Clinical Guideline

Treatment Pathway for Ritlecitinib (Litfulo®) in patients 12 years and older with severe alopecia areata

Guideline Summary
This clinical guideline outlines the usage of ritlecitinib (Litfulo®) in patients 12 years and older with alopecia areata within Secondary/Tertiary Care.

Approval date: July 2025 **Review date: July 2027**
South East London Integrated Medicines Optimisation Committee (SEL IMOC). A partnership between NHS organisations in South East London Integrated Care System: NHS South East London (covering the boroughs of Bexley/Bromley/Greenwich/ Lambeth/Lewisham and Southwark) and GSTFT/KCH /SLaM/ Oxleas NHS Foundation Trusts and Lewisham & Greenwich NHS Trust

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1. Scope

This treatment pathway applies to patients 12 years or older with a diagnosis of severe alopecia areata (AA) who are eligible for treatment with ritlecitinib in secondary and tertiary care, in accordance with NICE CKS and NICE TA958[1].

This pathway does not cover usage of other pharmacological and non-pharmacological management of alopecia areata that is available including licensed but non-NICE approved treatment. Further guidance and information regarding this is available via NICE[2], the British association of Dermatology and the British hair and nail society.

2. Rationale

This treatment pathway provides an evidence-based approach for the drug management of alopecia areata with ritlecitinib, an oral janus kinase (JAK) 3 and tyrosine kinase expressed in hepatocellular carcinoma (TEC) inhibitor. **This pathway is applicable to healthcare professionals in secondary and tertiary care only.**

3. Principles

This treatment guideline is based on current available national guidance (NICE TA958 and supplementary guidance by the British Hair and Nail Society (BHNS), British Association of Dermatologists' (BAD) and Alopecia UK) published in July 2024[3].

Prescribers should follow any internal trust guidance on prescribing of ritlecitinib and cross reference the relevant Summary of Product Characteristics (SPC) to inform clinical decision making for individual patients[4].

4. Definitions

Severe alopecia areata disease (AA) – defined as patients presenting with an absolute severity of alopecia tool (SALT) score* of at least 50 *or* as per supplementary guidance[3], people with a diagnosis of moderate alopecia areata (absolute SALT score of 21-49) may have their severity rating increased to severe if one or more of the additional functional and/or psychological factors are present:

- negative impact on psychological functioning resulting from AA
- noticeable involvement of eyebrows or eyelashes
- inadequate response after at least 6 months of treatment (treatments include topical or intralesional steroids or oral steroids, etc.)
- diffuse (multifocal) positive hair pull test consistent with rapidly progressive AA.

***SALT score** – This is a measure of alopecia areata severity and is calculated by estimating the percentage of hair loss in each of the 4 areas of the scalp (vertex 40%, posterior 24%, right profile 18% and left profile 18%). An online scoring tool is available here: Salt Score calculation, a measured with the Severity of Alopecia (dermatopics.dk).

Dermatology Life Quality Index (DLQI) or Teenager Quality of Life Index (T-QoL) or **Children's Dermatology Life Quality Index (CDDLQI)** – a questionnaire to measure the health-related quality of life of adults, adolescents or children with skin disease. Patient should be counselled to replace "skin" with "hair" when interpreting the questions.

Patient Health Questionnaire-9 (PHQ-9) or **PHQ-9 modified for Adolescents (PHQ-A) –** a questionnaire to measure the severity of depression.

General Anxiety Disorder-7 (GAD-7) – a questionnaire to measure the severity of anxiety.

Treatment Responder - SALT score of 20 or less by week 36. Consideration given to terminal regrowth and improvement of the parameters discussed by the clinician and patient prior to commencing the treatment.

or in those with a baseline SALT score of 21-49 plus additional factors outlined in section 6, improvement of the parameters discussed by the clinician and patient prior to commencing the treatment.

