Chelsea and Westminster Hospital NHS Foundation Trust
Trust Medicines Group

Summary of Main Points from the Meeting held on Monday 12th February 2018

2. Minutes and Summary Notes from last meeting

The Minutes and Summary notes from the 11th December 2017 Medicines Group meeting were approved and will be circulated.

3. Matters Arising

The Group noted the matters arising from the previous meeting.

4. Business to be transacted by the Medicines Group

4.1 Formulary Applications

- **Linaclotide 290mg Capsules 290mcg (Constella®) (Allergan)**

Requested by the Gastroenterology Team to be used in line with the licensed indication - Symptomatic treatment of moderate to severe irritable bowel syndrome with constipation in adults.
Linaclotide is a first in class locally acting Guanylate Cyclase-C (GC-C) receptor agonist for the symptomatic treatment of IBS with constipation (IBS-C). Linaclotide causes decreased visceral pain, increased intestinal fluid secretion and accelerated intestinal transit.
The intention is to use this agent 2nd line after an adequate trial of laxatives from two separate standard classes i.e. osmotic and stimulant.
NICE management guideline advises to consider Linaclotide for patient with IBS where optimal or maximum tolerated doses of previous laxatives from different classes have not helped and they have had constipation for at least 12 months.
There is currently no other licensed medication that improves both bowel habit and pain in functional bowel disorders. Patients with these problems can prove to be very refractory to treatment with osmotic laxatives and antispasmodics alone. Prucalopride (Selective, high affinity serotonin ($5\text{-}HT_4$) receptor agonist) is an option for managing these patients, but headache occurs very commonly.
Cost comparison with Prucalopride: £26.35 less per month per patient treated with Linaclotide. Potential cost saving of £1.8k per annum to the Trust if Linaclotide was used in place of Prucalopride. Linaclotide is currently included on the NWLIF so GPs can continue to prescribe this once patient is established on this in secondary care. Prucalopride may still be prescribed afterwards if necessary as it has a different mechanism of action.
Decision: Approved for addition to the formulary for its requested indication for use in patients who have failed at least 2 other lines of laxatives.

Ex-Panel

- **Contrast media including relating Risk Assessments for vial sharing**

The following were presented:

1. A table detailing a list of Contrast Media agents that have historically not been included on the formulary. The table detailed the agents and indication usage at both sites.
2. Three risk assessments to support vial sharing with three of these agents at the Cardiac Catheterisation Laboratory at both sites.

- Visipaque - Using NAMIC Squeeze device for vial sharing
- Omnipaque - Using NAMIC Squeeze device for vial sharing
- SonoVue - Using aseptic transfer system for vial sharing

According to NPSA Guidance on injectables, vials should not be shared. There is currently one exception to this in the Trust (Use of Botulinum Toxin (Botox®) in a single session - Relating risk assessment has been approved by the Trust Medicines Group.
It was asked if it was possible to aliquot these contrast media in the Pharmacy Technical Services Production Unit however this is not possible for Sonovue due to 6-hour window from reconstitution to administration. In addition, it is likely to cost more than the proposed saving of ~€5.08 per patient (indicated in the REBECCA study). It was mentioned that LPP have plans for some of the contrast media agents to be the supplied in pre-filled syringes via a tender process. In respect of the NAMIC Squeeze device, it was noted that the study is

sponsored by the manufacture of the device. The application mentioned use at Imperial College Healthcare NHS Trust, however, the set up in that Trust may be different, no further information is provided on this. Concerns were raised that the manufacturers of the contrast media agents recommend single use and if something were to inadvertently go wrong, the Trust would potentially be liable. It was concluded that there was a need for further information in order to assess the potential risk against the actual benefit to the Trust e.g. detailed localised cost analysis; details of what the NAMIC Squeeze device is; training of staff that will need to be provided.

