Chelsea and Westminster Hospital NHS Foundation Trust
Trust Medicines Group

Summary of Main Points from the Meeting held on Monday 14th November 2016

2. Minutes and Summary Notes from last meeting

The Minutes and Summary notes from the October 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.

4.0 Business to be transacted by the Medicines group

4.1 Formulary Applications

Full applications

- **Darifenacin 7.5mg and 15mg Tablets (Emselex®)**

Darifenacin is licensed for the symptomatic treatment of urinary incontinence and/or increased urinary frequency and urgency which may occur in adult patients with Overactive Bladder Syndrome. Requested by the Urology Team to be used first line as per NICE CG171 (Urinary incontinence in women) replacing solifenacin. Darifenacin is currently included on the NWLIF. It was agreed that Darifenacin should be used where Oxybutynin and Tolterodine are contraindicated or not appropriate due to intolerability. Liaison to be undertaken with UroGynae Department regarding the removal of Solifenacin, Duloxetine and Propantheline as this department may require these medicines to remain available on the formulary.

Action: To liaise with UroGynae regarding the removal of of Solifenacin, Duloxetine and Propantheline from the formulary.

Decision: Approved for addition to the formulary where Oxybutynin and Tolterodine are contraindicated or not appropriate due to intolerability.

- **Duavive® (Conjugated oestrogens 0.45mg & Bazedoxifene 20mg MR Tablets)**

Duavive® is licensed for the management of oestrogen deficiency symptoms in postmenopausal women with a uterus (with at least 12 months since the last menses) for whom treatment with progestin-containing therapy is not appropriate. Requested by the Gynaecology Team for use in postmenopausal women (licensed indication) and perimenopausal women (off-label indication). Discussion was had regarding the continuation of the patients already receiving Duavive® on a compassionate supply basis, lack of other pharmaceutical options for women who fall into the licensed use category and the unlikelihood of this being approved for addition to the NWLIF for the off-label indication. A decision was made to await publication of the NICE Clinical Guidance which is due to be published in December 2016. Once available a decision will be made regarding adding Duavive® to the formulary and making a submission to the NWLIF.

Decision: Await publication of the relevant NICE CG due December 2016.

- **Methoxyflurane Inhalation Vapour (Penthrox®)**

Methoxyflurane is licensed for the emergency relief of moderate to severe pain in conscious adult patients with trauma and associated pain. Requested by the Burns Department for off-label use for a trial on the Burns Unit at CWH Site for the relief of acute pain relief during dressing changes for 20 adult patients with burns who require dressing changes during booked out-patient appointments. Free of charge stock has already been negotiated from the pharmaceutical company to support the trial. Use in other countries has demonstrated that Methoxyflurane reduces the need for opioid analgesia which results in early discharge, is associated with prolonged analgesic effect which is not seen with Entonox and potentially better patient acceptance on account of reduced side effect profile compared with opioid analgesia and Entonox. It is intended that a full submission will be made if the trial demonstrates a favourable outcome. Results will be presented on completion of the trial to the Group.

Decision: Approved for use in the trial as described above. Results of the trial to be presented to the Group on completion of the trial and a full submission to be made if the trial demonstrates a favourable outcome.

Ex-panel

- **Treclin® (Clindamycin 1% & Tretinoin 0.025%) Gel**

Added to the NWLIF as an Ex-panel request in July 2016. A decision was made that Treclin® gel should be adopted onto the formulary for Hospitals and GPs to prescribe as an option for acne vulgaris treatment. Dr Louise Fearfield (Consultant Dermatologists) has supported its addition to the Trust Formulary. It was agreed that the Dermatologists should be asked to attend a forthcoming Antimicrobial Stewardship Group meeting to discuss their plans for the use of this topical antimicrobial agent.
Action: DR to ask the Lead Antimicrobial Pharmacist to arrange of the Dermatologists to attend a forthcoming Antimicrobial Stewardship Group meeting.
Decision: Await discussion at the Antimicrobial Stewardship Group meeting.