Partial Treatment Responder (Terminal regrowth) – Hair regrowth has been noted on examination but an absolute SALT score of ≤20 is not achieved by week 36

Non-responder - No noted hair regrowth by week 36

5. Recommended disease severity assessments (carried out in secondary care)

5.1. Assessment of disease severity

5.1.1. SALT score using online tool

5.1.2. Dermatology Life Quality Index (DLQI) or Teenagers Quality of Life Index (TQoL) or Children and young people version (CDLQI)

Mental health patient-reported outcome measures (PROMs) including:

5.1.3. Patient Health Questionnaire-9 (PHQ-9) OR PHQ-9 modified for Adolescents (PHQ-A)

5.1.4. General Anxiety Disorder-7 (GAD-7)

6. Eligibility criteria for ritlecitinib therapy

6.1 Initiation

Ritlecitinib may be initiated in secondary/tertiary care dermatology clinics for patients with alopecia areata if ALL of the following criteria are met (This must be documented in the patient's medical records):

- Patient is 12 years or older
- Patient has a diagnosis of severe alopecia areata defined by
    - a SALT score of 50 or more – link to SALT online scoring tool: http://dermatopics.dk/salt-score/.
    - a SALT score of 21 – 49 AND one of more of the following additional functional and/or psychological factors are present:
        - negative impact on psychological functioning resulting from AA (Consider DLQI/
        - T-QoL/CDLQI or PROMs as per section 5. PROMs scores should never be interpreted in isolation, as they cannot be used to make a definitive mental health diagnosis.

Thus, a holistic appraisal, supported by appropriate measures as necessary, should be applied[3]).

- noticeable involvement of eyebrows or eyelashes
- inadequate response after at least 6 months of treatment (treatments include topical or intralesional steroids or oral steroids, etc.)
- diffuse (multifocal) positive hair pull test consistent with rapidly progressive AA.

6.2 Continuation criteria

There is no defined outcome measure required for continuation of ritlecitinib therapy although the BAD recommends that treatment discontinuation is considered if a SALT score of 20 or less is not achieved by week 36 of treatment[3].

For patients in whom treatment was undertaken with a baseline SALT score of 21-49 (with additional functional and/or psychological factors), continuation should depend on improvement of parameters discussed prior to treatment initiation[3]. Currently, assessing psychological outcomes is not a recommended measure of the effectiveness of treatment with ritlecitinib as there is insufficient evidence a) that it has an impact on patients' psychology and b) on the most appropriate tool to use. Additionally, there is poor correlation between psychological and objective AA severity outcome measures[3].

The risks and benefits of therapy should be reviewed on regular intervals.

Patients may wish on clinician advice to stop therapy temporarily and restart on disease flare. A SALT score should be remeasured at point of restarting but does not need to be more than 50.

