# NewTherapiesSubgroup

**Minutes**

**21st April 2015, 12:30 - 2:30 pm**
**Pharmacy Dept. CMFT**

**Present:**

**Jennifer Bartlett (JB)** Senior Medicines Management Pharmacist – South Manchester CCG
**Dr Peter Budden (PB)** GP and Prescribing lead, Salford CCG (*Chair*)
**Rachael Fallon (RF)** Deputy Director of Pharmacy and Medicines Governance, CMFT
**Andrew Martin (AM)** Strategic Medicines Optimisation Pharmacist, GM CSU.
**Keith Pearson (KP)** Head of Medicines Management, Heywood Middleton and Rochdale CCG
**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.

Apologies received: EC, EA, JL, MG and HSo.

**Declarations of Interest**
RW declared that he had been chief investigator for the secukinumab clinical trial and had received research funding from Novartis. There were no other declarations of interest.

**1) Minutes of the meeting on February 2015.**

The minutes were accepted as a true and accurate record.

**ACTION RDTC to publish as final.**

**2a) Matters Arising:**

The group were updated on the matters arising document and noted the slight changes made to nabilone and sativex recommendations by GMMMG. The group were informed that these would be published on the website in May, following the election.

**2b) Matters arising – Draft GLP1 receptor agonists recommendation.**

The group discussed the draft GLP1 receptor agonist recommendation. The group was happy with the draft recommendation which recommended use as per the NICE guidance. The group noted that liraglutide and exenatide twice daily are the preferred options within the GMMMG formulary. However it was agreed that a once weekly preparation should now also be added to the available options that are currently on the formulary. It was also proposed that as the most cost effective option lixisenatide should also be considered for inclusion instead of exenatide. The review paper identified that based on currently available data liraglutide still appears to offer the best HbA1C and weight reductions, whilst the once weekly agents may cause less GI adverse effects compared with once daily or twice daily options. It was noted that of the weekly options available, currently only dulaglutide had demonstrated non-inferiority against once daily liraglutide. The group agreed that the issue of which drugs should be included in the formulary would be re-looked at once albiglutide was launched and after further discussion with specialists. In the meantime the group asked that the draft recommendation was updated to include the following sentence: '*Choice of GLP1 receptor agonist should be based on NICE guidance, licensed indications, device, frequency of administration, ease of use, reconstitution requirements and cost'*

**ACTION: BR to update recommendation as above**
**BR to add formulary choice of GLP1 RAs to agenda for further discussion.**

**2b) Airsonett protocol from specialists**

The group discussed the draft protocol that had been forwarded to the group by a paediatric respiratory specialist from CMFT. The group re-reviewed the evidence for use of Airsonett® laminar flow device for the treatment of uncontrolled asthma and noted that although a number of trials have been conducted, the bulk of the clinical data relates to quality of life changes which can be subjective and therefore subject to bias. It was however noted that a UK based clinical trial is underway looking at the effect on exacerbations, but this trial is not likely to report until 2017. Whilst Airsonett® may be cheaper than the NICE approved omalizumab, there is consistent evidence that omalizumab reduces the exacerbation rate in treated patients whereas this data is lacking for Airsonett®.

The group therefore felt that if the specialists were keen to use Airsonett® then the group needed clarity on how they would measure 'treatment successes' and what benefits they had seen so far in treated patients as they had indicated that it was currently used in some patients under a patient access scheme that was available from the manufacturer.

**ACTION BR to contact specialist to ask for response to questions as above.**

**3) Apremilast and Secukinumab for Psoriasis.**

RW summarised the clinical trial data for apremilast and secukinumab for the group. The group were informed that NICE is currently undertaking a TA for both apremilast and secukinumab; it is expected that these will be available in August and July 2015. The group noted the following:

- Apremilast (a twice-daily tablet) and secukinumab (a 4-weekly infusion) are licensed for the treatment of moderate to severe plaque psoriasis.
- Both are superior to placebo for the endpoint of 75% reduction in Psoriasis Area Severity Index. There is some evidence apremilast has comparable efficacy to etanercept, but further details are not yet available. Secukinumab appears to be superior to etanercept and ustekinumab, but data are limited.
- Most adverse effects associated with apremilast were mild to moderate, and the most commonly reported were gastrointestinal effects. Secukinumab has a similar safety profile to ustekinumab.
- The place in therapy of each drug is dictated in part by the licensed indication. Apremilast is licensed for people with moderate to severe plaque psoriasis who have failed to respond, have a contraindication or are intolerant to other systemic treatments or phototherapy. Secukinumab is licensed for adults with moderate to severe plaque psoriasis who are eligible for systemic therapy.
- Apremilast is more expensive than conventional systemic therapies, but cheaper than the biologics. The list price of secukinumab is lower than any of the other biologic therapies.
- Both drugs have access schemes in place that Greater Manchester can take advantage of prior to the publication of the NICE guidance.

