Clinical Protocol

Treatment Pathway for Adults with Moderate to Severe Atopic Dermatitis

Guideline Summary

This clinical guideline outlines the treatment pathway for adult patients with moderate to severe atopic dermatitis

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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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PART 1 – Atopic Dermatitis Specialist Treatment Pathway

1. Scope

This treatment pathway applies to adult patients with a diagnosis of moderate to severe atopic dermatitis who are eligible for treatment with systemic therapy, including standard immunosuppressants and targeted immunomodulatory medications in secondary or tertiary care, in accordance with NICE guidance.

2. Rationale

This treatment pathway provides an evidence-based approach for the treatment of moderate to severe atopic dermatitis that maximises cost-effectiveness and clinical outcomes. This pathway is applicable to secondary and tertiary care only and is for use by all healthcare professionals involved in patient care.

Currently this pathway covers the use of NICE-approved **targeted immunomodulatory medications**. This includes oral **janus kinase (JAK) inhibitors** (abrocitinib [Cibinqo®], baricitinib [Olumiant®] and upadacitinib [Rinvoq®]) and **biologic agents** (dupilumab [Dupixent®] or tralokinumab [Adtralza®] or lebrikizumab [Ebglyss®] or nemolizumab [Nemluvio®]), which are to be prescribed by the secondary or tertiary care team.

Refer to South East London Dermatology Guidelines for Primary Care for the management of atopic dermatitis in primary care with topical therapies.

When prescribing emollients to treat dermatological conditions, refer to the South East London Emollient Guideline.

