**Oxfordshire Area Prescribing Committee (APCO)**
**Bullet Points**
**9th July 2019**

Prescribing Points and the Traffic light system are available on the OCCG website. The OCCG Formulary is available online. -link below.
This document summarises the discussions and decisions taken at APCO in July 2019.

**Local Guidance: OCCG Formulary**

The classifications are:

- Red – Specialist Prescribing Only
- Amber Continuation - Medicines which should be initiated or recommended by a specialist for continuation in primary care. The specialist must notify the GP that the prescribing responsibility has been transferred.
- Amber Shared Care Protocol - Medicines which are appropriate to be initiated and stabilised by a specialist, once stabilised the medicine may be appropriate for responsibility to be transferred from secondary to primary care with the agreement of a GP and a formal 'shared care' agreement. The shared care protocol must be approved by the Area Prescribing Committee Oxfordshire (APCO).
- Green - Medicines which are suitable for initiation and ongoing prescribing within primary care.
- Brown – Prescribe only in restricted circumstances
- Black – Not recommended for use in primary or secondary care
- Holding List – Pending APCO / Priorities Forum decision

| Drug | Traffic Light Classification | Rationale |
|---|---|---|
| Inotersen for treating hereditary transthyretin amyloidosis | Red | In line with NICE HST9<br>NHS E commissioned |
| Brentuximab vedotin for treating CD30-positive cutaneous T-cell lymphoma | Red | In line with NICE TA577<br>NHS E commissioned |
| Durvalumab for treating locally advanced unresectable non-small-cell lung cancer after platinum-based chemoradiation | Red | In line with NICE TA578<br>NHS E commissioned |
| Abemaciclib with fulvestrant for treating hormone receptor-positive, HER2-negative advanced breast cancer after endocrine therapy | Red | In line with NICE TA579<br>NHS E commissioned |
| Nivolumab with ipilimumab for untreated advanced renal cell carcinoma | Red | In line with NICE TA581<br>NHS E commissioned |
| Atezolizumab in combination for treating metastatic non-squamous non-small-cell lung cancer | Red | In line with NICE TA584<br>NHS E commissioned |
| Ocrelizumab for treating primary progressive multiple sclerosis | Red | In line with NICE TA585<br>NHS E commissioned |
| Enzalutamide for hormone-relapsed non-metastatic prostate cancer | Black | In line with NICE TA580 |

| Drug | Traffic Light Classification | Rationale |
|---|---|---|
| Cabozantinib for previously treated advanced hepatocellular carcinoma (terminated appraisal) | Black | In line with NICE TA582 |
| Semglee (biosimilar insulin glargine) | Black | Concern that now three different glargine products available but not interchangeable. Still considerable generic prescribing that needs to be reviewed. To be reconsidered in 3-6 months once more work on generic prescribing has been done. |
| Lecicarbon A | Amber C | For use if other laxatives have failed, specifically on recommendation from the pelvic floor clinic |
| Neon Verifine | Brown | most cost effective insulin safety needle available. Will replace BD Autoshield Duo as first line |
| Invita D3 capsules | Brown | Cost effective option to be included in list of products on formulary |
| Tenfovir + emtrcitabine + darunavir + cobicistat (Symtuza) | Red | For HIV – specialist only |
| Teriparatide for Osteoporosis in Men | Red | NHS E commissioned |
| Intratympanic methylprednisolone (sodium succinate) | Red | For sensorineural hearing loss. Agreed at May MMTC |
| Ganciclovir eye ointment | Green | For acute herpetic keratitis. To replace aciclovir eye ointment which is no longer available |
| Tacrolimus suppositories | Red | Specialist prescribing only. MMTC May 2019 |

**Miscellaneous**

## DN administration of Methotrexate

A document clarifying the roles and responsibilities of DNs administering denosumab has previously been agreed by APCO. During this process it was identified that a similar document for parental methotrexate administered by DNs is also required to ensure that the correct process is followed and all monitoring is complete prior to administration. The document aims to clarify what the GP is responsible for, what the DNs responsibilities are (including being aware of the side effects which are listed). A flow chart has been included and is similar to the denosumab process agreed. A screenshot of how the repeat prescription should be set up is to be added

