

Derbyshire Joint Area Prescribing Committee (JAPC)

This is a countywide group covering NHS Derby & Derbyshire Clinical Commissioning Groups, Derbyshire Community Health Service Foundation Trust, Derbyshire Healthcare Foundation Trust, University Hospital of Derby and Burton and Chesterfield Royal Hospital foundation trusts. It provides recommendations on the prescribing and commissioning of drugs. See http://www.derbyshiremedicinesmanagement.nhs.uk/home

Due to the current COVID-19 pandemic an interim JAPC ToR has been devised to ensure that there is continuity of JAPC meetings during these extraordinary times. The increased pressures experienced by the CCG and providers necessitated the need to temporarily modify existing arrangements for the running of JAPC meetings and the work-up behind the review/production of clinical guidelines.

See http://www.derbyshiremedicinesmanagement.nhs.uk/medicines-management/joint_area_prescribing_committee

Derbyshire traffic light classification BLACK \rightarrow **Do Not Prescribe (DNP)** $\textbf{BROWN} \rightarrow \textbf{GREY}$

With the recent world-wide black lives matter movement, JAPC has taken the decision to rename the BLACK and BROWN drug traffic light classifications to avoid any negative connotations which may be associated with these references. Under the new proposal all BLACK drugs will change to "Do Not Prescribe (DNP)" and all BROWN drugs will change to "GREY". The Red, Green and Amber classification will remain the same.

This renaming of the BLACK/BROWN drugs will be a substantial piece of work which will include changeover of the traffic lights database, updating the local formulary, clinical guidelines and non-clinical guidelines, and any other relevant documents which make reference to the black or brown traffic light classification. Furthermore the practice based formularies and trust formularies will need to be updated to align to the amended JAPC traffic lights classifications. Users will see an immediate changeover to the new nomenclature of Grey and DNP in the traffic light section of the Derbyshire Medicines Management website (phase 1). BNF chapters, clinical and non-clinical guidelines will gradually be transitioned over (phase 2). Due to size of this task it is not practical to amend previously published communication; these include previous JAPC minutes, JAPC bulletins, JAPC Annual Reports and Medicines Management Newsletters. However an explanation of the current and previous traffic light classification will be added to the Derbyshire Medicines Management website for ease of use. The Clinical Policies and Decisions team are planning to complete phase 1 by the end of November 2020 and phase 2 by 31st March 2021. We apologise to our users for any confusion caused in the interim period whilst this work is ongoing.

Key Messages From The JAPC November Meeting - Clinical Guidelines

Nebulised colomycin (off-label) use for pseudomonas aeruginosa lung Infections in adults with Bronchiectasis (non-Cystic Fibrosis) – guidance updated with minor amendments including key contacts/references updated and nebuliser equipment Ventstream replaced by Side Stream Plus. Initiation and early monitoring remains under the specialist's responsibility. JAPC TOR - updated to include section on chairmanship and administrative jobs

Patient Group Directions (PGDs)

DCHS PGDs for Medroxyprogesterone acetate injection and combined hormonal contraceptive transdermal patch have been approved and ratified by DCHS. These PGDs are hosted on the Derbyshire Medicines Management website to enable community pharmacies access to these PGDs.

Oral semaglutide - Grey

The new oral GLP1 inhibitor - semaglutide has been classified by JAPC as GREY by exceptionality defined as intolerance to the preferred first-line GLP1choice (Lixisenatide) or restricted by its licence. Oral semaglutide may be an option for patients with type 2 diabetes mellitus, reserved for use if triple therapy with metformin and 2 other oral drugs are not effective and if use of a GLP1 is clinically appropriate, in line with licensing and if an oral option is preferred. However in patients with pre-existing cardiovascular disease or at high risk of cardiovascular events an agent with proven efficacy for CV risk reduction may be more suitable. Prescribers should note the effect of switching between oral and subcutaneous semaglutide cannot easily be predicted, thus clinical effectiveness should be considered when making switching decisions between formulations. Patients should be reminded that oral semaglutide should be taken on an empty stomach, at least 30 minutes before eating.

Familial Hypercholesterolemia (FH) guidance

Local FH guidance has been updated to include a recommendation of starting with atorvastatin at 20mg, with the option of using atorvastatin 10mg as a starting dose as a way to titrate up to limit adverse effects of the statin. Due to its loss of patent and lowered acquisition price, rosuvastatin replaces simvastatin as **Grey 2nd line** treatment option for FH. The guidance continues to recommend the Simon Broome criteria for the diagnosis of FH.

