



Summary of Main Points from the Meeting held on Monday 13th March 2017

2. Minutes and Summary Notes from last meeting

The Minutes and Summary notes from the February 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

Full applications

Diamorphine 720mcg/actuation and 1600mcg/actuation Intranasal Spray (Ayendi[®])

Diamorphine 720mcg/actuation and 1600mcg/actuation Intranasal Spray (Ayendi[®]) is licensed for the treatment of acute severe pain in children and adolescents 2 to15 years of age in a hospital setting. Requested by the Burns Department for intranasal use in children with burns injuries who require dressing changes. There will need to be a plan agreed regarding the documentation of priming doses from the spray device and the management of the residual volume when the optimal number of doses has been used from the spray device. DR will liaise with the relevant pharmacists.

Decision: Approved for addition to the formulary

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

Requested by the Gynaecology Team in November 2016. Duavive[®] is indicated for treatment 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.

This was reviewed at the November TMG meeting where 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 would be made regarding adding Duavive® to the formulary and making a submission to the NWLIF.

This application is now being reviewed in light of the recently published NICE Guidance (ES3) - Oestrogen deficiency symptoms in postmenopausal women: Conjugated oestrogens and Bazedoxifene acetate - Published 22/12/16.

On discussion with Dr Panay it has been agreed that based on the NICE guidance, Duavive® would be added to the Trust Formulary for the restricted prescribing in the following circumstances:

- Women with a uterus whom treatment with progestin-containing therapy is not appropriate after having persisted with a progestin-containing product for at least 3 months.
- Postmenopausal women (at least 12 months since last menses)
- Women under the age of 65
- Initiated only for symptoms that adversely affect quality of life.

In addition, patients need to be informed that due to the lack of available safety data, it is difficult to assess whether the associated drug related incidents of rare but important adverse events is increased.

According to the Gynaecology Team there are 20 patients who would be suitable for starting therapy immediately and 3-4 patients per month who would be suitable going forward.

Decision: Approved for addition to the formulary

• Trientene dihydrochloride Capsules 300 mg

Trientene dihydrochloride is licensed for the treatment of Wilson's Disease in patients intolerant to





penicillamine. Requested by the Neurology Team for prescribing within its licensed indication. There is currently only one patient who is receiving this medicine on an ongoing basis. It is likely that this medicine will become PBr excluded from April 2017 and therefore will require adding to the hospital formulary prior to any cost claims being made when this change comes into effect.

Decision: Approved for addition to the formulary

Ex-panel applications

Diamorphine 720mcg/actuation and 1600mcg/actuation Intranasal Spray (Ayendi[®])

Diamorphine 720mcg/actuation and 1600mcg/actuation Intranasal Spray (Ayendi[®]) is licensed for the treatment of acute severe pain in children and adolescents 2 to 15 years of age in a hospital setting. Request to replace diamorpine IV intranasally (Unlicensed use) in General Paediatrics and Paediatric Emergency Department at both sites with the licensed product as an analgesic in paediatric patients now that a licensed produce is available.

Decision: Approved for addition to the formulary

Fast-acting Insulin Aspart (Fiasp®) pre-filled Pen (Flextouch®) and Vial

Requested by the Diabetes Team. Fiasp[®] is new ultra-fast acting formulation of Insulin Aspart (Novorapid[®]).

It is the same price as Novorapid[®] and come in a Flextouch[®] pen which is already in use in the use in the Trust.

Active molecule is identical to that in Novorapid[®] - just has addition of vitamin B3, I-Arginine and Nicotinamide to act as formulation stabilising components which results in a more rapid acting . Dosing conversion is 1:1.

Request made for the inclusion of Flextouch® pen and vials for pump patients.

Benefits include:

- Acts within 4 mins Vs 9 mins for standard Novorapid®
- Can be injected up to 20 mins after starting a meal
- Better post-prandial glucose control
- Slightly better efficacy compared to Novorapid® (HbA1c drop -0.32 vs -0.17)
- May be better for insulin pump patients stable for 9 days at room temp Vs 7 days from Novorapid®

Proposing that this will be prescribed for a specific cohort of patient - those with high post prandial blood glucose levels on standard Novorapid[®] and those who need more flexibility with injecting after meals.

Insulin Aspart (Novorapid[®] and Novomix[®]) are currently included on the formulary.

It was noted that a request would need to be submitted to the NWLIF Panel to facilitate ongoing prescribing by GPs.

Decision: Approved for addition to the formulary

Pharmacoeconomic Board Approved

IFR - Tocilizumab IV for Adult Onset Still's Disease

Requested by Rheumatology for a patient with Adult Onset Still's Disease.

Approved by the Pharmoeconomic Board on 10/02/17.

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.