<u>Apremilast:</u>

The group agreed that the place in therapy of apremilast should be limited to those patients who fail treatment with conventional systemic therapy but who are not eligible for treatment with a biologic. Apremilast has been shown to have efficacy in those with psoriasis and psoriatic arthritis so may be a valuable option in this subgroup of patients.

The New Therapies Subgroup of the GMMMG considered the use of apremilast for the treatment of moderate to severe chronic plaque psoriasis in adult patients who have failed to respond, have a contraindication, or are intolerant to other systemic therapy including ciclosporin, methotrexate or

psoralen and ultraviolet-A light (PUVA) and for the treatment of active psoriatic arthritis in adults who have had an inadequate response or who have been intolerant to previous DMARD therapy.

**The group recommends the use of apremilast in those patients that have failed conventional systemic therapy but who are not eligible for treatment with a biologic.**

Apremilast was found to be superior to placebo for the endpoint of 75% reduction in Psoriasis Area Severity Index (PASI) and there is some evidence apremilast has comparable efficacy to etanercept however this has yet to be fully published. There is emerging evidence that shows that apremilast may be of benefit in those patients who suffer from both psoriasis and psoriatic arthritis.

At £7,150 per patient per annum, apremilast is more expensive than conventional systemic therapies, but is cheaper than the biologics and has the advantage of being an oral preparation so will not require admission to hospital for administration. However initiation of apremilast and ongoing monitoring should remain with specialists within secondary/tertiary care settings.

Patient access schemes may be available for some therapies used for moderate to severe plaque psoriasis which CCGs and Trusts can take advantage of that may further reduce initial costs to the health economy.

According to set criteria apremilast was found to be a high priority for funding within the specific patient group recommended.

Secukinumab:

The group agreed that whilst the clinical data for secukinumab is very promising the place in therapy of secukinumab should be limited to second line use for those patients who have failed on first line biologic therapy; this is due to the lack of long term safety information currently available for secukinumab compared to more established therapies. However the group agreed that this should be monitored closely and as more real world safety data emerges the place in therapy of secukinumab could be moved to joint first line.

The New Therapies Subgroup of the GMMMG considered the use of secukinumab for the treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic biologic therapy.

**The group recommends the use of secukinumab following failure of first line biologic therapies or in those with contraindications or intolerance to other biological therapies. i.e. as a second line option.**

Secukinumab was found to be superior to placebo for the endpoint of 75% reduction in Psoriasis Area Severity Index (PASI) and appears to be superior to etanercept and ustekinumab, but data are limited. Secukinumab has a similar safety profile to ustekinumab.

The list price of secukinumab is lower than any of the other biologic therapies. Patient access schemes may be available for some therapies used for moderate to severe plaque psoriasis which CCGs and Trusts can take advantage of that may further reduce initial costs to the health economy.

According to set criteria secukinumab was found to be a high priority for funding within the specific patient group recommended.

The group noted that patient access schemes may be available for some therapies used for moderate to severe plaque psoriasis and it was felt that if the drugs were used in line with NTS recommendations and the Salford Royal algorithm for patients requiring biologic therapy then it would seem sensible to take advantage or any discounts available.

**ACTION: BR to draft recommendations as above**
**RW to discuss place in therapy with colleagues**

**4) NTS Recommendation re-review: Sequential use of biologic agents in the treatment of chronic plaque psoriasis.**

Following on from discussions relating to agenda item 3, the group noted that the above recommendation and algorithm was now out of date and needed updating to include the two new preparations above but also to consider the use of infliximab biosimilars. The patent on infliximab has now expired, and two biosimilars (Inflectra® and Remsima®) are available, each with a list price 10% below that of branded Remicade®. The group agreed that the infliximab arm of the algorithm should now include a biosimilar. RW was in agreement with this and would discuss this further with colleagues at Salford Royal. The group agreed however that the recommendation and algorithm should be updated following publication of the NICE TA's for apremilast and secukinumab to prevent duplication of workload.

| **ACTION: RW to update the algorithm in conjunction with colleagues once NICE TAs are available.** |
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**5) Brinzolamide/brimonidine combination eye drops**

The group were informed this had been referred to them from primary care as there is confusion around use of eye drops for glaucoma. The group discussed the evidence presented in the evidence summary (new medicine) from NICE. The group noted the following points:

- Glaucoma is a group of eye disorders in which progressive damage to the optic nerve leads to impaired vision and, in some people, blindness. The most common form of glaucoma is chronic open angle glaucoma, also known as primary open angle glaucoma.
- Treatment options for chronic open angle glaucoma depend on its severity. NICE's full guideline on glaucoma suggests that reduction of intraocular pressure is a valid 'surrogate outcome' for treatment success and further discusses the treatment options available. http://www.nice.org.uk/guidance/cg85/evidence
- Brinzolamide/brimonidine combination eye drops (Simbrinza) are licensed for treating chronic open angle glaucoma or ocular hypertension in adults for whom monotherapy did not sufficiently reduce intraocular pressure. The drops contain a fixed dose combination of brinzolamide1%, a carbonic anhydrase inhibitor, and brimonidine 0.2%, an alpha 2 agonist (sympathomimetic) drug. The recommended dose is 1 drop into the affected eye(s) twice daily.
- The evidence for use of brinzolamide/brimonidine combination eye drops is based on two phase III studies that evaluated the efficacy and safety of using twice daily administration.
- In one phase III superiority study in people with glaucoma (n=560), at 3 months the mean change from baseline in diurnal intraocular pressure was statistically significantly lower in the group treated with brinzolamide/ brimonidine combination eye drops compared with the groups treated with brinzolamide and brimonidine monotherapy.
- In the other phase III non-inferiority study in people with glaucoma (n=890), at 3 months brinzolamide/brimonidine was non-inferior to brinzolamide plus brimonidine administered concomitantly for mean change from baseline in diurnal intraocular pressure.
- There are no published data comparing brinzolamide/brimonidine combination eye drops with other drug treatments used for managing glaucoma and ocular hypertension.
- Brinzolamide/brimonidine combination eye drops cost the same as the constituent products combined (£9.23 per 5 ml: 28-day treatment) however they are cheaper than most other combination products for glaucoma and ocular hypertension although they are not the cheapest product available.
- The SMC had approved use of the combination eye drops for their licensed indication.

The group agreed that brinzolamide/bromidine combination eye drops are a valuable option for patients as it would offer a simpler administration regimen for patients who need more than one treatment. Brinzolamide/bromidine combination eye drops also offer another option for patients in whom prostaglandin analogues and or beta-blockers are unsuitable. However the group were mindful that the patent for brinzolamide eye drops is due to expire soon and therefore the cost of the individual components separately may reduce in the future. The group agreed to monitor this, with the intention of reviewing this recommendation should costs fall substantially.

The New Therapies Subgroup of the GMMMG considered the use of brinzolamide 10mg/mL and brimonidine tartrate 2mg/mL eye drops (Simbrinza®) to decrease elevated intraocular pressure (IOP) in adult patients with open-angle glaucoma or ocular hypertension for whom monotherapy provides insufficient IOP reduction

**The group recommends the use of Simbrinza® eye drops for the above indication when the separate constituent components (brinzolamide and brimonidine) of the combination would normally be recommended.**

In clinical trials Simbrinza® was found to be superior to brinzolamide and brimonidine monotherapy and non-inferior to brinzolamide plus brimonidine administered concomitantly.

There are no published data comparing brinzolamide/brimonidine combination eye drops with other drug treatments used for managing glaucoma and ocular hypertension.

Simbrinza® eye drops cost the same as the constituent products combined (£9.23 per 5 ml: 28-day treatment) however they are cheaper than most other combination products for glaucoma and ocular hypertension although they are not the cheapest product available.

According to set criteria Simbrinza® eye drops were found to be a medium priority for funding.

**ACTION BR to update recommendations as above.**

**6) Current work plans & new submissions received since February & Horizon Scanning**

The group noted the current work plan and agreed that edoxaban could be considered at the next meeting. The group also asked if vorapaxar could be considered. BR agreed to identify whether it was close to launch and whether any of the clinical trials had been published. As an acute drug, the group agreed that cangrelor could be removed from the work plan.

It was agreed that the biosimilar insulins could be considered at the June meeting once they had been launched and further information regarding price was available.

It was also agreed that a GI pathway for use of the biosimilar infliximab's would be useful as most prescribing of infliximab is in gastroenterology.

The group noted that there were a large number of drugs for which a generic product is now available or will be available (e.g. duloxetine, ketoconazole, voriconazole and pregabalin for epilepsy and GAD); it was felt that these should be highlighted to CCGs by members.

**ACTION: BR to update work plan as above**

**7) Updates from other groups.**

**Formulary Subgroup**

The group was updated on the last formulary subgroup meeting.

Discussions took place around the formulary status of Relvar® combination inhaler. The group confirmed that Relvar® would not be added to the formulary as this time due to the limited safety data of both constituent products. This will be reviewed as and when further data (e.g. Salford Lung Study) is available.

**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 they had discussed chapters 1 and 8.

**8) AOB**

The group were informed that Dr Morais may be re-joining the group from the May meeting. The group welcomed his attendance.

**9) *Date of Next Meeting: 19th May 2015, 12.30-2.30pm, CMFT***