Oxfordshire Area Prescribing Committee (APCO) Bullet Points 10th January 2017

Prescribing Points and the Traffic light system are available on the OCCG website-link below. These bullet points summarise the decisions taken at APCO in January 2017.

Local Guidance: Traffic Light Document

The classifications are:

- Red List – Specialist Prescribing Only
- Yellow (Near Patient Testing LES) – Transfer of prescribing to primary care in line with Shared Care Protocol. Monitoring in Primary Care
- Yellow – Transfer of prescribing to primary care. Monitoring in secondary care
- Yellow Continuation List – Appropriate for continuation in primary care following specialist recommendation
- Brown – Prescribe only in restricted circumstances
- Black – Not recommended for use in primary or secondary care

Drug	Traffic Light Classification	Rationale
Dapagliflozin	YELLOW (continuation)	TA 418 in triple therapy for treating type 2 diabetes in combination with metformin and a sulphonylurea.
Apremilast	RED	TA 419 for treating moderate to severe plaque psoriasis
Ticagrelor	YELLOW (continuation)	TA 420 for preventing atherothrombotic events after myocardial infarction
Nivolumab	RED	TA 417 for previously treated advanced renal cell carcinoma
Everolimus with exemestane	RED	TA 421 for treating advanced breast cancer after endocrine therapy
Crizotinib	RED	TA 422 for previously treated anaplastic lymphoma kinase-positive advanced non-small-cell lung cancer
Eribulin	RED	TA 423 for treating locally advanced or metastatic breast cancer after 2 or more chemotherapy regimens
Pertuzumab	RED	TA 424 for the neoadjuvant treatment of HER2-positive breast cancer
Dasatinib and nilotinib	RED	TA 425 for treating imatinib-resistant

Drug	Traffic Light Classification	Rationale
		or intolerant chronic myeloid leukaemia
High-dose imatinib (600 mg in the chronic phase or 800 mg in the accelerated and blast-crisis phases)	BLACK	**TA 425** for treating imatinib-resistant or intolerant chronic myeloid leukaemia
Dasatinib, nilotinib and imatinib	RED	**TA 426** for untreated chronic myeloid leukaemia
Vedolizumab	RED	**TA352** for treating moderately to severely active Crohn's disease after prior therapy
Bevacizumab	BLACK	**TA353** for treating relapsed, platinum‑resistant epithelial ovarian, fallopian tube or primary peritoneal cancer (terminated appraisal)
Edoxaban	YELLOW (continuation)	**TA354** for treating and for preventing deep vein thrombosis and pulmonary embolism
Oral Nutritional Supplements	BROWN	In-line with OCCG Commissioning Statement
Toujeo	YELLOW (continuation)	“Prior Approval” no longer required
Bath and shower emollients	BROWN	Part of the Over The Counter (OTC) Policy
Degludec	YELLOW (continuation)	Treatment should only be initiated by a diabetes specialist
Sacubitril Valsartan	YELLOW (SCP)	Treatment initiated by secondary care and then transferred to primary care under the conditions of the SCP (see below for details)

Shared Care Protocols

(a) Sacubitril Valsartan

Sacubitril valsartan has been approved by NICE (TA 388) for patients with New York Heart Association class II to IV heart failure symptoms, left ventricular ejection fraction of 35% or less and taking a stable dose of an angiotensin converting enzyme inhibitor (ACEi) or an angiotensin receptor blocker (ARB).

A SCP for sacubitril valsartan, outlining a pathway for identifying patients suitable for therapy, was presented to APCO. Under the terms of the SCP, sacubitril valsartan therapy would be initiated by the hospital heart failure (HF) team during an out-patient clinic approximately 4 weeks post discharge, if the patient is stable. Treatment would be reviewed at regular intervals by the HF team and the dosage up-titrated as appropriate. Once patients are stabilised on the maximum tolerated dose of sacubitril valsartan or after 3 months, whichever is longer, the HF team would refer the patient back to the GP for prescribing of on-going treatment. There will be telephone support for the GP from the Heart Failure Specialist Nurse and there will be clear guidance in the SCP as to how to refer patients back to the hospital HF team. Once stabilised, monitoring by GPs will include blood pressure, renal function and electrolytes every 6 months and liver function tests and full blood count every 12 months.

The SCP for sacubitril valsartan was approved, subject to amendments and will be reviewed in 6 months. Sacubitril valsartan is traffic lighted as YELLOW

(b) Shared Care Protocol for Oral Anticoagulation with Vitamin K Antagonists in Adult Patients

The SCP has been developed to provide information on assessing anticoagulation control and to raise awareness of “Time in Therapeutic Range” (TTR) of INR in-line with NICE CG 180, The Management of Atrial Fibrillation. TTR is an effective way of establishing the quality of anticoagulation control and is an important predictor of bleeding and thrombosis. TTR is currently provided with each INR result for patients who have been on warfarin for longer than 6 months to help assess anticoagulant control for all patients under OUHFT warfarin service.

