforced.
- It was requested that prescribing data/usage figures be provided to the APC in a 6 months' time to illustrate any impact the formulary may have had.

ACTIONS:

• **Review RAG rating and incorporate this in the document**	**Incontinence sub-group**
• **Remove mention of cost in antimicrobial prophylaxis section.**	
• **Remove silver-coated catheters as agreed**	
• **Investigate issues raised around Instillagel® vs Optilube Active®**	**BCHC lead**
• **Provide usage figures in 6 months**	**CCGs/Sub-Gp**

The Chair thanked the incontinence sub-group for their useful presentation.

It was confirmed that, subject to the above actions being completed, the incontinence appliance formulary was approved.

The members also requested that it was fed back to the incontinence sub-group that the committee noted the hard work and considered approach that had gone into producing this very good piece of work.

The prices of Instillagel® and Optilube Active® were verified from the Drug Tariff (January 2017).

Product	6ml syringe	11ml syringe
Instillagel®	£1.41	£1.58
Optilube Active®	£1.08	£1.13

0117/06 **New Drug application – Riluzole oral suspension (Teglutik®)** – Martindale Pharma

It was established there were no Declarations of Interests for Martindale Pharma.

The Chair welcomed Dr Srinivasan, Consultant in Neurology, UHB NHS FT, to the meeting and introductions around the table were carried out. He was invited to present the new drug application for riluzole oral suspension.

Dr Srinivasan began with a brief outline of Motor Neurone Disease (MND) and stated that it was a progressive disease involving degeneration of the motor neurones in the brain and spinal cord and wasting of the muscles. It has different manifestations and there is not a set pattern of symptoms to enable a diagnosis.

There are 3 types of MND: ALS (Amyotrophic Lateral Sclerosis), PLS (Primary Lateral Sclerosis) and PMA (Progressive Muscular Atrophy).

This application will only consider its use in ALS.

Dr Srinivasan informed the members that 60-65% of all MND is of ALS type; of which 20% maximum will have bulbar presentation.

The liquid formulation of riluzole is of particular use in patients with bulbar presentation as these patients present with swallowing difficulties and speech problems.

The UHB clinic sees approximately 300 patients a year with MND (this figure includes patients from outside the catchment area as UHB is a referral centre).

Around 60 patients (20%) would have the bulbar presentation and would be initiated on the liquid form of riluzole. The tablet formulation would have been used until the availability of the liquid preparation.

Patients with swallowing difficulties have other modes of feeding such as nasogastric (NG) tubes or PEG (Percutaneous endoscopic gastrostomy) feeds. PEG feeds are only initiated once the patients present with bulbar symptoms or have respiratory problems. Once patients present with bulbar symptoms, they only have 9-12 months' life expectancy, so use of this product would be restricted to the end of life care of these patients.

In anticipation of a question why crushing riluzole tablets was not appropriate for these patients, Dr Srinivasan stated that tablets should not be crushed according to the manufacturers, and that as it was hydrophobic, it would not readily disperse/dissolve in water. Also, the concentration levels of the drug would not reach the therapeutic range if the tablets were crushed. The advantage of the liquid suspension is a thickened formulation which would benefit these patients.

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

- A member questioned the statement in the application form that this product was covered by a NICE TAG, when the guidance in question (NICE TA 20: Guidance on the use of riluzole (Rilutek®) for the treatment of Motor Neurone Disease) was published in January 2001 and the liquid formulation (Teglutik®) was launched in 2015. Dr Srinivasan clarified that the NICE Clinical Guideline on the assessment and management of MND (NG 42) published in early 2016 recommended that consideration should be made to patients with swallowing difficulties.
- The cost per QALY (quality-adjusted life year) quoted in the application form was also queried: the manufacturers quoted £18-29K, but NICE's assessment accepted a more conservative figure of £34-43.5K. The specialist explained that the cost per QALY figures were based on the branded product (Rilutek®), whereas a generic tablet preparation was now available at a much lower acquisition cost.
- The monthly cost comparison of the various formulations of riluzole was confirmed as follows (using a dose of 50mg twice daily): Rilutek® tablets £320.33, generic tablets £14.37 (DT Jan 2017), Teglutik® suspension £200.
- As patients with bulbar symptoms have difficulties in swallowing both liquid and solid formulations, it was pointed out that the marginal advantage of this product in these patients was even less obvious. It was for this reason SWB Hospitals NHS Trust Drugs and Therapeutics Committee did not support the application for Teglutik®.
  In response, Dr Srinivasan described the clinical scenarios he regularly encountered: crushed tablets administered via PEG tubes resulted in blockages which lead to a procedure (and associated costs) to replace the tube.
- Further clarification on the patient group was requested as the application included, in addition to patients on NG or PEG feeds, patients who have perioral tingling following administration of crushed riluzole tablets suspended in water which implies oral administration. The consultant explained that crushing the tablet resulted in an anaesthetic effect on the patient's mouth/throat, which could be troublesome in addition to their swallowing difficulties. The Teglutik® oral suspension does not have this anaesthetic effect. This perioral tingling effect may only last for 10-15mins but could result in the patient choking.
- The consultant confirmed that riluzole is the only drug currently licensed for the treatment of ALS however symptomatic management, nutritional and respiratory support, and palliative care are also available for patients with ALS. Although it prolongs median survival by 2 to 3 months, there was little information on the quality of life for riluzole- treated extended survival in ALS patients.