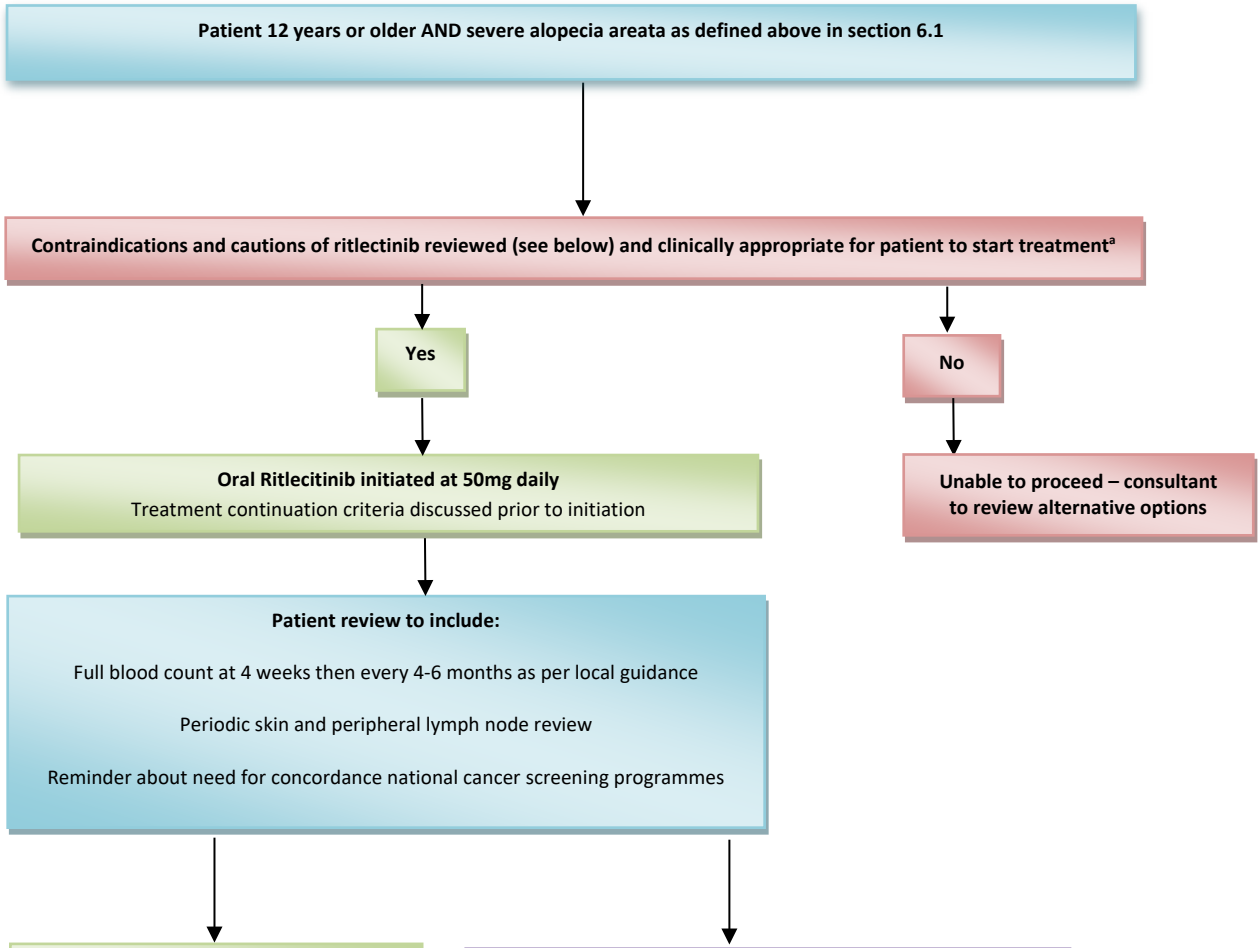
Treatment Responder - SALT score of 20 or less by week 36. Consideration given to terminal regrowth (see below) and improvement of the parameters discussed by the clinician and patient prior to commencing the treatment.

or in those with a baseline SALT score of 21-49 plus additional factors outlined in section 6.1, then continuation should depend on the improvement of the parameters discussed by the clinician and patient prior to commencing the treatment. Mental health PROMs scores do not need to be recorded for treatment continuation purposes, only for defining AA severity upon initiation.

Partial Treatment Responder (Terminal regrowth) - Regrowth has been noted on examination but an absolute SALT score of ≤20 is not achieved by week 36, consider extending treatment duration for a further 3 months. If at that extended point, an absolute SALT score of ≤20 is still not achieved, then treatment should be discontinued.

Non-responder - No noted regrowth by week 36, ritlecitinib should be stopped at this point. Review alternative options including psychological support.

7. Initiation of Ritlecitnib - Litfulo®



Interruption to therapy

Reasons for interruption of treatment may include haematological abnormalities, serious or opportunistic infections.

The risk of significant loss of regrown scalp hair after an interruption of less than six weeks is low. Longer extended interruption is associated with greater risk of significant hair loss[3].

[a]Contraindication to ritlecitinib

- Allergy to ritlecitinib, lactose or other excipients (see SPC[3] for full details)
- Active tuberculosis (including tuberculosis)
- Severe liver disease
- Pregnancy or breastfeeding
- Lymphocyte less than0.5 x 10^9/L or platelet count less than 100 x 10^9/L.

Caution for ritlecitinib prescription

- Age 65 years and over
- Increased risk of chronic or recurrent infection
- Previous untreated tuberculosis
- Significant smoking history
- Current or increased risk of malignancies except skin cancer
- End stage renal impairment or renal transplant recipient (ritlecitnib has not been studied in this cohort).
- Patients at risk of venous and arterial thromboembolism

Treatment Pathway for Ritlecitinib (Litfulo®) in patients 12 years and older with severe alopecia areata

8. Caution of ritlecitinib usage in line with other JAK inhibitors

It is not known whether selective JAK3 inhibition may be associated with adverse reactions of JAK inhibition predominantly involving JAK1 and JAK2. Long term safety evaluations are ongoing. The risks and benefits of ritlecitinib should be considered prior to treatment initiation. For full details refer to SPC of ritlecitinib[4].

