NHS Berkshire West Area Prescribing Committee
Minutes of Meeting held on 6th November 2013
Room G29/30, 57/59 Bath Road, Reading, RG30 2BA

Attendance:

[redacted]

1. Chairman's Introduction

[redacted] welcomed everyone to the meeting. The Chairman informed the committee that [redacted] had resigned and recorded his thanks for the major input made by [redacted] over the past year.

2. Apologies

[redacted]

3. Pecuniary Interests

No declarations received.

4. Minutes of the APC meeting held on 4th September 2013

A few amendments were made providing further clarification on why recommendations were made. This included section 10.2 where it was noted that Dymista® is not as cost effective a treatment as some alternative treatments. In addition the safety profile is not well established. Once these amendments where noted, the minutes were agreed as accurate.

5. Matters Arising from Meeting on 4th September 2013 not Included in Main Items

5.1 APC Terms of Reference (TOR)

No comments were received following the circulation of the amended TOR and it was agreed that these should go to GP MOT for sign off.

[redacted] updated the group that there is another Lay Member to join the APC in January 2014

5.3 EPC 12/40 Melatonin for the treatment of sleep disorders in paediatric patients – Review under progress .

5.8 Ketamin for Refractory Pain: [redacted] will follow this up and aim to resolve by March 2014

11.2 [redacted] updated the group that on the views of the diabetic network on the formulary noting that it was not an intention for it to be an extensive " formulary" but a more concise guide as to what we use in Berkshire West re medication etc. [redacted] are the people to liaise with re taking this forward. [redacted] to meet with [redacted]

11.7 APC 13/11 TA280: Abatacept for treating rheumatoid arthritis – [redacted] clarifying pathway in secondary care and will update at the meeting in May 2014.

11.9 APC 13/13 TA283: Ranibizumab for treating visual impairment caused by macular oedema secondary to retinal vein occlusion – [redacted] finalising pathway that will form a larger pathway within the PBRexcluded eyecare service (expected March/May 2014)

6. Horizon Scanning / NICE Update

The list of topics for November and subsequent meetings were discussed. In addition the expired EPC topics were also discussed. It was agreed that the various specialists would be given an opportunity to comment on the expired policies with no new evidence. For policies with new evidence available, these would be considered as new policies. [redacted] to circulate policies for comment and update all within the next 2 months

7. Preventing duplication of formulary submissions and submission forms

[redacted] informed the group that there is on-going work on selecting future topics and preventing duplication of formulary submissions – [redacted] to meet with RBH and BHFT to reduce risk of duplication.

8. Policies Agreed at Meeting Held on 3rd July 2013

APC 014 What priority to give to the prescribing of glycopyrronium for hyperhidrosis? Agreed

APC 015 What priority should be given to the prescribing of azelastine hydrochloride and fluticasone propionate Nasal spray, 137mcg/50mcg (Dymista®Nasal Spray) - Agreed

APC 016 Should leuprorelin continue to be the LHRH agonist of choice for

new initiations and could it be considered for existing patients on alternative LHRH agonists? - Agreed
APC 017 Updated shared care guideline for the treatment and prevention of venous thromboembolic disease (DVT/PE)- Agreed. Area of homecare to be explored once Homecare Steering Group has untangled homecare provision in Berkshire West.
APC 018 NOACs for treating intravenous drug users - Agreed
APC 019 TA287: Rivaroxaban for treating PE and preventing recurrent venous thromboembolism- Agreed
APC 020 TA288 Dapagliflozin in combination therapy for treating type 2 diabetes- Agreed
APC 021 TA292 Aripiprazole for treating moderate to severe manic episodes in adolescents with bipolar 1 disorder- Agreed
APC 022 TA293 Eltrombopag for treating chronic immune (idiopathic) thrombocytopenic purpura (review of TA 205)- Agreed
APC023 TA294 Aflibercept solution for injection for treating wet age-related macular degeneration (AMD)- Agreed

8. Papers

8.1 APC 13/13

TA283: Ranibizumab for treating visual impairment caused by macular oedema secondary to retinal vein occlusion – Pathway

- This paper was not presented as further work is needed and will encompass a wider pathway

Action:
Pathway to be produced March or May 2014

8.2 APC 13/24

Long acting antimuscarinic inhalers

- Aclidinium bromide and glycopyrronium bromide are 2 long acting muscarinic antagonists (LAMA) licensed for maintainance bronchodilator treatment to relieve symptoms in adult patients with chronic obstructive pulmonary disease (COPD).
- Both drugs were compared against placebo in clinical trials and shown to be superior in improving Forced Expiratory Volume in 1 second (FEV1) after 12 and 24 weeks.
- The APC expressed concern at the short duration of the measurement of the primary endpoint (FEV1) in these trials and the implications for patient safety.
- Patients with cardiovascular disease where excluded from trials and there is a lack of data in patients with very severe disease.
- Glycopyrronim is used once daily (as is tiotropium) with aclindinium used

twice daily and the APC debated the merits of once daily vs twice daily dosing in this clinical scenario concluding that there was unlikely to be a significant difference in compliance between the two LAMAs. NICE currently recommends once daily dosing as being preferred.