IFR Forms for noting

- **Certolizumab for IBD**

IFR form for Certolizumab for Irritable Bowel Disease. This request has been previously approved by the Pharmacoeconomic Board.
Decision: Noted

4.2 Trust Medicines Policy

- **Plan for unification of the Trust Medicines Policies at both hospital sites**

The timeline for unification of the Trust Medicines Polies at both sites was presented. The unification process involves reviewing the relevant sections that are currently in place at both sites and identifying areas of difference. A review will then take place to agree the unified process going forward and to produce a unified policy. Each unified section of the policy will be presented at the Trust Medicines Group meeting for ratification with an accompanying sheet that details of any changes in policy that specifically affect each site. This will then be used for communicating the change in policy following ratification.
Decision: Noted

- **TMP Section 14. Reporting of adverse reactions**

Unified policy
Decision: Approved

- **TMP Section 16. Ward openings and closings**

Unified policy
Decision: Approved

- **TMP Section 18. Medical Representatives**

Unified policy
Decision: Approved

- **TMP Section 22. Non-Medical Prescribing**

Changes to NMP application form
Unified policy.
Decision: Approved

- **TMP Section 24. Concentrated potassium solution**

Unified policy
Decision: Approved

- **TMP Section 28.Trust CD Governance Arrangement**

Routine review (full) and update
Decision: Approved

4.3 Medicines Optimisation

- **Hospital Pharmacy Assessment and Action Planning Tool and Transformation Plan**

Hospital Pharmacy Transformation Plan was presented
Decision: Noted

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4.4 NICE TA Guidance
NICE TA Guidance - September 2016

4 Technology Appraisals have been published in October 2016

TA413 - Elbasvir–grazoprevir for treating chronic Hepatitis C
Recommendations
Elbasvir–Grazoprevir is recommended, within its marketing authorisation, as an option for treating genotype 1 or 4 chronic hepatitis C in adults, as specified in table 1, only if the company provides the drug at the same price or lower than that agreed with the Commercial Medicines Unit.

Table 1 Elbasvir–grazoprevir for treating chronic hepatitis C in adults

Genotype	Treatment and duration
1a	Elbasvir–grazoprevir for 12 weeks.
	Consider elbasvir–grazoprevir plus ribavirin for 16 weeks in people with a baseline hepatitis C virus RNA level of more than 800,000 IU/ml or specific NS5A polymorphisms causing at least a 5-fold reduction in activity of elbasvir.
1b	Elbasvir–grazoprevir for 12 weeks.
4	Elbasvir–grazoprevir for 12 weeks.
	Consider elbasvir-grazoprevir plus ribavirin for 16 weeks in people with a baseline hepatitis C virus RNA level of more than 800,000 IU/ml.

It is recommended that the decision to treat and prescribing decisions are made by multidisciplinary teams in the operational delivery networks put in place by NHS England, to prioritise treatment for people with the highest unmet clinical need.
Action: Add Elbasvir–grazoprevir to the formulary following receipt of a signed, completed consultant supported application form.

TA414 - Cobimetinib in combination with vemurafenib for treating unresectable or metastatic BRAF V600 mutation-positive melanoma

Recommendations
1.1 Cobimetinib in combination with vemurafenib is not recommended within its marketing authorisation for treating unresectable or metastatic melanoma in adults with a BRAF V600 mutation.
1.2 This guidance is not intended to affect the position of patients whose treatment with cobimetinib in combination with vemurafenib 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: Nil - Not recommended.

TA415 - Certolizumab pegol for treating rheumatoid arthritis after inadequate response to a TNF-alpha inhibitor
Recommendations
1.1 Certolizumab pegol, in combination with methotrexate, is recommended as an option for treating active rheumatoid arthritis in adults whose disease has responded inadequately to, or who cannot tolerate, other

disease-modifying antirheumatic drugs (DMARDs) including at least 1 tumour necrosis factor-alpha (TNF-alpha) inhibitor, only if

  - disease activity is severe and
  - rituximab is contraindicated or not tolerated and
  - the company provides certolizumab pegol with the agreed patient access scheme.