Decision

1. **All contrast media agents approved for addition to the formulary.**
2. **Detailed cost analysis to be requested regarding vial sharing**
3. **Request for cardiology representative/catheterisation laboratory lead (Dr Kaprielian) to present cost analysis use of the NAMIC Squeeze device at TMG**
4. **If approved by TMG in principle, use of NAMIC Squeeze device to be approved by Patient Safety Group.**

- **Medicines to be added to formulary to align CWH and ICHT formularies**

The Cerner Project has identified a number of medicines that are included on the formulary at ICHT but not included on the formulary at CWH. However, some of these medicines are already in use at CWH and noted at TMG, although not added to the formulary. The table details the medicines that are being proposed for adding to the CWH formulary where usage justifies this addition.
Decision: All medicines approved for addition to the formulary

NICE Approved drug applications

- **Venteclax 10mg, 50mg and 100mg Tablets (Venclyxto®) in line with NICE TA487**

In line with NICE TA487 (Venetoclax for treating chronic lymphocytic leukaemia) (Published in November 2017)
Decision: Approved for addition to the formulary

- **Atezolizumab 1200mg Solution for Infusion (Tecentriq®) in line with NICE TA492**

In line with NICE TA492 (Atezolizumab for untreated locally advanced or metastatic urothelial cancer when cisplatin is unsuitable) (Published in December 2017)
Decision: Approved for addition to the formulary

Pharmacoeconomic Board requests

- **Azacitidine for AML**

Approved by the Pharmacoeconomic Board on 03/12/2017
Decision: Noted
Action: Patient outcome to be requested

- **Liraglutide prior to weight loss surgery**

Approved by the Pharmacoeconomic Board on 08/01/2018
Decision: Noted
Action: Patient outcome to be requested

- **Degaralix for Metastatic Prostate Cancer**

Approved by the Pharmacoeconomic Board on 23/01/2018
Decision: Noted
Action: Patient outcome to be requested

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- **Siltuximab for Idiopathic Multicentric Castleman's**

Request submitted to Pharmacoeconomic Board for approval 30/01/2018. Funding approved via CCG.
Decision: Noted

- **IVIG for Neuromyelitis Optica - Outcome of funding request**

Outcome of funding request for noting: IFR rejected by NHSE. Patient decided not to have IVIg.
Decision: Noted

- **Duavive for Pre-menstrual Syndrome**

Submission to Pharmacoeconomic Board for approval to prescribe Duavive for Pre-Menopausal Syndrome (PMS).

Duavive was approved in the Trust for use in line with its licensed indication: 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.

A request has been received to approve the prescribing of Duavive for management of Pre-Menstrual Syndrome in 4 women. The requestor stated that there is no evidence for its use in PMS or information on the long term adverse effect profile in pre-menopausal women. Currently 2 out of the 4 patients already initiated on this. If treatment continued there would potentially be more patients initiated. GPs would not be expected to undertake the ongoing prescribing of Duavive for this unlicensed indication, so if treatment continued this would all need to be provided by the secondary care. Even if it was prescribed privately, the Trust would take on liability for supply outside of the licensed indication.

After some discussion, the conclusion was that The Trust Medicines Group does not support this request and the Chair would write to the requester to inform them of the decision and their responsibility to adhere to the Trust policies in relation to prescribing.

It was agreed that it would place the Pharmacy Department in a difficult position if they had to intercept Duavive prescriptions at the point of receipt for dispensing, so the onus will be on the prescriber to adhere to the Trust policies in relation to prescribing. Adherence will be audited retrospectively and any non-compliance escalated to the Trust Medical Director and Chair of the Trust Medicines Group. Duavive will remain on the formulary for its licensed/approved indication. It was suggested that requester may wish to consider running a research trial to obtain the required evidence in this cohort of patients.
Action: Letter to be drafted to inform relevant clinician
Decision: TMG does <u>not</u> support the prescribing of Duavive for Pre-Menstrual Syndrome.

a) North West London Integrated Formulary Panel meeting - 8th January

A summary of changes made to the NWLIF following the meeting was provided. The outcome of two applications by CWH requesting Degludec to be added to the NWLIF for two restricted indications which were not approved were noted. It was also noted that a further application for Insulin Glargine 300units/ml (Toujeo) submitted by CWH was not approved.

The NWLIF panel were sympathetic to the use of Insulin Degludec in patients for whom the next step would be insulin pump therapy where the infusion is unsuitable due to practical reasons. However, it was not added to the NWLIF due to concerns that its use would significantly increase but not necessarily prescribed to patients who meet the proposed criteria. The process for these exceptional patients is to be clarified by the CCG in due course. It was noted by the NWLIF panel that signatories for the request had received funding from pharmaceutical companies as per ABPI website which can be readily accessed by the public. This highlights the need for Trust staff to register their declaration of interest appropriately.
Decision: Noted

<u>4.2 Trust Medicines Policy</u>

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- **TMP Audit 2017 - Action Plan**

Trust Medicines Policy Audit 2017 action plan updated as of December 2017 with all actions completed. Some actions will be ongoing such as for omitted and delayed doses, to have two 6 monthly audits.
Decision: Noted

