Chelsea and Westminster Hospital NHS Foundation Trust
Trust Medicines Group

Summary of Main Points from the Meeting held on Monday 11th July 2016

2. Minutes and Summary Notes from last meeting
The Minutes and Summary notes from the June 2016 Medicines Group meeting were approved and will be circulated.

3. Matters Arising
The Group noted the matters arising from the previous Medicines Group meeting in June 2016.

4.1 Formulary Applications
Full applications

- **Umeclidiunium and Vilanterol 55/22mcg (Anoro Ellipta®)**

Requested by the Respiratory Team as a maintenance bronchodilator treatment to relieve symptoms in adult patients with chronic obstructive pulmonary disease (COPD).
Umeclidinium/vilanterol is a combination inhaled LAMA/LABA. Following oral inhalation both compounds act locally on airways to produce bronchodilation by separate mechanisms.
It is intended that Anoro Ellipta® will be used:

- First line in patients with moderate COPD admitted with exacerbation
- Second line in mild-moderate COPD already established on monotherapy long-acting muscarinic receptor antagonist (LAMA) or long-acting $beta_2$-adrenergic agonist (LABA)
- Second line in severe COPD on triple therapy but not tolerating inhaled corticosteroid (ICS) or suffering frequent pneumonia.

Anoro Ellipta® is already included in the North West London Integrated Formulary.
Ellipta® device is the preferred choice as Relvar Ellipta® is the first line ICS/LABA in the Trust.
Decision: Approved

Micafungin 50mg Injection (Mycamine®)
Requested by the Microbiology Department for the treatment of invasive candidiasis in children (including neonates) as second line to fluclonazole or liposomal Ambisome. Use will be restricted to <25g as this will ensure the use on a single 50mg vial per dose per day which ensures cost effectiveness over the current choice Caspofungin. In addition, Mycamine® is currently licensed for <12 months of age whereas Caspofungin due to safety and efficacy not being sufficiently studied in clinical trials, is not currently licensed in neonates and infants below 12 months of age. The use of Mycamine® will be strictly on advice issued by the Microbiology Department.

Fosfomycin 3g Sachets (Monuril®)
Requested by the Microbiology Department for the treatment of simple and complex urinary tract infections (UTIs) showing sensitivity to fosfomycin but resistant to first and second line oral options. In complex UTIs, fosfomycin may be recommended in combination with other agents according to sensitivities and severity of infection. Monuril® is due to be licensed in the UK in July 2016 when the cost will significantly reduce. The addition of Monuril® on the formulary will coincide with it being licensed in the UK.
Decision: Approved

Elastometric pumps
Requested by the Microbiology Department as a non-electronic pumps designed to provide ambulatory infusion antibiotic therapy. These pumps can be used for self-administration of IV antibiotics providing greater patient flexibility, improved Antimicrobial Stewardship (allows clinicians to prescribe a wider range of antibiotics for OPAT) and increased capacity of the OPAT Service. As there are no Devices Group meetings taking place currently in the Trust and on account of this pump currently being in use for the infusion of IV Fluorouracil, it was agreed to note this application and to ensure that it is forwarded for approval at the next available Trust Devices Group meeting once meetings are reinstated.
Decision: Noted

Removals
Anidulafungin IV
In light of the addition of Mycamine® and Monuril® to the formulary it was proposed removing Anidulafungin IV from the

formulary following a review and rationalisation of the choice of antifungals currently available on the formulary. Anidulafungin IV is currently prescribed at WMUH for use in adults patients.
Decision: Approved
Ex-panel

- **Carbocisteine 750mg/10ml sachets**

Proposal made to replace Carbocisteine Oral Solution (250mg/5ml) presented in bottles with Carbocisteine 750mg/10ml presented in sachets resulting in less wastage and a minimum cost a saving or £5k per annum if 60% of patients were to be switched over.

- **Etanercept 50mg Injection (Benepali®) (Biosimilar)**

Requested by the Pharmacy Commissioning Pharmacist supported by the Rheumatology Department

Benepali® will be the first line choice for those patients who require Etanercept. It is unlikely to totally replace Etanercept (currently supplied as Enbrel®) as some patients may not wish to switch to it. Paediatrics and Dermatology are not switching at present.

It is indicated for all the same conditions as Enbrel® (Psoriasis, Psoriatic Arthritis, Rheumatoid Arthritis and Ankalosing Spondilitis). The main prescribing department will be Adult Rheumatology and will be dispensed via home delivery using Healthcare at Home.

Cost for 1 month is £440 compare to Enbrel® which is £536.25 (VAT excl.)

