Chelsea and Westminster Hospital NHS Foundation Trust Trust Medicines Committee

Summary of Main Points from the Meeting held on the 11th February 2013

2. Minutes and Summary Notes from last meeting

The Minutes and Summary notes from the December meeting were approved and will be circulated.

3. Matters Arising

The Committee noted the matters arising from the previous meeting.

4. NICE Guidance and IHW Initiative

NICE Guidance on developing and updating local formularies

NICE has recently published good practice recommendations for the systems and processes needed to ensure NHS organisations develop and update local formularies efficiently and in accordance with statutory requirements. Compliance will be a requirement of the NHS commissioning contract for next year. A gap analysis has been undertaken to identify any areas where processes do not currently meet the recommended standards as detailed within the publication.

The main areas where the recommended standards are not currently being met and where further work is required to be undertaken include:

- Declaration of interest by panel members
- Use of National Prescribing Centre Local decision making competency framework to ensure membership has the appropriate range of skills needed to undertaken all necessary activities.
- Inclusion of Horizon Scanning as a standing agenda item.
- Application of standard criteria for decision making.
- Implementation of an appeals process.

An action plan has been compiled and these actions will be undertaken to ensure processes meet the recommended standards. The action plan will be tabled at future meetings to update committee members on progress.

Compliance of local formulary with NICE Technology appraisals

It is a requirement of the *Innovation Health and Wealth: Accelerating Adoption and Diffusion in the NHS* (IHW) report which was published Dec 2011, that local formularies are compliant with all published NICE technology appraisals. An audit has been conducted to identify any drugs that have been NICE approved, are relevant to C&W but are not yet included on the local formulary.

The audit concluded the following:

- There are three drugs that are NICE approved, relevant to C&W but have not yet been added to the formulary. These Included: Pazopanib, Bendamustine and Febouxostat.
- The average time to implement NICE technology appraisals (excluding the above 3 drugs) does not exceed 90 days as recommended by the report.

It is a requirement that the Trust publishes the results of this audit. This data can be incorporated into the published local formulary. DL explained that it is a requirement that the local formulary is published by 1st April 2013 however funding for NeLM is likely to be terminated around this time. Further work will be undertaken to identify the most appropriate means of publication in light of these funding changes.

Applications for drugs which have been approved for use by NICE for retrospective inclusion on the formulary

The following three drugs were identified as being NICE approved, relevant to C&W but are not currently included on the local formulary. Approval was requested for these to be added retrospectively.

Additions:

Pazopanib 400mg/800mg tablets (Votrient®)

Decision: Approved. Tariff excluded Medicine.

Pazopanib is indicated as a first line treatment option for adults with advanced renal cell carcinoma who have received prior cytokine therapy in accordance with NICE Guidance TA215.

Bendamustine 25mg/100mg vials (Levact[®])

Decision: Approved. Tariff excluded Medicine.

Bendamustine is indicated as an option for the first-line treatment of chronic lymphocytic leukaemia (Binet Stage B or C) in patients for whom fludarabine combination chemotherapy is not appropriate in accordance with NICE guidance TA216.

Febuxostat 80mg/120mg tablets (Adenuric®)

Decision: Approved. Tariff included Medicine. Included on NWLIF

Febuxostat is indicated as an option for the management of chronic hyperuricaemia in gout only for patient who are intolerant of allopurinol or for whom allopurinol is contraindicated in accordance with NICE Guidance TA164.

Formulary status was approved for the above three drugs.

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5. Formulary Applications

Ex-Panel Additions

Glucose 20% 100ml vials

Currently only 500ml infusion bags included on the formulary. 100ml vials added for practical reasons.

Promethazine 10mg tablets

Promazine 25mg/5ml liquid

Used by Max Glatt Ward for patients with benzodiazepine addition.

Colecalciferol (Desunun®) 800unit tablet

To replace Fultium D3[®]. Unlike Fultium D3[®], Desunun[®] does not contain peanut oil, Soya and is suitable for vegans and vegetarians.

Removals

Colecalciferol (Fultium D3®) 800unit capsule

See above.

Tredaptive® (Nicotinic acid 1g/Latropiprant 20mg) tablet

To be removed from the formulary as the product license has been suspended by the MHRA as evidence indicates that benefits no longer outweigh the risks.

NWL Integrated Formulary (NWLIF) New Drugs Panel – feedback

Meeting held on 31st January.

Kelo-Cote[®] - C&W application. Status: Outside the scope of NWLIF

The panel did not consider this application as Kelo-Cote[®] is classified as a medical device and outside the scope of NWLIF. It is prescribable on FP10s and GPs could be requested to supply by a hospital doctors.

Qlaira[®] - C&W application. Status: Not approved

The panel did not approve a request from C&W to add the combined oral contraceptive - estradiol valerate & dienogest (Qlaira®) to the NWLIF. The requested indication was: 'Oral contraception, heavy menstrual bleeding'. Later in the C&W application form the following indication was mentioned – however the panel considered there wasn't specific data to support this indication.

Young women with premature ovarian failure still need adequate estrogen replacement and contraception due to the chance of a spontaneous ovulation. Normalisation or treatment with their peer group rather than using HRT is essential for psychological wellbeing and compliance. Bio / body identical estrogen is the recommend estrogen for POF rather than EE to ensure effective bone and heart health.