- **TMP Section 26: Critical list of omitted and delayed medicines**

Updated to incorporate clarity around definitions of timings of critical medicines. In particular that in septic patients the first dose of antimicrobial should be administered within 60 minutes of presentation of sepsis in line with NICE guidance.
Decision: Approved

4.3 Medicines Optimisation

- **Hospital Pharmacy Transformation Plan - Progress update**

Deferred to next meeting

- **Paediatric Short Stay Unit Medication Chart (WMUH)**

The updated medication chart for Paediatric Short Stay Unit at WMUH was presented to TMG Feb 2017. Additional section added for nebulised salbutamol and IV fluids. Will be used in PSSU and Paediatric Day Unit. Ultimately this will be replaced by an electronic version when CERNER electronic prescribing goes live. A recommendation was made for this chart to be forwarded to Trust Health Records Committee for noting.
Decision: Approved

- **Developing the Dean Street HIV PrEP additional private care service**
    - Several generic versions of Truvada (combination products of emtricitabline and tenofovir disoproxil) are licensed in the EU for PrEP.
    - The basic patent protecting Truvada expired on 24/07/17 and a number of generic manufacturers have sought to challenge the validity of the Supplementary Protection Certificate ('SPC'). The UK Patents Court handed down a judgment on 13/01/17, which confirmed that a reference to the Court of Justice of the European Union ('CJEU') would be made to decide the case.
    - The CJEU turned down a request to expedite their consideration of the case on the basis that a delay in the availability of generics would "entail higher costs for, and place a more onerous budgetary burden" on the NHS.
    - UK licensed versions of Generic E&TD are being marketed in the UK 'at risk'.
    - There is a London regional contract with Gilead for Truvada, for use in NHS patients.

The IMPACT trial for PrEP is using Generic E&TD (Mylan). However, clinical trials are exempt from patent litigation.

Legal Advice
As matters currently stand, there is a valid SPC (effectively a patent for our purposes) and Gilead can take action for infringement of the SPC. However, any action is only likely to follow the CJEU's decision about the SPC (the CJEU's ruling is expected to be handed down in the first half of 2018).

On review of the legal advice received and relative risk, it has been agreed that the Trust will be using a licensed generic for a licensed indication, in line with previous precedents therefore the manufacturer's liability will apply.

Patients not in the IMPACT trial will pay for PrEP as additional private care and will receive the generic preparation.
Decision: Noted

- **NHS England Consultation: Conditions for which over the counter items should not routinely be prescribed in primary care**

Enclosures which were noted included:

- Consultation document published December 2017
- Response from Dr Babb

Responses to the consultation are being requested from Group members.

The consultation is proposing that certain items such as probiotics, vitamins and minerals, and items for self-limiting conditions would be bought by patients over-the-counter. There are some exceptions and challenges to this e.g. for some items which could otherwise be bought over-the-counter, would not be within the licence to buy if the patient were pregnant or breast feeding. The Trust has been requested to identify any exception that has not already been covered - Dr Babb (Haematology) has identified the scenario of Myeloma patients receiving bisphosphonates requiring Calcium and Vitamin D supplements.
Action: Responses to the consultation to be forwarded to Deirdre Richardson by 16th February 2017
Decision: Noted

- **NHS England Guidance: Items which should not routinely be prescribed in Primary Care**

Overall there is a low volume of prescribing of Lidocaine patches. Lidocaine patches are licensed for post-herpetic neuralgia (PHN), so if they are being prescribed for non-acute pain with PHN, GP could continue to prescribe them, if necessary. On a number of occasions lidocaine patches are being prescribed outside of this indication. Prescribers have been made aware that GPs would not be permitted to issue ongoing prescriptions unless there is a very good rationale and the circumstances are exceptional and this has been communicated to the GP.
Decision: Noted

- **MHRA Letter re aseptically Manufactured Unlicensed Medicines (Specials)**

A letter from MHRA to Chief Pharmacist re aseptically Manufactured Unlicensed Medicines (Specials) was noted. This letter highlights the need for sufficient contingency to be in place for the preparation of aseptically manufactured products on-site.

CWH site procures all TPN from ITH Pharma. WMUH site compounds some TPN. Across both sites there is a need to have a contingency plan of what would happen if ITH Pharma were not able to supply.
There are currently 2 aseptic units in the Trust (1 at each site). For the longer term there is a need to maintain both units because there is insufficient resilience in the supply chain. The Deloitte review of technical services is still on-going.
Decision: Noted. The Pharmacy Service will need to draw up a contingency plan in light of the above letter. This action will be monitored via the Medicines Optimisation Steering Group.