- The APC noted that patients with dexterity problems might benefit from one of the LAMAs. Glycopyrronium is simple to use and could be manipulated by a patient with dexterity problems.
- The APC also noted that only 30% of patients taking tiotropium had an improvement when taking longterm and it was agreed that it was important to review all patients started on tiotropium. [redacted] noted that a recent audit at his practice showed that 75% of patients with COPD were on triple therapy (inhalers)
- LAMAs offer symptomatic improvement and decrease in the number of exacerbations of COPD and if after a month there has been no improvement then therapy with a LAMA should be stopped.

After consideration of the evidence and the stakeholder comments, the APC reached a recommendation.

Recommendation:
Aclidinium and/or glycopyrronium are NOT recommended for new initiations but may be tried in patients not responding adequately to tiotropium. The APC noted that aclidinium and glycopyrronium were priced lower than tioptropium however safety was considered paramount and until more data becomes available (especially comparing both LAMAs against tiotropium), tiotropium remains the LAMA of choice.

Action:
Policy to be taken to GP's Medicines Management Committee for ratification and then published on Website and Net Formulary.

8.3 APC 13/125
Alogliptin for type 2 diabetes

- Alogliptin is an oral dipeptidyl peptidase-4 inhibitor due to be licensed in quarter 4 of 2013.
- The proposed indication is to improve glycaemic control in adults with type 2 diabetes mellitus in combination with other glucose-lowering agents including insulin when these together with diet and exercise have not provided adequate glycaemic control.

- The cost is yet to be determined but is anticipated to be around £30 and £35. Alogliptin is the 5th DDP-4 to the UK market.
- The published clinical evidence for alogliptin as add on treatment showed a reduction in HBA1c of 5.5 mmol/mol compared with placebo.
- Adverse events recorded during the trial were not of concern however in view of recent safety concerns/withdrawal of anti-diabetic drugs from the market, the APC were cautious when interpreting safety data.
- The APC agreed that there was insufficient advantage over alternative treatments including other DDP-4 inhibitors and selected option 3.

Recommendation:
Alogliptin is not recommended for prescribing within the Berkshire West localities. There was insufficient advantage over other alternative treatments.

Action:
Policy to be taken to GP's Medicines Management Committee for ratification and then published on Website.

8.4 APC 13/26
Choice of DDP-4 inhibitor

- Information on cost of treatments as well as previous total spend on individual DDP4 inhibitors were presented to the APC.
- The APC reviewed all 4 DDP4 drugs based on use as add on treatment, dosing in renal impairment, hepatic insufficiency, use in the elderly and cost.
- Saxtagliptin was found to currently be the cheapest DDP4 inhibitor with sitagliptin the most costly. The majority of prescribing of DDP4 within Berkshire West is for sitagliptin with over £900,000 spent within the last financial year.
- The APC did not agree that savings of £20 per patient per year warranted switching patients and therefore did not support a switch program.
- As all DDP4 have broadly similar characteristics and there is now considerable years of use of saxtagliptin and this is the currently the cheapest DDP4, option 1 was agreed with saxtagliptin considered as the DDP4 of choice.
- Recommendation: Saxtagliptin should be the DDP4 agent of choice with the other DDP4 reserved for patients unable to tolerate or not responding to saxtagliptin.
- GPs should be reminded of the place off DDP4-inhibitors in the treatment pathway.

Action:
Document to be updated and taken to GP's Medicines Management Committee for ratification and then published on Website.

