Oxfordshire Area Prescribing Committee (APCO)
Bullet Points
8th May 2018

Prescribing Points and the Traffic light system are available on the OCCG website. The OCCG Formulary is available online. -links below.
This document summarises the decisions taken at APCO in May 2018.

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
Brodalumab for treating moderate to severe plaque psoriasis	Red	In line with NICE TA511
Daratumumab monotherapy for treating relapsed and refractory multiple myeloma	Red	In line with NICE TA510. NHS E commissioned
Tivozanib for treating advanced renal cell carcinoma	Red	In line with NICE TA512. NHS E commissioned
Obinutuzumab for untreated advanced follicular lymphoma	Red	In line with NICE TA513. NHS E commissioned
Cabozantinib for treating medullary thyroid cancer	Red	In line with NICE TA516. NHS E commissioned
Avelumab for treating metastatic Merkel cell carcinoma	Red	In line with NICE TA517. NHS E commissioned
Tocilizumab for treating giant cell arteritis	Red	In line with NICE TA518. NHS E commissioned
Pembrolizumab for treating locally advanced or metastatic urothelial carcinoma after platinum-containing chemotherapy	Red	In line with NICE TA519. NHS E commissioned
Regorafenib for previously treated advanced hepatocellular carcinoma	Black	In line with NICE TA514

Drug	Traffic Light Classification	Rationale
Eribulin for treating locally advanced or metastatic breast cancer after 1 chemotherapy regimen	Black	In line with NICE TA515
Anastrozole for prevention of breast cancer	Amber C	For women at high and moderate risk of breast cancer following recommendation from genetics service in line with NICE CG164
Tamoxifen for prevention of breast cancer	Amber C	For women at high and moderate risk of breast cancer following recommendation from genetics service in line with NICE CG164
Raloxifene for prevention of breast cancer	Amber C	For women at high and moderate risk of breast cancer following recommendation from genetics service in line with NICE CG164
Progesterone for prevention of pre-term labour	Amber C	Initiated by pre term labour clinic at 12 weeks and continued by GP until 34 weeks gestation
Tear -Lac® [hypromellose 0.3%]	Green (restricted)	If preservative free formulation required, in line with OCCG Ocular Lubricant Guidelines
Sno Tears® [Polyvinyl alcohol drops 1.4%]	Green	In line with OCCG Ocular Lubricant Guidelines
Clinitas® Gel [Carbomer 980]	Green	Second line, in line with OCCG Ocular Lubricant Guidelines
Geltears® [Carbomer 980]	Green	Second line, in line with OCCG Ocular Lubricant Guidelines
Systane® [Hydroxypropyl guar]	Green	Third line, in line with OCCG Ocular Lubricant Guidelines
Optive® [Carmellose 0.5%]	Green	Third line, in line with OCCG Ocular Lubricant Guidelines
Celluvisc® [Carmellose 1.0%]	Green (restricted)	If preservative free formulation required. Third line, in line with OCCG Ocular Lubricant Guidelines
Systane® [Hydroxypropyl guar] unit dose vials	Green (restricted)	If preservative free formulation required. Third line, in line with OCCG Ocular Lubricant Guidelines
Clinitas® [Sodium Hyaluronate 0.4%] unit dose vials	Green (restricted)	If preservative free formulation required. Third line, in line with OCCG Ocular Lubricant Guidelines
Hylo -Tear® [Sodium Hyaluronate 0.1%]	Green (restricted)	If preservative free formulation required. Third line, in line with OCCG Ocular Lubricant Guidelines
Hylo-Forte® [Sodium Hyaluronate 0.2%]	Green (restricted)	If preservative free formulation required. Third line, in line with OCCG Ocular Lubricant Guidelines

Drug	Traffic Light Classification	Rationale
Lacri-Lube, Liquifilm, Vismed, Hypromellose 1%, Lumecare, Mandanol	Non formulary	No longer included in OCCG Ocular Lubricant Guidelines
Fentanyl intranasal spray	Red	For acute severe pain in adolescents at Helen House (EoL)
Macitentan	Red	For Pulmonary arterial hypertension. Only approved via Specialised centre at Royal Brompton. NHS E will not fund at OUH.
Diobotermin alfa	Red	Primary and revision spinal fusion. NHS – E funded
Gastrografin	Red	For short bile obstruction
Etrivex shampoo	Brown	In line with psoriasis pathway only – 2nd line for scalp
Silkis	Brown	In line with psoriasis pathway only – 2nd line option for vulva
Ulipristal acetate (Esmya®)	Black	In line with NICE guideline [NG88] - Heavy menstrual bleeding: assessment and management. EMA is reviewing the use of Esmya for uterine fibroids and have introduced temporary safety measures. These include not starting new treatment courses of Esmya and performing liver function tests at least once a month for all women already taking Esmya. See the EMA website for the full safety measures and information about the review
Sodium Valproate medicines in pregnancy	Black	The MHRA published a new drug safety update in April 2018 on valproate medicines. New absolute contraindication for use of valproate medicines in pregnancy for the bipolar disorder indication.