It was clarified that DNs should inform the GP once it has been administered and enter onto EMIS. The GPs stated that this does always happen in practices, so asked if this can be communicated via bulletin to increase awareness of the process. A template has been tested in Berinsfield to allow it to be entered in to EMIS which may help, it will also feedback to the specific teams. The GP is responsible for instigating the monitoring, check monitoring has been done and is satisfactory then issuing the DTA and prescription and asking the DN to give it. DN then does the safety checks with the

patient, administers and informs the GP. The DTA lasts until the next monitoring is due. It was noted this can be a significant workload if monitoring is monthly. It was confirmed that this is for very small number of patients who are housebound and would require to DNs to administer. It was confirmed that all relevant SCPs will be updated.

**Approved.**

**Teriparatide in Men**
Teriparatide is newly commissioned for use in men by NHSE. Current arrangements for shared care are for women as per NICE and is OCCG commissioned. Rheumatology requested if use in men could be shared care and prescribed by GPs as it is for women. OCCG confirmed that the GP prescribing of teriparatide for men would not be appropriate as there would be no robust way to recharge NHSE, however if they wanted to raise the issue with NHSE to find a way around the charge issue they can. However, it would still need to be discussed at APCO to discuss whether GPs would be happy to take on shared care. We are not aware that GPs have been asked to prescribe for men, although it was stated that OCCG do sometimes get IFR requests. It was agreed that teriparatide in men can be added to the formulary as red for clarification for the time being. OUH is in conversation with NHSE about potential ways to allow prescribing in primary care.

## RMOC (Regional Medicines Optimisation Committee)

**RMOC newsletter**
The RMOC newsletter was circulated for noting. Includes update on Freestyle Libre (updating of RMOC position statement in line with NHSE), noted to expect a holding statement for use of Rivaroxaban for CAD/PAD while waiting for NICE, highlighted STOMP work (stopping overmedication of people with a learning disability, autism or both) and that shared care work continues.

**Principles guiding the decision making about the route of supply of medicines to outpatients**
For APCO to note. Outlines the various routes of supply to patients from hospital Increasing urgent requests for medication from secondary care was raised, GPs have no information at the time so have to repeat the consultation. It was confirmed that anything within 14 days should be prescribed by OUH. A contact to report these issues too was asked for and it was confirmed that Datix would be the correct route to get a system wide approach.

## Guidelines

**Lipid Modification Guidance – update**
It was noted that OCDEM has updated the Lipid Modification Guidance with some minor changes, and has also asked APCO to consider allowing the Lipid Clinic to initiate Omega 3 in a small number of patients for continuation by the GP.

The use of Omega-3 would have a very restricted use in a small number of patient groups on endorsement from the lipid clinic (amber continuation). The suggestion is that this would only be for 10 patients per year, where there are no other options.

Currently, Omega 3 is black listed (do not prescribe) in Oxfordshire as per recommendation from NHSE as part of Items which should not routinely be prescribed in primary care guidance. This is in line with NICE which states do not offer omega‑3 fatty acid compounds for the prevention of CVD to any of the following people who are being treated for primary or secondary prevention. The lipid clinic have provided a link to the new REDUCE-IT study that showed a reduction in the risk of ischemic events in patients using 2g Icosapent ethyl (highly purified EPA) twice a day. Omacor, which is what would be used in practice, contains a combination of EPA and DHA.

It was felt that OCCG should not go against NHSE. It was raised that the trial is quite strong evidence, and is newer than the NHSE recommendation so should be considered. However, it was noted that the product used was not the same, and confirmed that the study used a highly purified EPA whereas Omacor is a mix of EPA and DHA. It was raised that the need to de-prescribe omega 3 may have been missed in primary care, so this needs to be picked up. It was suggested that omega-3 goes to MMTC first and also this needs raising to NHSE.

It was also raised that, in the updated wording for Familial Hypercholesterolaemia (FH) and Familial Lipid Disorders it suggests that primary care records should be systematically searched for certain patients - this will only happen if practices are specifically directed to do this. It was noted that this was taken directly from the NICE guidance.

