Derby & Derbyshire JAPC Bulletin

www.derbyshiremedicinesmanagement.nhs.uk

This is a countywide group covering NHS Derby & Derbyshire Integrated Care Board, 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

Key Messages from June 2025 JAPC meeting

The Derbyshire Shared Care Pathology Guideline for onychomycosis in adults has been updated to remove the need for nail clippings to be sent to the laboratory for testing before starting treatments with oral terbinafine. This was agreed due to capacity issues at the laboratory causing long delays in getting results and the high level of false negative results when nail clippings are tested.

A Shared Care Agreement (SCA) for relugolix and a change of traffic light to **AMBER** was agreed. Relugolix is an oral androgen deprivation therapy (ADT) for treating hormone-sensitive prostate cancer, criteria for use are in the NICE TA995. Treatment will be initiated in the secondary care clinic with a loading dose on day 1 and after a month prescribing will then transfer to primary care. The consultant must contact the patients GP to request prescribing under shared care using the letter in appendix 1 of the SCA specifying PSA threshold on an individual basis.

Guideline Group Key Messages

The Emergency Contraception guideline has been updated, the use of pregnancy testing prior to oral emergency contraception or insertion of an IUD and the statement regarding there being no guarantee of normal pregnancy if treatment with levonorgestrel (Upostelle 1500) fails have been removed. Wording has been clarified regarding follow up appointments at 3-6 weeks post IUD insertion.

A new Biosimilar FAQ document developed by Nottingham ICB has been added to the Endocrine Chapter page. This includes information on biosimilars which are currently used in primary care, what a biosimilar is, the difference between biosimilars and generic medications, why biosimilars are used, switching to and dispensing biosimilars.

Triamcinolone injections (Kenalog & Adcortyl) have been discontinued. The SPS website has information on alternative steroid injections.

MHRA Drug Safety Update (DSU)

Thiopurines and intrahepatic cholestasis of pregnancy - Intrahepatic cholestasis of pregnancy (ICP) has been rarely reported in patients treated with azathioprine products and is believed to be a risk applicable to all drugs in the thiopurine class (azathioprine, mercaptopurine and tioguanine). Cholestasis of pregnancy associated with thiopurines tends to occur earlier in pregnancy than non drug-induced cholestasis of pregnancy, and elevated bile acid levels may not reduce with ursodeoxycholic acid.

Advice for Healthcare Professionals:

- cholestasis of pregnancy has rarely been reported in association with azathioprine therapy
- this risk is believed to also apply to the other thiopurine drugs, mercaptopurine and tioguanine
- it may occur earlier in pregnancy than non drug-induced cholestasis of pregnancy, and it may not respond to ursodeoxycholic acid
- withdrawal or dose reduction of the thiopurine drug may improve liver function tests
- remain vigilant to signs and symptoms of ICP in pregnant patients taking thiopurines and discuss any concerns with clinicians managing the patient's immunosuppressant therapy and a hepatologist, as necessary
- if cholestasis of pregnancy occurs, a case-by-case assessment is required to determine the appropriate course of action. Consider the risks and benefits of remaining on the product against the risks and benefits of stopping.
- in patients with ICP, measure serum bile acids to identify pregnancies at particular risk of spontaneous preterm birth (≥40uM) or stillbirth (non-fasting serum bile acids ≥100uM)
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Kaftrio▼ (Ivacaftor, tezacaftor, elexacaftor): risk of psychological side effects - Psychological side effects such as anxiety, low mood, sleep disturbance, poor concentration, and forgetfulness have been infrequently reported in people with cystic fibrosis treated with Kaftrio. Healthcare professionals should advise patients and their caregivers that, while the risk is small, they should be alert to changes in mood and behaviour and, if they occur, to seek medical advice as soon as possible.

Advice for Healthcare Professionals:

- there is a small increase in the risk of psychological side effects in people with cystic fibrosis treated with Kaftrio
- there is also an indirect risk of psychological side effects from difficulty adjusting to Kaftrio-related improvements to physical health and quality of life
- individuals with life-limiting conditions such as cystic fibrosis also have an increased background risk of developing poor mental health
- advise patients and their caregivers to be alert to the development of psychological side effects usually within the first three months of treatment including anxiety or low mood, sleep disturbance, poor concentration, or forgetfulness. The side effects may occur in people who have no history of these problems
- in some children, the psychological side effects may manifest themselves as persistent changes in behaviour while taking Kaftrio. Signs of this could include being more disruptive or difficult to manage
- discuss the benefit-risk balance of Kaftrio treatment with the patient or caregiver and consider treatment discontinuation if a patient develops these symptoms
- report suspected adverse drug reactions associated with Kaftrio on a Yellow Card

Traffic Light Changes Summary

Drug	Decision	Details
lazertinib (Lazcluze)	**RED**	as per NHSE commissioning intentions
brentuximab vedotin (Adcetris)	**RED**	As per NICE TA1059 - in combination for untreated stage 3 or 4 CD30-positive Hodgkin lymphoma
omaveloxolone (Skyclarys)	**DNP**	as per NICE TA1061 (terminated appraisal)
relugolix	**AMBER**	New Shared Care Agreement

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.

www.derbyshiremedicinesmanagement.nhs.uk

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 **not** recommended or commissioned* (*unless agreed through the individual funding request route)

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:
a. There is no immediate need for the treatment and is line with discharge policies and
b. The patient response to the treatment is predictable and safe