8.5 APC 13/27
What priority should be given to the management of vitamin D deficiency in adults?

- High dose vitamin D supplementation was previously considered low priority (expired policy statement EPC 013). Vitamin D preparations were at the time unlicensed and the cost of purchasing could prove prohibitive and was difficult to regulate due to be an unlicensed special. Since this time, several colecalciferol preparations have been licensed including Futilim, Desunin.
- Guidance was published in April 2013 by the National Osteoporosis Society (NOS) which recommends treating vitamin d deficiency in adult patients.
- Additionally, the low priority statement EPC 013 was in direct conflict with guidance issued by RBFT rheumatology department.
- The key recommendations from the NOS guidelines are summarised below:
- Measurement of serum 25OHD is the best way of estimating vitamin D status.
- Serum 25OHD measurement is recommended for:

1. patients with bone diseases that may be improved with vitamin D treatment
2. patients with bone diseases, prior to specific treatment where correcting vitamin D deficiency is appropriate
3. Patients with musculoskeletal symptoms that could be attributed to vitamin D deficiency.
4. Routine vitamin D testing may be unnecessary in patients with osteoporosis or fragility fracture, who may be co-prescribed vitamin D supplementation with an oral antiresorptive treatment.

• In agreement with the Institute of Medicine (IOM), the NOS propose that the following vitamin D thresholds are adopted by UK practitioners in respect to bone health:

- **serum 25OHD < 30 nmol/L is deficient**
- **serum 25OHD of 30–50 nmol/L may be inadequate in some people**
- **serum 25OHD > 50 nmol/L is sufficient for almost the whole population.**

- Oral vitamin D3 is the treatment of choice in vitamin D deficiency.
- Where rapid correction of vitamin D deficiency is required, such as in patients with symptomatic disease or about to start treatment with a potent antiresorptive agent (zoledronate or denosumab), the recommended treatment regimen is based on fixed loading doses followed by regular maintenance therapy: a loading regimen to provide a total of approximately 300,000 IU vitamin D, given either as separate weekly or daily doses over 6 to 10 weeks maintenance therapy comprising vitamin D in doses equivalent to 800–2000 IU daily (occasionally up to 4,000 IU daily), given either daily or intermittently at higher doses.
- Where correction of vitamin D deficiency is less urgent and when co-prescribing vitamin D supplements with an oral antiresorptive agent, maintenance therapy may be started without the use of loading doses.
- Adjusted serum calcium should be checked 1 month after completing the loading regimen or after starting vitamin D supplementation in case primary hyperparathyroidism has been unmasked.
- Routine monitoring of serum 25OHD is generally unnecessary but may be appropriate in patients with symptomatic vitamin D deficiency or malabsorption and where poor compliance with medication is suspected.

Recommendation:
The NOS guidelines should be adopted within practices in Berkshire West

Action:
Policy to be taken to GP's Medicines Management Committee for ratification and then published on Website.

8.6 Rifamixin for the reduction of episodes of overt hepatic encephalopathy in patients aged 18 years and over.

- A paper produced by the gastroenterology department at the Royal Berkshire Foundation Trust was circulated to the APC for consideration.
- The APC were made aware that NICE were due to publish a technology appraisal in January 2014 and their initial draft recommendation had been to decline the use of treatment with this drug.

Recommendation:
The APC therefore took the decision to defer this paper until NICE has issued guidance on this treatment.

9. Shared care

9.1 Mercaptopurine shared care

Mercaptopurine is the active form of azathioprine and the gastroenterology department would like to initiate this treatment in secondary care then transfer treatment to the GP.
The inconsistency of DMARD prescribing and monitoring across the different specialities was noted and concerns to patient safety registered.

The APC took the decision to support the guidelines issued for mercaptopurine but have requested that the newly set up priorities committee consider the issue of how DMARDs are monitored and commissioned and the inconsistency of specialities across the centres.

9.2 Prescribing arrangements for ADHD medications

Lisdexamphetamine has been approved for 2nd line use in ADHD after failure of methylphenidate and the APC asked for a treatment pathway which incorporates this treatment and other treatments for ADHD. Prescribing arrangements were written which encompass methylphenidate, lisdexamphetamine, atomoxetine and dexamphetamine. OT was asked to make a few amendments and circulate the document for comment and subsequent discussion at the meeting in January 2014.

9.3 Lithium

This was also advised to be circulated for comment and to make the document less repetitive etc. For discussion March 2014.

10 Any Other Business

[redacted] mentioned a proposal by RBFT to take over the monitoring of NOACs in primary care using the DAWN database. It was agreed that this proposal needs to come through the APC.

Dates of Future Meetings

Date of Meeting	Venue
Wed 8th January 2014	Room G29/30, 57/59 Bath Road, Reading, RG30 2BA
Wed 5th March 2014	Room G29/30, 57/59 Bath Road, Reading, RG30 2BA

All Meetings 10.00am – 12.00pm