SCA for neurological disease modifying agents

JAPC has approved the inclusion of neurological conditions to the shared care agreement for azathioprine. These unlicensed conditions include neuromuscular junction disorders (e.g. Myasthenia Gravis, Lambert-Eaton syndrome), inflammatory neuropathies, central nervous system inflammatory diseases and autoimmune encephalitis. Small patient numbers are expected across Derbyshire, with monitoring arrangements remaining unchanged.

Guideline Group key messages

Colestyramine - Green specialist recommendation for Familial Hypercholesterolaemia. See local guideline

Co-careldopa - Green specialist recommendation. BLACK for brand prescribing (Sinemet) removed due to price reduction.

Vitamin D (Colecalciferol) - GREY: Strivit D3 800units capsules cost-effective choice for exceptional use for maintenance following treatment of deficiency or insufficiency in patients with osteoporosis, osteopenia or hyperparathyroidism. DNP: Vitamin D in strengths of 1000 units and below for maintenance following treatment of deficiency or insufficiency (excluding patients with osteoporosis, osteopenia or hyperparathyroidism)

NOAC for suspected DVT- JAPC guideline removed. Well score criteria and detailed NOAC Prescribing information have been incorporated within the Derbyshire Shared Care Pathology Primary Care Management of Suspected DVT guideline. The SCP guideline has been recently updated following NICE NG158 to clearly direct referrals/ set out initial treatments for suspected DVT

FreeStyle Libre - update

JAPC endorse the following statement for Freestyle Libre:

People with learning difficulties People living with Type 1 or Type 2 diabetes on insulin and coded on your learning disability register are now eligible for Freestyle Libre. If you feel it would help their diabetes management, have spoken to them about it and they are keen to consider it, please refer them to your specialist diabetes service in the usual way. We are all aware of the pressures of the second wave of Covid, and would ask that we just refer those patients who have a real clinical need to start now, and then refer others later when you come across them when completing their annual review. Our specialist teams are happy to see the patient and their main carer face to face or do a virtual consultation depending on patient preference.

Many of our patients with type 1 diabetes with Freestyle Libre are asking about the new Freestyle Libre 2. This is not yet available but we are working on a plan for Derbyshire in the next few months. Please suggest that they ask their specialist team after February 2021 as by then we should have a plan to share with them. Local Freestyle Libre briefing will be updated following JAPC meeting in December.

MHRA NOTICES

Warfarin and other anticoagulants: monitoring of patients during the COVID-19 pandemic. Healthcare professional reminded that:

- Acute illness may exaggerate the effect of warfarin and necessitate a dose reduction; patients on warfarin or other vitamin K antagonists should therefore be asked to tell their GP or healthcare team if they have symptoms of, or confirmed, COVID-19 infection.
- continued INR (international normalised ratio) monitoring is important in patients taking warfarin or other vitamin K antagonists if they have suspected or confirmed COVID-19 infection, so they can be clinically managed at an early stage to reduce the risk of bleeding

- both vitamin K antagonists and direct-acting oral anticoagulants (DOACs) may interact with other medicines and if a patient using these oral anticoagulants is also prescribed antibiotics or antivirals, follow advice in the product information for minimisation of risk of potential interactions – this includes INR monitoring in patients taking vitamin K antagonists who have recently started new medicines
- if patients are switched from warfarin to a DOAC, warfarin treatment should be stopped before the DOACs is started to reduce the risk of overanticoagulation and bleeding

5-fluorouracil (intravenous), capecitabine, tegafur: DPD testing recommended before initiation to identify patients at increased risk of severe and fatal toxicity

Flucytosine (Ancotil): new contraindication in patients with DPD deficiency. flucytosine should not be used in patients with known complete dihydropyrimidine dehydrogenase (DPD) deficiency due to the risk of life-threatening toxicity.

Niraparib (Zejula ▼): reports of severe hypertension and posterior reversible encephalopathy syndrome (PRES), particularly in early treatment.

