NewTherapiesSubgroup

Minutes

19th May 2015, 12:30 - 2:30 pm
Pharmacy Dept. CMFT

GMMMG Greater Manchester Medicines Management Group

NHS

Present:

Elizabeth Adcock (formerly Craig) (EA) Medicines Information Pharmacist, PAHT
Elizabeth Arkell (EA), Associate Director of Pharmacy, UHSM Foundation Trust
Jennifer Bartlett (JB) Senior Medicines Management Pharmacist – South Manchester CCG
Dr Peter Budden (PB) GP and Prescribing lead, Salford CCG (*Chair*)
Makrand Goré (MG) Medicines Management Pharmacist, Bolton CCG
Jane Law (JL) Deputy Director of Pharmacy and Medicines Governance, CMFT
Andrew Martin (AM) Strategic Medicines Optimisation Pharmacist, GM CSU.
Bhavana Reddy (BR) Head of Prescribing Support, RDTC *(Professional Secretary)*
Dr Hina Siddiqi (HS) General Practitioner, Trafford CCG
Zoe Trumper (ZT) Medicines Management Pharmacist, Wigan Borough CCG
Dr Richard Warren (RW) NIHR Senior Clinical Lecturer and Consultant Dermatologist, Salford Royal Foundation Trust.

In attendance:
Julie Mullings (JM) Clinical Lead Tissue Viability, Acute & Community Integrated Services, UHSM
Dr Naveed Younis (NY) Consultant Physician & Endocrinologist, UHSM.

Apologies received: KP, HSo

Declarations of Interest
No declarations of interest relating to the agenda were made.

1) Minutes of the meeting on April 2015.

The minutes were accepted as a true and accurate record following a minor update.

ACTION: To be sent to GMMMG then to be published on website.

2a) Matters Arising:

The group were updated on the matters arising document. It was noted that feedback from specialists regarding the new drug for Parkinson's disease – safinamide was still awaited. It was agreed that the items on hold (i.e. AMD service review) could be removed as these were outside the remit of NTS and could not be progressed any further at this present time.

2b) Matters arising – PICO® dressings

JM gave the group a brief overview of the PICO® dressing. The PICO® dressing would be suitable for patients who would benefit from a Negative Pressure Wound Therapy (NPWT) system with low levels of exudate. This may be in patients with difficult to manage wounds or in those with diabetic ulcers or post caesarean section in patients with a high BMI who are more prone to infections. Advantages of the PICO® dressing are: increased perfusion and granulation, better healing rates and decreased nursing and healing time. Despite the limited evidence base, when used correctly for the right patients PICO® dressings are cost effective and allow a quicker discharge from hospital back into the community so may decrease the number of bed days required however they can also be used inappropriately first line in patients that don't require them as they are quick and easy. The dressing pack costs around £125 - £142 (depending on the size of dressing required) for two dressings and 1 canister pump. This would be a 14 day supply.

The group agreed that it would seem sensible to define criteria for use within the recommendation. It was agreed that PICO® dressings should only be initiated by physicians with a special interest in wound therapy or by tissue viability nurses. Patients must have a full wound assessment documented prior to initiation. The underlying cause of the wound and any complications must be established to enable assessment of the appropriate application. Negative pressure wound therapy is contraindicated in certain wound types. The position of the wound may also prevent NPWT being applied effectively. Once initiated and the patient has been discharged into the community then all patients should be reviewed by the tissue viability community teams after 2 weeks to ensure ongoing need of PICO® dressings before they are continued. A long term treatment plan should be outlined at this stage and training on the use of PICO® dressings for district nurses should be arranged if required.

The group assessed PICO® dressings against the approved devices criteria and agreed the following category: '*Case for adoption is partially supported and technology has potential to provide significant healthcare system benefits - Recommendation for use in specific circumstances'*

The New Therapies Subgroup of the GMMMG considered the use of PICO® dressings for the treatment of wounds that would benefit from a negative pressure wound therapy system.

The group recommends the use of PICO® dressings in those patients with more difficult to manage wounds or in those at an increased risk of infection and would benefit from a negative pressure wound therapy system.

Whilst the published data for PICO® dressing is limited the data that is available shows benefits of increased perfusion and granulation, better healing rates, decreased nursing and healing time. When used in appropriate patients PICO® dressings are likely to be cost effective. The group therefore recommends that PICO® dressings should only be initiated by physicians with a special interest in wound therapy or by tissue viability nurses. Patients must have a full wound assessment documented. The underlying cause of the wound and any complications must be established to enable assessment of the appropriate application. Once initiated and the patient has been discharged back into the community then **all** patients must be reviewed by community tissue viability teams at **two weeks**, to ensure on-going need of PICO® dressings.

A long term treatment plan should be outlined at this stage. Any ongoing prescribing of PICO® dressings in primary care must be overseen by the tissue viability nurses.