- **CCP report - December 2017**

The CCP report for December 2017 was noted. The list of SSC letters sent as part of CCP were also noted. The SSC letters are instructions of how certain treatments are commissioned and they are over and above NICE guidelines and need to be actioned. The report includes the relevant action that has been taken to provide assurance to the Trust.
Decision: Noted

4.4 NICE Technical Appraisals and Guidance
NICE Technical Appraisals

5 Appraisals were published in December 2017

TA492 - Atezolizumab for untreated locally advanced or metastatic urothelial cancer when cisplatin is unsuitable
Formulary status / Action
Add to the formulary - Signed formulary application from Dr Brock (Included in Section 4.1)

TA493 - Cladribine tablets for treating relapsing–remitting multiple sclerosis
Formulary status / Action
No action - Not applicable to CWH

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TA494 - Naltrexone - bupropion for managing overweight and obesity
Formulary status / Action
Nil action - Not recommended

TA495 - Palbociclib with an aromatase inhibitor for previously untreated, hormone receptor-positive, HER2-negative, locally advanced or metastatic breast cancer
Formulary status / Action
Nil action - Added to the formulary in December 2017

TA496 - Ribociclib with an aromatase inhibitor for previously untreated, hormone receptor-positive, HER2-negative, locally advanced or metastatic breast cancer
Formulary status / Action
Nil action - Added to the formulary in December 2017

1 Appraisal published in January 2018

TA497 - Golimumab for treating non-radiographic axial spondyloarthritis
Formulary status / Action
Nil - Currently included on formulary

4.5 IVIG Update

- **IVIG requests**

December 2017
CWH Site
There were 24 IVIG issues in December 2017, with 1 new requests
WMUH Site
There were 21 IVIG issues in December 2017, with 2 new requests

CWH Site
There were 19 IVIG issues in January 2018, with 7 new requests:

WMUH Site
There were 20 IVIG issues in January 2018, with 3 new requests
Decision: Approved

4.6 Items for noting

- **Medication Safety Bulletin (Controlled Drugs) - January 2018**

Medication Safety Bulletin relating to Controlled Drugs.
The publication and circulation of this bulletin closes an outstanding action relating to the NICE Guideline (NG46) Controlled Drugs: Safe Use and Management (April 2016)
Decision: Noted

- **NICE Guidance (NG46 - April 2016) - Completed action plans**

Completed action plans for both hospital sites following a gap analysis that was undertaken against NICE Guidance NG46 - April 2016
Action: To be forwarded to Clinical Governance
Decision: Noted

- **MHRA Drug Safety Update - December 2017**

MHRA update for November 2017
To go to Trust Medication Safety Group and ensure that it is disseminated to all the relevant prescribers.
Decision: Noted

- **MHRA Drug Safety Update - January 2018**

MHRA update for January 2018To go to Trust Medication Safety Group and ensure that it is disseminated to all the relevant prescribers.
Decision: Noted

4.7 Meeting minutes for noting

- **Medication Safety Bulletin (Controlled Drugs) - January 2018**

Medication Safety Bulletin relating to Controlled Drugs.
The publication and circulation of this bulletin closes an outstanding action relating to the NICE Guideline (NG46) Controlled Drugs: Safe Use and Management (April 2016)
Decision: Noted

- **NICE Guidance (NG46 - April 2016) - Completed action plans**

Completed action plans for both hospital sites following a gap analysis that was undertaken against NICE Guidance NG46 - April 2016
Action: To be forwarded to Clinical Governance
Decision: Noted

- **MHRA Drug Safety Update - December 2017**

MHRA update for November 2017
To go to Trust Medication Safety Group and ensure that it is disseminated to all the relevant prescribers.
Decision: Noted

- **MHRA Drug Safety Update - January 2018**

MHRA update for January 2018To go to Trust Medication Safety Group and ensure that it is disseminated to all the relevant prescribers.
Decision: Noted

4.8 Additional papers to go to Trust patient Safety Group
Nil

5. Any other business
Nil

6. Date of next meeting
Date: Monday 12th March 2018
Time: 8am-9am
Location: Board Room (CWH Site) and Meeting Room A (WMUH Site via video conferencing)
Closing date: 16th February 2018