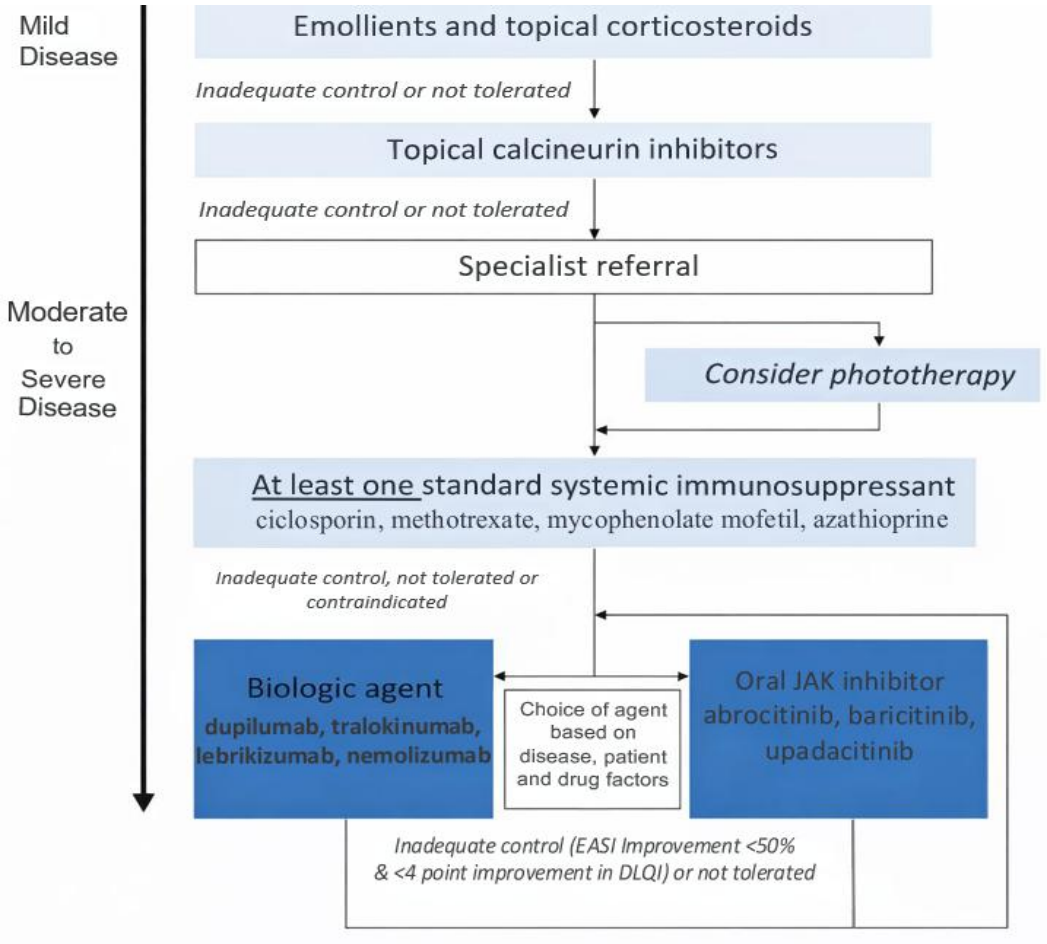
3. Principles

This treatment pathway is based on current national guidance (NICE technology appraisals, TA534, TA681, TA814, TA986 and TA1077); source evidence of efficacy, safety and cost effectiveness (see references); and locally approved guidance on the use of both oral JAK inhibitors and biologics in adults with atopic dermatitis, which draws on expert opinion from Medical Dermatology multi-disciplinary teams and the relevant Summary of Product Characteristic (SPCs).

This pathway is subject to change as guidance is updated, new agents to treat atopic dermatitis emerge and costs change. This guideline will therefore be under active review in light of the above. This document is not designed to replace the above guidance; URLs are embedded within the document where relevant. This pathway assumes that prescribers cross-reference

the relevant SPC to inform clinical decision making for individual patients (www.medicines.org.uk/emc).

4. Pathway



Patients in South East London should be referred to specialist dermatology services via the appropriate Single Point of Access pathway. This may mean triage to secondary care services via a Community Dermatology triage process

5. Definitions

Moderate to severe disease – disease that cannot be controlled with topical therapy; has a significant impact on physical, psychological or social wellbeing; and is either extensive, or localised but associated with significant functional impairment and/or high levels of distress (for example severe hand and foot eczema, or head and neck eczema).

Criteria for stopping therapy– failure to achieve at least a 50% reduction in the Eczema Area and Severity Index score (EASI>50) and at least a 4-point reduction in the Dermatology Life Quality Index (DLQI) at 16 weeks from when treatment started.

6. Standard systemic treatments

Standard systemic therapies traditionally include ciclosporin, methotrexate, azathioprine and mycophenolate mofetil. Ciclosporin or methotrexate are now considered first line systemic agents for moderate to severe atopic dermatitis. Where these drugs are contraindicated or cannot be used, consider using mycophenolate mofetil, although evidence for efficacy in atopic dermatitis is very limited. Consider reserving azathioprine for patients where other treatments, including targeted therapies, cannot be used or are contraindicated due to the risk of nonmelanoma skin cancer and the possible, unquantified risk of lymphoma with long term azathioprine use.

Such agents should be trialled for at least three months at a clinically appropriate, therapeutic dose as follows:

Licensed treatments

- Ciclosporin (licensed for short-term use only, up to 1 year maximum): 2.5mg/kg/day in divided doses increased to 5mg/kg/day, depending on tolerability and response.

Unlicensed treatments:

- Methotrexate: In healthy adults, start at 15mg once a week, titrating to a maximum dose of 25mg once a week, depending on tolerability and response. Consider starting with a lower dose in those with renal impairment and therefore at risk of toxicity (see BAD Guideline for advice)
- Mycophenolate mofetil: 1g/day in divided doses increased to a maximum of 3g/day depending on tolerability and response
- Azathioprine: 1-3mg/kg/day, depending on thiopurine methyltransferase (TPMT) range, tolerability and response (see BAD Guideline for advice)

Patients should be counselled prior to the initiation of the above medications if they are being prescribed outside of the terms of their license (‘off label’).

Strategies for maximising the use of standard systemic treatments:

If only a partial response is observed, ensure the dose of the systemic treatment is optimised:

- Allow an 8-week interval following a dose change before assessment of response.
- Consider subcutaneous methotrexate to mitigate gastrointestinal adverse effects, or where there are concerns about poor oral absorption; supervised subcutaneous methotrexate may be useful if adherence is limiting effectiveness.

7. Eligibility criteria for targeted immunomodulators

NICE-approved targeted immunomodulators for moderate to severe atopic dermatitis include small molecule/JAK inhibitors (abrocitinib [Cibinqo®], baricitinib [Olumiant®] and upadacitinib [Rinvoq®]) and biologic agents (dupilumab [Dupixent®] or tralokinumab [Adtralza®]) or lebrikizumab [Ebglyss®]) or nemolizumab [Nemluvio®]).