New Therapies Subgroup Device classification: Case for adoption is partially supported i.e. recommended for use in particular circumstances.

According to set criteria PICO® dressings were found to be a medium priority for funding in the patient group specified

ACTION: BR to draft recommendation as above

2b) Draft recommendation: apremilast

The group discussed the draft recommendation. A minor change was proposed; it was agreed that a line should be included regarding use of apremilast in those patients who may be at risk of side effects from biologics. No further comments were made and the group approved the recommendation as final.

ACTION BR to take to GMMMG for sign off.

2c) Draft recommendation: secukinumab

The group discussed the draft recommendation and following a minor wording change, approved it as final.

The group agreed that the previous algorithm around biologic use in psoriasis should be updated following publication of the NICE TA's for apremilast and secukinumab to prevent duplication of workload.

ACTION: BR to take to GMMMG for sign off.

2d) Draft recommendation: Simbrinza® combination eye drops

The group discussed and approved the draft recommendation as final.

ACTION: BR to take to GMMMG for sign off.

2e) GLP1 RA formulary status

The group welcomed NY who had attended to aid discussions in this area. Currently liraglutide (NICE TA 203) and exenatide bd are the formulary first choices with lixisenatide and exenatide once weekly (NICE TA248) as alternative choices. It was agreed that as the cheapest option lixisenatide should move to a first choice option alongside liraglutide. It is generally accepted that liraglutide appears to offer the best advantage in terms of HbA1c and weight reduction. The 1.8mg liraglutide dose however is not recommended as per the NICE TA. The once weekly agents may cause less GI adverse effects compared with the daily preparations. The group then discussed the option of including dulaglutide as another weekly preparation. The advantages over exenatide once weekly are that it was found to be non-inferior to liraglutide however exenatide once weekly did not meet its primary end point of non-inferiority to liraglutide in the DURATION-6 trial. In addition dulaglutide's simple injection device incorporates mechanisms which may help to minimise sharps injuries in alignment with recent Health and Safety Regulations. At £90.95 for 28 days, however it is the most expensive of the weekly preparations. A price for albiglutide is not currently available however albiglutide did not demonstrate non-inferiority against liraglutide. It was agreed that a price for albiglutide is required before a definite decision can be made but the group agreed provisionally to include dulaglutide and exenatide MR as alternative weekly preparations for those patients in whom GI side effects were a problem.

ACTION: BR to add to agenda once price for albiglutide is issued

2f) Xultophy® (insulin degludec/liraglutide) re-review

The group noted Xultophy® was now launched so a price was now available. The group had indicated on their recommendation that they would re-review the position of Xultophy® on launch. The group had also received a letter from the company – Novo Nordisk as well as an accompanying business case. The group noted the following points:

- The combination of insulin with GLP-1 analogues has only recently been licensed and is not specifically covered by NICE guidelines, although these do not exclude addition of insulin to baseline therapy including a GLP-1 analogue. NPH is the first line choice for most patients requiring insulin.

- Xultophy® is less costly than use of degludec and liraglutide separately and reduces injection frequency. However, the fixed dose ratio makes dosing less flexible than use of single preparations, and other insulin/GLP-1 pairings are considerably less expensive.

- The highest licensed dose contains liraglutide 1.8 mg which is not currently recommended by NICE.

- Xultophy may be useful as an alternative to intensification of insulin therapy, or where triple therapy including a GLP-1 analogue has ceased to be effective and the patient has been identified as being suitable for insulin degludec. However, there is no high quality evidence comparing it to current UK practice in these populations. In addition insulin degludec is not often used in type 2 diabetics.

- Xultophy is unlikely to be cost effective in patients not already on optimised insulin therapy. Regular treatment review, such as that recommended by NICE for liraglutide monotherapy, is advised.

- There are no long term safety data available for any combination of basal insulin with a GLP-1 analogue.

The group agreed that they would re-consider this at the next meeting, once further detail around local pathways from Specialists had been received.

3) Edoxaban for AF Review

The group reviewed the clinical data for edoxaban (Lixiana®▼) for the treatment of AF. Edoxaban is a new oral anticoagulant which directly inhibits factor Xa. It received a positive opinion from the European Medicines Agency in April 2015 for the prevention of stroke in patients with atrial fibrillation (AF). Edoxaban is administered in a fixed dose of 60mg once daily, with dose reductions in patients with moderate to severe renal impairment. It does not require routine coagulation monitoring or regular dose adjustments. Edoxaban is licensed in Japan and the US for both stroke prevention and the treatment of thrombosis. The US license carries a black box warning, which states that the product should not be used in people with good renal function (CrCl >95ml/min). The group noted the following points from the clinical trial:

- Edoxaban in AF has been evaluated in a single double-blind, double-dummy, non-inferiority trial (ENGAGE AF-TIMI 48)
- A total of 21,105 patients with AF and a $CHADS_2$ score of ≥2 were randomised to either warfarin, high dose regimen edoxaban (60mg with a dose reduction to 30mg in some circumstances in line with the UK licence), or low dose regimen edoxaban (30mg or 15mg).
- Patients in the warfarin arm had a target INR of 2.0-3.0.
- Patients with AF due to reversible causes, an estimated CrCl <30ml/min, or a high risk of bleeding were excluded.
- The edoxaban dose was halved in patients of any group if they had a body weight of ≤60kg or a CrCl of 30-50 mL/min, or if they were taking verapamil, quinidine, or dronedarone concurrently.
- The primary efficacy endpoint was time to first stroke (both ischaemic or haemorrhagic) or systemic embolic embolism (SEE) in the modified intention to treat population.
- In patients with normal renal function (CrCl ≥80ml/min), annualized primary outcome event rate was 1.07% for high dose edoxaban and 0.76% for warfarin in (HR 1.14 [95% CI 0.97-2.05])
- Those with impaired renal function did significantly better with edoxaban, with event rates of 1.04, and 2.01 for high dose edoxaban and warfarin respectively (HR 0.51 for high dose [95% CI 0.38-0.69]). Though the results for normal renal function are statistically insignificant, they suggest a trend towards worse outcomes in patients with good renal function.
- There are currently no trials directly comparing edoxaban with any other novel oral anticoagulant agents.

The group felt that other available NOACs have a less complex relationship with renal function, as well as greater clinical experience, and these will remain the preferred option alongside warfarin until more is known about edoxaban in practice.

The New Therapies Subgroup of the GMMMG considered the use of edoxaban for the prevention of stroke in patients with atrial fibrillation (AF).

The group does not recommend the use of edoxaban over existing more established therapies.

In the main clinical trial, the licensed edoxaban regimen was non-inferior to warfarin, although there was a trend towards less favourable outcomes in patients with normal renal function. Bleeding rates appear to be lower than for warfarin; however as with other Novel Oral Anticoagulant Drugs (NOACs) there is no readily available antidote. There are currently no trials directly comparing edoxaban with any other NOACs however other NOACs have a less complex relationship with renal function as well as greater clinical experience and these remain the preferred option alongside

warfarin.

Edoxaban is priced at £58.80 for 28 tablets which is the same list price as rivaroxaban but cheaper than dabigatran and apixaban. All NOACs are more expensive than warfarin.

According to set criteria edoxaban was found to be a low priority for funding

ACTION: BR to draft recommendation as above

4) Jaydess® levonorgestrel intrauterine system.

The group discussed the above product and noted that a request to review this for addition to the formulary had already been discussed by the formulary subgroup. The FSG had agreed not to add it to the formulary as the potential benefit of it being easy to insert was now negated by the launch of the new Mirena® preparation. It was felt that it may be of benefit in those women who wanted a shorter duration of treatment of 2-3 years. The group felt that an additional recommendation from NTS was not required on this product as this had been dealt with by FSG.

5) Current work plans & new submissions received since April & Horizon Scanning

The group discussed the current work plan and agreed that the biosimilar insulins could be considered once they had both been licensed. This was likely to be end of August so could be looked at in the September meeting. The group also agreed to look at the new antidepressant vortioxetine at the July meeting. A new product for acne rosacea – topical Ivermectin was raised as a potential topic for review. It was noted that this may not be launched till later in the year so could be added to the agenda a later meeting depending on its UK launch date.

Post meeting note: a request has been received to review Qufora an anal irrigation system at the July meeting. However it was also noted that it would be useful to review all anal irrigation systems at the same time as no advice currently exists. This would therefore be added to the agenda in September.

6) Updates from other groups.

Formulary Subgroup

The group was updated on the last formulary subgroup meeting. It was noted that the DNP/Grey lists may merge so that it is easier for users. FSG also reviewed Chapters 9 and 13.

GMMMG

The group noted that the next GMMMG meeting is on Thursday. Agenda items that were due to be discussed were highlighted to the group.

Interface Subgroup

The group was updated on the interface subgroup meeting and noted that the full RAG list review was now complete and that the group was concentrating on shared care guidelines.

7) AOB

Frequency of meetings:

The group discussed the need for monthly meetings. It was noted that the group was now on top of their work plan and the reduced numbers of new drugs coming through meant that the group could now move to bi-monthly meetings which was what had been intended when the group was initially set up in 2007. It was agreed however that this should be reviewed in November as changes to specialised commissioning may increase the numbers of reviews needed.

It was noted that it was Jane Law's last meeting prior to retirement. The group officially thanked her for her hard work and input into the group since its inception and wished her well for the future.

ACTION: BR to send out updated meeting dates.

8) *Date of Next Meeting: 21st July 2015, 12.30-2.30pm, CMFT*