Minutes of the Medicines Advisory Group Meeting of

Wednesday 27 January 2016

UH Bristol, Conference Room, Trust HQ, 12.00 – 14.00

1. **Welcome and Apologies**
[redacted] welcomed all to the meeting.

Present:
[redacted]

Apologies:
None received.

2. **Minutes of the meeting held on 25 November 2015**
The minutes were accepted as a true record.

3. **Matters Arising from November Minutes**

3.1. BNF edition 70 and BNFC
[redacted] reported that the BNFC has been annotated with the necessary corrections and circulated. The labelling of the BNF edition 70 is currently underway, highlighting the major errors prior to distribution.

3.2 Biosimilar communication and timeline
This is being prepared by [redacted] and [redacted]. The implementation of etanercept biosimilar is being planned.

3.3. Apremilast
[redacted] noted that the NICE decision is being appealed and it was decided to await the outcome of that appeal before making any further decisions.

3.4. Teduglutide
[redacted] is attending to address the outstanding questions.

3.5. Autologous serum eye drops
This is still under discussion with the CCG as NHS England have considered that it is within tariff. [redacted] will follow this up with [redacted].
Action: [redacted]

3.6. Discontinuation of statins
[redacted] reported that [redacted] is keen to implement the recommendation of the November meeting regarding discontinuation of statins when nearing the end of life and agreed this will provide enhanced quality of life for patients. He is currently reviewing the evidence submitted and considering how to communicate implementation.

4. **Strategic Issues**

4.1. MHRA Drug Safety updates
These were reviewed and [redacted] will forward the mycophenolate information in the December update to appropriate prescribers.

4.2. Electronic prescribing update
[redacted] reported that the timeline is being finalised with the pilot scheduled in summer 2016 followed by rapid rollout.

4.3. Medicines not reimbursed through national prices and directly commissioned by NHS England v9.1.
This updated list of the NHS England high cost drugs commissioning position is now available and the Trust high cost medicines standard operating procedure has been updated.

4.4. NHS England Early Access to Medicines Scheme - osimertinib
This current EAMS was noted.

4.5. Cancer Drugs Fund consultation
[redacted] noted the current consultation with a February 2016 deadline and which focuses upon the transfer of the Cancer Drugs Fund to NICE coordination with more rapid decision making.

4.6. Procurement of providers for the prescribing of bedaquiline and delamanid for defined patients with multidrug resistant/extensively drug resistant tuberculosis.
[redacted] noted that the Trust is submitting a combined application with North Bristol Trust to provide this service.

5. **Joint Bristol Formulary Group**

5.1. BNSSG Formulary Decisions
[redacted] reported the following formulary decisions:

Rivaroxaban - DVT post limb fracture and immobilisation; the current guidelines suggest that there is insufficient evidence to recommend oral treatment in place of a LMWH and therefore this approach is not evidence based. The JFG felt that the local haematologists' views should be sought. To be brought back to the next meeting.

Olsalazine - Ulcerative colitis; the JFG approved the addition of olsalazine onto the formulary, TLS blue only for these patients.

Peppermint enemas - Patients with glaucoma having a colonoscopy; to include on the formulary, TLS Red.

Infliximab - steroid refractory colitis due to ipilimumab; agreed for inclusion onto the formulary, TLS Red with guidelines.

Cangrelor - co-administered with aspirin in adult patients with coronary artery disease undergoing percutaneous coronary intervention (PCI) who have not received an oral P2Y12 inhibitor prior to the PCI procedure and in whom oral therapy with P2Y12 inhibitors is not feasible or desirable. More information required.

Levonorgestrel intrauterine system - LARC for women with heavy menstrual bleeding. Levosert does not appear to confer any additional benefit over Mirena so there appears to be no indication for including Levosert on the BNSSG formulary.

5.2. Idarucizumab
[redacted] noted the availability of this agent to reverse dabigatran effects. A BNSSG position needs to be identified.

6. **Matters arising from BNSSG Drugs and Therapeutics Committee**

6.1. Feedback from meeting 20 January 2016

6.1.1. New oral anticoagulant choice
Although an antidote to dabigatran is available the first line local drugs remain as apixaban and rivaroxaban.

6.1.2. Paediatric prescribing responsibilities
[redacted] reported on a discussion in which there was concern expressed by both GPs and paediatric consultants about prescribing being referred to them rather than addressed in the other care setting. Concerns were noted from both sets of clinicians and [redacted] and [redacted] will consider how to give further guidance in the formulary.

Action: [redacted]

7. [redacted]

7.1. [redacted]

[redacted]

7.2. [redacted]

7.3. [redacted]

7.4. [redacted]

[redacted]

7.5. [redacted]

8. **Clinical guidelines and documentation**

None submitted this month.

9. **Immunoglobulin assessment panel**

9.1. New IVIG guidance SSC 1539 Access to normal human immunoglobulin products and demand management poster

[redacted] drew attention to this helpful new guidance from NHS England which clearly differentiates those indications that require consideration at the immunoglobulin assessment panel, which is undertaken by MAG.

9.2. IVIG approvals

[redacted] requested the use of IVIG for a patient with autoimmune encephalitis. Alternative treatments have had little effect and this condition was previously reviewed and approved by MAG. Treatment for this patient was considered to be appropriate.

9.3. Quarter 3 IVIG dashboard results

The IVIG dashboard again shows that there is very little information being submitted with regard to patient outcomes, adverse events and ongoing monitoring of patients receiving IVIG. This therefore requires ongoing review and action.

10. **Homecare medicines**

10.1. New medicines via Homecare

[redacted] outlined the request for eculizumab for administration via Homecare. This is a national arrangement being organised through the specialist centre in Manchester where specialist nurses are trained through Bupa Homecare to administer this treatment. The NHS England Commissioning Policy has outlined this as the recommended process so it was approved.

11. **Cost-effective prescribing**

[redacted] noted that the savings board has requested some challenge questions to address the different workstreams, so in the medicines workstream he is exploring issues around the implementation of biosimilar products, the inhalational anaesthetic variations observed in benchmarking, and the difficulties arising from implementing some generic substitutions. Further discussion may be brought to MAG.

12. **NICE**

[redacted] reported on the recent NICE publications.

13. **Applications for one off drugs**

13.1. One request was received for the use of aprepitant for a patient with cystic fibrosis who did not respond to other drugs in the formulary. This was approved.

13.2. One request was received for the use of rimexolone in a patient with high intraocular pressure. This was approved.

14. **Any other business**

14.1 [redacted] reported that a patient had requested trametinib on a self-funding basis. It was considered that any such requests should still be reviewed by Medicines Advisory Group so this will be brought back to the next meeting.

14.2. Vecuronium
[redacted] noted that this agent is being discontinued so consideration needs to be made about whether to purchase unlicensed product or to use an alternative product such as cisatracurium. Views will be sought from the specialist anaesthetists and a further discussion will be held at the next meeting.

15. **Dates of future meetings**

These were noted for 2016

Date	Time	Venue
30 March	12.00 – 14.00	Board Room, THQ
25 May	12.00 – 13.30	Board Room, THQ
27 July	12.00 – 14.00	Board Room, THQ
28 September	12.00 – 14.00	Board Room, THQ
30 November	12.00 – 14.00	Conference Room, THQ

Minutes of the Medicines Advisory Group Meeting of

Wednesday 25 January 2017

UH Bristol, Conference Room, THQ, 12.00 – 13.30

1. **Welcome and Apologies**

[redacted] welcomed all to the meeting.

Present:

[redacted]

Apologies:

[redacted]

2. **Minutes of the meeting held on Wednesday 30 November 2016**

The minutes were accepted as true record.

3. **Matters arising from November Minutes**

3.1. NHS England Regional Medicines Optimisation Committees

[redacted] updated the group on progress, with the expectation that the RMOC will commence in May or June 2017, and a regional workshop is being held in Reading to address stakeholder questions.

3.2. NICE approval of talimogene laherparepvec

[redacted] reported that [redacted] has requested the Trust Health and Safety Leads to oversee biological safety of gene therapies so such issues are outside the remit of MAG.

3.3. Botulinum toxin treatment criteria based assessment policy

[redacted] reported that there has been liaison with divisions and evidence is being compiled for submission to the Joint Formulary Group regarding indications not covered by the present formulary.

3.4. Medicines Optimisation CQUIN 2017/18

[redacted] updated the group with regard to the 2017/18 Medicines Optimisation CQUIN which is in four sections, these being implementation of biosimilars and generics, the digital requirements of the minimum data set, the uptake of efficient dispensing services, and the data flow to national databases (SACT and IVIG). The details are being finalised and implementation plans being addressed.

3.5. Carter Hospital Pharmacy Transformation Plan

[redacted] reported that the HPTP for UHBristol has been updated following review by NHS Improvement (in which it was classified as green rated), and the revised plan is being submitted to the Diagnostic and Therapies Divisional Board prior to Trust Board review at the Qualities and Outcomes Committee in February. This is a comprehensive three year plan that will be reviewed on an ongoing basis by NHS Improvement.

4. Strategic Issues

4.1. MHRA Drug Safety updates December 2016/January 2017

These were reviewed and guidance noted.

4.2. Electronic prescribing and chemotherapy electronic prescribing updates

Progress is still ongoing with regard to EPMA implementation and paediatric chemotherapy e-prescribing with rollout anticipated in 2017.

4.3. BNSSG STP (Sustainability and Transformation Plan) medicines optimisation workstream

[redacted] submitted the approved medicines optimisation workstream for the STP and noted the eleven projects detailed that will be implemented over the next 3 years in conjunction with the other healthcare providers and CCGs in the BNSSG footprint. Further information is detailed in the 'plan on a page' included with the MAG papers.

4.4. Commissioning policies

The following commissioning policies were noted, in particular those where the providers are specified. [redacted] confirmed that although SSC1684 policy for sodium oxybate for symptom control of narcolepsy with cataplexy (children) did not specify UH Bristol as a provider, NHS England have subsequently agreed that they will commission this treatment from the Trust.

4.4.1 SSC1666 NICE Technology Final Appraisal Determination: Eribulin for treating locally advanced or metastatic breast cancer after 2 or more chemotherapy regimens - available via interim funding from the Cancer Drugs Fund (CDF)

4.4.2 SSC 1655 Policy 16064/P: Use of plerixafor for stem cell mobilisation (update to include paediatrics)

4.4.3 SSC 1650, 1651, 1672, 1681 Update on the Implementation Timescales for Switch Initiatives (Anti-Retroviral Therapies); Clarification to Support Implementation of Tenofovir Alafenamide Clinical Commissioning Policy (Ref: NHS England: 16043/P); Reimbursement of further TAF containing products under the Tenofovir Alafenamide Clinical Commissioning Policy (Ref: NHS England: 16043/P)

4.4.4 SSC 1654 Policy 16070/P: Treatment of iron-overload for transfused and non-transfused patients with chronic inherited anaemias (Note – UHBristol commissioned)

4.4.5 SSC 1670; 1671; 1673; 1678; 1679 and 1680 - ref updated CDF funding positions re Dasatinib in CML; Pertuzumab in breast cancer;

Pomalidomide in 3prior Myeloma; Pembrolizumab; Talimogene laherparepvec; Crizotinib

4.4.6 SSC 1674 and 1675 ref IVIg Policy 16030/P: Intravenous immunoglobulin for acute disseminated encephalomyelitis and autoimmune encephalitis; Guidance on use of appropriate dose of intravenous immunoglobulin in the treatment of immune thrombocytopenic purpura and the recording of intravenous immunoglobulin usage on the National Immunoglobulin Database (MDSAS) (Note – UHBristol commissioned)

4.4.7 SSC 1683, 1686, 1700, 1701 and 1702 in relation to CDF Ibrutinib for previously treated chronic lymphocytic leukaemia and untreated chronic lymphocytic leukaemia with 17p deletion or TP53 mutation; Tolvaptan for hyponatraemia secondary to the Syndrome of Inappropriate Antidiuretic Hormone (SIADH) in patients requiring cancer chemotherapy; Nivolumab for previously treated advanced renal cell carcinoma; Eribulin for treating locally advanced or metastatic breast cancer after 2 or more chemotherapy regimens; Everolimus with exemestane for treating advanced breast cancer after endocrine therapy (Cancer Drugs Fund reconsideration of TA295)

4.4.8 SSC 1685 Policy (16057/P) for Rituximab for immunoglobulin G4-related disease (IgG4-RD)

4.4.9 SSC 1684 Policy (16065/P) for sodium oxybate for symptom control of narcolepsy with cataplexy (children) (Note – UHBristol not commissioned in circulated paperwork but subsequent confirmation of approval received as the trust has about three patients who are eligible for treatment.)