It is noted that malignancies including non-melanoma skin cancer (NMSC) have been reported in patients receiving ritlecitinib. Periodic skin examination is recommended for patients who are at increased risk of skin cancer[4].

Events of venous and arterial thromboembolism, including major adverse cardiovascular events (MACE), deep venous thrombosis (DVT) and pulmonary embolism (PE) have been reported in patients receiving ritlecitinib[3].

Ritlecitinib should therefore be used cautiously in the following patient groups:

- Those aged 65 years or above
- Those at increased risk of MACE (including significant cardiovascular disease, diabetes, BMI of more than 30kg/m^2)
- Patients at risk of thromboembolism (previous venous thrombotic event (VTE), inherited coagulation disorder, active malignancy undergoing major surgery, immobilisation, use of combined hormonal contraception or replacement therapy). Discontinue use if suspected thrombotic event and re-evaluate therapy
- Those who smoke
- Those at increased risk of cancer

Cases of herpes virus reactivation (herpes zoster, herpes simplex), have been reported in clinical studies of JAK inhibition. For patients with a history of recurrent herpes simplex infection consider starting prophylactic anti-viral therapy prior to ritlecitinib therapy. Consider checking varicella serology. Patients with absent or low immunity to varicella can consider varicella vaccination (e.g. Shingrix® inactive recombinant vaccine if already on systemic immunosuppressant agent) although this may not be available via local NHS pathways (as per the Green Book Chapter 28a).

For further information refer to the Treatment pathway for Adults with Moderate to Severe Atopic Dermatitis for further safety information regarding JAK inhibitor usage including the MHRA safety alert[5,6].

9. Pre-treatment screen in children 12 or older, or adult patients

Refer to local and national guidance for full list of assessments needed pre-ritlecitinib therapy. The following should be completed by secondary/tertiary care provider pre-initiation.

Assessment	Further information and actions
Disease severity assessment	
SALT score, DLQI/ CDLQI, Mental Health PROMs where relevant (GAD-7, PHQ-9/ PHQ-A)	
Identification of cautions to therapy	
Thorough history, symptom enquiry, clinical examination (including enquiry regarding potential side effects e.g. • Age 65 years and over • history of haematological abnormalities • Increased risk of chronic or recurrent infection • Previous untreated tuberculosis • Significant smoking history/ significant cardiovascular disease risk factors • Current or increased risk of malignancies except skin cancer. Full skin check, assessment for lymphadenopathy • End stage renal impairment or renal transplant recipient (ritlecitnib has not been studied in this cohort). • Patients at risk of venous and arterial thromboembolism	Caution where identified
Consider risk factors for VTE	
- Previous VTE - Undergoing major surgery - Immobility - Heart failure, MI within previous 3 months, diabetes, uncontrolled hypertension - Oral hormonal replacement therapy or combined oral contraceptive - Inherited coagulation disorder - Active malignancy - BMI ≥30 kg/m2 - Smoker	JAKi should be used with caution when risk factors are present. Prescribing consultant should review (+/- anticoagulation team as appropriate).
Blood tests	
Full blood count	Do not start treatment if: Lymphocytes less than 0.5 x10^9 cells/L

