JAK inhibitors and MHRA safety warnings

SWL pathway relaxations for existing patients on JAK inhibitors, who require a switch to an alternative drug due to MHRA safety warning.

Background

Janus Kinase (JAK) inhibitors include tofacitinib (Xeljanz®), abrocitinib (Cibinqo®▼), baricitinib (Olumiant®), upadacitinib (Rinvoq®▼), and filgotinib (Jyseleca®▼). JAK inhibitors are locally commissioned and NICE approved for use in rheumatoid arthritis, psoriatic arthritis, juvenile idiopathic arthritis, ankylosing spondylitis, non-radiographic axial spondyloarthritis, ulcerative colitis, Crohn's disease and atopic dermatitis.

On 26 April 2023 the Medicines and Healthcare products Regulatory Agency (MHRA) issued updated safety advice to reduce risk of major adverse cardiovascular events, malignancy, venous thromboembolism (VTE), serious infections and increased mortality for all JAK inhibitors, in line with measures previously introduced for tofacitinib (Xeljanz®) in 2021, as follows:

- JAK inhibitors **should not** be used in patients with the following risk factors unless there are no suitable treatment alternatives:
    - age 65 years or older
    - current or past long-time smokers
    - other risk factors for cardiovascular disease or malignancy
- JAK inhibitors should be used with caution in patients with risk factors for VTE other than those listed above
- Where applicable, use lower doses in patients with risk factors (refer to Summary of Product Characteristics of each medicine for further detail)
- Carry out periodic skin examinations in all patients on JAK inhibitor medicines to check for signs of skin malignancy
- Inform patients of these risks and key signs and symptoms that could warrant urgent medical attention (i.e., new growths on skin or changes to moles (including itching, shape and discharge, which may not be as obvious on darker skin tones))
- Report suspected adverse drug reactions associated with JAK inhibitors via the Yellow Card scheme.

SWL agreement

Patients on JAK inhibitors may be switched to an alternative treatment option within the same treatment step in SWL pathways if the request to switch is in response to the MHRA safety advice for one of the following reasons:

- age is 65 years or older
- current or past long-time smoker
- other risk factors for cardiovascular disease or malignancy
- risk factors for VTE other than those listed above

This does not apply to patients with primary or secondary treatment failure to JAK inhibitors. These patients should move to the next step in treatment pathways as per usual practice.

This should be recorded on Blueteq as follows:

1. Complete relevant initiation form for the new drug the patient is switching to
2. Depending on the options presented in the Blueteq form, select one of the following (wording may vary slightly in each Blueteq form):
    a. Previous approved drug had to be stopped due to a side effect / adverse event/side effect or new contraindication before efficacy could be assessed.
    b. Patient was responding to last approved drug, but this had to be stopped due to a side effect/adverse event/side effect or new contraindication.
3. Then add the reason for stopping the relevant JAK inhibitor in the drug history section of the Blueteq form i.e., select contraindication and then add the following reason: "Switching due to JAK inhibitor MHRA contraindication /caution i.e. ....."(specify the reason)

Document History

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