4.4.10 SSC 1687 and 1688 re not routinely clinical commissioning policies; Policy (16054/P) for Eculizumab in the treatment of recurrence of C3 glomerulopathy post-transplant; Policy (16055/P) for Riociguat for Pulmonary Arterial Hypertension

4.4.11 SSC 1690 Policy (16050/P) for Pegvisomant for acromegaly as a third-line treatment (adults) (Note – UHBristol commissioned)

4.4.12 SSC 1692 Policy (16049/P) for Ivacaftor for Children (2 to 5) with Cystic Fibrosis (named mutations) (Note – UHBristol commissioned)

4.4.13 SSC 1699 Radium-223 dichloride for treating hormone-relapsed prostate cancer with bone metastases (Note – UHBristol commissioned)

4.4.14 SSC 1703 Paediatric Insulin Pumps and Continuous Glucose Monitoring - change in responsible commissioner from NHS England to Clinical Commissioning Groups (CCGs) (Note – UHBristol commissioned)

5. Joint Bristol Formulary Group

5.1. BNSSG Formulary Decisions:

5.1.1 Alogiptin- for the licensed indications in patients with type 2 diabetes. [redacted], Consultant in Diabetes and Endocrinology, Weston Area Healthcare Trust.

Whilst there was no new evidence of the efficacy of alogliptin, there is further data since the last Joint Formulary consideration of this drug to support non-inferiority and this combined with the lower acquisition cost will make it a useful addition to the 3 gliptins currently on the formulary. It was felt that prescribing guidance would be useful for this class of drugs. The JFG agreed to add this drug as TLS Green to the formulary.

5.1.2 Degludec Treatment of diabetes mellitus type II in adults, adolescents and children from the age of 1 year. [redacted]. Lead Diabetes Specialist Nurse, Weston Area Healthcare Trust

The group felt that the current formulary insulin options for type 2 diabetics were sufficient for all but exceptional patients. There was no evidence to show significant superiority of degludec over the current formulary analogue basal insulins. It was decided that degludec will not be added to the formulary for a wider cohort of type 2 patients.

5.1.3 Degludec Treatment of diabetes mellitus type I in adults, adolescents and children from the age of 1 year. [redacted]. Lead Diabetes Specialist Nurse, Weston Area Healthcare Trust.

It was felt that the current formulary defined cohort in Type 1 diabetes '.... hypoglycaemia or issues of non-compliance, after all other options have been tried, that may result in the need for an insulin pump' was supported by the current evidence. The group did feel that initiation of degludec in these patients should remain with a specialist in diabetes but that if an appropriate Shared Care Protocol was developed the group would review it and consider degludec in type 1 diabetics being Shared Care.

5.1.4 Fexofenadine Seasonal allergic rhinitis and chronic idiopathic urticarial. [redacted]. Specialist Rotational Pharmacist – Pharmacoeconomics. Presented by

The group considered the evidence for use of fexofenadine in allergic rhinitis and chronic urticaria, in conjunction with the current prescribing data for non-sedative antihistamines. It was felt that fexofenadine should always be third line non-sedating anti-histamine, due to the higher cost in comparison to the current formulary choices of cetirizine and loratidine. The group noted that fexofenadine is being used widely, despite currently being non-formulary. Fexofenadine will be added to the formulary as 'Blue' with wording to reflect its third line use in the conditions specified in the application.

5.2 BNSSG issues for consideration

5.2.1 Adjuvant bisphosphonates in Breast Cancer

Scheduled for next BNSSG JFG meeting.

6. **Matters arising from BNSSG Drugs and Therapeutics Committee**

6.1. Matter arising from the January meeting

The STOPP START policy was circulated and reviewed and was considered to be appropriate prescribing action in the context of making decisions both within the Trust and in the community. This will be added to the Joint Formulary Group website.

7. [redacted]

7.1. [redacted]

7.1.1. [redacted]

[redacted]

7.1.2. [redacted]

7.1.3. [redacted]

7.1.4. [redacted]

7.1.5. [redacted]

7.1.6. [redacted]

7.2. [redacted]

7.2.1. [redacted]

7.2.2. [redacted]

[redacted]

7.3. [redacted]

[redacted]

8. Clinical guidelines and documentation

8.1. Intrathecal drug delivery for the treatment of severe cancer pain
The draft clinical guideline was discussed and it was noted that this is a Bristol-wide Clinical Guideline for multiple organisations (UHBristol, NBT, St Peters Hospice), that it addresses issues that are broader than the specific medicines used, and that it includes non-formulary drugs such as sufentanil. This therefore requires discussion with [redacted] about formulary applications for non-formulary drugs and with Clinical Effectiveness Committee regarding the most appropriate authorisation route.

Action: [redacted]

8.2. Prescribing and administration of red traffic light drugs
A process was proposed for the district nursing teams to administer red traffic light drugs following prescribing by UH Bristol clinicians onto a form agreed by Bristol Community Health; this would be sent by secure e-mail to GPs and linked if possible to electronic systems. This process was agreed.

9. Immunoglobulin assessment panel

9.1. Grey or Black indications for IFR approval
None were documented.

9.2. Grey indications for internal approval
None documented.

9.3. Blue indications for authorisation
These were noted as circulated and approved.

9.4. UH Bristol IVIG database report
This was reviewed and the improvement in documentation of outcomes was noted as extremely positive.

10. Homecare medicines

10.1. Homecare Medicines Management Group

[redacted] noted that the PPSA (Peninsula Purchasing Supply Agency) have developed a contract for homecare services which incorporates UH Bristol so this contract provides better control and pricing of homecare medicines. He also noted the Homecare Medicines Management Group has completed its review of the national Hackett standards, and two remain as amber rated which relate to measuring audit outcomes and documentation of the annual plan. These are being worked on.

11. **Cost-effective prescribing**

11.1. NHS Improvement
NHS Improvement are circulating a top ten list of drug savings and these have just been received. They will be considered in more detail at the next meeting.

11.2. Imatinib is now available in a generic formulation although this is not licensed for all indications further information and guidance is being followed up.

11.3. The commissioners have funded a clinical commissioning pharmacist role that is currently being appointed to focus upon addressing best value from pass through medicines.

12. **NICE**

12.1. NICE recent publications
[redacted] circulated information concerning the recent publications from NICE and noted guidance on multimorbidity and polypharmacy. The list of drugs in the pipeline were also reviewed. He also drew attention to the consultations on NICE guidance that are currently open.

13. **Applications for one off drugs**

13.1. Granulox was requested by [redacted] on the advice of tissue viability team for a patient with difficult to treat wounds. This was approved.

14. **Any other business**
No further matters were raised.

15. **Dates of future meetings**

Date	Time	Venue
29 March	12.00 – 14.00	Board Room, THQ
31 May	12.00 – 14.00	Conference Room, THQ
26 July	12.30 – 14.00	Conference Room, THQ
27 September	12.00 – 14.00	Board Room, THQ
22 November	12.00 – 14.00	Conference Room, THQ

University Hospitals Bristol NHS
NHS Foundation Trust

Minutes of the Medicines Advisory Group Meeting of

Tuesday 26 July 2016

UH Bristol, Board Room, THQ, 12.00 – 14.00

1. **Welcome and Apologies**
[redacted] welcomed all to the meeting.

Present:
[redacted]

Apologies:
[redacted].

2. **Minutes of the meeting held on Wednesday 25 May 2016**
The minutes were accepted as true record.

3. **Matters arising from May Minutes**

3.1. [redacted]

3.2. Biosimilars
[redacted] reported that the Division of Medicine are progressing with the transfer of patients to biosimilar etanercept and that discussion in ongoing with rheumatology clinicians concerning detailed arrangements.

3.3. NHS England Regional Medicines Optimisation Committees
[redacted] reported that he is on the central organising group to develop these regional committees. The aim is to provide guidance on any new drugs or indications that are not incorporated in the advanced NICE programme. A briefing paper and consultation document has been developed and will circulated by NHS England. The aim is for the four regional committees to act in a collegiate basis and for local formulary committees to focus more upon implementation.

3.4. Drugs of animal origin

[redacted] reported that he has forwarded the draft guideline to the Trust faith leaders and is still awaiting feedback. He will follow this up.

Action: [redacted]

3.5. ORLA Homecare Service

[redacted] reported that the ORLA service has now commenced and details are being addressed with regard to medicines management. Trust polices are applicable to such patients in the homecare setting, in addition to the requirements of the Hackett report. [redacted] is liaising with the Division of Medicine and has forward his perspective with regard to performance measures to apply.

3.6 CQUINs

[redacted] reviewed the three main CQUINs which focus upon medicines, these being hepatitis C treatment, antibiotic usage and the dose banding of chemotherapy. The Trust has still not signed off the hepatitis C CQUIN due to a disagreement about the number of patients requiring treatment, and some details concerning the dose banding CQUIN are still being finalised. The antibiotic CQUIN is being progressed, and initial results indicate some good progress.

The Trust Drugs and Therapeutics Committee is required to sign off the chemotherapy dosebanding CQUIN. The detailed tables have now been received and reviewed and these will require significant changes to be made in the Chemocare prescribing system during the next 8 months. The advantage is standardisation across NHS England and the risk arising from transfer to the new tables is low. The new dosebanded arrangements were approved.

3.7. Ranibizumab in retinopathy of prematurity

[redacted] has forwarded this indication to the NHS England Specialist Commissioners as one that requires a cohort policy rather than urgent IFR submissions. He is still awaiting feedback with regard to this proposal. [redacted] has written a summary of the evidence and this has been forwarded to the Commissioners.

4. **Strategic Issues**

4.1. MHRA Drug Safety updates June and July 2016

These were reviewed and it was proposed that a record is made of distribution to specific lead consultants. [redacted] will follow this up in Pharmacy.

Action: [redacted]

4.2. Electronic prescribing update

[redacted] reported that the Cardiology pilot of the System C EPMA system is scheduled to go ahead in November and work is currently underway to ensure that this is safe and the pilot will incorporate the System C discharge module. Rollout is planned in 2017 after a second pilot area in Care of Elderly patients.

4.3. Chemotherapy electronic prescribing

[redacted] reported that the project group implementing chemotherapy electronic prescribing in paediatrics is moving forward with a detailed plan

required by the end of September 2016 and implementation by September 2017. There is currently liaison with the seven regional paediatric units in order to plan a 'hub and spoke' approach from an IT platform in UHBristol.

4.4. STOMPwLD

Information was circulated with the papers concerning the NHS England work to stop over-medication of people with learning disabilities. [redacted] will follow this up in the CCG to distribute through primary care.

Action: [redacted]

4.5. Prescribing competency framework

[redacted] noted the Royal Pharmaceutical Society publication 'A competency framework for all prescribers' which is a revision of the previous NPC prescribing standards. These are very helpful in the context of teaching and training of prescribing, and are likely to be of particular relevance to undergraduate level prescribing professions. [redacted] will bring them to the attention of the relevant junior doctor tutors.

Action: [redacted]

5. **Joint Bristol Formulary Group**

5.1. BNSSG Formulary Decisions:

5.1.1. Brivaracetam – epilepsy – Approved TLS red.

5.1.2. Pliaglis (lidocaine 7% and tetracaine gel) topical anaesthetic – Further evidence required.

5.1.3. Benepali – biosimilar etanercept – Approved and to be prescribed by brand.

5.1.4. Rivastigmine – Parkinson's disease dementia – Approved TLS amber three months.

5.1.5. Clopidogrel – prevention of atherothrombotic and thromboembolic events in paediatrics – Further information required.