	Platelets less than 0.5 x10^9 cells/L
Creatinine, electrolytes	No dose adjustment is required in patients with mild, moderate, or severe renal impairment. Ritlecitinib has not been studied in patients with end-stage renal disease (ESRD) and is therefore not recommended for use in these patients.
Liver function tests	No dose adjustment is required in patients with mild (Child Pugh A) or moderate (Child Pugh B) hepatic impairment. Ritlecitinib is contraindicated in patients with severe (Child Pugh C) hepatic impairment.
Lipid profile	Refer to primary care provider for management according to national or local clinical guidelines where appropriate (e.g. SEL Lipid Management Guidance)
Hepatitis B sAb/sAg/core Ab	Manage as per local hepatitis screening guidelines
Hepatitis C IgG Ab	Manage as per local hepatitis screening guidelines
HIV Ab	Review by referring consultant
Interferon-Gamma Release Assay for TB (IGRA/Tspot)	Do not start if positive; Refer to local infection/TB team for guidance
Radiology	
Chest x-ray	Review by referring consultant
Infection	
Establish any history of herpes zoster and/or herpes simplex infection and previous/current need for prophylaxis or vaccination. Consider varicella serology Consider risk factors for tuberculosis; sexual history; drug abuse; history of blood transfusions; any past or current chronic infection.	
Malignancy	
Ensure concordant with national cancer screening programmes; any past or current malignancy; gynaecological review if history of cervical dysplasia; regular review for skin cancer	

10. Ongoing monitoring of Ritlecitinib

Follow local protocols for monitoring of Ritlecitinib, including full blood count, renal and liver profile as well as clinical benefit (via SALT/DLQI scoring). Bloods are taken within secondary/tertiary care at suggested follow up appointments.

Ritlecitinib treatment has been associated with decreased in lymphocytes and platelets (see above) a full blood count should be taken approximately four weeks after initiation of ritlecitinib.

Assessment	Frequency	Action
Disease severity assessment		
SALT score Consider where appropriate improvement in additional functional and/or psychological factors. DLQI/T-Qol/CDLQI and mental health PROMs	At 3-6 monthly intervals to establish disease response (NICE time point to assess response = week 36)	See section 6.2 for more information Mental health PROMs scores do not need to be recorded for treatment continuation purposes but may be monitored as part of ongoing patient care.
Identification of cautions to therapy and/or development of therapy induced toxicity		
Thorough history, symptom enquiry, clinical examination	At 3-6-month intervals	Patients should be closely monitored for the development of signs and symptoms of infection during and after treatment with ritlecitinib. Interrupt or consider stopping therapy where clinically necessary. Monitor for changes in risk factors for VTE Periodic skin examination is recommended for patients who are at increased risk of skin cancer. This will be carried out at baseline and follow up appointments in secondary

		care, patients will be educated on self-surveillance and informed to seek advice where concerned.
Blood tests		
Full blood count	**At week 4 as per license** Then 3-6 monthly or as per local practice	**Discontinue treatment if platelet count is less than 50 x10^9 cells/L** **Hold treatment if lymphocyte count less than 0.5 x 10^9 cells/L (retest and restart when more than 0.5**)
Creatinine, electrolytes	3 – 6 monthly intervals	No dose adjustment is required in patients with mild, moderate, or severe renal impairment. Ritlecitinib has not been studied in patients with end-stage renal disease (ESRD) and is therefore not recommended for use in these patients.
Liver function tests	3 – 6 monthly intervals	If increases in ALT or AST are observed during routine patient management and drug-induced liver injury is suspected (e.g. ALT ≥2 x ULN) hold treatment and investigate.
Lipid profile	At 3-4 months Only monitor if abnormal at 3 – 4 months	Refer to primary care provider for management according to national or local clinical guidelines where appropriate (for example SEL Lipid Management Guidance)
Creatinine kinase	If patient reports muscle pain	Creatinine kinase > 3 ULN - Hold treatment and investigate
Hepatitis B sAb/sAg/ core Ab	Repeat if change in risk profile	Manage as per local hepatitis screening guidelines
Hepatitis C IgG Ab	Repeat if change in risk profile	Manage as per local hepatitis screening guidelines
HIV Ab	Repeat if change in risk profile	Review with referring consultant

11. Additional potential adverse effects

The most frequently reported adverse reactions are diarrhoea (9%), headache (9%), acne (6%), urticaria (5%), rash (4%), folliculitis (3%) and dizziness (2%)[4].

Treatment with ritlecitinib should be discontinued in case unexplained neurological symptoms occur[4].

If patients report muscle aches, consider measuring creatinine kinase. Hold treatment and investigate if creatinine kinase is > 3 ULN.

For further information on JAK inhibitor monitoring and side effects refer to the SPC for ritlecitinib[4] and the treatment pathway for Adults with Moderate to Severe Atopic Dermatitis[5]. Consider reporting suspected side effects to the MHRA via the yellow card scheme.