The plan is for new patients to be started on Benepali® from the outset and for old patients to be switched over, over the next 6 months.
Decision: Approved

- **Adenosine 1mg/ml Solution for Injection - Unlicensed**

Requested by Cardiology for use in the new Cardiac Catheter Laboratory (Due to open Autumn in WMUH) for Fractional Flow Reserve (FFR) measurement which involves determining the ratio between the maximum achievable blood flow in a diseased coronary artery and the theoretical maximum flow in a normal coronary artery.
Decision: Approved

- **Abciximab 2mg/ml injection (ReoPro®)**

Requested by Cardiology for use in the new Cardiac Catheter Laboratory for use in line with NICE Guidance TA47 (*Guidance on the use of glycoprotein IIb/IIIa inhibitors in the treatment of acute coronary syndromes).*
Decision: Approved

For noting

- **Ixazomib 2.5, 3mg and 4mg Capsules (Ninlaro®) - Unlicensed**

Approved by the relevant MDT at WMUH for 2 patients for relapsed refractory Myeloma.
Decision: Noted

- **Sacubtiril valsartan (various strengths) Tablets (Entresto®)**

For use in line with NICE TA388 *(Sacubitril Valsartan for treating symptomatic chronic heart failure with reduced ejection fraction).*
Decision: Noted

- **Edoxaban 30mg and 60mg Tablets (Lixiana®)**

For use in line with NICE TA354 (Edoxaban for treating and preventing deep vein thrombosis and pulmonary embolism
For use in line with NICE TA355 (Edoxaban for preventing stroke and systemic embolism in people with non-valvular atrial fibrilliation.
(This was submitted to fulfil adding Edoxaban retrospectively to the formulary at WMUH)
Decision: Noted

Chelsea and Westminster Hospital NHS Foundation Trust
Trust Medicines Group

Pharmacoeconomic Board requests / Individual Funding Requests

- **Teriparatide for severe osteoporosis**

IFR request for the use of Teriparatide for severe osteoporosis. This request has been approved by the Pharmacoeconomic Board.
Decision: Noted

4.2 Trust Medicines Policy
The following changes were proposed to the Trust Medicines Policy - CWH Site:

- **TMP Section 4. Safe storage of medicines**

Updated to include a requirement to archive records of temperature monitoring for refrigerators and freezers for at least one year.
Decision: Approved

TMP Section 2. Prescribing
Update to section relating to infusion therapy in light of:

a) Electronic prescribing
b) IV infusion parameters for medicines to be administered via IV infusion only need to be stated if not detailed in the Trust IV Administration Guide.

Decision: Approved

- **TMP Section 15. Clinical Trials**

Routine review and update. Updated 15.2 to include details of new HRA approval process.
Decision: Approved

- **TMP Audit 2016 - Audit standards**

Audit standards for the Trust Medicines Policy Audit 2016 including a plan of prescription sample selection for both CWH and WMUH sites.
Decision: Approved

4.3 Medicines Optimisation

- **National implementation of dose banding of intravenous Anti-cancer Therapy – Proposal and Supporting letter**

Details of the dose banding of intravenous Anti-cancer Therapy as proposed by NHS England and associated letter providing Trust support by Trust Medicines Group Chairperson and Chief Pharmacist
Decision: Approved

4.4 NICE TA Guidance
a) NICE TA Guidance - June 2016

6 Technology Appraisals have been noted in June 2016

TA392 - Adalimumab for treating moderate to severe hidradenitis suppurativa

Recommendations
Adalimumab is recommended, within its marketing authorisation, as an option for treating active moderate to severe hidradenitis suppurativa in adults whose disease has not responded to conventional systemic therapy. The drug is recommended only if the company provides it at the price agreed in the patient access scheme.

1.2 Assess the response to adalimumab after 12 weeks of treatment, and only continue if there is clear evidence of response, defined as:

- a reduction of 25% or more in the total abscess and inflammatory nodule count and
- no increase in abscesses and draining fistulas.

Chelsea and Westminster Hospital NHS Foundation Trust
Trust Medicines Group

Action: Update the formulary to indicate that Adalimumab is now used in line with NICE TA392

TA393 - Alirocumab for treating primary hypercholesterolaemia and mixed dyslipidaemia

Recommendations

Alirocumab is recommended as an option for treating primary hypercholesterolaemia or mixed dyslipidaemia, only if:

- Low-density lipoprotein concentrations are persistently above the thresholds specified in table 1 despite maximal tolerated lipid-lowering therapy. That is, either the maximum dose has been reached or further titration is limited by intolerance (as defined in NICE's guideline on familial hypercholesterolaemia: identification and management).
- The company provides alirocumab with the discount agreed in the patient access scheme.

