

## Pharmfax Lights

Welcome to the September edition of Pharmfax Lights which highlights recent medicine traffic light classifications in Leeds. For definitions of the different classifications please see the foot of this page.

### TRAFFIC LIGHT CLASSIFICATIONS

The following classifications were ratified by the Leeds Area Prescribing Committee on the 16<sup>th</sup> September 2020

### Secondary Care Requests for Primary Care Prescribing

Occasionally, a secondary care clinician may ask a GP to prescribe a medicine which not on the Leeds Formulary, or is not on it for that particular indication. The Leeds Area Prescribing Committee has produced some guidance for GPs to manage these situations. The process to follow in these circumstances can be found [here](#)

COVID-19 MEDICINES INFORMATION [Link to Medicines information /Leeds CCG Website](#)

### Black Light - Not Yet Reviewed (in Leeds)

- Darolutamide 300 mg film-coated tablets (Nubeqa) - for the treatment of adult men with non-metastatic castration resistant prostate cancer (nmCRPC) who are at high risk of developing metastatic disease
- Delafloxacin meglumine - 300 mg powder for concentrate for solution for infusion, 450 mg tablets (Quofenix) for the treatment of acute bacterial skin and skin structure infections (ABSSSI) in adults when it is considered inappropriate to use other antibacterial agents that are commonly recommended for the initial treatment of these infections.

- Esketamine hydrochloride 5mg/ml & 25mg/ml solution for injection/infusion - Indicated for:
  - Induction and maintenance of general anaesthesia, as the only anaesthetic or possibly in combination with hypnotics.
  - Supplementation of regional or local anaesthesia.
  - Anaesthesia and pain relief (analgesia) in emergency medicine.
  - Pain control in artificial respiration (intubation)
- Estradiol 1.53 mg/spray, transdermal spray, solution (Lenzetto) - Hormone Replacement Therapy (HRT) for estrogen deficiency symptoms in postmenopausal women (in women at least 6 months since last menses or surgical menopause, with or without a uterus).
- Fostamatinib disodium - 100mg and 150mg F/C tablets (Tavlesse) - for the treatment of chronic immune thrombocytopenia (ITP) in adult patients who are refractory to other treatments.
- Human cytomegalovirus immunoglobulin 100 U/mL solution for infusion (Cytotect) Indicated for prophylaxis of clinical manifestations of cytomegalovirus infection in patients subjected to immunosuppressive therapy, particularly in transplant recipients (The concomitant use of adequate virostatic agents should be considered for CMV-prophylaxis)
- Leuprorelin 10.72 mg implant (Staladex) Indicated in men for the treatment of:
  - Hormone-dependent, advanced prostate cancer.
  - High risk, localized and locally advanced, hormone-dependent prostate cancer in combination with radiotherapy.
- Onasemnogene abeparvovec 2 × 10<sup>13</sup> vector genomes/mL solution for infusion (Zolgensma) Indicated for the treatment of:
  - patients with 5q spinal muscular atrophy (SMA) with a bi-allelic mutation in the SMN1 gene and a clinical diagnosis of SMA Type1, or
  - patients with 5q SMA with a bi-allelic mutation in the SMN1 gene and up to 3 copies of the SMN2 gene
- Ropeginterferon alfa-2b (Besremi) - for polycythemia vera without symptomatic splenomegaly - monotherapy

### **Black Light classification**

- Nicotine 0.45 mg Inhaler (Voke) - Nicotine replacement product
- Mesalazine 400mg EC tablets (Zintasa brand) - only licensed up to 2.4g and only available in 400mg tablets

## Amber Level 1 - standard guidance

### [LINK TO AL1 STANDARD GUIDANCE](#)

- Leuprorelin (Prostap) - fibroids is an additional indication
- Renavit Tablets (Renavit) - Vitamin supplement in dialysis patients (reclassified from Amber level 2)

## Amber Level 2 – standard guidance

### [LINK TO AL2 STANDARD GUIDANCE](#)

- Leuprorelin acetate 11.25mg prolonged release subcutaneous injection in a pre-filled pen (3 monthly injection) – Breast Cancer  
Multiple classifications: Amber 1 for endometriosis, Amber 2 for prostate cancer, Amber 3 for gender reassignment
- Penicillamine 125 and 250mg Tablets - Wilsons disease (patients will receive a patient specific care plan with their clinic letter with a hyperlink to the monograph. link to National Formulary <http://www.bimdg.org.uk/site/formularies.asp>)