12. Interactions

Ritlecitinib is a moderate inhibitor of CYP3A and CYP1A2 therefore should be used in caution with these substrates (dose adjustment of the substrate may be required). For further information see SPC[4].

Ritlecitinib is not advised to be used alongside ciclosporin due to increased exposure to ciclosporin and increased risk of generalised infection.

13. Vaccinations (click for Department of Health Green Book)

GPs should update the patient's medical record to reflect that they are prescribed ritlecitinib by the hospital. Additionally, the patient should be flagged as being on immunosuppressive therapy, which requires vaccination according to Department of Health guidance.

Vaccination status should be reviewed and, where possible, updated before starting therapy, in line with the Department of Health guidance and the clinical risk category of 'immunosuppression.'

Inactivated vaccines are safe to administer alongside ritlecitinib therapy. Whenever possible, these vaccines should be given at least 2 weeks prior to starting treatment to ensure optimal immune responses.

Ensure the patient receives the following vaccines through primary care in line with the Department of Health and Social Care Green Book: the pneumococcal polysaccharide vaccine (PPV) every 5 years, the inactivated annual influenza vaccine, and the seasonal Covid-19 vaccine.

The risk of shingles (herpes zoster) is significantly higher in individuals who are severely immunosuppressed. According to the UK Green Book, this includes individuals aged 50 years or over who:

•Have been treated with a Janus Kinase (JAK) inhibitor within the past 3 months, or

•Are aged 50 years or over and are anticipating treatment with a JAK inhibitor.

Patients initiated on ritlecitinib will be counselled regarding the increased risk of shingles. Patients will be advised to contact their GP urgently if they develop signs or symptoms suggestive of shingles so that antiviral treatment (e.g. aciclovir) can be initiated promptly. The Dermatology

team should inform the patient's GP in writing about the initiation of ritlecitinib and highlight the need for urgent antiviral treatment should shingles occur.

Current management of patients starting JAK inhibitors does not routinely include the administration of varicella zoster virus vaccination prior to treatment in secondary care. Therefore, individuals starting ritlecitinib who are eligible for the shingles vaccine according to the Green Book should be advised to obtain the recombinant zoster vaccine (Shingrix®) via primary care and this will be documented in the letter to the GP.

If the patient has not previously been vaccinated, the Shingrix® course should be started as soon as possible in primary care.
Ideally, vaccination should be completed at least 14 days—and preferably 28 days—before starting immunosuppressive therapy, to allow optimal vaccine efficacy where timelines permit.

Shingrix® is administered in two doses, 8 weeks apart. If immunosuppressive therapy with ritlecitinib commences after the first Shingrix® dose has been given, the second dose can still be administered between 8 weeks and 6 months after the first dose.

Individuals who become eligible for Shingrix® while already receiving ritlecitinib are recommended to proceed with vaccination, as Shingrix® is a non-live vaccine. There is currently no data on the immunological response to Shingrix® in patients receiving ritlecitinib. Therefore, it should be recognised that these individuals may not achieve a full protective response to the vaccine. Patients should be counselled accordingly about this potential limitation and advised to remain vigilant for symptoms of shingles, even if vaccinated.

Those who are under 50 and not eligible for Shingrix within the NHS program may consider obtaining it privately. In cases where there is a significant risk of shingles, such as previous episodes, this should be discussed with virology for further advice when considering ritlecitinib therapy.

Do not give **live vaccines** to people taking ritlecitinib therapy. Generally, immunosuppressants can be started **4 weeks** after administration of a live or live attenuated vaccine. Stop immunosuppressants for at least **3 months** before giving live vaccines, unless otherwise directed by a specialist. Refer to the drug-specific SPC and Green Book (immunisation against infectious disease; Chapter 6) for further information.

Patients with absent or low immunity to varicella as determined by clinical history and/or varicella serology are at risk of primary varicella, which can be severe. The varicella vaccine (Varilrix® and Varivax®) is a **live vaccine** which is not routinely available on the NHS. Those who consider obtaining it privately will need to either interrupt existing immunosuppressant therapy or delay immunosuppressant therapy initiation, as advised above.