- Certolizumab pegol, as monotherapy, is recommended as an option for treating active rheumatoid arthritis in adults whose disease has responded inadequately to, or who cannot tolerate, other DMARDs including at least 1 TNF-alpha inhibitor, only if:

  - disease activity is severe and
  - rituximab is contraindicated or not tolerated and
  - the company provides certolizumab pegol with the agreed patient access scheme.

1.2 Continue treatment only if there is at least a moderate response measured using European League Against Rheumatism (EULAR) criteria at 6 months. After an initial response within 6 months, withdraw treatment if at least a moderate EULAR response is not maintained.

1.3 This guidance is not intended to affect the position of patients whose treatment with certolizumab pegol 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: Update formulary to indicate that Certolizumab pegol is now used in line with NICE TA415.

TA416 - Osimertinib for treating locally advanced or metastatic EGFR T790M mutation-positive non-small-cell lung cancer

Recommendations

1.1 Osimertinib is recommended as an option for use within the Cancer Drugs Fund for treating locally advanced or metastatic epidermal growth factor receptor (EGFR) T790M mutation-positive non-small-cell lung cancer in adults whose disease has progressed only:

  - after first-line treatment with an EGFR tyrosine kinase inhibitor and
  - if the conditions in the managed access agreement for osimertinib are followed.

1.2 This guidance is not intended to affect the position of patients whose treatment with osimertinib 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: Add Osimertinib to the formulary following receipt of a signed, completed consultant supported application form.

4.5 IVIG Update

- **IVIG requests**

October 2016

CWH Site

There were 16 IVIG issues in October 2016, with 7 new requests:

- Two for Myasthenia Gravis (Blue indication)
- One for ITP (Red indication)
- One for CIDP (long term) (Blue indication)
- Two for Haemolytic Disease for the Newborn (Red indication)
- One for Stiff Person Syndrome (Red indication)

WMUH Site

There were 20 IVIG issues in October 2016, with 4 new requests:

- One for Dermatomyositis (inflammatory myopathy) (Blue indication)

- Two for Acute ITP (Red indication)
- One for Secondary Immune Deficiency (Blue indication)

Decision: Approved

4.6 Items for noting

- **Medicines Safety Bulletin - Issue 1**

First issue of the Trust Medicines Safety Bulletin.
Decision: Noted

- **Trust Medicines Group Meetings - Dates for 2017**

Meeting dates for 2017
June and July dates are subject to change. To be updated and included in the December meeting papers.
Decision: Noted

- **MHRA Update - October 2016**

MHRA Update for October 2016.
Action: Retigabine was withdrawn in June 2017. Neurology Team to be informed.
Decision: Noted

4.7 Meeting minutes for noting

- **Clinical Directorate of HIV and GUM, Drugs Sub-Group Meeting - September 2016**

Meeting minutes for September 2016
Decision: Noted

- **Antimicrobial Stewardship Group Meeting - 27th September 2016**

Meeting minutes for 27th September 2016
Decision: Noted

- **Local Chemotherapy Group Meeting - August 2016**

Meeting minutes for August 2016
Decision: Noted

- **Local Chemotherapy Group Meeting - October 2016**

Meeting minutes for October 2016

- **Clinical Chemotherapy Service Group (CCSG) Meeting - June 2016**

Meeting minutes for June 2016
Decision: Noted

4.8 Additional papers to go to Trust patient Safety Group

Nil

Date of next meeting

Next meeting
Date: Monday 12th December 2016
Time: 8am-9am
Location: Board Room (CWH Site) and Meeting Room B (WMUH Site via video conferencing)
Closing date: 18st November 2016