The Chair thanked Dr Srinivasan for his presentation and advised him that the decision would be relayed to him within 7 days, in line with APC policy.

Further discussion points raised in the absence of Dr Srinivasan included:

- It was confirmed that the liquid formulation was not available when the neurology section of the BNF was harmonised.
- The liquid formulation is a licensed product, whereas crushing the tablets is an off-label use of a licensed product.
- The product's Summary of Product Characteristics does not mention administration via PEG or NG tubes, but only oral route.
- The NEWT guidelines and the Handbook of Drug Administration via PEG/NG tube are recognised reference sources for such administration routes and both of these advise crushing tablets, without any mention of the risk of blockage or effect on bioavailability. The gauge of the NG or PEG tube may also be a factor in the risk of blockage.
- A member summarised the two issues that the members were not convinced had been answered :
    - Does the local anaesthetic effect of crushed tablets increase the risk of aspiration in some patients?
    - Does crushing the tablets cause blockage of NG/ PEG tubes?

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

Patient Safety: No established evidence of increased patient safety with liquid formulation; risk of aspiration may still be present.

Clinical effectiveness: Similar to tablet form. There is no evidence that Teglutik® exerts a therapeutic effect on motor function, lung function, fasciculations, muscle strength and motor symptoms. It has not been shown to be effective in the late stages of ALS.

Strength of evidence: Modest

Cost-effectiveness or resource impact: Considerable resource impact (£144,000 a year based on 60 patients initiated on oral suspension). £200 per patient per month compared to £15 a month for oral tablet.

Place of therapy relative to available treatments: Only licensed drug for this condition. Second line to tablet form.

National guidance and priorities: NICE TA20 (2001), based on tablet formulation. NICE NG 42 (Feb 2016): MND

Local health priorities: Would not support in view of resource impact.

Equity of access: N/A

Stakeholder views: N/A

Implementation requirements: Would require ESCA if approved.

Decision Summary: Not approved. Rationale: very expensive medicine; the committee was not convinced by the argument put forward for the patient group identified for this formulation (i.e. NG/PEG feeding tubes), as the NEWT guidelines support crushing of tablets.

Action:

- **Relay decision to Dr Srinivasan by Thursday 19th January 2017.** **APC sec**

0117/07 New Drug application – Triptorelin s.c. injection (Decapeptyl® SR) –Ipsen Ltd.

It was established there were no Declarations of Interests for Ipsen Ltd.

Although the applicant had been invited to attend the meeting to present the application for Decapeptyl® SR injection, attendance had not been confirmed.

It was agreed to proceed with consideration of the application in the absence of the clinician, as this had been done previously.

The APC secretary reminded the committee members that triptorelin was included in the formulary for use in endometriosis in BNF section 6.7.2. However its use in prostate cancer was considered during harmonisation of chapter 8 in June 2015 and the committee decided to remove triptorelin from this section. The rationale was that clinicians have more experience with the other two agents, and have concerns about switching between GNRH agents, and there was not much use in the area.

It was clarified that the reference to NICE approval in the application form was in fact a NICE Evidence Summary for New Medicine, published in January 2014, not a TAG.

The APC secretary referred to a PrescQIPP® bulletin (bulletin 88, April 2015), which was in the public domain and provided a useful summary of the available luteinising hormone-releasing hormone (LHRH) agonists in prostate cancer, together with a detailed comparison table which included drug, dose, brand name, presentation form, administration interval, needle size, injection route and cost per year. This table was circulated to the members.

PrescQIPP's bulletin included a summary from the Midlands Therapeutic Review & Advisory Committee (MTRAC®) commissioning support review which states that when considering cost effectiveness and which product to use, patient frequency of GP surgery attendance, the frequency of drug administration and associated monitoring, and any GP practice fees for administration of the injections need to be taken into account. Fees for drug administration may vary as goserelin is an implant and leuprorelin is a liquid injection. MTRAC also states that commissioners should engage with providers to reach agreement on product use to achieve the most economic model for LHRH agonist use across the health economy. This should take into account product price and local discounts available from manufacturers.