14. Method of medication supply

Subject to local arrangements patients may be offered a choice of method of supply. This may include a traditional homecare service or enhanced outpatient pharmacy service via outsourced outpatient pharmacies on main hospital sites. Where there is agreement with pharmaceutical companies, unbundling of homecare and direct procurement via outsourced pharmacies may result in a reduction in the drug acquisition cost.

If using a homecare service, ensure the patient is aware and has consented to their details being shared with the third-party homecare provider, and provide them with the details of the homecare service (trust specific agreement).

15. Extended Interval dosing (Off-label)

The recommended licensed dose of **ritlecitinib in adults and children age 12 and over is 50 mg orally once daily**. After discussion with the patient a Consultant may decide to extend the dosage interval, to minimise drug exposure in those with stable disease who have been on treatment for more than a year, as appropriate for the clinical situation. Please note this is outside of the recommendations of NICE TA958[1]. At present there are only anecdotal reports extended interval dosing, therefore this would be need to be discussed with the patient as off label use on a case by case basis. Outcomes for patients on extended interval dosing could be captured as part of KPI data to add to the literature and inform future practice.

16. Practice Points for Primary Care

16.1 Vaccinations

Refer to section 13 for full details.

16.2 Identification of patient on treatment

It is the GP's responsibility to update a person's medical record to state that they are receiving treatment with ritlecitinib as a medicine prescribed by the hospital.

16.3 Increased risk of infection (TB, herpes simplex and herpes zoster, skin and soft tissue)

GPs must be aware that patients taking ritlecitinib therapy are at an increased risk of infection, including upper and lower respiratory tract infections, herpes simplex, herpes zoster, cellulitis and urinary tract infections. If a patient taking ritlecitinib presents with infective signs and symptoms that are not responding to standard treatment, please contact the patient's specialist dermatology team for advice.

16.4 Events of venous and arterial thromboembolism, including MACE, have been reported in patients receiving ritlecitinib.

It is not known whether selective JAK3 inhibition may be associated with adverse reactions of JAK inhibition predominantly involving JAK1 and JAK2.

If clinical features of VTE occur such as a painful, swollen leg, chest pain or shortness of breath, the patient should be evaluated promptly, followed by appropriate treatment. If diagnosed with a VTE, the patient's specialist dermatology team should be contacted as soon as possible in order to discontinue their JAK inhibitor therapy and consider alternative treatment options.

16.5 Pregnancy and lactation

Ritlecitinib therapy is contraindicated in pregnancy and breastfeeding. Women of childbearing potential should be advised to use effective contraception during and for at least one month after taking ritlecitinib. When considering treatment with ritlecitinib, women of childbearing potential should discuss conception plans with the consultant supervising their care. Available pharmacodynamic/toxicological data in animals have shown excretion of ritlecitinib in milk. A risk to newborns/infants cannot be excluded therefore ritlecitinib is contraindicated during breast-feeding

16.6 Surgery (elective)

A break in treatment in the peri-operative period should be considered on an individual patient basis. If a patient is due to have elective surgery, advise them to contact their dermatologist/clinical nurse specialist for advice on when/if to stop therapy prior to surgery. Ritlecitinib has a short half-life of 1.3-2.3 hours. Ritlecitinib should be used with caution in patients with known risk factors for thromboembolism such as patients undergoing major surgery and immobilisation.

17 Monitoring adherence with the guideline

Adherence to this pathway will be reviewed using the SEL Dermatology Pathways, Outcomes and Monitoring Framework which includes Key Performance Indicators agreed by South East London Integrated Medicine Optimisation Committee (SEL IMOC). The Dermatology and Pharmacy Departments may undertake separate clinical audits as part of their annual clinical audit plan.

17 Supporting documents

Patient information leaflet for alopecia areata updated April 2024. Accessible online: British Association of Dermatologists (bad.org.uk)

Patient information leaflet for ritlecitinib updated October 2024. Accessible online: British Association of Dermatologists

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7. Department of Health Immunisation against Infectious disease –The Green Book https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book#the-green-book

Consultation Process

SEL Dermatology Pathway Group: Finalised in November 2024
SEL IMOC: December 2024