5.1.6. Jaydess – contraception for up to three years – Not currently approved.

5.1.7. Fulvestrant – oestrogen receptor-positive locally advanced metastatic breast cancer – Not approved.

5.1.8. Evra contraceptive transdermal patch – Approved TLS blue for patients in whom compliance is an issue.

5.1.9. Ibandronate zoledronic acid – adjuvant therapy for postmenopausal women treated for breast cancer – Clinically approved but further commissioning discussions required.

5.10. Fosaprepitant – prevention of acute and delayed nausea and vomiting associated with highly emetogenic cisplatin based cancer chemotherapy in adults and prevention of nausea and vomiting with moderately emetogenic cancer chemotherapy in adults – Approved in accordance with the guidelines.

5.11. Rituximab – monotherapy for rheumatoid arthritis – Approved TLS red.

5.2. UH Bristol consultant representation
[redacted] will follow up discussions with the Division of Medicine.
Action: [redacted]

5.3. Botulinum toxin treatment criteria based access policy
It was noted that this BNSSG policy would restrict access to botulinum toxin for a number of specialty treatments within UH Bristol. [redacted] is tabulating the various indications and liaising with consultants. He will present the results of this analysis to the next MAG meeting.
Action: [redacted]

6. **Matters arising from BNSSG Drugs and Therapeutics Committee**

[redacted] noted that the next meeting is scheduled the following day (27 July 2016) so feedback will be provided at the next MAG meeting.

7. [redacted]

7.1. [redacted]

7.1.1. [redacted]

7.1.2. [redacted]

7.1.3. [redacted]

7.1.4. [redacted]

7.1.5. [redacted]

7.2. [redacted]

7.2.1. [redacted]

7.3. [redacted]

7.3.1. [redacted]

8. **Clinical guidelines and documentation**
No new guidelines were reviewed at this meeting.

9. **Immunoglobulin assessment panel**

9.1. Clinical Commissioning Policy: IVIG for ADEM and autoimmune encephalitis

[redacted] noted the new policy from NHS England which indicates that IVIG is not commissioned for these two indications due to a lack of evidence. It was noted however that these indications occasionally require treatment in paediatric neurology patients at the Bristol Childrens Hospital, so there has been discussion with the paediatric neurologists concerning the impact of this decision. The consultants are extremely concerned about this stance and will be following it up. NHS England will however not be implementing a restriction on commissioning until all of the grey IVIG indications have been reviewed.

9.2. Grey indications for internal approval

9.2.1. Acute disseminated encephalomyelitis (post steroids)

[redacted] requested this treatment (see section 9.1. above) for one patient, and this was approved.

9.2.2. Autoimmune encephalitis

[redacted] has requested IVIG for one patient for this indication (see 9.1. above) and this was approved.

9.3. Grey and black indications for IFRs

No requests were received.

10. **Homecare medicines**

10.1. [redacted] reported that the implementation of the ORLA virtual ward was progressing and he is in liaison with the Division of Medicine with regarding key performance indicators concerning the use of medicines in this context.

10.2. New Homecare medicines

10.2.1. Alirocumab and evolocumab are new agents indicated for hypercholesterolaemia and the manufacturers are implementing a homecare scheme. A risk assessment is required with regard to this development.

Action: [redacted]

11. **Cost-effective prescribing**

11.1. Gentamicin nasal sinus rinse

This remains outstanding so [redacted] will request a summary of criteria for treatment from [redacted], and will forward this to the lead microbiologist for comment.

Action: [redacted]

12. **NICE**

12.1. NICE recent publications

[redacted] circulated information concerning the recent publications from NICE and noted the sacubitril/valsartan technology appraisal guidance has been implemented and approved as an amber agent on the BNSSG traffic light system.

13. **Applications for one off drugs**

13.1. Buspirone for a patient with severe apneusis
This was requested by [redacted] and approved.

13.2. Tacrolimus suppository for a patient with UC proctitis
This was requested by [redacted] and approved.

13.3. Prothionamide for a patient with rifampicin resistant tuberculosis
This was requested by [redacted] and approved.

13.4. Nepafenac for a patient with high intraocular pressures
This was requested by [redacted] and approved.

14. **Any other business**

No other business was raised.

15. **Dates of future meetings**

These were noted as below:

Date	Time	Venue
28 September	12.00 – 14.00	Board Room, THQ
30 November	12.00 – 14.00	Conference Room, THQ

Minutes of the Medicines Advisory Group Meeting of

Monday 17 July 2017

UH Bristol, Rheumatology Seminar Room, 12.00 – 14.00

1. **Welcome and Apologies**
[redacted] welcomed all to the meeting.

Present:
[redacted]

Apologies:
[redacted]

It was noted that the meeting was non quorate.

2. **Minutes of the meeting held on 24 May 2017**
The minutes were accepted as a true record.

3. **Matters arising from May Minutes**

3.1. Botulinum toxin treatment criteria based assessment policy
This report will be collated and presented to the next meeting after review by the Joint Formulary Group.

Action: [redacted]

3.2. Nusinersen commissioning
NHS England do not commission this treatment, therefore, if we use it then it is in tariff. This has been referred to legal services and Women and Children's Division to decide if to use this drug or not.

3.3. NOACs following mitral valve repair
Consultant Haematologist [redacted] has been contacted and is supportive of this of this off label use of the NOACs. The new drug request form to be submitted to the Joint Formulary Group by the consultant.

Action: [redacted]

4. **Strategic Issues**

4.1. Biosimilar implementation

[redacted] reiterated that there is a national focus on biosimilar uptake and therefore overall NHS saving. The requirement will be for trusts to move to biosimilars at speed. Following on national discussions [redacted] reiterated two points of hierarchy with regard to licensing if a branded product is licensed but the generic biosimilar is unlicensed then we continue to use the branded product in that license indication. If neither the biosimilar or the branded product are licensed then we are to use the biosimilar. The Group agreed with this approach.

4.2. MHRA Drug Safety updates
The June update was tabled but it was noted that there were no relevant secondary care issues.

4.3. Electronic prescribing and Chemotherapy electronic prescribing updates
Electronic prescribing and medicines implementation for Medway system should be live in October on one cardiology ward as a pilot. Paediatric chemotherapy is being rolled out.

4.4. Commissioning policies
The following commissioning polices were noted:

4.4.1. SSC 1751 Pembrolizumab for untreated PD-L1-Positive metastatic Lung Cancer

4.4.2. SSC 1752 Nivolumab for treating relapsed or refractory classical Hodgkin lymphoma

4.4.3. SSC 1753 Carfilzomib for previously treated Myeloma

4.4.4. SSC 1754 Olaratumab in combination with doxorubicin for treating advanced soft tissue sarcoma

4.4.5. SSC 1756 Trastuzumab emtasine in HER2 positive, unresectable, locally advanced or metastatic breast cancer

4.5. Commissioning letters
The following commissioning letter was noted:

4.5.1. SSC 1746 Technology Appraisal 443: Obeticholic acid for treating primary biliary cholangitis (revised)
We have one patient due to be treated with this and a request to start before the 90 day NICE deadline is in progress.

4.6. Pregabalin NHS England Gateway Ref No: 06910 notification
The NHS communication dated 21 June 2017 was noted. All prescribing should now be generic from 17 July 2017 for all indications.

4.7. EAMS (Early Access to Medicines Schemes)
The following EAMS were noted:

4.7.1. SSC 1748 Early Access to Medicines Scheme – Glecaprevir/ Pibrentasvir for the treatment of chronic hepatitis C (HCV) infection in adults with compensated cirrhosis

4.7.2. Early Access to Medicines Scheme – Cenegermin (Oxervate) in the treatment of moderate (persistent epithelial defect) or severe (corneal ulcer) neurotrophic keratitis in adults

4.7.3. Early Access to Medicines Scheme – Idebenone as treatment for slowing the decline of respiratory function in patients with Duchenne Muscular Dystrophy (DMD) from the age of 10 years who are currently not taking glucocorticoids

4.7.4. [redacted]

[redacted]

[redacted] concluded by noting that EAMS schemes may be picked up by the Regional Medicines Optimisation Committees in the future.

5. **Joint Bristol Formulary Group**

5.1. BNSSG Formulary Decisions:
[redacted] noted that the formulary group decisions had been circulated on 20 June and that MAG has no further comment.

5.2. BNSSG Paediatric Formulary
[redacted] noted that the paediatric formulary is due to go live hopefully on 1 August with an inaugural meeting in September.

6. **Matters arising from BNSSG Drugs and Therapeutics Committee**

6.1. STP Medicines Optimisation Programme
A de-prescribing working group is to be set up. Trusts are being asked for a consultant contact this is being internally identified.

7. [redacted]

7.1. [redacted]

7.2. [redacted]

7.3. [redacted]

[redacted]

8. **Clinical guidelines and documentation**

It was noted there were no clinical guidelines or documentation to review this month.

9. **Immunoglobulin assessment panel**

9.1. Grey or black indications for IFR approval

There were no grey or black submissions this month.

9.2. Grey indications for internal approval

There were no grey or black submissions this month.

9.3. Blue indications for authorisation

All blue submissions have been retrospectively authorised. [redacted] reminded the group that intravenous immunoglobulin is part of this years medicines optimisation CQUIN and looking at our data so far we have acceptable data entry in areas such as patient wait but we still have work to do on areas in patient outcome recording as we are somewhere between 40 and 70%.

10. **Homecare medicines**

10.1. Homecare Medicines Management Group; new drugs

It was noted there were two new drugs for in homecare, Ustekinumab for Crohn's disease and ixekizumab for plaque psoriasis. Both are NICE approved and Homecare recommended. The group accepted both of these for homecare management.

11. **Cost-effective prescribing**

11.1. Cost effective prescribing guidance for 2017/18

[redacted] tabled a paper around medicines workstream cost improvement programmes signposting clinicians and giving general advice. [redacted] noted to the group of the increase in use of Blueteq especially by CCGs the number of IFR challenges and the increasing number by biosimilars over the next couple of years that may require Blueteq. [redacted] asked for this paper to be circulated through the Divisions.

11.2. Carter Dashboard Metrics

[redacted] commented that this is now becoming more helpful and we have started internal discussion particularly at Savings Board. One issue brought up at the Savings Board was inhalational anaesthetic choice and usage. We are still outlying from the median and therefore seen as expensive. This is leading to questions about how much appropriate or inappropriate use of desflurane there is in the Trust especially with respect to comparative Trusts such as

Exeter who use no desflurane at all. [redacted] is following this up through the Anaesthetics department.

12. **NICE**

12.1. NICE recent publications
The group was referred to the NICE website for any new publications.

13. **Applications for one-off drugs**

13.1. Simvastatin + cholesterol in ung merck for the 'CHILD' genetic condition
A submission from [redacted] was agreed for simvastatin + cholesterol. This is for a patient recommended by Great Ormond Street and was accepted.

14. **Any other business**
No items were tabled.

15. **Dates of future meetings**

Date	Time	Venue
27 September	12.00 – 14.00	Board Room, THQ
22 November	12.00 – 14.00	Conference Room, THQ

[redacted] noted that this would be his last MAG meeting. The group thanked [redacted] for all of his input and successful management of MAG during his term of Director of Pharmacy and wished him all of the very best in his new role.

[redacted] noted that in September the Chair will be [redacted] and in November the new Director of Pharmacy will take over. The new Director, [redacted], will then discuss with the new Medical Director about ongoing arrangements for future chairmanship of the meeting.

Minutes of the Medicines Advisory Group Meeting of

Wednesday 30 March 2016

UH Bristol, Board Room, Trust HQ, 12.00 – 14.00

1. **Welcome and Apologies**

[redacted] welcomed all to the meeting.

Present:

[redacted]

Apologies:

[redacted]

2. **Minutes of the meeting held on 27 January 2016**

The minutes were accepted as a true record.

3. **Matters Arising from January Minutes**

3.1. [redacted]

[redacted]

[redacted]

3.2. Vecuronium

[redacted] reported that the cardiac anaesthetists had requested a small supply of imported vecuronium to be made available but that the standard drug of choice will be cisatracurium. [redacted] agreed that this would be appropriate and that vecuronium should be held at a central point in Heygroves Theatres to be available as required.