The plan spreadsheet presented was updated as of February 2017. Current status: After February meeting 29/34 (85%) sections will have been updated and harmonised across both sites. Harmonised sections of the Trust Medicines Policy are now available on the new Trust Intranet web site.

Decision: Noted

TMP Section 8: Administration of medicines

Unified policy

Decision: Approved

TMP Section 29: Additional Private Care Policy

Unified policy.

Decision: Approved

TMP Section 30: Supply of discharge medicines packs by nurses/midwives on

wards/departments

Unified policy.

Decision: Approved

• TMP Section 31: Medicines Management Training Programme

Unified policy.

Decision: Approved

TMP Section 34: Equality Impact Assessment

Unified policy.

Decision: Approved

4.3 Medicines Optimisation

• Ward Controlled Drug Registers

New Controlled Drug Registers to be piloted on the following wards:

- Paediatric HDU
- David Erskine Ward
- Emergency Department
- Ron Johnson Ward
- Surgery TBC
- WMUH TBC

This register has the advantage of having an integrated section where stock checks can be recorded and also a section where if a proportion of a vial is administered; the amount administered and wasted can be recorded.

Decision: Approved

GP Information leaflet: NSAIDs and Anticoagulants

Newly compiled information leaflet for GPs relating to NSAIDs and Anticoagulants.

Compiled for the attention of: GPs managing patients newly established on anticoagulation therapy and prescribed (by the Trauma and Orthopaedic Team) a NSAID to manage inflammatory conditions e.g. osteoarthritis rather than surgery as initial management.

Due to be presented at the Thrombosis and Thromboprophylaxis Group on 15th March.

Decision: Approved

• Patient Information leaflet: Voriconazole

Newly compiled information leaflet for patients relating to Voriconazole.

Compiled for the attention of: Patients newly started on long-term Voriconazole. To be used by pharmacists when counselling such patients. The patient can keep the PIL once counselled.

Previously approved by the Anti-microbial Stewardship Group.





Decision: Approved

Trust Medicines Group - Terms of Reference

Updated Terms of Reference for the Trust Medicines Group for 2017/18. Updates include addition of Trust Homecare Clinical Chemotherapy Service Group. Sent to the Trust Patient Safety Group for approval.

Decision: Approved

Trust Medicines Homecare Group - Terms of Reference

Updated Terms of Reference for the Trust Homecare Group. This is a new Group which is being set up in line with the Hackett Report which will report to the Trust Medicines Group.

Decision: Approved

TMP Section 1. Introduction

Updated TMP Section 1. Introduction to include the existence of the Trust Homecare Group which reports to the Trust Medicines Group.

Decision: Approved

Hospital Pharmacy Transformation Plan

A summary was provided of the Hospital Pharmacy Transformation Plan - Version: 22/02/17

Decision: Noted

4.4 NICE TA Guidance

NICE TA Guidance - February 2017

5 Appraisals were published in February 2017

TA429 - Ibrutinib for previously treated chronic lymphocytic leukaemia and untreated chronic lymphocytic leukaemia with 17p deletion or TP53 mutation

Recommendations

- 1.1 Ibrutinib alone is recommended within its marketing authorisation as an option for treating chronic lymphocytic leukaemia in adults:
 - who have had at least 1 prior therapy or
 - who have a 17p deletion or TP53 mutation, and in whom chemo-immunotherapy is unsuitable and
 - only when the company provides ibrutinib with the discount agreed in the patient access scheme.

Action: Add to the formulary following receipt of a compiled and signed application form from the relevant supporting medical team (Haematology Team).

TA430 - Sofosbuvir-velpatasvir for treating chronic hepatitis C

Recommendations

1.1 Sofosbuvir–velpatasvir is recommended as an option for treating chronic hepatitis C in adults, as specified in table 1, only if the company provides the drug with the discount agreed in the simple discount agreement.

Table 1 Sofosbuvir-velpatasvir for treating chronic hepatitis C in adults

	•	· ·	
HCV	Liver disease stage	Treatment	Recommendation according to treatment





genotype			history	
			Untreated	Treated
1	With or without compensated cirrhosis	Sofosbuvir– velpatasvir	Recommended	
2	Without cirrhosis	Sofosbuvir– velpatasvir	Recommended only for people who cannot tolerate interferon or it is not suitable for them	Recommended
	Compensated cirrhosis	Sofosbuvir– velpatasvir	Recommended	
3	Without cirrhosis	Sofosbuvir– velpatasvir	Recommended	
	Compensated cirrhosis	Sofosbuvir– velpatasvir (with or without ribavirin)	Recommended	
4	With or without compensated cirrhosis	Sofosbuvir– velpatasvir	Recommended	
5 With or without compensated cirrhosis		Sofosbuvir– velpatasvir	Recommended	
6	With or without compensated cirrhosis	Sofosbuvir– velpatasvir	Recommended	
1–6	Decompensated cirrhosis	Sofosbuvir– velpatasvir (with ribavirin)	Recommended	

Abbreviation: HCV, hepatitis C virus.

