NewTherapiesSubgroup

Minutes

March 15th 2016, 12:30 - 2:30 pm
Pharmacy Dept. CMFT

Present:

Elizabeth Arkell (EAr) Medicines Management Lead, UHSM
Elizabeth Adcock (EA) Medicines Information Pharmacist, PAHT
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
Rachael Fallon (RF) Deputy Director of Pharmacy and Medicines Governance, CMFT
Dr Peter Selby (PS) Consultant Physician and Honorary Clinical Professor of Metabolic Bone Disease, CMFT.
Zoe Trumper (ZT) Medicines Management Pharmacist, Wigan Borough CCG

Support:
Andrew Martin (AM) Strategic Medicines Optimisation Pharmacist, GM CSU.
Bhavana Reddy (BR) Head of Prescribing Support, RDTC *(Professional Secretary)*

Apologies received: HS.

The group welcomed Dr Selby to the group.

Declarations of Interest:
A declaration was made regarding the vitamin D agenda item however the declaration was regarding payment received for lecture fees two years ago so is now out of date.

1) Minutes of the meeting on January 2015.

The minutes were accepted as a true and accurate record.

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

2 Matters Arising:

The group were updated on the matters arising document. Safinamide still hadn't been launched. The group noted that exenatide once weekly had been removed from the formulary as the NICE TA was no longer valid. The group were happy with this decision.

It was noted that NHS England was the responsible commissioner for Airsonett® so this recommendation had been archived.

2a) Review Dates on recommendations and NTS recommendation template:

BR proposed some changes to the current format of the NTS recommendation template. It was noted that the current format had been developed in 2007 and it was now due for review. The group agreed that the updated format was clearer and approved this new format. The issue of review dates was raised as it was noted that adding review dates to documents was increasing the workload of the group as it was expected that the group would review the document as soon as it hit the review date whether there was new data available or not. Whilst this increased workload for the subgroup, it did not always result in a change to the recommendation. The group agreed therefore that rather than proactively reviewing every recommendation after two years a statement would be included at the end to say:

'*This recommendation is valid unless it is has been superseded by a NICE TA or national guidance. The recommendation will only be reviewed when there is substantial new data that may change the*

initial recommendation. For recommendations that are >24 months old please note that there may be new data available and this should be checked prior to prescribing'. The group also agreed that healthcare professionals could write to the group asking them to prioritise particular recommendations for review where they know that new data is available. This could be done by contacting the professional secretary as currently. Whilst Industry could highlight new data to the secretary they would not be permitted to put in a request for re-review; this was to ensure that all requests received are due to a real clinical need.

ACTION: BR to use new format for all new recommendations and to update old recommendations over a period of time as and when they expire. Website to be updated to remove expiry dates altogether.

2b) PCSK-9 Inhibitors Draft recommendation and NICE update

The group noted that NICE had now issued another ACD for evolocumab and the first ACD for alirocumab. The ACD for evolocumab has been updated and now recommends use within its licensed indication. It was noted that the ACD for alirocumab wasn't approved however. The group discussed the NTS recommendation and whether it was still required in light of the NICE guidance being imminent. The group agreed that if the patient group it covered (those suitable for apheresis) weren't included in the NICE TA then this recommendation should be issued however if this was covered then a recommendation may not be necessary. It was felt that issuing a recommendation now may lead to confusion once the TA is published. It was however agreed that a pathway or protocol for use of these new drugs should be looked at so that appropriate patients can be targeted.

2c) Guanfacine for the treatment of ADHD in children and adolescents,

The group discussed the feedback they had received from mental health regarding the above recommendation and made some slight changes to the recommendation based on this. The group then approved the final recommendation.

Post meeting note: comments had been received by various healthcare professionals regarding guanfacine following sign off. It was noted that these seem to have been prompted by the manufacturer who have been active with regards promoting guanfacine across GM. These comments were noted and feedback was sent to commentators that if they were aware of further published comparative efficacy data and longer term safety data that the group hadn't reviewed to back up the claims being made then the group would be happy to review the recommendation.

ACTION: BR to take to GMMMG for sign off.

2d) e-Voke® draft recommendation

The group approved the above recommendation. It was noted that this was due to go to GMMMG for final approval on Thursday.