Most aspects of the SCP were accepted, but it was agreed that further work needs to be done to clarify the responsibilities around interpretation and follow-up of the TTR results. This is to be explored further.

Traffic light Classifications

(a) Toujeo

Currently in Oxfordshire, Toujeo is traffic lighted YELLOW: For specialist initiation only following ‘Prior Approval’. In the 13 months this drug has been on prior approval, 9 patients have been started. It was commented that the prior approval system has added little benefit.

It was agreed that the necessity of “prior approval” should be removed from Toujeo. The traffic lights for Toujeo should be updated as follows and changes in prescribing levels can be monitored on ePACT:

YELLOW (continuation): On recommendation of the diabetes specialist team for patients who are already on optimised complex regime, who have already tried other insulins (including degludec if patient meets criteria) and on a total long acting insulin dose of more than 80 units per day (or lower if they have very limited injections sites or require 3rd party administration).

d) Degludec

The current degludec criteria based guideline has been reviewed. Consideration has been given to the 35% price reduction making it much more comparable to the other long acting insulins.

It was agreed that the degludec guideline should be withdrawn and the traffic light status of degludec should be as follows:

Degludec 100units/ml

YELLOW (continuation): Treatment should only be initiated on recommendation from a diabetes specialist (including nurse or GP specialist). Degludec can be considered for type 1 or 2 patients who are having more than 2 hypoglycaemic events per week, or have had more than 1 diabetic ketoacidosis episode in the past 12 months, or require a more flexible dosing interval. All patients MUST be entered into the national degludec audit. Degludec is available as 100units/ml and 200units/ml, please follow MHRA guidance when prescribing.

Degludec 200units/ml

YELLOW (continuation): entry on the traffic lights would have the same wording as for degludec 100units/ml plus an additional statement allowing those who are on a total long acting insulin dose of more than 80 units per day to be considered.
Changes in prescribing levels can be monitored on ePACT.

Local Guidance

(a) TREND Sick day rules patient information leaflet

A sick day rules patient information leaflet (PIL) produced by TREND (Training, Research and Education for Nurses in Diabetes) was presented to APCO. The leaflet is intended to complement the two Type 2 Diabetes Guidelines in Oxfordshire (Insulin Initiation and Blood Glucose Management). The use of the leaflet is supported by the joint OCCG/OCDEM diabetes group. It was noted that a drug company supported the original printing and distribution of the leaflet, but had no input to the content.

The leaflet was approved for adoption on condition that it reflects local ketone testing guidelines.

(b) Emollient Guidelines

An updated emollient formulary which recommends cost-effective products and advises on their use was presented. It was recommended that bath and shower emollients are no longer prescribed as a similar effect can be achieved by dissolving an emollient ointment in hot water or using emollients as a soap substitute.

The emollient guidelines were accepted. The recommendation that the bath and shower emollients should be included in the OTC policy and traffic lighted as BROWN (restricted prescribing) was also accepted

(c) Primary Care prescriber decision support for direct oral anticoagulants (DOACs) for stroke prevention in atrial fibrillation

A revised version of this guideline was presented to APCO. This updated guideline provides information on edoxaban, how to establish the most appropriate anticoagulants for specific patients, where to access drug information booklets, switching between anticoagulant regimens and on-going monitoring. It was agreed to use the term direct oral anticoagulant 'DOAC' rather than new oral anticoagulant 'NOAC' in line with national recommendations.

The guideline was approved.

(d) DOACs for Treatment and Secondary Prevention of Deep Vein Thrombosis (DVT) and Pulmonary Embolism (PE) in Primary Care

A revised version of this guideline was presented to APCO. The updated guideline provides information on edoxaban , referral information to the Churchill DVT service for suspected lower limb DVT, duration of treatment, ongoing monitoring by GP, and where to access drug information booklets.

The guideline was approved.

Matters arising

Colesevelam

A verbal update was given about the treatment for bile acid malabsorption. The first line treatments for this condition are colestyramine of which there are several different brands.and colestipol. Colesevelam is available for patients with a true intolerance to the first line treatments. It should be recommended by Secondary Care (gastroenterologists) and requires prior approval from the Medicines Optimisation Team. The Teva UK brand of colestyramine is currently unavailable and it is possible that this may lead to increased requests for colesevelam. It should, however, be noted that the restrictions for prescribing mentioned above, still apply.

(APCO recommendations January 2017 ratified at February OCCG Clinical Ratification Group)