In view of the cost differential, the NWLIF panel view was that while the paper by *Ahrendt*⁽¹⁾ was helpful in suggesting a benefit for Qlaira® in terms of reduced bleeding, it was not enough of a benefit to justify the significant increase in cost – it is more than 10x cost of Microgynon 30 (£25:18 vs £2.82 for a 3 cycle pack ex VAT). It was also pointed out that the comparator in this study was a 20 mcg estrogen pill. A Cochrane⁽²⁾ review of quadriphasic pills stated that 20mcg pills are more likely to cause bleeding disturbances than pills containing 30mg of estrogen and concluded that:

The available evidence is insufficient to determine whether quadriphasic differ from monophasic oral contraceptives in contraceptive effectiveness, bleeding pattern, minor side effects and acceptability. Studies that compare quadriphasic and monophasic oral contraceptives with an identical progestogen and estrogen type are needed to determine whether the quadriphasic approach differs from the monophasic approach. Studies that compare quadriphasic pills with monophasic pills containing 30 µg ethinylestradiol are indicated to determine whether quadriphasic oral contraceptives have an advantage over the current, first choice oral contraceptive. Until then, we recommend monophasic pills containing 30 µg estrogen as the first choice for women starting oral contraceptive use.

And

At first prescription, monophasic pills containing 30 µg estrogen are preferred over monophasic pills containing 20 µg since the latter cause more bleeding disturbances and discontinuation (Gallo 2011). Women experiencing heavy menstrual bleeding may benefit from quadriphasic oral contraceptives but continuous use of a monophasic oral contraceptive to avoid menstrual bleeding may also be an alternative.

The applicant (Mr Panay) has been advised of the NWLIF panel decision. Qlaira[®] will be removed from the C&W Formulary and the options available to Mr Panay are to resubmit the application with more evidence for use in women with premature ovarian failure (unlicensed indication) and to continue to supply from hospital for those women in whom it is indicated.

References (1) and (2) available from the Committee Secretary on request

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6. Medicines Management and Medicines Policy

• IV Administration Guide - Oxytocin

Updated to include that this drug should be administered via a large peripheral vein/central line for high concentrations. Approved.

IV Administration Guide - Infliximab

Updated to include Rainsford Mowlem Ward as a ward where administration can take place as this ward is now admitting gastroenterology patients. All nursing staff have been trained accordingly to administer infliximab. Approved.

Venofer[®] prescription

Updated recently by Imperial College Hospital NHS Trust. Proposal for this to be used by the Renal Specialist Nurse on her visit weekly to MDU. This was not approved with a view to revisiting the introduction of electronic prescribing on MDU. Not approved.

PGD Tracker January 2013

Updated as of January 2013. Approval granted for No: 3010 (Adjustment of non-insulin diabetes therapies / doses of insulin therapies) to be extended by a further 3 months. This PGD is in its updated version being circulated for comments. Approved.

Trust Register of non-medical prescribers January 2013

Updated as of January 2013. The format has been updated. To request registration numbers and date added to register from individuals. Updated register to be circulated in May/June. Approved.

7. NICE Guidance

Nice Guidance November 2012

• TA268 - Ipilimumab for melanoma

Ipilimumab is recommended as an option for treating advanced (unresectable or metastatic) melanoma in people who have received prior therapy, only if the manufacturer provides ipilimumab with the discount agreed in the patient access scheme.

TA269 – Vemurafenib for melanoma

Vemurafenib is recommended as an option for treating BRAF V600 mutation-positive unresectable or metastatic melanoma only if the manufacturer provides vemurafenib with the discount agreed in the patient access scheme.

TA270 – Decitabine for Acute Myeloid Leukaemia

NICE is unable to make a recommendation about the use in the NHS of decitabine for acute myeloid leukaemia because no evidence submission was received from the manufacturer of the technology

The Committee noted the above NICE guidance. Formulary status for Ipilimumab and Vemurafenib was approved.

8. IVIG Update

The Panel noted the IVIG report.

There were 9 IVIG issues in December 2012, with 3 new requests:

- One was for idiopathic thrombocytopenic purpura adult (red indication)
- One was for Kawasaki disease (red indication)
- One was for paraneoplastic syndrome (grey indication) approved locally, awaiting NWL individual funding outcome

There were 10 IVIG issues in January 2013, with 4 new requests:

- o One was for Guillian-Barre syndrome (red indication)
- o One was for chronic inflammatory demyelinating polyradiculoneuropathy (red indication)
- o One was for adult HIV-associated thrombocytopenia (blue indication)

One was for acquired red cell aplasia due to parvovirus B19 (blue indication)

9. Items for Noting

2012-2013 Medicines Related CQUINs Performance Report: NWL Integrated Formulary Adherence Quarter 3 results

Noted. The overall compliance rate for Q3 was 99.5%.

Medicines Reconciliation Audit December 2012

Noted. The % of patients with medicines reconciled within 24 hours is 61% (Target: 65%). This is being taken forward within clinical pharmacy teams and a reaudit is scheduled.

Safe Storage of Medicines Audit October 2012

Noted. KR requested a re-audit of all areas where areas of significant non-compliance was identified.

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• Controlled Drug Quarterly Report 2012/13 Q2

Noted. It was noted that there are a number of incidents relating to the lack of pain control post operatively in Surgery (RM & D Evans wards). A proposal was made for a check of the post operative pain control practices relating to the incidents detailed in the report and any other incidents reported since Q2 to be undertaken. Dr Mike Weston to request a review involving a Surgical Consultant, Nurse and lead Directorate Pharmacist

Controlled Drug Occurrence Report 2012/13 Q3

Noted. There were 6 incidents relating to controlled drugs reported.

10. Papers to go to the Trust Quality Committee

The following papers should be sent to the Trust Quality Committee:

- Medicines Committee December 2012 Summary Notes
- CD Quarterly Report 2012/13 Q2
- CD Quarterly Occurrence Report 2012/13 Q3
- NICE Guidance Gap analysis
- NICE TAG Formulary adherence audit results

12. Date of the next meeting

Monday 11th March 2013 8.00 – 9.00 Board Room, Lower Ground Floor

Closing date for papers: Friday 15th February 2013