With regards to clinical effectiveness, the bulletin goes on to state that there is limited comparative data of the different LHRH agonists. However:

- There is evidence that LHRH agonists are similar in effectiveness to surgical castration in terms of survival, testosterone suppression, symptom control and prostate volume reduction.
- A NICE new medicine evidence summary for triptorelin SR states that the evidence on differences in adverse effects (e.g. impotence, hot flushes, glucose intolerance, increase risk of cardiovascular disease, osteoporosis) among the agents within each class is limited and does not suggest that one agent is superior to the others.
- Taking cost effectiveness, route and frequency of administration into account, 6 monthly triptorelin and 3 monthly triptorelin and leuprorelin are the most cost effective products for prostate cancer in new patients.

- Use 12 weekly/3 monthly or 6 monthly injections in preference to 4 weekly/monthly injections to support administration, convenience to the patient and costs.

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

- It was confirmed that the recommendations from the urologists were worded in such a way that the choice of LHRH agonist was left with the GP.
- The Chair confirmed that most of his GP colleagues no longer use the monthly injection, except when initiating treatment.
- The members could see the benefit of a 6 monthly injection.
- The principle of one new product in, one out was reiterated to deliver an effective local formulary: the applicant has suggested it could replace Prostap® if a replacement is required, rather than complementing the current options.
- The commissioners confirmed that goserelin attracts a primary care discount, but this cannot be disclosed; leuprorelin is also available at a discounted price. However the commissioners would favour a lower list-price product over a discounted product.
- A member raised a concern regarding the availability of a needle safety device. New EU legislation on needle stick injuries recommends that organisations eliminate the use of needles where possible, implement safe procedures for the use and disposal of needles, including use of protective equipment, and to introduce devices that incorporate safety-engineered protection mechanisms. This has been an issue for patients having their insulin administered by district nurses and has led to much more expensive safe needles being prescribed for their insulin pens.
- The comparison table would suggest that the triptorelin products did not incorporate a needle safety device. However, it was suggested that this may be due to the fact that the form was as a powder for suspension with a diluent, as opposed to a prefilled syringe in the case of goserelin and leuprorelin.
- The BCHC lead confirmed that district nurses would use a needle safety device if it was available, but if this was not the case they would take appropriate steps and care to minimise the risk of needle stick injuries.
- The APC secretary confirmed that the 3 LHRH agonists were included on the formulary for endometriosis, and it seemed appropriate to include a third agent for prostate cancer for equity of access.

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

Patient Safety: Equivalent to other LHRH agonists, however the members noted that there was no needle safety device for this product.

Clinical effectiveness: As effective as other agents in this class.

Strength of evidence: There is limited comparative data of the different LHRH agonists, but there is evidence that LHRH agonists are similar in effectiveness to surgical castration in terms of survival, testosterone suppression, symptom control and prostate volume reduction.

Cost-effectiveness or resource impact: 10% less expensive than its direct comparator. It is the only 6 monthly preparation which leads to reduced costs of administration.

Place of therapy relative to available treatments: Equal to other agents in class.

National guidance and priorities: NICE guidance on prostate cancer, MTRAC has produced a commissioning support review.

Local health priorities: CCGs would support application

Equity of access: Provision for prostate is similar to provision for endometriosis.

Stakeholder views: N/A

Implementation requirements: None

Decision Summary: accepted on the formulary as Amber: specialist initiation or recommendation. Rationale: RAG rating in line with other agents in this class, offers a cost-effective alternative to current formulary options and a longer administration interval.

Actions:

- **Relay decision to Mr Viney by Thursday 19th January 2017.** **APC sec**
- **Add triptorelin to APC formulary as Amber.** **APC sec**

0117/08 Issues with products not listed in the Drug Tariff.

A paper outlining the various issues with the current NHS reimbursement scheme for primary care prescribed medicines, and the number of loopholes that may be exploited by the medicines supply chain to the detriment of the prescribing budget was circulated for information. This paper has been written to advise the Area Prescribing Committee about some of the factors that may affect prescribing spend adversely and often unexpectedly.

The members commented on the usefulness of this document and that it had raised their awareness of the difficulties encountered by commissioners and prescribing budget holders. There was no action to be taken.

0117/09 Antimicrobial dressings section of wound formulary- updated RAG rating and rationale- For ratification.