3.3 Biosimilars

Biosimilar etanercept is now available and discussions are ongoing with clinicians in rheumatology and dermatology. The product (benepali) is not currently licensed for use in paediatrics. The gastroenterologists have noted no risks with transferring patients to biosimilar infliximab although the Royal Colleges are still hesitant to recommend switching a patient. The Norwegian study results are awaited to provide assurance that switching to a biosimilar product is appropriate. It was agreed that switching to biosimilars should be

encouraged in accordance with the information circulated from NHS England (as circulated).

4. **Strategic Issues**

4.1. MHRA Drug Safety updates
The updates from January, February and March 2016 were reviewed and noted.

4.2. Electronic prescribing update
[redacted] reported that System C will require further development time to improve a number of EPMA aspects so the pilot date is likely to be delayed from summer 2016. A revised guaranteed timeline is awaited.

4.3. Chemotherapy electronic prescribing
It is noted that the application of electronic prescribing to chemotherapy is now mandated, so although we have adult chemotherapy prescribing systems with Chemocare, the paediatric service needs to be developed. Guidance has been published requiring a plan by June 2016 and implementation by April 2017 so the Trust is addressing these requirements at present.

4.4. BNSSG Contract Prescribing Schedule
The prescribing schedule for 2016/17 was reviewed and noted. A question was raised regarding whether further detail needs to be added concerning paediatric prescribing as discussed in the BNSSG Drugs and Therapeutics Committee. [redacted] will follow this up.

Action: [redacted]

4.5. Cancer Drugs Fund
[redacted] noted the new Cancer Drug Fund arrangements as circulated, following on from the recent consultation.

4.6. Specialist High Cost Drugs Prior Approval Scheme
NHS England are extending further the application of the Blueteq prior approval scheme for high cost drugs. These arrangements are detailed in the circulated letter and Pharmacy will alert prescribers to any new drugs prior to the commencement of these arrangements.

4.7. NHS England IFR Process
[redacted] noted that NHS England have revised the application form for individual funding of high cost drugs. The new application form requires signature by the Medical Director and [redacted] is reviewing the internal delegated approval process. This will be brought to the attention of consultants when agreed.

Action: [redacted]

4.8. NHS England Regional Medicines Optimisation Committees
[redacted] reported that the regional medical directors have been asked to chair new medicines optimisation committees but will make decisions about all new drugs and new indications that are not on the NICE programme. The

terms of reference for these committees are being arranged at present and it is anticipated that these will commence during the early summer. The local joint formulary group will therefore need to take into account any decisions circulated by this group and focus attention on issues such as shared care and the traffic light system. Further information will be circulated when available.

4.9. Chemotherapy dose banding

[redacted] noted the current CQUIN for dose banding of chemotherapy. The dose banding tables are awaited so until these are available it is not possible to assess the level of change required compared to the current arrangements. UH Bristol has developed chemotherapy dose banding significantly but the CQUIN focuses on having a standard national set and this will require amendment of the adult Chemocare system. The first part of the CQUIN dictates that the Trust Drugs and Therapeutics Committee needs to sign off the dose banding arrangements so these will be brought to the next meeting when available.

Action: [redacted]

5. **Joint Bristol Formulary Group**

The BNSSG Formulary Decisions are as detailed below:

5.1 Ceftolozone / tazobactam approved for specialist use only for multi-drug resistant pseudomonas infection

5.2 Alirocumab for hypercholesterolaemia rejected prior to NICE publication

5.3 Cangrelor approved for specialist use only for patients who have suffered out of hospital cardiac arrest

5.4 Idarucizumab approved for consultant only use for dabigatran reversal

5.5 Rituximab for autoimmune haemolytic anaemia – deferred for further discussion

5.6 Rivaroxaban approved for specialist use for DVT prophylaxis in lower limb immobilisation.

6. **Matters arising from BNSSG Drugs and Therapeutics Committee**

[redacted] drew attention to the BNSSG update of NOAC prescribing guidelines and also to the launch of the opioids aware guidance. Further discussion around the interface between paediatric consultants and GPs concluded that we need to ensure the BNSSG formulary is clear with regard to all paediatric guidance.

7. [redacted]

7.1. [redacted]

7.2. [redacted]

[redacted]

7.3. [redacted]

7.4. [redacted]

7.5. [redacted]

7.6. [redacted]

8. Clinical guidelines and documentation

8.1. Drugs of animal origin

This revised Trust guidance arose from a clinical incident and was agreed as a suitable and important document to bring to the attention of the Trust

prescribers. Firstly however it was considered appropriate to forward to the faith leaders via the chaplaincy for comment.

Action: [redacted]

8.2. Pharmacy medication switch policy
This was updated and reviewed and was approved.

9. **Immunoglobulin assessment panel**

9.1. Grey indications for internal approval
No submissions have been received although [redacted] noted that the tables circulated at the last meeting do not specify 'infection following BMT or HSCT' as a blue approved indication, but it is noted as such in the narrative of the DH clinical guidelines.

9.2. Grey and black indications for IFR
One request has been received from [redacted] for use in a patient with Langerhans cell histiocytosis. This application was reviewed by [redacted] and supplied as the patient was receiving chemotherapy and had received live MMR vaccine. One dose was requested by the MDT as the patient was in PICU. Due to the low cost it was agreed to fund this treatment internally.

10. **Homecare medicines**

10.1. Homecare Medicines Management Group
It was noted that the Trust is commencing a virtual ward through the ORLA Homecare Service. Further information is awaited so the Homecare Medicines Management Group will follow up whether this service meets the national required standards.

Action: [redacted]

11. **Cost-effective prescribing**

11.1. Gentamicin nasal sinus rinse and budesonide nasal washes in rhinosinusitis and nasal polyps
This question was forwarded by the Antimicrobial Steering Group in order for MAG to assess the evidence behind topical gentamicin in this condition. [redacted] had forwarded information regarding some patients with pseudomonas infection in a biofilm through which systematic antibiotics do not penetrate. She commented that she is very selective with regard to this treatment and would attend the next meeting if available to discuss further. A decision will therefore be made at the next meeting.

11.2. Dexmedetomidine
It was noted that the use of dexmedetomidine in cardiac ICU has decreased since controls have been formalised, but usage in ICU is increasing as it is deemed to be helpful in a larger number of patients. This will be followed up with [redacted] prior to the next MAG meeting.

Action: [redacted]

12. **NICE**

12.1. NICE recent publications

[redacted] provided information about the latest publications related to medicines. He also summarised the horizon scanning process which has recently concluded and identified a potential £16.4m cost for 2016/17.

12.2. Sacubutril/valsartan

This NICE publication will be a significant cost pressure for the trust as it is amber (3 months) on the formulary and approximately 100 patients are likely to require treatment.

13. **Applications for one off drugs**

13.1. Utrogestan

[redacted] has requested this product for 2 patients who required a bioidentical progesterone. These were approved.

13.2 Capreomycin

[redacted] requested capreomycin for one patient as sensitivities identified capreomycin to be preferred to streptomycin. This was approved.

14. **Any other business**

No further issues were raised.

15. **Dates of future meetings**

These were noted as below:

Date	Time	Venue
25 May	12.00 – 13.30	Board Room, THQ
27 July	12.00 – 14.00	Board Room, THQ
28 September	12.00 – 14.00	Board Room, THQ
30 November	12.00 – 14.00	Conference Room, THQ

Minutes of the Medicines Advisory Group Meeting of

Wednesday 29 March 2017

UH Bristol, Board Room, THQ, 12.00 – 14.00

1. **Welcome and Apologies**

[redacted] welcomed all to the meeting.

Present:

[redacted]

2. **Minutes of the meeting held on Wednesday 25 January 2017**

The minutes were accepted as a true record.

3. **Matters arising from January Minutes**

3.1. Revised Terms of Reference
These were agreed as circulated but will need to be formally adopted at the next meeting as the current meeting is not quorate.

3.2. NHS England Regional Medicines Optimisation Committees
Mr [redacted] reported that the operating model has been finalised and the committees will commence during the Spring and will focus on medicines optimisation priorities. Work addressing new product guidance will be implemented at a later date.

3.3. Botulinum toxin treatment criteria based assessment policy
Trust specialties are completing templates and submitting to the Joint Formulary Group so progress will be reviewed with Mr [redacted] at the next meeting.

3.4. Sacrosidase
Mr [redacted] had committed to check the commissioning status of this drug at the last meeting and noted that it is not 'pass through' so would need to be addressed within tariff.

3.5. Creatine and ornithine
Mr [redacted] reported on ongoing discussions with the NHS England Commissioners and the current position is that it is likely to be funded as a food supplement rather than through an IFR. This arrangement is to be finalised.

3.6. Neilmed
The prescribing arrangements for this product have not been finalised as it has not been clarified whether Sterimar would be appropriate. This is to be confirmed prior to the next meeting.

Action: Mr [redacted]

3.7. Cabozantinib
[redacted] confirmed the arrangements are for a single patient only.

3.8. Intrathecal drug delivery for the treatment of severe cancer pain.
The application for sufentanil has not been finalised to date.

4. **Strategic Issues**

4.1. MHRA Drug Safety updates February 2017/ March 2017
These were reviewed and the guidance noted.

4.2. Electronic prescribing and chemotherapy electronic prescribing updates.
These are still moving forward as discussed at the last meeting.

4.3. CQUINs

4.3.1. Medicines Optimisation CQUIN
The four sections of the CQUIN were reviewed as circulated and it was noted that monthly review meetings have been scheduled to assess progress.

4.3.2. Chemotherapy Dose Banding
The content of the CQUIN was reviewed as circulated and it was noted that this needs to be approved at a meeting that is quorate.

Action: Mr [redacted]

4.4. Commissioning policies
The following commissioning polices were noted:

4.4.1. Clinical Commissioning Policy (16052/P) for Pasireotide disparate injectable medical therapy for the treatment of Cushing's disease

4.4.2. Specialised Commissioning Circular SSC 1704 – Everolimus in advanced RCC CDF

4.4.3. Interim Clinical Commissioning Policy Statement: Adalimumab for Severe Refractory Uveitis Reference: NHS England: 170010/PS ('This interim policy proposes that for the minority of cases with chronic sight threatening and visually disabling uveitis, who are unresponsive to previously available standard treatment, treatment with adalimumab should commence'.)

4.4.4. SSC1707 Atezolizumab for metastatic urothelial carcinoma, Early Access to Medicines Scheme

4.4.5. SSC1708 Ponatinib for chronic myeloid leukaemia/acute lymphoblastic leukaemia

4.4.6. SSC1709 Pembrolizumab for PD-L1-positive non-small-cell lung cancer after chemotherapy

4.4.7. SSC1713 Levatinib for locally advanced/unresectable/metastatic differentiated thyroid cancer after radioactive iodine via a compassionate use scheme

4.4.8. SSC1705 Belimumab Addendum – Managed Access Agreement: Belimumab for treating active autoantibody-positive systemic lupus erythematosus

[redacted] noted the following points:

Adalimumab for Severe Refractory Uveitis – this is particularly important as we have previously submitted numerous IFRs for this treatment.

Ponatinib for ALL – [redacted] has escalated to NHS England that the policy states that ponatinib should be used following dasatinib, but dasatinib is not commissioned or NICE approved at present. This is being followed up by NHS England and NICE.

Belimumab for treating active autoantibody positive SLE – a total cap nationally of 300 patients was noted so it is important for any patients needing this treatment to be commenced promptly.

5. **Joint Bristol Formulary Group**

5.1. BNSSG Formulary Decisions:
It was noted that the group has not met since the last Medicines Advisory Group meeting.

6. **Matters arising from BNSSG Drugs and Therapeutics Committee**
One of the main areas of work is the STP Medicines Optimisation Programme so this range of collaborative projects will become increasingly more important as the STP structure develops.

7. [redacted]

7.1. [redacted]

7.2. [redacted]

7.3. [redacted]

[redacted]

7.4. [redacted]

7.5. [redacted]

8. **Clinical guidelines and documentation**

No documents were submitted for review at this meeting.