Shared Care Protocols (SCP)

Shared Care, revised national guidance

The revised national shared care guidelines have been published. The committee are asked to discuss how to take this forward with regards to shared care protocol templates and work with providers around communication and initiation.

The key points for going forward are summarised below.

- Currently OCCG SCPs are medicine specific, the new guidance suggests that SCPs should be disease specific
- GPs Communication process – need to work with OUH for better two way communication. GP should confirm agreement and acceptance of shared care arrangements. Telephone details for both parties, secure email addresses for both parties. Should have OOH contact details.
- Circumstances where may not be appropriate for shared care protocol. Ongoing specialist intervention and specialist monitoring and medicines which are unlicensed or being used of outside product license. APCO need to be careful of these.

The paper included the report from recent MMTC minutes regarding communication with OUH and GPs to highlight that it has been recognised from both sides. OCCG have started collating evidence of difficulties and challenges, and will share with OUH to see how this can inform the process.

Discussion about when requests for shared care should happen – should be at point of initiation by secondary care to aid transition.
It was felt that the interface from Primary to Secondary care needed to be looked at and that GPs would need baseline information before prescribing for a patient as well as a clear plan. Question about how GP confirms that they will take on prescribing.

It was suggested that there is a task and finish group and that they could do a joint piece of work around the communication with GPs and Consultants.

Guidelines

Ocular Lubricant Prescribing Guidelines

It was reported that the previous set of guidelines were issued in 2013 and haven't been reviewed since. Some of the products in the guidelines have ongoing out of stock problems, for example Lacrilube. In the proposed update the products have been classified into two columns, either following the preserved route, or preservative free route. There are also options of increasing viscosity.

The costs of the ocular lubricants have been reviewed. £370k spent on ocular lubricants over the last 4 quarters, of which £8k for blepharitis treatments. This is

something that should be dis-invested from under the OTC policy. Approx. 70% of costs are relating to the old guidelines. Most expenditure on 3rd line products - £120k. Whilst the products still exist in proposed guidelines there would be a specific process to follow to get to these options.

New guidelines not expected to produce many savings but would potentially be much clearer to follow. A few changes will be made to the formulary as a result (see above) It was queried whether ophthalmology had been involved in this update. It was noted that they had not. There was concern that the 2nd/3rd line options were more likely to be chosen by secondary care when making recommendations to prescribe.

It was agreed to put a link to the OTC policy on the front page with stronger message. The expectation would be that OUH would need to let patients know that they are expected to purchase certain products under the OTC policy. It was asked what mechanism is in place for informing patients of this. It was suggested a leaflet that could be given to patients to inform them of what products and where to purchase.

It was noted that all of the products can be purchased OTC. It was suggested blacklisting all ocular lubricant products and informing patients to buy OTC. Concerns expressed that if all products were blacklisted, that would be considered a withdrawal of services and may form the need for a consultation.

Can be recorded on the clinical system when a patient expected to buy OTC. Community Pharmacy would also need leaflet to advise patients. Agreed to liaise with OUH to discuss how ophthalmology can support the OTC policy and to share the guidelines.

It was discussed that if these products are purely for dry eye then the expectation would be for patients to buy OTC. However, for patients with chronic eye conditions this may not be appropriate. It was agreed that the guideline should say patient advised to purchase OTC instead of GP to prescribe it. The national policy is about short term conditions.

Agreed that all products relating to Blepharitis should be blacklisted.