These agents are all recommended as an option for treating moderate to severe atopic dermatitis in adults *and* the disease has not responded to at least 1 other systemic therapy, such as, ciclosporin, methotrexate, azathioprine and mycophenolate mofetil, or if these treatments are contraindicated or not tolerated.

All patients who fulfil the above eligibility criteria for a targeted immunomodulator should be offered these treatments in line with NICE guidance.

All patients receiving such treatments should also be under the care of a consultant dermatologist competent in prescribing these medications.

8. Choice of agent

When selecting which agent to use, tailor the choice to the needs of the person. A more detailed discussion of considerations prior to targeted therapy is considered in Part 2 of this document. Consider the following factors:

Disease factors:

- The goal of therapy (for example, likelihood of 'clear' or 'nearly clear' skin or rapid disease control)
- Disease phenotype and pattern of activity (e.g. prominent head and neck involvement, HSV infections)
- Disease severity and impact
- The outcomes of previous treatments for atopic dermatitis

Patient factors:

- Person's age
- Past or current comorbid conditions (e.g. atopic asthma, atopic eye disease, renal impairment, high VTE risk, cancer)
- Conception plans
- The person's views and stated preference on administration route
- Likelihood of adherence to treatment

Drug factors (see also Decision Aid):

- Side effects
- Drug interactions
- Route of administration
- Acquisition cost
- Dosage frequency

9. Assessing disease response

In line with NICE technology appraisals, targeted immunomodulators should be stopped at **week 16** of treatment if the atopic dermatitis has not responded adequately. Adequate response has been defined as a reduction of at least:

- 50% in the Eczema Area and Severity Index score (EASI 50) from when treatment started, and
- 4 points in the Dermatology Life Quality Index (DLQI) from when treatment started.

10. Sequential use of targeted immunomodulators

If a patient fails to adequately respond (primary or secondary failure), is intolerant or becomes contraindicated to a specialist targeted medication, treatment may need to be discontinued. When choosing the next-line therapy consider:

- Is systemic therapy still required?
- The reason for switching therapy and if that influences the choice of next agent.
- The disease, patient and drug factors that guided the original choice of agent (see Section 9).
- If a standard systemic agent may be appropriate.
- Advice about modifiable factors that may have contributed to poor response (e.g. poor adherence).
- Optimising adjunctive therapy (e.g. topical corticosteroids or calcineurin inhibitors).
- If a specialist multi-disciplinary review meeting*, including a consultant with extensive expertise in use of targeted immunomodulators for atopic dermatitis, would help decide the management plan.

*If virtual review/discussion of the patient for advice and guidance is appropriate, this should be made explicit in the referral to the specialist centre

11. Reducing risk of VZV reactivation with systemic immunomodulation

The risk of shingles (herpes zoster) is significantly higher in individuals who are severely immunosuppressed**. From September 2025, Shingrix® should be offered to all severely immunosuppressed individuals aged 18 years and over** (with no upper age limit). Previously this was offered to immunosuppressed individuals aged 50 years and over. Eligible individuals should be offered two doses of Shingrix®. For this cohort the second dose should be given 8 weeks to 6 months after the first dose. Severely immunosuppressed

individuals represent the highest priority for vaccination given their risk of severe disease. **Individuals who should be offered Shingrix® include those who are on or starting an immunomodulator such as a biologic, JAK inhibitor or dose dependant standard systemic immunosuppression** (see Box 1 within the Green Book chapter for more details).

Patients who are at even higher risk of developing shingles include those who are age 65 or older when starting immunomodulatory therapy, those who are taking a higher dose of immunomodulatory drug (e.g. for JAK inhibitors, abrocitinib 200mg vs 100mg orally per day) or those who have had shingles before (especially if herpes zoster opthalmicus). If there is any doubt, individual patients should be discussed with their specialist.

Patients initiated on one of these therapies 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 Specialist team should inform the patient's GP in writing about the initiation of the treatment and highlight the need for urgent antiviral treatment should shingles occur.

Individuals 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 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 on immunosuppressive therapy are recommended to proceed with vaccination, as Shingrix® is a non-live vaccine. 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. Refer to local Trust guidance where appropriate.