Treated - the person's hepatitis C has not adequately responded to interferon-based treatment.

- 1.2 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.
- 1.3 This guidance is not intended to affect the position of patients whose treatment with sofosbuvir—





velpatasvir 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 to the formulary following receipt of a compiled and signed application form from the relevant supporting medical team (Hepatology Team).

TA431 - Mepolizumab for treating severe refractory eosinophilic asthma

Recommendations

- 1.1 Mepolizumab, as an add-on to optimised standard therapy, is recommended as an option for treating severe refractory eosinophilic asthma in adults, only if:
 - the blood eosinophil count is 300 cells/microlitre or more in the previous 12 months and
 - the person has agreed to and followed the optimised standard treatment plan and
 - has had 4 or more asthma exacerbations needing systemic corticosteroids in the previous 12 months or
 - has had continuous oral corticosteroids of at least the equivalent of prednisolone 5 mg per day over the previous 6 months and
 - the company provides the drug with the discount agreed in the patient access scheme.

1.2 At 12 months of treatment:

- stop mepolizumab if the asthma has not responded adequately or
- continue treatment if the asthma has responded adequately and assess response each year.

An adequate response is defined as:

- at least 50% fewer asthma exacerbations needing systemic corticosteroids in those people with 4 or more exacerbations in the previous 12 months or
- a clinically significant reduction in continuous oral corticosteroid use while maintaining or improving asthma control.
- 1.3 This guidance is not intended to affect the position of patients whose treatment with mepolizumab 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 applicable to C&W

TA432 - Everolimus for advanced renal cell carcinoma after previous treatment

Recommendations

1. Everolimus is recommended within its marketing authorisation as an option for treating advanced renal cell carcinoma that has progressed during or after treatment with vascular endothelial growth factor targeted therapy, only if the company provides it with the discount agreed in the patient access scheme.

Action: Already included on formulary - Update formulary as appropriate

TA433 - Apremilast for treating active psoriatic arthritis





Recommendations

- 1.1 Apremilast, alone or in combination with disease-modifying antirheumatic drugs (DMARDs), is recommended as an option for treating active psoriatic arthritis in adults only if:
 - they have peripheral arthritis with 3 or more tender joints and 3 or more swollen joints and
 - their disease has not responded to adequate trials of at least 2 standard DMARDs, given either alone
 or in combination and
 - the company provides apremilast with the discount agreed in the patient access scheme.
- 1.2 Stop apremilast at 16 weeks if the psoriatic arthritis has not shown an adequate response using the Psoriatic Arthritis response Criteria (PsARC), defined as an improvement in at least 2 of the 4 PsARC criteria (including joint tenderness or swelling score) with no worsening in any criteria. If the disease has a Psoriasis Area and Severity Index (PASI) 75 response, a dermatologist should decide whether to continue treatment with apremilast after 16 weeks based on skin response.
- 1.3 When using the PsARC healthcare professionals should take into account any physical, sensory or learning disabilities, or communication difficulties that could affect a person's responses to components of the PsARC and make any adjustments they consider appropriate.
- 1.4 This guidance is not intended to affect the position of patients whose treatment with apremilast 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: Already included on formulary - Update formulary as appropriate

4.5 IVIG Update

IVIG requests
February 2017
CWH Site

There were 13 IVIG issues, with 4 new requests:

- One for Kawasaki's disease (Red indication)
- One for ITP (Red indication)
- One for Multifocal motor neuropathy (Blue indication)
- One for Guillain Barre Syndrome (Red indication)

WMUH Site

There were 11 IVIG issues in February 2017, with 2 new requests:

- One for acute encephalopathy (Grey indication)
- One for ITP (Red indication)

Decision: Approved

4.6 Items for noting

MHRA Update for February 2017

Decision: Noted

4.7 Meeting minutes for noting

Antimicrobial Steering Group Meeting minutes - February 2017

Minutes from meeting held in February 2017.

Decision: Noted

• Local Chemotherapy Group - February 2017

Minutes from meeting held in February 2017



Decision: Noted

4.8 Additional papers to go to Trust patient Safety Group

• Trust Medicines Group - Terms of Reference

5. Any other business

Trust Controlled Drug Accountable Officer

Deirdre Linnard was asked by the Medical Director to take on the role of Trust Controlled Drug Accountable Officer. She is now on the CQC register and will assume this role with immediate effect. There will be a Trust wide communication to staff so they are aware of the role.

6. Date of next meeting

Next meeting

Date: Monday 10th April 2017

Time: 8am-9am

Location: Board Room (CWH Site) and Meeting Room A (WMUH Site via video conferencing)

Closing date: 17th March 2017