**Minor updates approved but omega 3 section to remain as do not do**

**Guidance on COPD Management in Primary care—Inhaled Therapies – update**

The updated OCCG COPD guidelines were presented, which are now based on the NICE guideline published in December 2018 (previously based more on GOLD). The main change in the guidance is where in the pathway inhalers are recommended and the focus on whether a patient is likely to be steroid responsive or not. The LABA/LAMA combination inhaler is now recommended further up the pathway (for non-asthma type patients) and initially NICE suggested that triple therapy would not be an option in this group. However, an update is due to be published at the end of July that suggests triple therapy could be used in this group in some cases, generally on a trial basis. ICS/LABA would be the main option for patients who have asthma-type features. Formulary options have not changed but where they are used in the pathway has. Using LABA/LAMA earlier is likely to cost more, but there will be savings elsewhere so it is suggested that the additional cost could only be £15K (using NICE cost calculator). Some questions about what is the best option for triple therapy ‘trial’ suggested in non-asthma group – currently triple inhalers are recommended but has been suggested a single steroid could be added into LABA/LAMA instead. Noted that this is not licensed and may end up being used alone which is a risk in a group where steroids are likely to not give much benefit. Agreed to use triple inhaler device. Noted that IRT will help to promote updated guidance in City and Banbury if approved.

As NICE will be published soon, it was suggested we should wait to approve. However it was agreed that that APCO could approve subject to NICE and will only publish if in line with NICE.
It was stated that it needs to be clear what is meant be inspiratory flow and to use an in-check device to help decide on inhaler. It was confirmed that the OUH respiratory team (including pharmacy) has been involved, and the MIL will be updated and taken to MMTC.

**Approved subject to NICE**

**Update - South Central Antimicrobial Network Guidelines for Antibiotic Prescribing in the Community (UTIs)**

It was noted that this guidance has already been presented through the SCAN group for comments and will be used across a number of areas, so this at APCO for information. However, as it has not been published yet issues can be raised if needed. The changes have been due to updated NICE guidance and PHE diagnostic guidance for UTIs. The main changes are: updated diagnostic criteria, dipstick interpretation, low resistance risk definition, trimethoprim no longer for use in pregnancy, recurrent UTI treatment updates, removal of ciprofloxacin for standby/prophylaxis, updated referral advice and treatment options for pyelonephritis.
It has been agreed that the guidance will be transferred onto the microguide app/website over the coming months but that the pdf will be updated until this is done. OUH currently use microguide so will be in line with this and, as regional guidance, means that cost will be shared.

It was raised that this is the third big change to this guidance and that GPs really require an algorithm. It was discussed that an algorithm would be helpful and needs to start with how to process urine samples. It was stated that PHE do have flow charts so can share these re diagnosis or could adapt to make simpler, but the risk is you may lose some of the messages. It was stated that in OUH the Microguide app is incredibly useful and can adapt it to include a flowchart including how the patient presents. It was stated that reception won't use an app, so would need a paper version.

**Approved – algorithm will be produced locally**

**Use of biological and immunomodulatory therapies in Rheumatoid Arthritis**

It was explained that the current TVPC policy states that patients must be reviewed every 6 months, including a measurement of their DAS28 score. This is based on NICE TA 195 which states 'Treatment should be monitored, with assessment of DAS28, at least every 6 months and continued only if an adequate response is maintained'.

The issue of 6 monthly reviews for RA has been raised on several occasions by the rheumatology team who stated that stable patients were only reviewed annually (occasionally 9 monthly). This has always been the standard process in Oxfordshire. Changing these patients to 6 monthly reviews would result in 450-600 additional follow-

ups a year, which is not sustainable with the existing clinic appointments available. The same issue has been raised in Berkshire West, the CCG is considering a similar approach as suggested in this paper. Bucks do not have this issue so do not want to change their policy.