PART 2 – Practical Prescribing Information for Targeted Immunomodulators

This section provides practical prescribing information for clinical staff on the use of targeted immunomodulators in adults with moderate to severe atopic dermatitis. This covers the use of biologic agents (dupilumab, tralokinumab, lebrikizumab and nemolizumab) and JAK inhibitors (abrocitinib, baricitinib and upadacitinib).

1. Considerations prior to starting therapy

Counselling the patient:

All patients receiving these treatments should be under the care of a consultant competent in the use of targeted immunomodulators in adults with atopic dermatitis.

Provide information on the benefits and potential harms of targeted therapy, including the relevant drug-specific information. Support the discussion with written information.

Explain to the patient that some of the risks are uncertain and/or unknown given they are new, and experience in real world practice is limited.

Explain the care pathway and long-term monitoring requirements (Appendix 1).

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.

2. Posology of targeted immunomodulators

2.1 Biologic therapy

Intervention	Recommended dosing schedule for adults according to license	Pharmaceutical form
Dupilumab (Dupixent▼)	Initial dose of 600 mg, followed by 300 mg given every other week administered by subcutaneous injection.	300 mg pre-filled pen 300 mg pre-filled syringe

Tralokinumab (Adtralza▼)	Initial dose of 600 mg, followed by 300 mg given every other week administered by subcutaneous injection. At prescriber's discretion, every fourth week dosing may be considered for patients who achieve clear or almost clear skin after 16 weeks of treatment.	300 mg pre-filled pen 150 mg pre-filled syringe
Lebrikizumab (Ebglyss▼)	Initial dose of 500 mg via subcutaneous injection at week 0 and 2, followed by 250 mg given every two weeks up to week 16 then maintenance 250 mg every four weeks thereafter. If partial response at week 16 consider continuing 250 mg every two weeks from week 16 to week 24.	250 mg pre-filled pen 250 mg pre-filled syringe
Nemolizumab (Nemluvio▼)	Initial dose of 60 mg via subcutaneous injection, followed by 30 mg given every four weeks up to week 16. After 16 weeks of treatment, for patients who achieve clinical response, the recommended maintenance dose is 30 mg every 8 weeks	30 mg pre-filled pen

2.2 JAK inhibitor therapy

Intervention	Recommended dosing schedule for adults according to license	Pharmaceutical form
Abrocitinib (Cibinqo▼)	100 mg or 200 mg orally once daily* <u>A dose of 100 mg once daily is recommended in those:</u> - with a creatinine clearance between 30-60ml/min - who have risk factors for developing an adverse reaction to abrocitinib or those who are less likely to tolerate the adverse reactions - established on treatment with 200mg once daily dosing with good disease control - aged ≥ 65 years (only when there are no suitable alternative agents) In patients with severe renal impairment (creatinine clearance < 30ml/min) a starting dose of 50mg once daily is recommended. The maximum daily dose is 100mg once daily.	200 mg tablets 100 mg tablets 50 mg tablets

Baricitinib (Olumiant)	2mg or 4mg orally once daily* <u>A dose of 2 mg once daily is recommended in those:</u> - with a creatinine clearance between 30-60 ml/min - on concomitant OAT3 inhibiting drugs - established on treatment with 4mg once daily dosing with good disease control <u>A dose of 2mg once daily can be used with caution in patients:</u> - with a history of chronic or recurrent infection - intolerant of dose of 4mg once daily - aged ≥ 65 years (only when there are no suitable alternative agents)	4 mg tablets 2 mg tablets
Upadacitinib (Rinvoq▼)	15 mg or 30 mg orally once daily* <u>A dose of 15 mg once daily is recommended in those:</u> - established on treatment with 30mg once daily dosing with good disease control - aged ≥ 65 years (only when there are no suitable alternative agents)	30 mg prolonged release tablets 15 mg prolonged release tablets

**for most patients, particularly those with severe disease, the higher dose is the recommended starting dose.*

<u>Oral JAKi and drug-drug interactions:</u>

Abrocitinib is metabolised by the enzymes CYP2C19, CYP2C9, CYP3A4, CYP 2B6 and is a substrate for the renal tubule organic anion transporter 3 (OAT3). Abrocitinib itself is an inhibitor of P glycoprotein (P-gp) and CYP2C19. Baricitinib is a substrate for OAT3. Upadacitinib is metabolised by CYP3A4.Therefore, when initiating oral JAKi therapy refer to the relevant SPC and/or BNF to identify any potentially relevant drug-drug interactions.