Action: Add Alirocumab to the formulary pending receipt of a completed and signed application from the Lipid Clinic that details plans for ongoing supply once initial dose is provided by the hospital.

TA394 - Evolocumab for treating primary hypercholesterolaemia and mixed dyslipidaemia

Recommendations
Evolocumab is recommended as an option for treating primary hypercholesterolaemia or mixed dyslipidaemia, only if:

- The dosage is 140 mg every 2 weeks.
- Low-density lipoprotein concentrations are persistently above the thresholds specified in table 1 despite maximal tolerated lipid-lowering therapy. That is, either the maximum dose has been reached, or further titration is limited by intolerance (as defined in NICE's guideline on familial hypercholesterolaemia).
- The company provides evolocumab with the discount agreed in the patient access scheme.

Action: Add Evolocumab to the formulary pending receipt of a completed and signed application from the Lipid Clinic that details plans for ongoing supply once initial dose is provided by the hospital.

TA395 - Ceritinib for previously treated anaplastic lymphoma kinase positive non-small-cell lung cancer

Recommendations

Ceritinib is recommended, within its marketing authorisation, as an option for treating advanced anaplastic lymphoma kinase positive non-small-cell lung cancer in adults who have previously had crizotinib. The drug is recommended only if the company provides it with the discount agreed in the patient access scheme.

Action: Add Ceritinib to the formulary pending receipt of a completed and signed application from the Oncology Team.

TA396 - Trametinib in combination with dabrafenib for treating unresectable or metastatic melanoma

Recommendations

Trametinib in combination with dabrafenib is recommended, within its marketing authorisation, as an option for treating unresectable or metastatic melanoma in adults with a BRAF V600 mutation only when the company provides trametinib and dabrafenib with the discounts agreed in the patient access schemes.

Action: Add Trametinib to the formulary pending receipt of a completed and signed application from the Oncology Team.

TA397 - Belimumab for treating active autoantibody-positive systemic lupus erythematosus

Recommendations

Chelsea and Westminster Hospital NHS Foundation Trust
Trust Medicines Group

1.1 Belimumab is recommended as an option as add-on treatment for active autoantibody-positive systemic lupus erythematosus in adults only if all of the following apply:

- There is evidence for serological disease activity (defined as positive anti-double-stranded DNA and low complement) and a Safety of Estrogen in Lupus National Assessment – Systemic Lupus Erythematosus Disease Activity Index (SELENA-SLEDAI) score of greater than or equal to 10 despite standard treatment.
- Treatment with belimumab is continued beyond 24 weeks only if the SELENA-SLEDAI score has improved by 4 points or more.
- The company provides belimumab with the discount agreed in the patient access scheme.
- Under the conditions for data collection, monitoring, patient eligibility and consent, ongoing treatment, cost to the NHS, and review by NICE as laid out in this document.

1.2 This guidance is not intended to affect the position of patients whose treatment with belimumab was started within the NHS before this guidance was published. Treatment of those patients may continue without change to whatever funding arrangements were in place for them before this guidance was published until they and their NHS clinician consider it appropriate to stop.

Action: To confirm with the Rheumatology Team is applicable to CW Trust.

4.5 IVIG Update

- **IVIG requests**

June 2016
CWH Site
IVIG issues for June 2016
There were 14 IVIG issues in June 2016, with 3 new requests:

- Two for ITP (Red indication)
- One for Alloimmune Thrombocytopenia - neonatal (Red indication)

WMUH Site
IVIG issues for June 2016
There were 23 IVIG issues in June 2016, with 6 new requests:

- Three for ITP (Red indication)
- Two for secondary antibody deficiencies (Blue indication)
- One for Staphylococcal or streptococcal toxic shock syndrome (Blue indication)

Decision: Approved

4.6 Items for noting

- **Letter re. Duavive - Compassionate supply**

Letter re. the compassionate supply of Duavive
Decision: Noted

- **Patient Group Directions Tracker - July 2016**

Patient Group Directions Trackers for July 2016 for CWH and WMUH sites
Decision: Noted
During subsequent discussion it was agreed that nurses who are already trained and passed the WMUH PGD competencies do not have to repeat the C&W PGD training or undergo further assessment of competence

- **MHRA Update - June 2016**

MHRA Update for June 2016
Decision: Noted

6. Date of next meeting
Next meeting
Date: Monday 12th September 2016
Time: 8am-9am
Location: Board Room (CWH Site) and Meeting Room B (WMUH Site via video conferencing)

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Trust Medicines Group

Closing date: 19th August 2016