ACTION: await GMMMG sign off then publish on website

2e) Dymista® draft recommendation

The group approved the updated Dymista® recommendation and noted it was due for GMMMG approval on Thursday. The group were also pleased to note that the NW allergy group were drafting an allergic rhinitis guideline that could be used alongside this recommendation.

ACTION: await GMMMG sign off then publish on website

2f) Ulipristal intermittent use draft recommendation

The group reviewed the recommendation and were happy with the content however they felt that further clarification was needed with regards the patient pathway and where mirena coil etc. would fit into potential treatment options. This wasn't currently clear. It was greed that specialists should be contacted to discuss this further. The group agreed that this recommendation should be put on hold in the meantime.

ACTION: BR to contact specialists regarding a patient pathway.

3) Idarucizumab (for the reversal of dabigatran)

Idarucizumab is a monoclonal antibody fragment which is indicated for the reversal of dabigatran anticoagulation in patients with uncontrolled bleeding or requiring emergency surgery. Interim data from phase III case series suggest that Idarucizumab completely reversed the anticoagulant effects of dabigatran and was associated with normalised clotting times in most patients however safety data are limited. Idarucizumab is expensive however there are no other licensed options for reversal of dabigatran or treatment of associated bleeding. The group agreed that Idarucizumab should be available for all patients treated with dabigatran who have uncontrolled bleeding or require emergency surgery. It was noted that Idarucizumab is an in-tariff drug. According to set criteria Idarucizumab was deemed to be a high priority for funding.

ACTION: BR to draft recommendation in new format and take to GMMMG for sign off.

4) Etanercept Biosimilar (Benepali®)

In February 2016, a biosimilar formulation of etanercept was launched in the UK under the brand name of Benepali®. Benepali is only licensed to be given as a 50 mg once-weekly dose, and therefore is not licensed for the paediatric indications of Enbrel (paediatric plaque psoriasis, juvenile idiopathic arthritis). The group reviewed the clinical evidence for Benepali® as below:

- In extensive product characterisation exercises all major physicochemical characteristics and biological activities of Benepali® were shown to be comparable to those of the reference product Enbrel®.
- In a Phase III, randomised, double-blind, study in 596 subjects with moderate to severe RA despite methotrexate therapy, the efficacy of Benepali was shown to be comparable to that of Enbrel in the primary outcome of ACR20 response at week 24. As the 95% CIs for the difference in ACR20 were contained within the predefined equivalence margin of ±15% the results are sufficient to demonstrate equivalent efficacy.
- The secondary efficacy outcomes at week 24 support the primary findings, and response rates were sustained to a similar degree in both treatment groups up to week 52.
- Overall, the type and incidence of treatment-emergent adverse events (TEAEs) observed in the pivotal study were similar between the two treatment groups and were in line with the well-characterised safety profile of Enbrel as outlined in the SPC. The majority of TEAEs were of mild to moderate severity, and no significant new safety signals, were reported.
- Although the clinical studies were only performed in patients with RA, efficacy and safety for other indications is assumed from the demonstration of equivalence to the reference product in accordance with regulatory procedures. Based on the totality of evidence, the EMA concluded that similarity has been convincingly demonstrated enabling extrapolation of Benepali approval to all other indications for which the reference product Enbrel® is approved, except the aforementioned paediatric indications.
- On 1st April 2016, a new CMU contract which will include the TNF inhibitors is due to start. The current list price for Benepali® is 10% below that of the reference product however locally negotiated discounts may be available.
- The group approved use of Benepali® first line for existing and new patients. For existing patients consideration should be given to switching where it is clinically appropriate and as part of a clinician led management programme which has appropriate monitoring in place.

The recommendation was deemed to be a high priority for funding due to the cost savings available.

ACTION: BR to draft recommendation in new format based on above.

5) Sufentanil sublingual tablet system for acute moderate to severe post-operative pain relief.