9. **Immunoglobulin assessment panel**

No grey or black indications were submitted for review. The blue indications were reviewed and approved.

10. **Homecare medicines**

10.1. Homecare Medicines Management Group referrals of new drugs

10.1.1. C1 esterase inhibitor
This was approved for patients who may urgently require treatment.

10.1.2. Apremilast
This was reviewed and approved.

11. **Cost-effective prescribing**

11.1. NHS Improvement top 10 list
[redacted] reported on the current review of implementation and the transition of cyclizine or metoclopramide to ondansetron was discussed and agreed. It was also agreed that multiple doses post operatively would be appropriate for ondansetron.

11.2. Cost effective prescribing guidance
A draft document was reviewed and suggestions made to update. Mr [redacted] will add the comments regarding formulary application and resubmit to the next meeting.

Action: Mr [redacted]

11.3 Off label prescribing of imatinib in CML
Mr [redacted] reported that the recently launched generic imatinib product is not licensed for GIST so the branded original will be used for that indication. There are also some patients with CML who would not be covered by the initial license but there is common consensus that it should be used for all CML patients. MAG agreed to this approach.

12. **NICE**

12.1. NICE recent publications
Mr Osborne summarised the latest NICE publications.

13. **Applications for one-off drugs**

13.1. Moxifloxacin in ophthalmology
It was noted that we have received repeated requests for this product and Dr [redacted] (consultant microbiologist) considers it to be appropriate for formulary application. The ophthalmologists will therefore be asked to submit to the Joint Formulary Group.

14. **Any other business**

14.1 It was noted that Orkambi (lumacaftor/ivacaftor) is being made available on a compassionate scheme and Dr [redacted] are keen to obtain access to this product for patients who meet the scheme criteria. This has been discussed by MAG on a previous occasion when one paediatric patient benefitted from the clinical trial and MAG agreed the compassionate access scheme which enabled a continuation of treatment. It was agreed that a similar arrangement should be permitted for other patients as the company are committing to provide ongoing treatment, on condition that the trust consent policy is adhered to.

15. **Dates of future meetings**

Post meeting note; May and July meetings have been rescheduled as below:

Date	Time	Venue
24 May	12.00 – 14.00	Rheumatology Seminar Room, BRI B403/room 4-025
17 July	12.00 – 14.00	Rheumatology Seminar Room, BRI B403/room 4-025
27 September	12.00 – 14.00	Board Room, THQ
22 November	12.00 – 14.00	Conference Room, THQ

University Hospitals Bristol NHS
NHS Foundation Trust

Minutes of the Medicines Advisory Group Meeting of

Wednesday 25 May 2016

UH Bristol, Board Room, THQ, 12.00 - 13.30

1. **Welcome and Apologies**

[redacted] welcomed all to the meeting.

Present:

[redacted]

[redacted] also attended as an observer.

Apologies:

[redacted]

[redacted] is now undertaking the role of Assistant Medical Director and will be attending future meetings.

2. **Minutes of the meeting held on Wednesday 30 March 2016**

The minutes were accepted as true record.

3. **Matters arising from March Minutes**

3.1. [redacted]

3.2. [redacted]

[redacted]

3.3. NHS England Regional Medicines Optimisation Committees

[redacted] fed back details concerning the development of these four regional committees. The focus will be on reviewing new treatments or new indications for drugs that are not being assessed through the NICE Technology Appraisal Process. A document concerning the role, membership and governance of these committees is being developed and will be circulated for comment before the summer. The linkage with local Drugs and Therapeutics Committees is recognised as the implementation of any decisions will be a key part of the process.

3.4. NHS England IFR Process

The new IFR process is on the NHS England website and has a revised template for applications. The approval by the Trust requires details of the Medicines Advisory Group process to be signed by the Chief Pharmacist and also an authorisation by the Medical Director. Within UH Bristol [redacted] has agreed to delegate responsibility for the drug related IFRs to [redacted], so all such IFR applications will need to be assessed by [redacted] prior to submission. Separately [redacted] from Finance has convened a group to ensure that the IFR process internally is robust and that all applications are being processed appropriately.

3.5. Dornase alpha in non CF lung disease

[redacted] discussed the outcome of the March discussion with [redacted], who is updating an IFR for submission to the CCG.

3.6. 5-aminolevulinic acid in glioma

Following discussion at the March meeting [redacted] raised this issue nationally and NHS England agreed to review the tariff payments for such operations in order to assess whether this drug could be incorporated in the tariff process. The drug is also available in less expensive formulations so a simple exclusion from tariff is unlikely. [redacted] also discussed this with [redacted] who advised that the potential use would be fairly infrequent but that it is important to have the agent available for certain operations.

3.7. Drugs of animal origin

[redacted] forwarded the draft protocol to the [redacted] who is the chaplaincy team leader. This will be circulated to leaders of the various faiths for comment and [redacted] will respond to [redacted] in due course with any comments.

3.8. ORLA Homecare Service

[redacted] outlined the new arrangements being implemented in June in which the company ORLA will be caring for up to 35 patients in the home environment, these patients originating from ED/MAU or patients whom have come from medical wards and are suitable for ongoing care at home. The patients are under the responsibility of the Trust so are prior to discharge and

[redacted] is assessing the governance arrangements with regard to homecare medicines management.

Action: [redacted]

4. **Strategic Issues**

4.1. MHRA Drug Safety updates
These were reviewed. [redacted] will forward the information regarding tyrosine kinase inhibitors and hepatitis B reactivation to relevant consultants.

Action: [redacted]

4.2. Electronic prescribing update
[redacted] reported that the first pilot ward is now due to go live in November 2016 with the second ward scheduled for January 2017.

4.3. Chemotherapy electronic prescribing
[redacted] reported that the deadline of September 2017 is a mandatory requirement for the implementation of paediatric chemotherapy electronic prescribing. A plan is required by September 2016 and work is underway to deliver this. The adult service is compliant. [redacted] is chairing the group to deliver the paediatric chemotherapy requirement.

4.4. Specialised Commissioning Drugs Briefing
The Spring 2016 NHS England Specialised Commissioning Drugs Briefing was circulated, this detailing relevant circulars, further information concerning IFR applications, future developments such as Blueteq, Early Access to Medicines Schemes, Dose Banding and the Cancer Drugs Fund. [redacted] will circulate this information to clinical chairs.

Action: [redacted]

4.5. Medicines Optimisation Clinical Reference Group
[redacted] attends this group and circulated his personal notes from the most recent quarterly meeting. This provides an overview of national developments concerning specialised commissioning drug use, particularly with regard to high cost drugs.

4.6. Carter hospital pharmacy and medicines optimisation programme
The Carter Report focused upon hospital pharmacy and medicines optimisation and numerous requirements are incorporated under recommendation 3. These are being reviewed at the moment in order to ensure that implementation can be completed within the asigned deadlines. The medicines CIP workstream (Cost Improvement Plan) is focusing upon the Carter requirements in more detail, and a hospital pharmacy transformation programme will be required, for implementation April 2017. An executive lead for this programme is being identified.

4.7. CQUINs
[redacted] reported that there are a number of drug related CQUINs. The antimicrobial resistance and antimicrobial stewardship CQUIN focuses upon the range and quantity of antibiotics being used, the hepatitis C programme

focuses upon appropriate use of the new agents for these patients, and the chemotherapy dose banding CQUIN requires the uptake of nationally standardised dose bands. Work is underway in each of these areas to provide assurance of delivery.

5. **Joint Bristol Formulary Group**

5.1. BNSSG Formulary Decisions:

5.1.1. Aviptadil 25 mcgs/phentolamine 2mg – Approved for any prescriber for erectile dysfunction.

5.1.2. Denosumab – Approved for specialty consultant teams for malignant hypercalcaemia which is resistant to bisphosphonates.

5.1.3. Clonidine transdermal patches for paediatric use – This item will be revisited when further information is provided.

5.1.4. Insulin glulisine (Apidra) – Approved for any prescriber.

5.1.5. Pliaglis 7% gel (Lidocaine/tetracaine) – More information required for review.

5.2. Further issues
Denosumab shared care arrangements are still being considered and a conclusion to the arrangements will be followed up.

5.3. UH Bristol consultant representation
[redacted] reported that [redacted] is seeking medical representation for the group.

5.4. Sacubitril valsartan
A shared care protocol is being approved for use of this agent as an amber 3 month product.

6. **Matters arising from BNSSG Drugs and Therapeutics Committee**
No issues were raised that are not covered on other parts of the agenda.

7. [redacted]

7.1. [redacted]

7.2. [redacted]

[redacted]

7.3. [redacted]

7.4. [redacted]

7.5 [redacted]

7.6. [redacted]

7.7. [redacted]

7.8. [redacted]

[redacted]

8. **Clinical guidelines and documentation**
No draft documents were received for this meeting.

9. **Immunoglobulin assessment panel**

9.1. [redacted] submitted a request for a patient with opsoclonus myoclonus
This is in the grey indication category which requires internal approval by the immunoglobulin assessment panel. As with previous patients with this indication, this was approved.

No requests were received for any grey or black indications that require IFR application.

10. **Homecare medicines**

10.1. ORLA virtual ward
[redacted] reported that he will confirm governance arrangements for the ORLA service as discussed in Section 3.8. through the Homecare Medicines Management Group.

11. **Cost-effective prescribing**

11.1. Gentamicin nasal sinus rinse
This will be referred to the next meeting.

11.2. Dexmedetomidine in ICU
A review paper on the use of dexmedetomidine on the adult Intensive Care Unit has been received from [redacted] and circulated. [redacted] commented that 70% of patients on ventilation for over 48 hours will have an increased length of stay and level of morbidity and mortality. Experience has shown that acutely delirious patients are extubated earlier under dexmedetomidine and therefore have a reduced length of stay. The unit therefore wish to continue the current arrangements for using dexmedetomidine for patients suffering from delirium, and [redacted] noted that the clinical trial is also ongoing which will potentially show benefit in broader use of the agent. Continued application of the current guidelines was approved as adjunctive sedation in agitated patients who are refractory to haloperidol. There will also be rare usage for sedation in patients who do not tolerate non-invasive ventilation. The use of dexmedetomidine for first line sedation in ICU for patients who require mechanical ventilation will not be approved at present but will be reconsidered following completion of the current SPICE trial. The group is very grateful for the comprehensive report provided.

12. **NICE**

12.1. NICE recent publications

It was noted that alirocumab and evolocumab have now been approved by NICE and will be implemented after the standard 90 day implementation period.

12.2. Sacubutril/valsartan
See notes under Matters Arising.

13. **Applications for one off drugs**
No applications were received.

14. **Any other business**
No further business was raised.

15. **Dates of future meetings**

These were noted as below:

Date	Time	Venue
27 July	12.00 – 14.00	Board Room, THQ **(Post meeting note this meeting has been brought forward to Tuesday 26 July at the same time and location)**
28 September	12.00 – 14.00	Board Room, THQ
30 November	12.00 – 14.00	Conference Room, THQ

Minutes of the Medicines Advisory Group Meeting of

Wednesday 24 May 2017

UH Bristol, Rheumatology Seminar Room, 12.00 –14.00

1. **Welcome and Apologies**
[redacted] welcomed all to the meeting.

Present:
[redacted]

2. **Minutes of the meeting held on Wednesday 29 March 2017**
The minutes were accepted as a true record.

3. **Matters arising from March Minutes**

3.1. Revised Terms of Reference
The revised Terms of Reference and other decisions made at the March meeting were formally adopted as the March meeting was non quorate.

3.2. NHS England Regional Medicines Optimisation Committees
Mr [redacted] reported that the new committees will be commencing in June, that there will be one in each region every four months (therefore one RMOC will meet each month), and that the first agenda will focus on variations in biosimilar uptake, polypharmacy and antimicrobial drug therapy. Future agendas will focus on such topics as the list of medicines of limited clinical value, and plans will be further developed for new drug guidance for those medicines that are not reviewed by NICE. Applications are open at present for those wishing to be a member.