3. Summary recommendations for baseline assessment and monitoring of Biologic Therapy

3.1 Biologic therapy

Assessment	Baseline	Monitoring	Action
Disease severity assessment: EASI, DLQI, POEM, Physician's and Patient's Global Assessments	Yes	At 4 months to establish disease response (NICE time point; week 16) Then 6 – 12 monthly thereafter	If at week 16: <50% response in EASI and <4-point improvement in DLQI – discontinue treatment
Identification of cautions to therapy and/or development of therapy induced toxicity: - History and symptom enquiry - Clinical examination: to include enquiry regarding: - potential side effects (e.g. eye and musculoskeletal symptoms) - full skin check - assess for lymphadenopathy	Yes	Where appropriate; at 4 months then 6 – 12 monthly thereafter Routine clinical examination is not required in the absence of any risk factors/new symptoms	Ophthalmology review prior to initiation if significant/severe ophthalmic disease that may be worsened by biologic therapy
Infection: History and symptom enquiry - Establish any history of herpes simplex infection and previous/current need for prophylaxis. - Consider history of helminth infections or foreign travel. - Consider risk factors for: tuberculosis; sexual history; drug abuse; history of blood transfusions; any past or current chronic infection.	Yes	If clinically indicated every 6-12 months	
Lung Function: Spirometry, Fractional exhaled nitric oxide (FeNO). Consider in patients with severe or unstable asthma (via the patient's respiratory team)	If clinically indicated	If clinically indicated	Refer to patient's respiratory team
Virology: Hepatitis B (surface antigen sAg and core antibody cAb) Hepatitis C (IgGAb) HIV (Ab)	Yes	Not routinely. Consider repeat if change in risk profile as appropriate.	Manage as per local hepatitis screening guidelines
Full blood count	Yes	No routine blood monitoring required. Consider specific tests on an individual basis where appropriate (e.g. if screening bloods demonstrate an abnormality or concerns regarding co-morbidity)	Note lymphopaenia can associate with AD, refer to local Trust guidance where appropriate
Creatinine, electrolytes	Yes		When abnormal, investigate as clinically indicated
Liver function tests	Yes		When abnormal, investigate as clinically indicated

4. Summary recommendations on baseline assessment and monitoring for JAKi Therapy

4.1 JAKi therapy

Assessment	Baseline	Monitoring	Action
Disease severity assessment: EASI, DLQI, POEM, Physician's and Patient's Global Assessments	Yes	At 4 months to establish disease response (NICE time point; week 16) Then 6 – 12 monthly thereafter	If at week 16: <50% response in EASI and <4-point improvement in DLQI – discontinue treatment
Identification of cautions to therapy and/or development of therapy induced toxicity - History and symptom enquiry - Clinical examination: to include enquiry regarding: - potential side effects (e.g. history of haematological abnormalities, significant cardiovascular disease, significant cardiovascular disease risk factors, VTE risk, diverticular disease, cancer - full skin check - assess for lymphadenopathy	Yes	At 4 months then 6 – 12 monthly thereafter where appropriate Routine clinical examination is not required in the absence of any risk factors/new symptoms	Consider low dose where caution identified
Consider VTE risk factors - 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	Yes	At 4 months then 6 – 12 monthly thereafter where appropriate	Use JAKi with caution when risk factors are present. Prescribing consultant should review (+/- anticoagulation team as appropriate).
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	Yes	If clinically indicated every 6-12 months	Refer to local Trust guidance where appropriate
Malignancy: - Past or current malignancy - Gynaecological review if history of cervical dysplasia - Regular skin cancer review	Yes	If clinically indicated every 6-12 months	Ensure concordant with national cancer screening programmes