## Amber Level 1 additional information

- Tamoxifen tablets: for the chemo prevention of familial breast cancer in line with NICE and Yorkshire & Humber Strategic Clinical Networks Guidance ([Link](#))
- Soya Infant Formula (SMA Wysoy®): for the treatment of : ([Link](#))
  - All infants with galactosaemia (from birth to 2 years) or
  - Infants (>6 months to 2 years) with Cow's Milk Protein Allergy unable to tolerate a first line extensively hydrolysed formula or second line amino acid formula and where the family would usually qualify for Healthy Start vouchers
- Varicella Vaccine: for Paediatrics ([Link](#))

## Amber level 2 additional information

- Melatonin: Prescribing Guidance for the Treatment of Parasomnias (including Delayed Sleep Phase Syndrome) ([Link](#))

### Amber Level 3

- Mercaptopurine amber guidance in adult IBD ([Link](#))
- Mesalazine: for the Treatment of Inflammatory Bowel Disease (IBD) in Adults ([Link](#))
- Mycophenolate mofetil for Paediatric Solid Organ Transplant Rejection (Liver/Renal) ([Link](#))
- Mycophenolate: for the use in Adults Non-Transplant Indications (Rheumatology, Dermatology, Respiratory, Ophthalmology, Neurology, Hepatology & Oral Medicine) ([Link](#))
- Sacubitril valsartan: for the treatment of symptomatic chronic heart failure with reduced ejection fraction ([Link](#))
- Tacrolimus: for the Treatment of Nephrotic Syndrome in Children ([Link](#))
- Warfarin: Guidance for prescribing for children ([Link](#))
- SGLT2 inhibitors and GLP-1 agonists: Amber Drug Guidance for cardiovascular risk reduction in patients with recent cardiology admission with type 2 diabetes\* and atherosclerotic cardiovascular Disease (ASCVD) ([Link](#))
- DOACs : for the treatment of left ventricular thrombus with direct oral anticoagulants (DOACs) (unlicensed use) - ([Link](#))

### Red classification

- Bevacizumab intravitreal injection (ULM) - for Coats' Disease and exudative retinopathy in children under 16
- Chloroprocaine hydrochloride injection, 10 mg per 1 ml (Ampress) - For intrathecal anaesthesia
- Clostridium botulinum type a toxin-haemagglutinin complex 300units and 500 units Powder for Solution for Injection (ULU) (Dysport) - for paediatric abdominal closure
- Darolutamide 300mg film coated tablets (Nubeqa) - for prostate cancer
- Fentanyl 100micrograms/2mL ampoules via Mucosal Atomiser Device (MAD) - for severe pain in children
- Meropenem-vaborbactam 1 g/1 g powder for concentrate for solution for infusion (Vaborem) - for bacterial infections
- Ruxolitinib phosphate tablets - multiple strengths (Jakavi) - New indication - For Acute Graft Versus Host Disease (for use in line with NICE TA386 -treating disease-related splenomegaly or symptoms in adults with myelofibrosis)
- Triamcinolone intravitreal injectable suspension 40 mg/mL (preservative free) (riesence) - for ocular inflammation unresponsive to topical steroids and not suitable for Ozurdex

## Red classification - commissioned by NHSE

- Autologous serum eye drops : note dual classification
  - Black for new patients
  - Red for patients who started treatment before April 2019
- Belimumab subcutaneous injection 200mg prefilled pen (Benlysta)
- Carboplatin infusion + Paclitaxel infusion - For anal cancer
- Dolutegravir-lamivudine 50mg/300mg film-coated tablets (Dovato) - For HIV-1 infected adults and adolescents >12 years
- Dolutegravir-rilpivirine 50mg/25mg film-coated tablets (Juluca) - for treating HIV-1 in adults
- Lenalidomide capsules with rituximab – for previously treated follicular lymphoma
- Lorlatinib tablets (Lorviqua) - for previously treated ALK-positive advanced non-small-cell lung cancer
- Parathyroid hormone subcutaneous injection (Natpar) - For chronic hypoparathyroidism
- Ranibizumab 10mg/ml solution for injection (Lucentis) - New indication - Retinopathy of prematurity
- Remdesivir 100 mg concentrate for solution for infusion - For the treatment of patients hospitalised with suspected or laboratory-confirmed SARS-CoV-2 infection
- Temozolomide capsules - For astrocytoma
- Uridine triacetate (ULM) - For treatment of patients exhibiting early-onset severe toxicities following 5-fluorouracil or capecitabine administration (all ages)

## Grey classification

- Coagucheck & Coagucheck Softclix - *Children who are under the care of the Leeds paediatric warfarin clinic or anticoagulation service who will assume responsibility for ensuring that the training is appropriate and that the testing machines are appropriately calibrated at least every 6 to 12 months against either a venous blood sample or a healthcare professional's coagulometer which is checked in line with an external quality assurance scheme.*
  - *Note: Red classification for adults*
- Dual Glucose & Ketone Meter Test Strips- cost more than £10/50 strips (Freestyle Optium Neo) - Testing of ketone and blood sugar levels in blood : Patients should be initiated on dual glucose and ketone meters where the associated strips cost less than £10 per 50 strips.