3.3. Botulinum toxin treatment criteria based assessment policy
Mr [redacted] reported that submissions to the Drug Formulary Group are being finalised. These focus on indications for which botox is required but not yet approved in the BNSSG Formulary. It is important to complete this work and update the formulary, and a summary page was requested regarding those indications that are already in the formulary, those that are being submitted for review, and those indications that have not been submitted.

Action: Mr [redacted]

3.4. CQUIN CA2 – Nationally standardised dose banding for adult intravenous anticancer therapy (SACT)

Mr [redacted] provided the background to this CQUIN which is the second year of a three year programme in which cancer chemotherapy doses are standardised by a dose banding process. Doses are calculated on an individualised basis that are within defined ranges and rounded up or down to predetermined standard doses. The principles and process were agreed in 2016 for the first year of the CQUIN, and the current CQUIN extends the list of drugs as circulated to the committee. The UH Bristol performance against the CQUIN in year one was excellent, and all necessary work was completed in Chemocare. A similar approach is proposed for 2017/18 with the extended list of drugs. There will be a further piece of work to standardise formulations, but this will not commence until the third year of the CQUIN. The CQUIN states that local Drugs and Therapeutics Committees must approve the principles of dose standardisation and the dose adjustments required. Mr Brown reported that the Chair of the Chemotherapy Group, Dr Dangoor, has confirmed that the Chemotherapy group has reviewed the CQUIN requirements and agree to the actions required. These actions were reviewed by MAG, discussed and unanimously approved.

4. Strategic Issues

4.1. Five year forward view next steps

Mr [redacted] drew attention to the Five Year Forward View next steps document which was published at the end of March, and particularly to the sections in pages 41 and 42 that focus upon future changes in the context of medicines optimisation. These include an increasing number of clinical pharmacists engaged in GP Practices, the use of NHS RightCare to drive improvements, the implementation of regional medicines optimisation committees, the review of medicines with low clinical value, medicines savings through NHS Improvement initiatives, and a focus on medicines management across STP footprints. A number of these strategic developments will impact upon medicines management within the Trust.

4.2. MHRA Drug Safety updates April 2017/May 2017

These were reviewed and the guidance noted.

4.3. Electronic prescribing and chemotherapy electronic prescribing updates

Mr [redacted] noted that the EPMA system is to be piloted in October on one ward in Cardiology, and the chemotherapy electronic prescribing for paediatrics is being implemented on a region wide basis based at UH Bristol and due to be operational by the end of September.

4.4. CQUINs

The dose banding CQUIN was discussed under Matters Arising (see above), and the Medicines Optimisation CQUIN is now being implemented. Mr [redacted] drew attention to the biosimilar pipeline as the rapid implementation of these agents will be required. The most challenging implementation processes are likely to be in the context of rituximab and adalimumab, so initial discussions are underway.

4.5. CCG policy

4.5.1. NICE CCG policy
Mr [redacted] drew attention to the requirement in the latest policy for zero cost or free stock programmes. Where such schemes are being made available in advance of the publication of the NICE TAG, the policy states that it must cover the 90 day implementation period. This is to be noted in any MAG discussions around such schemes.

4.6. Commissioning policies
The following commissioning polices were noted:

4.6.1. SSC 1725 – Individual Funding Requests relating to treatments commissioned by NHS England Specialised Services: Continuation of funding for medicines following initial approval

4.6.2. SSC 1726 – Individual Funding Requests relating to treatments commissioned by NHS England Specialised Services: Continuation of funding for chemotherapy following a break in treatment

4.6.3. SSC 1739 – Impact of the exclusion oftrientine and chenodeoxycholic acid from tariff (see letter below and circulated)

4.6.4. Clinical Commissioning Policy: Eculizumab in the treatment of recurrence of C3 glomerulopathy post-kidney transplant (all ages)
Reference: NHS England: 16054/P

4.6.5. SSC 1728 Commissioning for Serum Eye Drops (circulated)

4.7. Commissioning letters
The following commissioning letters were noted:

4.7.1. Biosimilar rituximab 2.5.17

4.7.2. Prior approval of cancer drugs 3.5.17

4.7.3. Impact of the exclusion of trientine and chenodeoxycholic acid from tariff 4.5.17.
It was noted that the hepatology unit has a small number of patients receiving trientine and these need to be referred to national centres.

4.7.4. Publication of Interim Clinical Commissioning Policy: for Adalimumab for Adults with Severe Refractory Uveitis 31.3.17.
It was noted that numerous IFR submissions have been made for this treatment so it is anticipated that these patients will now have access to treatment through this policy.

4.7.5. NHS England Specialised Clinical Commissioning Policy 170001/P: Commissioning Medicines for Children in Specialised Services 5.4.17

5. **Joint Bristol Formulary Group**

5.1. BNSSG Formulary Decisions:
The following formulary decisions were noted:

5.1.1 Symbicort MDI, for adults aged 18 and older, for the symptomatic treatment of patients with COPD with forced expiratory volume in 1 second (FEV1) <70% predicted normal (post bronchodilator) and an exacerbation history despite regular bronchodilator therapy. As an alternative ICS/LABA MDI to fostair for COPD patients, Dr [redacted], Consultant Respiratory Medicine, NBT.
There is no evidence for superiority over the current formulary pMDI ICS/LABA fostair however the group felt that this offers another device option for patients with COPD which should improve compliance and therefore outcomes. It was noted that COPD guidelines are due for revision in June and therefore this should be considered as part of the guidelines review process. It was agreed it should be included on the joint formulary as TLS green.

5.1.2 Moxifloxacin eye drops- Microbial keratitis, Mr [redacted] Consultant Opthalmologist. Bristol Eye Hospital, UHB.
It was felt that although the microbiological evidence for the place of moxifloxacin was not robust, anecdotal evidence and current best practice from Moorfields Eye Hospital supported its inclusion onto the joint formulary, as TLS red, for use at Bristol Eye Hospital only.

5.1.3 Ivermectin cream, for patients with moderate to severe erythematotelanectatic, popular, pustular rosacea, Dr [redacted], Consultant Dermatologist, NBT.
Although ivermectin represents an increase in cost from current therapy, evidence for efficacy and tolerability for ivermectin was good and it was felt it has a clear place in therapy as second line treatment after metronidazole and allows GPs another option before a secondary care referral. It was agreed it should be included on the joint formulary as TLS blue.

5.2. NOAC in valvular heart disease
Dr [redacted] attended the meeting and presented his paper on the use of NOACs instead of warfarin following surgery for mitral valve repair due to regurgitation. It was noted that this is an off label indication but Dr [redacted] proposes NOACs to be superior to warfarin with regard to bleeding complications. It is proposed that the treatment is continued for six months. The committee agreed that such an approach is clinically sound but would require confirmation from [redacted] as Trust Thrombosis Lead that she would approve. This decision should however be part of the BNSSG Formulary, and the commissioner position was that a full submission should be made to the Joint Formulary Group. Dr [redacted] was asked to liaise with Dr [redacted] concerning this treatment and Mr [redacted] will follow up submission to the Joint Formulary Committee.

Action: Mr [redacted]

6. **Matters arising from BNSSG Drugs and Therapeutics Committee**

Mr [redacted] noted that the STP Medicines Optimisation work stream is being overseen by the BNSSG DTC and so the important focus on medicines optimisation across the BNSSG footprint is being developed through a number of projects in that context.

7. [redacted]

7.1. [redacted]

7.1.1. [redacted]

[redacted]

[redacted]

[redacted]

[redacted]

7.1.2. [redacted]

7.1.3. [redacted]

7.1.4. [redacted]

7.2. [redacted]

7.2.1. [redacted]

7.2.2. [redacted]

7.3. [redacted]

8. **Clinical guidelines and documentation**

8.1. Pharmacy Medication Switch Policy
This policy has been reviewed and updated and was approved.

9. **Immunoglobulin assessment panel**

9.1. Grey or black indications for IFR approval
No applications had been received.

9.2. Grey indications for internal approval
No applications had been received.

9.3. Blue indications for authorisation
These were reviewed and approved.

10. **Homecare medicines**
No new drug applications were received from the Homecare Medicines Management Group.

11. **Cost-effective prescribing**

11.1. NHS England review of medicines with low clinical value
NHS England has identified ten medicines which are perceived as having low clinical value and these include liothyronine, lidocaine plasters and sustained release doxazosin. A consultation exercise will be undertaken by NHS England but there is concern that some of these treatments may be referred to hospital consultants if restrictions on prescribing are implemented in primary care.

11.2. QIPP schemes
NHS England has introduced a range of QIPP schemes in order to make cost improvements on medicines expenditure. These were discussed and the key elements for UHBristol are likely to be the expansion of prior approval through Blueteq, a tightening of antifungal stewardship, and the improved management of new NICE Technology Appraisals. In addition the elements medicines optimisation CQUIN discussed previously are also important.

11.3. Cost effective prescribing guidance for 2017/18
Mr [redacted] is completing the guidance document circulated at the last meeting and this will be distributed through clinical divisions.

Action: Mr [redacted]

11.4. Second use patents – Pregabalin
The clarification letter on second use patents was circulated for information.

12. **NICE**

12.1. NICE recent publications
Mr [redacted] circulated a summary of the recent NICE publications and the future pipeline of new drugs being reviewed.

13. **Applications for one-off drugs**

13.1. Dr [redacted] requested Fluvastatin for a patient intolerant to other statins and this was approved.

13.2. Interferon gamma for mucoraceous mould infection
Dr [redacted] requested interferon gamma in accordance with guidance from the National Aspergillosis Centre. This was approved.

13.3. Quinidine for KCNT1 epilepsy
Dr [redacted] is requesting quinidine for a single patient with this rare form of epilepsy. Evidence submitted consists of one paper detailing two case reports so it was considered that this should only be used if other treatment fails.

14. **Any other business**

14.1. [redacted]

15. **Dates of future meetings**

Date	Time	Venue
17 July	12.00 – 14.00	Rheumatology Seminar Room, BRI B403/room 4-025
27 September	12.00 – 14.00	Board Room, THQ
22 November	12.00 – 14.00	Conference Room, THQ

University Hospitals Bristol NHS
NHS Foundation Trust

Minutes of the Medicines Advisory Group Meeting of

Wednesday 30 November 2016

UH Bristol, Conference Room, THQ, 12.00 – 14.00

1. **Welcome and Apologies**
[redacted] welcomed all to the meeting.

Present:
[redacted]

Apologies:
[redacted]

2. **Minutes of the meeting held on Monday 17 October 2016 (rescheduled from Wednesday 28 September 2016)**
The minutes were accepted as true record.

3. **Matters arising from October Minutes**

3.1. NHS England Regional Medicines Optimisation Committees
[redacted] provided an update on the progress of this development and noted that they will be important in the context of strategic decision making. The new drug evaluation process is being addressed at present so they will be coming into existence during 2017.

3.2. NICE approval of talimogene laherparepvec
[redacted] reported back a meeting with the biological safety officer from the University ([redacted]) and the Trust leads for health and safety and control of infection. A process is required to provide assurance of biological safety prior to implementation of these new agents into clinical practice, and the Trust has a cohort of patients requiring this NICE approved therapy. [redacted] will respond with regarding his potential future input, and [redacted] will be following up future Trust requirements with [redacted]. It was noted to be an important issue as UH Bristol should be at the forefront of implementation of these new advanced therapy medicinal products into clinical practice.

3.3. Botulinum toxin treatment criteria based assessment policy
[redacted] has identified the range of indications for which botulinum toxin is being used and is in the process of contacting clinical chairs about any that are

not supported by the BNSSG Joint Formulary. A full formulary submission is required in order to update the BNSSG Formulary appropriately.

3.4. Clinical Commissioning Policy: IVIG for ADEM and autoimmune encephalitis

[redacted] reported back that NHS England will be withdrawing the IVIG policy for ADEM and autoimmune encephalitis from the website so these indications will remain as grey but approved with internal IV assessment panel authorisation. NHS England have specified that they require patient outcomes to be uploaded onto the IVIG database in order for the treatment to continue to be made available. [redacted] has fed this back to the paediatric neurologists.