The APC secretary reminded the members that this section of the wound formulary had been discussed at length at the September 2016 away day after the algorithm had been reviewed, modified and approved.

The document presented today is the result of a final review by the wound care group based on feedback from the away day, taking on board APC members' comments on cost etc., and revised the RAG rating accordingly.

The changes were highlighted:

- L-Mesitran® hydro/border: changed from Amber to Red (hospital only)
- Cutimed Sorbact®, Suprasorb® X + PHMB and Prontosan® wound Gel X: changed from Green to Amber.
- Prontosan® wound irrigation solution: changed from Green to Amber. A duplicate entry with a different RAG rating was highlighted. It was

confirmed that Amber is the proposed RAG status.

A member requested it was minuted that some members of the committee still had reservations about the widespread use of very expensive products with no quality evidence for their use. It was acknowledged that adding costs to this section of the formulary was difficult in view of the various sizes available. The member reiterated that there was no evidence for honey, no evidence that silver dressings are of any value, and there is very little evidence for iodine. However the overall consensus of the APC members was to accept this section of the formulary for practical reasons and to support clinicians in what is standard practice in wound management.

Further changes to the algorithm were proposed/ discussed:

- It had been suggested at a previous meeting to swap the first two boxes on the left hand side and prioritise checking for symptoms of sepsis as the first step.
- As this algorithm would be the first document clinicians refer to, it was suggested to list the Green and Amber dressings in the appropriate box rather than in a separate box at the bottom. This may lead to overcrowding of the box, so an asterisk was proposed.
- It was observed that the colours used in the algorithm are similar to the RAG status, and could lead to confusion. The text in Amber is difficult to read.
- It was also suggested to use the terms “first line Green antimicrobial dressings” and “second line Amber dressings”.

For information: the APC secretary has been informed that the manufacturer of Advadraw® had discontinued this product with immediate effect. It has therefore been removed from the published formulary. Aquacel® is a suitable alternative and is already included in the formulary.

Decision: it was agreed that, subject to the slight reformatting of the algorithm and changes to the colours used, the algorithm was approved and ratified. The antimicrobial section was also approved.

Actions:

- **Modify antimicrobial dressings algorithm as discussed.** **SSN**
- **Remove duplicate entry for Prontosan® wound irrigation solution.** **SSN**
- **Upload algorithm and antimicrobial dressings to the APC formulary** **APC sec**
- **Circulate final documents to APC members.** **APC sec**

Whilst on the subject of dressings, the APC secretary notified the members that she had received an email from the company that manufactures Mepilex® requesting clarification on the issues raised in the minutes of the November 2016 meeting. It was confirmed that the APC’s decision was irrespective of the involvement of industry, and that if a clinician wanted to appeal the decision to remove Mepilex® from the formulary, the appropriate route was via the appeal process.

0117/10 Minutes of the meeting held on Thursday 8th December 2016

The minutes of the meeting held on Thursday 8th December 2016 were discussed for accuracy.

Page 9: 1216/08: remove first sentence as not accurate.

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

The following documents were also approved:
DST for Desitrend®, DST for Episenta®, DST for Binosto®, DST for Esmya® intermittent use- revised Dec 2016, DST for Resp-Ease® 7%.

0117/11 Matters arising – Action Table

The Chair moved onto the action table for comments and updates:

(see separate document attachment for updated version – only actions for APC secretary that are not closed were discussed):

- 1216/11 – Matters arising- degarelix RICaD-Redraft as ESCA and circulate to APC members for consultation. Update: This will be circulated for consultation shortly.

- 1216/AOB – ESCAs- Review current ESCAs and include a statement regarding the appropriate patient population covered by the shared care agreement. Update: This is a big piece of work and is on-going. SSN's support with this was acknowledged.

- 1016/08 – Review Methotrexate ESCA for rheumatology to include dermatology use.
  Update: Outstanding- Pharmacist from HEFT has offered to support.

0117/12 Summary of decline to prescribe forms

- BCH summary was circulated for information. This summary highlighted once again the variability in GPs' willingness to pick up prescribing of Amber drugs. It was noted that the majority of the decline to prescribe were for valid reasons i.e. unlicensed, Red on the formulary or complex children. However some of the rationales put forward were perceived as unreasonable. The Trust leads were reminded to approach the Heads of Medicines Management of the respective CCG in the first instance to facilitate discussions with the GPs, but as independent contractors they could only be advised to prescribe.

0117/13 NICE Technology Appraisal (TAs)

There were 7 NICE Technology Appraisals published in December 2016; six commissioned by NHSE and one commissioned by CCGs.