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<u>Dolutegravir (Tivicay▼, Triumeq▼,</u>	Juluca ▼): updated advice on increased risk of neural tube defects	

Drug	Date considered	Decision	Details
Semaglutide (oral)	Nov 2020	GREY	 By exceptionality defined as intolerance to the preferred 1st line GLP-1 choice (Lixisenatide) or restricted by their licensing. GLP-1s to be used by exception only as per NICE NG28 guidance for further intensification the use of the oral preparation is reserved for patients unsuitable for the SC injection, but able to comply with daily administration. the effect of switching between oral and SC cannot easily be predicted thus clinical effectiveness should be considered when making switching decisions between formulations. oral semaglutide is taken on an empty stomach and at least 30 minutes before eating or taking other medicines.
Rosuvastatin	Nov 2020	GREY	Grey 2 nd line treatment option for Familial Hypercholesterolemia
Alpelisib (Piqray)	Nov 2020	RED	Advanced or metastatic breast cancer. NHSE commissioned
Remdesivir (Veklury)	Nov 2020	RED	Treatment of coronavirus disease 2019 (COVID-19) in adults and adolescents (aged ≥12 years with body weight ≥40kg) with pneumonia requiring supplemental oxygen. NHSE commissioned
Trastuzumab biosimilar (Zercepac)	Nov 2020	RED	Metastatic and early breast cancer, and metastatic gastric cancer. NHSE commissioned
Cefiderocol (Fetcroja)	Nov 2020	DNP	Treatment of infections due to aerobic Gram-negative organisms. Await TA or clinician request
Solriamfetol (Sunosi)	Nov 2020	DNP	To improve wakefulness and reduce excessive daytime sleepiness (EDS) in adults with narcolepsy (with or without cataplexy) and in adults with obstructive sleep apnoea (OSA) whose EDS has not been satisfactorily treated by primary OSA therapy, such as continuous positive airway pressure. CCG commissioned
Volanesorsen	Nov 2020	RED	NICE HST13 - treating familial chylomicronaemia syndrome
Alpelisib	Nov 2020	DNP	NICE TA652 - Alpelisib with fulvestrant for treating hormone-receptor positive, HER2-negative, PIK3CA-positive advanced breast cancer.
Osimertinib	Nov 2020	RED	NICE TA653 - Osimertinib for treating EGFR T790M mutation-positive locally advanced or metastatic NSCLC. NHSE commissioned
Osimertinib	Nov 2020	RED	NICE TA654 - Osimertinib for untreated EGFR mutation-positive NSCLC. (Replaces TA621). NHSE commissioned
Nivolumab	Nov 2020	RED	NICE TA655 - Nivolumab for treating locally advanced or metastatic squamous NSCLC. NHSE commissioned
Alverine + simeticone (SimAlvia)	Nov 2020	DNP	Relief of abdominal pain in irritable bowel syndrome in adults
Lauromacogol 400 (Aethoxysklerol)	Nov 2020	DNP	Sclerotherapy of varicose veins of the lower extremities

Definitions:

RED: drugs are those where prescribing responsibility lies with a hospital consultant or a specialist.

AMBER: drugs are those that although usually initiated within a hospital setting, could appropriately become the responsibility of the GP, under a shared care agreement.

GREEN*: drugs are regarded as suitable for primary care prescribing.

GREY*: drugs are those that JAPC does not recommend for use, except in exceptional circumstances, due to lack of data on safety, effectiveness, and/or cost-effectiveness.

Do Not Prescribe (DNP)*: drugs, treatments or medical devices are <u>not</u> recommended or commissioned* (*unless agreed through the individual funding request route)

*Old nomenclature:

• All BLACK drugs are now \rightarrow Do Not Prescribe (DNP)

• All BROWN drugs are now \rightarrow GREY

CONSULTANT/SPECIALIST INITIATION: consultant/specialist issues the first prescription usually following a consultation because:

a. The patient requires specialist assessment before starting treatment and/ or

b. Specialist short term assessment of the response to the drug is necessary.

GPs will be asked to continue prescribing when the patient is stable or predictably stable

CONSULTANT/SPECIALIST RECOMMENDATION: consultant/specialist requests GPs prescribe initial and on-going prescriptions, but ensures:

DERBYSHIRE MEDICINES MANAGEMENT, PRESCRIBING AND GUIDELINES WEBSITE

This website is the first port of call for information on local NHS decisions and guidance on medicines use. It includes: local prescribing formularies, JAPC decisions, traffic lights, shared care guidelines, medicines guidelines, newsletters, controlled drug resources, and other medicines management resources. The site improves upon previous sites in several ways. It is faster, more reliable, has its own search engine, and it is easier to find information. Content is constantly being updated and you can sign up for e-mail alerts to keep you up to date.