3.5. UH Bristol consultant representation on BNSSG Joint Formulary Group

[redacted] reported back a conversation with the Clinical Chair for the Division of Medicine ([redacted]) in which [redacted] was optimistic he has identified a suitable consultant to provide input to the committee.

3.6. Gentamicin for bacterial overgrowth

[redacted] obtained further clarification from [redacted] that he would not anticipate using oral gentamicin routinely for bacterial overgrowth so does not envisage using the Nottingham protocol again in the foreseeable future.

4. Strategic Issues

4.1. Review of Medicines Advisory Group Terms of Reference

[redacted] circulated the present terms of reference and these were reviewed in detail. These are now to be updated.

Action: [redacted]

4.2. MHRA Drug Safety updates October 2016 and November 2016

The updates were reviewed.

4.3. Electronic prescribing and chemotherapy electronic prescribing updates

[redacted] reported that plans are still being finalised for the EPMA system, and that the paediatric chemotherapy system is being implemented by September 2017.

4.4. Medicines Optimisation Clinical Reference Group November meeting

[redacted] circulated notes from the Medicines Optimisation Clinical Reference Group. A number of points are of importance including:

Consultation by NHS England on in year service developments, individual funding requests, funding for experimental and unproved treatments, and continuing funding of post clinical trial medicines.

The Medicines Optimisation CRG is developing guidance for compassionate use drugs.

The dose banding arrangements for chemotherapy will be developed further in 2017/18.

The Medicines Optimisation CQUIN will focus on implementation of biosimilars, development of the digital medicines agenda, cost effective dispensing arrangements, full completion of SACT and IVIG databases, and repatriation of some medicines to the acute sector.

The NHS England improving value programme will focus on (amongst other areas) IVIG, immunosuppressant repatriation, home parenteral nutrition, antifungal stewardship.

4.5. NHS England Commissioning intentions 2017/18 and 2018/19
[redacted] drew attention to this document as it focuses upon forthcoming changes. These include digital developments, the Carter Hospital Pharmacy Transformation programme, work to expedite early access to innovative medicines, and changes in the individual funding requests process. Further details were circulated.

4.6. Specialised Commissioning drugs briefing Autumn 2016
[redacted] noted this helpful circular which incorporates all NHS England medicines related policies in the last quarter, updates on individual funding request process, updates on Blueteq prior approval, update on the Cancer Drugs Fund, dose banding of chemotherapy and update on hepatitis C treatment. This will be circulated to clinical divisions.

4.7. Commissioning policies were noted as follows:

4.7.1. NICE Technology Appraisal 400: Nivolumab in combination with ipilimumab for treating advanced melanoma

4.7.2. Early Access to Medicines Scheme – Nivolumab for treatment as monotherapy of adult patients with classical Hodgkin Lymphoma (cHL) who have failed autologous stemcell transplant (ASCT) and brentuximab vedotin

4.7.3. NICE Technology Final Appraisal Determination: Everolimus with exemestane for treating advanced breast cancer after endocrine therapy (Cancer Drugs Fund reconsideration of TA295)

4.7.4. NHS England Clinical Commissioning Policy 16056/P: Tocilizumab for Takayasu arteritis (adults) – UHBristol a commissioned provider

4.7.5. Technology Appraisal 397: Belimumab for treating active autoantibody-positive systemic lupus erythematosus – UHBristol a commissioned provider

4.7.6. NHS England statement on evolocumab for the treatment of homozygous familial hypercholesterolaemia – UHBristol a commissioned provider

5. **Joint Bristol Formulary Group**

5.1. BNSSG Formulary Decisions:

Decisions from the October meeting were as follows:

5.1.1. Dermatonics heel balm – Diabetic patients at risk of developing cracked heels and ulceration of the footLiothyronine
Whilst the evidence is extremely limited, it does show that the higher concentrations of urea are more effective to hydrate the skin in patients with diabetes. It is already widely used across BNSSG, however it should be being used appropriately. The JFG agreed to include on the formulary for diabetic patients at risk from ulceration under recommendation from podiatry services.

5.1.2. Enstilar – Topical treatment of body psoriasis vulagaris [plaque psoriasis] in adults
The evidence has shown that this is a useful agent compared to the ointment and gel which are already included on the formulary. Patient compliance is significantly important and it is suggested that patients prefer the foam preparation. This will give a further option in the treatment of psoriasis. The costs currently are similar to Dovobet. The JFG agreed for inclusion onto the formulary with additional information regarding treatment pathway. To review again if the costs change. TLS Green.

5.1.3. Guanfacine – ADHD in children and adolescents when stimulant not effective/tolerated
There is a concern about the lack of long term safety and efficacy evidence and head to head trials comparing to the other non-stimulant atomoxetine. The JFG agreed to wait to make a final decision until the applicant was able to attend the meeting.

5.1.4. Esomeprazole granules – Paediatric patients who require treatment with proton pump inhibitors (PPIs) which need to be administered via enteral feeding tubes such as naso-gastro tubes, percutaneous endoscopic gastrostomy (PEG) & jejunal tubes
Esomeprazole granules are licensed and designed for administration for administration via NJ tubes and there are problems with the current options omeprazole and lansoprazole. By using the esomeprazole granules, a licensed product is being prescribed which will reduce the amount of tubes being needed to be replaced, and is cheaper than prescribing omeprazole with sodium bicarbonate. The JFG approved the addition of esomeprazole granules on the formulary, TLS Blue for NJ administration and second line for those children with swallowing difficulties.

Decisions of the November meeting were as follows:

5.1.5 Guanfacine - for treatment of Attention deficit hyperactivity disorder (ADHD) in children and adolescents 6-17 years old for whom stimulants are not suitable, not tolerated or have been shown to be ineffective. [redacted], Consultant Paediatrician, Community Children's Health Partnership
The JFG felt that evidence of long-term safety of Guanfacine was lacking and was also keen to see evidence that shows improved patient outcomes due to a quicker onset of action than atomoxetine, the current formulary non-stimulant treatment for ADHD. [redacted] is invited to submit further evidence to support the application. Based upon the application received and discussions at the meeting the group did not feel that Guanfacine offered advantages over atomoxetine and will remain non-formulary at this current time.

5.1.7 Feraccru - IBD patients with anaemia or iron deficiency anaemia who are intolerant to other oral iron preparations and would therefore require IV iron preparations instead. [redacted], Lead Inflammatory Bowel Disease (IBD) CNS, UHBristol
The JFG felt that Feraccru would improve patient's care and benefit the healthcare system by reducing secondary care attendances for IV iron infusions. It was agreed that Feraccru would be added to the formulary as Amber, dependent on the production of a SCP, for patients with mild to moderate IBD who are intolerant to standard oral iron, for a 12 month period. Audit data is needed to prove that patient outcomes with Feraccru are comparative to those seen with IV iron infusion and that secondary care attendances are reduced.

5.1.8 Metvix - Treatment in adults over 18 years of thin or non-hyperkeratotic and non-pigmented actinic keratoses on the face and scalp when other therapies are considered less appropriate. Only for treatment of superficial and/or nodular basal cell carcinoma unsuitable for other available therapies due to possible treatment related morbidity and poor cosmetic outcome; such as lesions on the mid-face or ears, lesions on severely sun damaged skin, large lesions, or recurrent lesions. Treatment of squamous cell carcinoma in situ (Bowen's disease) when surgical excision is considered less appropriate. [redacted], Consultant Dermatologist, UHBristol
After reviewing the historic commissioning information about Photodynamic therapy (PDT) and the evidence relating to Metvix it was agreed that Metvix would be added to the formulary TLS RED when confirmation of the commissioning of the PDT service is received. It was agreed that Metvix can be used for its licensed indications, but not for prophylaxis in transplant patients, due to a lack of evidence for this indication. The group agreed that Metvix could be used for the trial of the PDT due to begin in January 2017.

5.1.9 Nexobrid - Admitted patients with a thermal burn injury requiring surgical debridement. The burn injury should be older than 72 hours from injury and maximum TBSA per procedure less than 15%. [redacted] Consultant Burns and Plastic Surgery, NBT

The group noted that the evidence for Nexobrid is limited to 2 small trials. It was felt that Nexobrid appears to be a promising treatment that can debride wounds more quickly than current treatment of surgical debridement. It would also remove the need for surgery and the potential complications that can arise from this intervention. Due to the two small studies it is difficult assess if Nexobrid will improve patient outcomes when treating burns. The cost-implications of treatment are also difficult to assess. Nexobrid is an expensive treatment which is not excluded from PbR but may reduce costs due to reduced surgical time, reduced dressing costs and possibly reduced inpatient length of stay. The treatment of burns is commissioned by NHS England, and the introduction of Nexobrid at the NBT Burn's Unit needs to be agreed by the directorate before being added to the formulary as TLS RED.

5.1.10 Jaydess appeal. Contraception (IUS). [redacted], Consultant in Sexual and Reproductive Health, Bristol Sexual Health Services
The JFG acknowledged the patient considerations of having greater choice of IUS and felt that Jaydess may be preferred by some patients and offer some advantages. For example those who would prefer a smaller dose of levonorgestrel, or a shorter period of contraception, or who require a smaller device. The JFG agreed to add Jaydess as TLS BLUE, for patients as an alternative to to Mirena. Mirena is to remain the JFG first choice for IUS.

6. **Matters arising from BNSSG Drugs and Therapeutics Committee**

6.1. [redacted] fed back that the BNSSG DTC is now the overarching group for the STP (Sustainability and Transformation Plan) Medicines Optimisation Programme. This is a separate workstream that sits under the acute care collaborative and consists of eleven different projects for implementation over the next two to three years. These projects include biosimilar uptake, deprescribing of agents of limited use, polypharmacy management in care homes, and other areas of work that focus on cost savings, efficiencies and cost avoidance.

7. [redacted]

7.1.

7.1.1. [redacted]

7.1.2. [redacted]

7.1.3. [redacted]

7.1.4. [redacted]

7.1.5. [redacted]

7.1.6. [redacted]

7.1.7. [redacted]

[redacted]

7.2. [redacted]

7.2.1. [redacted]

7.2.2. [redacted]

7.2.3. [redacted]

8. **Clinical guidelines and documentation**

8.1. Injectable iron preparations

The various injectable iron preparations are now available on a framework contract and a useful overview document was provided by [redacted]. The use of products is somewhat dictated by the location in which they are administered and the time available, so [redacted] will create a flow chart advising the most appropriate choice.

Action: [redacted]

It was noted that a new oral iron preparation is being produced and this may provide an alternative to injectable products.

9. **Immunoglobulin assessment panel**

9.1. Immunoglobulin assessment panel roles
[redacted] circulated a paper indicating that the DH expect more of a focus from the immunoglobulin assessment panel on the completion of the IVIG national database, the assessment of blue indications, the outcome reports following usage, the dosage and length of treatment used, and local audit of decisions. It was considered that medicines advisory group is the correct location to address IVIG usage but there is limited capacity to go into great detail. It was felt important however that review of outcomes needs to be followed up and this will be a priority in the same way as is currently being addressed with the paediatric neurology consultants.

Action: [redacted]

9.2. Grey or Black indications for IFR approval
None have been submitted.

9.3. Grey indications for internal approval
Two requests for IVIG in ADEM were noted and approved.

9.4. Blue indications for authorisation
A table was circulated detailing the blue indications which were approved.

10. **Homecare medicines**

10.1. [redacted] noted that the Homecare Medicines Management Group has completed a gap analysis against the national homecare medicines standards and implementation of the necessary improvements. The outstanding issues are being addressed.

11. **Cost-effective prescribing**
No issues to raise.

12. **NICE recent publications**
No issues raised as [redacted] was unavailable.

13. **Applications for one off medicines**

13.1. Memantine for intractable nystagmus
This was approved.

14. **Any other business**
No further business was raised.