- TA420 Ticagrelor for preventing atherothrombotic events after myocardial infarction: ticagrelor, in combination with aspirin, is recommended as an option for preventing atherothrombotic events in adults who had a myocardial infarction and who are at high risk of a further event.
  Treatment should be stopped when clinically indicated or at a maximum of 3 years.

Ticagrelor is already on the formulary as Amber with a RICaD following NICE TAG 236 on ticagrelor for the treatment of acute coronary syndromes (ACS) which recommends, as an option, ticagrelor 90mg with aspirin for up to 12 months in adults with ACS to prevent further atherothrombotic events.

This technology appraisal recommends ticagrelor 60 mg with aspirin as extended therapy (for up to 3 years) after the initial 12-month treatment with dual antiplatelet therapy.

It was agreed to add it to the formulary as Amber with RICaD. A separate RICaD would need to be developed as combining it with the current document would lead to confusion in view of the different dose and length of treatment.

Actions:

- **Update APC formulary with decisions on NICE TAs.** **APC sec**
- **Develop draft RICaD for ticagrelor for preventing atherothrombotic events after myocardial infarction.** **SSN/ APC sec**

0117/14 Trust Chairs non-Formulary approvals

None were received this month.

0117/15 Inequity in NICE process- response from Prof D. Haslam, Chair of NICE.

The APC secretary has received a reply to the APC Chairs' follow-up letter sent in May 2016, apologising for the delay in responding. The ongoing concerns of the APC have been discussed and considered by colleagues within NICE's Centre for Health Technology Development and System Engagement Programme.

It was suggested that these issues be raised with NHS Clinical Commissioners (NHS CC), as the membership organisation and collective voice of CCGs, which may help to encourage CCG participation and engagement in the development of NICE TA guidance.

Collectively, Birmingham and Solihull CCGs have a route into NHS CC and can pick this up.

ACTION: Heads of MM to discuss and feedback any actions taken. **CCGs HoMM**

Any other business:

1. Alfentanil use across interface- issues with palliative care discharges.
This has been raised by one of the Acute Trusts leads in that the current formulary status of alfentanil (Red) is causing interface issues when palliative care patients are discharged on alfentanil syringe drivers, and GPs are unwilling to pick up ongoing prescribing. The Trust clinicians are proposing to work with the relevant teams to take this forward and identify a more stable long term solution for providing alfentanil in palliative care, whilst recognising the off label use.

It was acknowledged that a review of the palliative care formulary had been recommended some time ago, and was now due.

It was proposed therefore that relevant palliative care specialists e.g. hospice clinicians, palliative care consultants, come together and form a sub-group similar to the wound care group, and look at what is currently on the formulary, what would be required and anything new would need a drug application to be submitted for consideration.

Acute and non-Acute Trust leads will forward relevant contact details of palliative care specialists respectively. It was requested that a representative of the Sheldon Unit be included. CCG representative may also put forward names and contact details of clinicians with an interest in Palliative care.

ACTION: APC members to forward contact details of Palliative Care clinicians to the APC secretary to form a palliative care sub-group. **ALL**

2. Dantrolene: proposed ESCA

As a result of a GP declining to prescribe dantrolene for muscle spasticity in a patient with a neurological disorder without the support of an ESCA, the UHB clinicians have drafted an ESCA for this use, and sent it for APC consideration.

The APC secretary confirmed that dantrolene was on the formulary as Amber (no ESCA) for muscle spasticity; it is widely used for this indication and the majority of patients with muscle spasticity will have a neurological condition.

It was agreed that it was not appropriate to develop an ESCA on the grounds of one GP declining to prescribe.

It was emphasised that the local body charged with developing ESCAs and deciding when ESCAs are needed is this APC committee. The response to the GP should therefore be that there is no ESCA; however if it is felt that such an ESCA is required, the GP can submit an application to the APC and attend a meeting to make the case.

ACTION: Relay the APC's comments to the UHB team for information. **APC sec**

3. Update on COPD guidelines

The APC secretary reminded the committee members that the applications to be considered at the February meeting included several COPD inhalers. The applications made reference to "new" COPD guidelines. The clinicians confirmed that these revised guidelines were to be discussed and finalised at the next Respiratory network meeting on 19th January. These would be forwarded to the APC members as soon as received from the respiratory clinicians.

ACTION: Circulate revised COPD guidelines once received from respiratory network. **APC sec**

The chair thanked the members for their input today. The meeting closed at 16:40 pm.

Date of next meeting: Thursday 9th February 2017 14:00 – 16:45
Conference Room A,
Birmingham Research Park,
Vincent Drive.
Birmingham B15 2SQ.