- Sublingual sufentanil (Zalviso®) was licensed in the EU for the management of acute moderate to severe post-operative pain in adult patients in September 2015. Sublingual sufentanil (Zalviso®) is to be administered in hospital only.
- The sublingual sufentanil tablet system (Zalviso®) is a new and novel device for drug administration which has not yet demonstrated its reliability and practicability in the broad clinical setting in the UK.
- Sublingual sufentanil is a hybrid medicine of intravenous sufentanil (Sufenta®), which has been authorised in the Netherlands since 1978 as an anaesthetic-analgesic. The potency of sufentanil in humans 7 to 10-fold higher than fentanyl and 500 to 1,000-fold higher than morphine (per oral). The high lipophilicity of sufentanil allows it be administered sublingually and achieve a rapid onset of analgesic effect.
- The Zalviso® administration system is an innovative, pre-programmed, non-invasive, handheld device designed to deliver a single sufentanil 15 microgram sublingual tablet at a time, on a patient-controlled as needed basis, with a minimum of 20 minutes (lockout interval) between doses, over a period of 72 hours (the maximum recommended treatment duration). The delivery system has obtained a CE mark; hence, its technical function is certified.
- Efficacy of Zalviso® has been studied in two placebo controlled phase III trials and one phase III study controlled against an IV PCA with morphine sulphate. A 48 hour treatment period was chosen in all of the phase III studies because that is the typical duration of use of an IV PCA following surgery.
- Sufentanil sublingual tablet system was found to be non-inferior when compared to IV morphine sulphate PCA in one phase III study. Patients using the sufentanil system reported more rapid onset of analgesia and patient and nurse ease of care and satisfaction scores were higher than IV PCA MS.
- Costs of Zalviso® versus standard morphine PCA in the UK remain unknown currently but Zalviso® is likely to be significantly more than a standard IV morphine PCA even taking into account any savings in nursing time and reduction in complications associated with IV PCAs.
- The potential of abuse or divergence by patients or staff of Zalviso® via the novel administration system remains unknown.
- The license is currently limited to a max 72 hours of therapy.
- There is limited clinical evidence available to support the use of Zalviso® in patients with renal or hepatic impairment.
- Patients are required to not eat or drink, and to minimise talking for 10 minutes after each dose is administered. In addition the sublingual sufentanil tablet system would be tethered to

a fixed point e.g. bed or patient locker so wouldn't move with the patient unlike a PCA system.

- The sublingual tablets contain an azo dye to which allergic reactions have been reported.
- Hospital Trusts will need to consider how to record the administration of a dose of sufentanil sublingual tablets to comply with UK laws governing controlled drugs and local policies for the administration of controlled drugs.
- There is currently no data available comparing Zalviso® with oxycodone or fentanyl IV PCAs.

Due to the gaps in knowledge regarding the use of the new sufentanil system the group did not recommend use. Further information on the reliability and practicality of the device are required before the system can be recommended for use. In addition there is no comparative data against other systems and therefore its place in therapy is difficult to ascertain. A price is not yet available for the system and the group agreed to re-review this recommendation should a price become available.

ACTION: BR to draft recommendation based in above.

6) Vitamin D updates

The group noted the minor updates to the vitamin D documents made by AM following some updates to products available. It was noted that the NOS document was also currently under review but it was thought that this would stay more or less the same as currently. The group agreed with the updates as outlined.

ACTION: AM to send final versions to BR for uploading onto the GMMMG website.

7) Lurasidone re-review

The group had been asked to re-look at the lurasidone recommendation as it had a review date of March 2016. Whilst it had been highlighted for re-review there was no new data that the group hadn't already reviewed. It was noted that a pooled analysis of existing data had now been published. The objective of the analysis was to evaluate the effect of 12 months of treatment with lurasidone on weight in patients with schizophrenia. This showed that treatment with lurasidone was weight neutral. It was agreed therefore that the current status i.e. use where aripiprazole was not tolerated or had failed was still appropriate. This recommendation was therefore re-authorised. As there were no changes it did not need to go to GMMMG.

ACTION: BR to remove review date on current recommendation and republish.

8) Horizon Scanning and Work plan

The group agreed to add the following new drugs/indications to the work plan: new licensed indications for ticagrelor, birch bark extract gel and Lesinurad (gout).

It was also agreed that the group would need to keep an eye on the new anti-interleukin therapy for asthma that was currently being evaluated in clinical trials.

ACTION: BR to update work plan as above.

8) Update on other groups
Formulary Subgroup
The group was updated on the last formulary subgroup meeting.
GMMMG
The group was updated on the agenda for the next GMMMG meeting which is on Thursday.

Interface Subgroup
The group was updated on the interface subgroup meeting

9) AOB
No other issues were raised under any other business.

10) *Date of Next Meeting: 17th May 2016, 12.30-2.30pm, CMFT*