15. **Dates of future meetings**

2017

Date	Time	Venue

25 January	12.00 – 13.30	Conference Room, THQ
29 March	12.00 – 14.00	Board Room, THQ
31 May	12.00 – 14.00	Conference Room, THQ
26 July	12.30 – 14.00	Conference Room, THQ
27 September	12.00 – 14.00	Board Room, THQ
22 November	12.00 – 14.00	Conference Room, THQ

University Hospitals Bristol NHS
NHS Foundation Trust

Minutes of the Medicines Advisory Group Meeting of

Monday 17 October 2016 (rescheduled from Wednesday 28 September 2016)

UH Bristol, Board Room, THQ, 12.30 – 14.00

1. **Welcome and Apologies**
[redacted] welcomed all to the meeting.

Present:
[redacted]

Apologies:
[redacted]

2. **Minutes of the meeting held on Tuesday 26 July 2016**
The minutes were accepted as true record.

3. **Matters arising from July Minutes**

3.1. NHS England Regional Medicines Optimisation Committees
[redacted] reported that work is progressing to commence the evaluation of new products in April 2017, although before this date the groups will be formed and will initially focus on areas such as variation in practice.

3.2. Drugs of animal origin
[redacted] noted that the draft policy has been forwarded to the faith leaders on three occasions for comment but that no response has been received. [redacted] then agreed that the policy should be approved as written.

3.3. Botulinum toxin treatment criteria based assessment policy
The new BNSSG policy was briefly discussed and again noted that numerous areas of use of the product sat outside those approved. A full formulary submission is required for each of these indications, although [redacted] confirmed that a reasonable time-line will be permitted. She did propose that no new patients should be commenced, but this will be challenging for routine indications. Urgent feedback is therefore required through Divisions in order to generate the formulary applications and [redacted] will follow this up in detail through the Clinical Chairs.

Action: [redacted]

3.4. Clinical Commissioning Policy: IVIG for ADEM and autoimmune encephalitis

[redacted] provided further feedback to the meeting from the paediatric neurologists who were escalating their concerns about the commissioning policy to their Royal College. NHS England have commented that even though the policy does not commission this treatment this will not be imposed until a review has been undertaken for all of the grey indications. This update has been fed back to the clinicians.

3.5. Alirocumab and evolocumab homecare arrangements

[redacted] followed up the discussion at the last meeting with [redacted] and [redacted] who agreed that the two agents were of low risk other than the general concern with regard to potential reaction to biologicals at first doses, and the need to be alert for an allergic reaction. The consultant team therefore agreed to administer first doses within the pathology day unit and transfer the patients to homecare for subsequent doses.

4. **Strategic Issues**

4.1. MHRA Safety updates

The updates for August and September 2016 were reviewed and are being circulated to relevant clinicians.

4.2. Electronic prescribing and chemotherapy electronic prescribing update

[redacted] noted the digital exemplar status awarded to the Trust and the resulting revision of the EMPA programme. Further details will be forthcoming. The paediatric chemotherapy electronic prescribing plan is underway, with access being made available to regional paediatric chemotherapy sites.

4.3. Clinical Commissioning Policy proposition MXO00X01 Commissioning Medicines in Children

This policy was circulated and considered helpful in that it makes available those drugs that are approved for adults through NICE Technology Appraisal Guidance to children where this is relevant.

4.4. Clinical guidance on alternative options for oral prophylaxis in hereditary angioedema when danazol and stanozolol are not available. This policy was noted and agreed as to where to circulate.

4.5. SSC1641 Cancer Drugs Fund National CDF cohort list

The policy was noted.

4.6. Commissioning of palivizumab (to reduce the risk of RSV in high risk infants) for the 2016 vaccination season

The policy was noted and has been circulated to relevant clinicians.

4.7. Early Access to Medicines Scheme Venetoclax for treatment of adult patients with chronic lymphocytic leukaemia

This EAMS scheme was noted by the oncologists.

4.8. Outcome of procurement of providers for the prescribing of bedaquiline and delamanid for defined patients with multi drug resistant extensively drug resistant tuberculosis
This outcome was noted as documenting North Bristol Trust as the successful provider, but feedback has been made to NHS England that the submission was a joint proposal with UHBristol as tuberculosis patients are generally treated in UHBristol.

4.9. Medicines Optimisation Clinical Reference Group August meeting
[redacted] circulated notes of the meeting for information.

4.10. NICE approval of talimogene laherparepvec
This product is a gene therapy product used in melanoma and is likely to be required for a number of patients in the Trust. A process is therefore required to assess the biological safety of using such a product in the clinical environment, and the current research committee assessing such products does not cover clinical implementation. [redacted] is therefore in contact with the biological safety officer from the University ([redacted]) and the Trust lead for Health and Safety, and will feed back progress to the next meeting. It was noted that UH Bristol is likely to be the regional leader for this and other advanced therapy medicinal products, so [redacted] requested that [redacted] keeps [redacted] and [redacted] from the executives aware of progress.

Action: [redacted]

5. **Joint Bristol Formulary Group**

5.1. BNSSG Formulary Decisions:

[redacted] summarised the recent decisions as follows:

Liothyronine – Treatment of severe thyroid deficiency, including patients with thyroid cancer, in combination with levothyroxine, in compliant T-4-treated patients who have persistent complaints despite reference range serum TSH, provided they have received adequate chronic disease support and associated auto-immune diseases have been ruled out
The limited evidence does not appear to suggest that the combination of liothyronine and levothyroxine is significantly better than levothyroxine monotherapy. However there remains a small subset of patients who remain symptomatic despite being biochemically euthyroid. There are National, European and International guidelines that recommend the combination should be offered as an experimental trial to those patients and monitored for effect. This cohort of patients is extremely difficult to manage as the symptoms are so subjective. The JFG agreed to include liothyronine onto the formulary when used in combination with levothyroxine in this cohort only, TLS Red. The proposed pathway needs further detail and clarification. The existing cohort of patients who are currently managed in primary care should be offered a specialist review to confirm whether continuation of liothyronine is clinically warranted, however they should continue to receive their prescription from the

prescriber who currently holds responsibility. Liothyronine monotherapy continues to be non-formulary.

Pramipexole – Restless Legs
The evidence supports the use of both pramipexole and ropinirole for the treatment of RLS. The BNSSG JFG currently does not include anything for this indication. The JFG agreed the inclusion of both pramipexole and ropinirole onto the formulary, TLS Green with the inclusion of a treatment pathway outlining the lifestyle changes to be made prior to pharmacological treatment, and the IRLS rating scale. Pramipexole was agreed to be first line (based on more evidence and lower acquisition cost), with ropinirole second line.

Ropinirole – Restless Legs
The evidence supports the use of both pramipexole and ropinirole for the treatment of RLS. The BNSSG JFG currently does not include anything for this indication. The JFG agreed the inclusion of both pramipexole and ropinirole onto the formulary, TLS Green with the inclusion of a treatment pathway outlining the lifestyle changes to be made prior to pharmacological treatment, and the IRLS rating scale. Pramipexole was agreed to be first line (based on more evidence and lower acquisition cost), with ropinirole second line.

Melatonin – Children with neurodevelopmental disorder/disability
The evidence supporting its use demonstrates that melatonin can decrease sleep latency by 20mins in some patients. Melatonin should only be considered for patients when behavioural interventions have been optimised. Any decrease in sleep latency, and increase in sleep time for these patients can have a profound effect on not just the patient but the whole family. The JFG acknowledged the size of this cohort and is greater than the numbers submitted in the application. The JFG agreed that there was sufficient evidence and rationale to include melatonin on the formulary and to include it as amber. In order to include it on the formulary, it will be necessary to fully investigate the potential numbers and cost implication to the CCGs.

Agomelatine – Major depression
It is emerging from the evidence that agomelatine may be an alternative antidepressant for patient's whose treatment is limited by adverse effects from SSRIs or SNRIs. However the increased cost of agomelatine over standard antidepressants without any data of superiority limits its use. The JFG agreed to await the forthcoming NICE depression guidelines where its place in therapy would hopefully be clearly outlined.

Azyter (Azithromycin 1.5% eye drops) – (1) Patients with Trachomatous conjunctivitis caused by Chlamydia trachomatis. (2) Purulent bacterial conjunctivitis in pregnant women and children. (3) An alternative 3rd line treatment in purulent bacterial conjunctivitis in adults. (4) An alternative treatment for blepharitis (unlicensed). (5) Resistant cases of chronic meibomianitis and blepharitis in children

The JFG acknowledged that there was limited evidence in chlamydia; this is to be expected given the patient cohort. However it is necessary to ensure effective treatment of chlamydia trachoma and therefore the JFG agreed the inclusion in addition to systemic treatment. The JFG also agreed for the inclusion as an alternative to chloramphenicol for the treatment of purulent conjunctivitis. The JFG did not approve the inclusion for blepharitis given that there is a suitable treatment option at this current time, and there is no evidence to suggest that azithromycin is more effective.

5.2. UH Bristol consultant representation

It was noted again that a consultant representative is still awaited from UH Bristol so [redacted] requested that [redacted] follow up with [redacted], Clinical Chair for the Division of Medicine.

Action: [redacted]

6. **Matters arising from BNSSG Drugs and Therapeutics Committee**

6.1. Meeting 21 September 2016

[redacted] reported that a proposal has been made to create a Medicines Optimisation STP (Sustainability and Transformation Programme) Plan. This was discussed at the DTC and will be overseen by this group. Various projects are being proposed and [redacted] will feed back when further discussion has been completed.

7. [redacted]

7.1. [redacted]

7.1.1. [redacted]

7.1.2. [redacted]

7.1.3. [redacted]

7.1.4. [redacted]

7.1.5. [redacted]

7.1.6. [redacted]

7.1.7. [redacted]

7.1.8. [redacted]

7.1.9. [redacted]

7.1.10. [redacted]

7.1.11. [redacted]

7.1.12. [redacted]

7.1.13. [redacted]

7.1.14. [redacted]

7.2. [redacted]

7.2.1. [redacted]

7.2.2. [redacted]

7.2.3. [redacted]

[redacted]

7.2.4. [redacted]

8. **Clinical guidelines and documentation**

8.1. Intravenous isosorbide dinitrate clinical guideline
The guideline was agreed.

9. **Immunoglobulin assessment panel**

9.1. Assessment panel role
[redacted] noted the expectation of a higher level of scrutiny over such issues as patient outcomes and adverse events and will bring more detail to the next meeting.

Action: [redacted]

9.2. Grey and Black indications for approval and submission as IFRs

9.2.1. Fulminant systemic lupus erythematosis – [redacted]
This submission was reviewed and approved.

9.2.2. Chronic relapsing inflammatory optic neuropathy – [redacted]
This submission was reviewed and approved.

9.3. Grey and blue indications for authorisation

These were circulated and approved.

10. **Homecare medicines**
No further homecare issues were raised for this meeting.

11. **Cost-effective prescribing**
No further issues were raised for this meeting.

12. **NICE**
12.1. NICE recent publications
These were circulated by [redacted] and reviewed.

13. **Applications for one off drugs**
13.1. Gadoxetate for evaluation of focal liver lesion
This was requested by [redacted] and approved.

14. **Any other business**
14.1. Gentamicin for bacterial overgrowth
[redacted] noted a request from [redacted] for oral gentamicin for a patient with suspected bacterial overgrowth, using a protocol from Nottingham Hospitals. [redacted] had followed this up with [redacted] from Microbiology who was concerned that bacterial overgrowth is very difficult to diagnose and was not convinced that such a protocol should be in regular use. [redacted] will follow up whether this treatment is likely to be requested again for any further patients.

Action: [redacted]

14.2. Sodium bicarbonate solution in Bristol Childrens Hospital
The paediatric medicines safety group are proposing to use an unlicensed sodium bicarbonate solution as the labelling is more appropriate for the manner in which the product is prescribed in the hospital this was approved.

15. **Dates of future meetings**

Date	Time	Venue
2016		
30 November	12.00 – 14.00	Conference Room, THQ
2017		
25 January	12.00 – 13.30	Conference Room, THQ
29 March	12.00 – 14.00	Board Room, THQ
31 May	12.00 – 14.00	Conference Room, THQ
26 July	12.30 – 14.00	Conference Room, THQ
27 September	12.00 – 14.00	Board Room, THQ
22 November	12.00 – 14.00	Conference Room, THQ