The risk of extending to review period to 12 monthly after the initial 6 month review is that patients may experience a loss of response but will be continued on an expensive biologic that is ineffective. The clinical team feel this is low risk as any patient experiencing a loss of response would contact the service due to worsening symptoms, which would be particularly noticeable in the group. They would then have their treatment reviewed. Patients are counselled on reporting a loss of response at initiation via the support line.

APCO is asked to consider a local amendment to the policy that states patients should be reviewed at 6 months and then annually thereafter.

It was added that NICE requested 6 monthly monitoring not on safety grounds but for cost effectiveness.

**Approved**

**Hydroxychloroquine Retinopathy Screening for Oxfordshire**

This is a complicated issue that is affecting one of our shared care protocols. The royal college of ophthalmologists published new guidance last year recommending specific screening for retinopathy in patients starting taking and those on long term hydroxychloroquine. Currently patients do have checks for visual acuity and have a yearly check up with an optometrist but this guidance recommends more specific checks. The paper for discussion has mainly been put together by the ophthalmology team giving their views on how the guidance should be implemented locally noting the current constraints on the eye clinic and costs associated with running an additional service. There are some practical suggestions on how clinics may be run for example as a virtual clinic including via a community provider with ophthalmology input remotely. APCO cannot make a decision about commissioning the service but can make a recommendation and discuss who should be taking the responsibility for referring to screening (GP or specialist) and what we should be doing now with regards to shared care.

It was queried that a lot of these patients could have been discharged, so rheumatology won't have them on their list to recall anymore. Noted that an OUH database and EMIS Enterprise can potentially be used to support in identifying patients in primary care.
It was suggested that the dose in the SCP is lowered to 5mg/kg. From the rheumatology audit, it does look like numbers of patients on higher doses have been reduced.
The guidance states that annual referral should be done by the responsible clinician – this would be the prescriber but discussed that this should maybe be rheumatology. The shared care protocol will need to be clear on this matter, and the general consensus is that it will be secondary care responsibility to refer for retinopathy screening at appropriate times.

It was summarised that we will add information to prescribing points and will get advice from ophthalmology/rheumatology on risk stratification and recalling patients. The dose, review and duration needs to be built in to the SCP. This will be brought to the next meeting.

**Post meeting note**:
Further discussions have been had outside of APCO on this topic at MMTC and internal OUH rheumatology and ophthalmology meetings and actions are in progress. The LMC have also written to the OUH.

**Chair's Actions**

**South Central Antimicrobial Network Guidelines for Antibiotic Prescribing in the Community**
Interim update to include a note to take into account the recent MHRA alert 'Fluoroquinolone antibiotics: new restrictions and precautions for use due to very rare reports of disabling and potentially long-lasting or irreversible side effects' after all recommendations to use these drugs in the guideline.
UTI section is in the process of being reviewed fully in line with NICE guideline (see section above under guidelines)

**Toujeo Doublestar**
Toujeo (insulin glargine 300 units/ml) is now available in 2 different pre-filled pens
- 3 x 1.5ml SoloStar pre-filled pen=£33.13.
- 3 x 3ml DoubleStar pre-filled pen=£66.26

The strength of glargine in each device is the same (300 units/ml), but the DoubleStar contains double the volume. The price per unit is the same. The dose increment in the SoloStar is 1 unit, and in the DoubleStar 2 units. As the strength of insulin is the same, and the units are displayed on the display screen, the risk for error has been deemed as low by the specialist teams. However, the difference should be made clear on the formulary and on ScriptSwitch

The following wording will be added to the formulary entry:
Caution must be used when prescribing this and should be prescribed by brand. Care must be taken when selecting the pen device. Majority of patients should be prescribed the SoloStar device.
- Toujeo SoloStar 300units/ml (1.5ml pen): The pen will dial up in increments of 1 unit and will give maximum of 80units.

If injection burden is an issue and is already taking more than 80units of Toujeo, the DoubleStar should be considered.
- Toujeo DoubleStar 300units/ml (3ml pen): The pen will dial up in increments of 2 units and will give maximum of 160units. Although not mentioned in the SPc we would recommend a maximum dose of 120unit injection site to help with insulin absorption