## Green classification

- Dymista Nasal Spray - Severe Allergic or Seasonal Rhinitis Pathway
- Trimovate Steroid Cream

## Dual classification

Pigmanorm® cream (hydroquinone, tretinoin, hydrocortisone) [unlicensed] - Licensed in Germany (but not the UK) for melanin-related hyperpigmentation (brown patches on the skin), e.g. melasma (chloasma) or hyperpigmentation following inflammation.

- Melasma - Black light classification
- hyperpigmentation secondary to medications/ post inflammatory hyperpigmentation/ vitiligo depigmentation - Red classification

Becolemtasone dipropionate inhaler - Soprobe

- Use in asthma, alternative drugs or inhaler devices may be cheaper or easier to use for an individual patient – Grey classification
- Use in COPD-Unlicensed - Black Light classification

Liraglutide 6 mg/ml solution for injection prefilled pen (Victoza) - For diabetes mellitus in adolescents and children 10 years and above

- Amber level 1 standard – adolescents and children 10 years and above
- Green classification – adults
- Green classification – when used alone

Vitamin B Compound Strong - For Re-feeding only

- Red for use in Secondary Care for re-feeding only
- Amber level 1 standard on the advice of community dietitian for re-feeding

Triamcinolone IM Injection (Kenalog)

- Red classification for the reduction of restructuring rate following dilation of Crohn's strictures and oesophageal strictures (unlicensed use)
- Green classification for all other licensed uses

## Guidance, Policies and Pathways

- Acute and Chronic Prostatitis in Primary Care ([Link](#))
- Advice on the Management of Adults over 18 years with Vitamin D Deficiency or Insufficiency in Primary and Secondary Care ([Link](#))
- Dry Eye Prescribing Guidelines for Primary Care ([Link](#))
- Management of Adult Malnutrition ([Link](#))
- Primary Care Guidance for Reviewing Patients on All Oral Formulations of Ranitidine ([Link](#))
- Advice on the Management of Adults and children over 12 years with Allergic Rhinitis and non-allergic rhinitis ([Link](#))
- Urgostart Pathway for the treatment of leg ulcers ([Link](#))
- Wound care formulary ([Link](#))

Cardiovascular Risk Reduction in Patients with Type 2 Diabetes and Cardiovascular Disease ([Link](#))

## Leeds Traffic Light Classifications - Definitions

**GREEN DRUGS:** Medicines which are appropriate for initiation and ongoing prescribing in both primary and secondary care. Due to the extensive number of Green Drugs, there is currently not a list of these medicines.

**AMBER DRUGS:** These are medicines which are recommended or initiated by a specialist, but can then be prescribed by primary care physicians. Amber Drugs will be classified under three different headings:-

- Amber Drugs recommended by a specialist (Amber Level 1)
- Amber Drugs initiated by a specialist (Amber Level 2)
- Amber Drugs with specialist initiation and ongoing monitoring requirements (Amber Level 3)

**RED DRUGS:** Medicines for hospital use only. Primary care prescriber initiation or continuation of treatment is not recommended.

**RED DRUGS – commissioned by NHSE:** Medicines for hospital use only commissioned by NHSE. Primary care prescriber initiation or continuation of treatment is not recommended.

**GREY DRUGS:** are locally-agreed medicines which are recommended for specific indications but not others. The Grey List outlines circumstances in which specific prescribing is appropriate. The Grey List is intended to support good prescribing and help prescribers make balanced decisions. .

**BLACK LIGHT DRUGS:** These drugs are not recommended for prescribing within the Leeds health economy. All new drugs will be assumed Black Light until they have been through the appropriate approval process.

**BLACK LIGHT - ( NOT YET REVIEWED)** These drugs are newly licensed and will not receive a review unless requested by a clinician in Leeds

**DEVICES:** The Leeds Area Prescribing Committee will usually only consider traffic light classifications for devices that facilitate medicines use or are used in a “medicines like way”. For devices that are listed in the drug tariff but do not meet this definition prescribing is at the discretion of the prescriber. Please note that devices do not go through the same process as medicines before inclusion in the drug tariff, therefore listing in the drug tariff does not necessarily mean the device is evidence-based and cost effective.

## USEFUL LINKS

For full details of traffic light classifications and the traffic light list:

<http://www.lhp.leedsth.nhs.uk/common/guidelines>

Leeds Formulary: <http://www.leedsformulary.nhs.uk>

Next Pharmfax Lights bulletin : December 2020