The guidance was agreed subject to amendments discussed

Osteoporosis – Guidance for Fracture Risk Assessment and Prevention
It was reported that this guideline is being resubmitted following the discussions in January APCO meeting. The guidance has been updated as a result of this discussion. The following has been updated:

- Qfracture clarified as risk assessment of choice
- Noting of NICE guidance that states it is cost effective (although not necessarily clinically effective) to treat at 1% risk but advising that SIGN is used to help make a decision to treat
- Clarification of when a DEXA scan is required
- Creating a risk assessment flow chart that includes both primary and secondary prevention on one page

- Inclusion of information about bone protection in patients taking aromatase inhibitors or GnRH Analogues
- Updating of the duration of treatment pathway to reflect APCO discussions and split into 'primary and secondary prevention'
- General format changes

The process if a patient re-fractures whilst on treatment was discussed. There is a pathway on OUH website put together by the FRISCY group but refers to PN1P test and commissioning policy statement 114b states that this is low priority. This policy statement may be reviewed. The draft guideline does include a statement giving some advice about re-fracture.

It was reported that there are approximately 15 IFRS per year relating to Osteoporosis treatment. Sometimes patients are within the guidelines, however there are situations when a patient fractures on treatment and there is a request to go straight onto an IV option. This can often be age related. Potentially a cohort of patients where bone markers suggest that will not get benefit from denosumab but this conflicts with commissioning policy statement so cannot add into guidance.

It has been suggested that the commissioning policy statement will be reviewed. In the meantime, make the guidance clearer and more prominent what to do if the patient re-fractures.

It was noted that if these are Primary Care guidelines then they need to state Primary Care guidelines only.

Aromatase Inhibitors –there is a pathway on OUH website that gives a summary of treatment, however thresholds are slightly different for treatment. OUH will be asked if there are any plans to update this. The information on this guidance has come from NICE.Patients who would be offered ibandronic acid or women who would be taking Zoladex, have not been covered as would become a specialist case.

Guideline was agreed following the circulation to committee an updated version with amendments as discussed above.

Risk of vertebral fractures after discontinuing Denosumab.
It was reported that this issue was raised at APCO in January. A paper recently published suggesting that there was a higher risk of vertebral fractures immediately after stopping denosumab. It should be noted that there have been no safety alerts issued as a result of this and no national guidance on the implications.
The proposal is for a section to be written into the existing denosumab guidelines that clearly explains this risk, summarising the paper in terms of possible risks and what the SCP says and leaving it up to the clinician to make an informed decision. The paper states that careful monitoring should be taken of when next dose is due. If Denosunab is stopped, patients should promptly receive a bisphosphonate if possible

It also notes that Secondary Care should be consulted. For the Osteoporosis guidelines a line has been added to state the potential high risk of vertebral fractures and to be aware of this before stopping.

The committee agreed that the statement should be added to the guideline to highlight the risk.

A question about what happens to patients that were initiated at the time the protocol was put in place was raised as this is coming up to 5 years. A decision will need to be made whether or not these patients stay on Denosunab. It was thought that this would be the decision of the individual clinician to evaluate. The committee agreed that there were not in a position to make a formal decision on this yet.

Heavy Menstrual Bleeding (HMB) Guidelines

This is an update of previous guidance. It was reported that NICE have brought out new guidelines on HMB. This is an update of the Pharmacotherapy section of current guidelines. The original guidelines were produced when transitioning from PCT to CCG and OCCG do not have the original document to amend. APCO are asked to withdraw the whole document and replace with this until Planned Care have updated guidance around ultrasound. It can be produced as a whole document.

Noted the impact on LARC issue as guidance currently states 'fit according to council's service'. OCCG have been asked to remove this statement.

There were no concerns raised by the committee and the document was approved.

Chair's Actions

Policy 42e NHS prescribing of gluten free foods

The revision is minimal:

1. Page 1 'This is in line with the Department of Health 'Report of Responses Following the Public Consultation on Gluten Free Prescribing in Primary Care' (January 2018).' Inserted.
2. Page 2 inclusion of a link to the updated Referral Guidelines Coeliac Disease Adults (September 2014).
3. Page 2 hyper link to Gluten Free diet information on Coeliac UK website
4. Page 2 Updated contact details for specialist dietitians at OUH.
5. Page 2 'Women are more likely to develop coeliac disease than men4.' Changed to 'Reported cases of coeliac disease are two to three times higher in women than in men 4.'
6. Page 3 1The law requires that foods labelled 'gluten free' can contain no more than 20 parts per million of gluten.' Changed to 'The law requires that foods labelled 'gluten free' can contain less than 20mg per kg of gluten.'
7. References and Notes updated to reflect the above changes (Updated NICE Guidelines, link to the systematic review mentioned on page 3 in the last paragraph, inclusion of 'Please check that you are using the most recent version of this policy'.)