Assessment	Baseline	Monitoring	Action
Virology: Hepatitis B (surface antigen sAg and core antibody cAb) Hepatitis C (IgG) HIV (Ab)	Yes	Not routinely. Consider repeat if change in risk profile as appropriate.	Manage as per local hepatitis screening guidelines. Review with referring consultant
Interferon-Gamma Release Assay for TB (IGRA/Tspot)	Yes		Do not start if positive; Refer to local infection/TB team for guidance
Chest x-ray	Yes		Review by referring consultant**.** Refer to local infection/TB team for guidance where relevant.
Full blood count	Yes*	At week 4 and 4 months then 4 – 6 monthly thereafter Repeat 4 weeks after an increase in dose	*__Do not start treatment if:__ Neutrophils < 1.0 x10^9 cells/L Lymphocytes < 0.5 x10^9 cells/L Haemoglobin <80 g/L
			Monitoring: • **Neutrophils <1.0 x10^9 cells/L** Hold treatment, repeat bloods in 1 week. If on repeat, neutrophils are: - **>1 x10^9** cells/L – restart treatment at same dose - **<1 x10^9** cells/L – hold treatment and consider repeat weekly monitoring until neutrophils **>1 x10^9** cells/L • **Lymphocytes < 0.5 x 10^9 cells/L** Hold treatment, repeat bloods in 1 week. if: - **>0.5 x10^9** cells/L – restart treatment at same dose - **<0.5 x10^9** cells/L – hold treatment and consider repeat weekly monitoring until lymphocytes **>0.5 x10^9** cells/L • **Haemoglobin <8.0g/dL or decrease by >2g/dL** - Confirmed by repeat testing. Dosing should be interrupted until haemoglobin values have normalised • **Platelets <50 x 10^9 /L** Hold treatment, repeat bloods in 1 week, if: - **>50 x10^9** /L – restart treatment at same dose - **<50 x10^9** /L – hold treatment and consider repeat weekly monitoring until platelets **>50 x10^9** /L
			Note lymphopaenia can associate with AD, refer to local Trust guidance where appropriate

Assessment	Baseline	Monitoring	Action
Creatinine, electrolytes	Yes	At week 4 and 4 months then 4 – 6 monthly thereafter Repeat 4 weeks after an increase in dose	Refer to drug-specific SPC if: eGFR < 60ml/min When abnormal, investigate as clinically indicated
Liver function tests	Yes*	At week 4 and 4 months then 4 – 6 monthly thereafter Repeat 4 weeks after an increase in dose	* Do not start if severe liver impairment (Child Pugh C 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	Yes	At 4 months Only monitor if abnormal at 3 – 4 months	Manage dyslipidaemia as per standard practice Refer to primary care provider for management according to national or local clinical guidelines where appropriate (for example SEL Lipid Management Guidance)
Creatinine kinase	Yes	If patient reports muscle pain	When abnormal, investigate as clinically indicate Creatinine kinase > 3 ULN - Consider holding treatment and investigating where appropriate

When starting a patient on a targeted immunomodulator for atopic dermatitis, consider if the patient may be eligible to participate in clinical research, such as in local and/or national studies, including pharmacovigilance registries.

5. Transitioning from other systemic treatment

Co-administration of biologic or JAKi therapy with other immunosuppressants has not been studied in atopic dermatitis. Therefore combination therapy is not routinely recommended and is outside the license of these medications in adult patients with atopic dermatitis. Note, baricitinib and upadacitinib are licensed to be used in combination with methotrexate for the treatment of arthritis.

When switching between systemic immunosuppression, consider if a washout period is required before commencing biologic or JAKi therapy (Appendix 2).

6. Reported side effects

Refer to the medication SPCs for up-to-date information regarding reported adverse reactions. Relevant potential adverse reactions should be discussed with the patient prior to starting treatment.

Consider reporting suspected side effects to the MHRA via the Yellow card scheme.

7. Practical prescribing information specific to biologic therapy

7.1 Biological therapy and ocular side effects

Ocular symptoms such as blepharitis, conjunctivitis and eye pruritus are reported as a very common side effect of dupilumab therapy and common side effects of tralokinumab and lebrikizumab therapy. There is currently no head to head comparative trials to indicate the relative risk of ocular surface disease between dupilumab, tralokinumab and lebrikizumab. However indirect comparisons suggest the incidence is lower with tralokinumab in comparison to dupilumab and lebrikizumab. Drugs targeting the IL-31 pathway (such as nemolizumab) are not currently associated with ocular surface disease and therefore the SPC does not have these listed as recognised adverse effects.

There is insufficient evidence to recommend prophylactic use of ocular lubricants or olopatadine eye drops for patients with no current or pre-existing corneal or conjunctival eye disease prior to commencement of dupilumab, tralokinumab and lebrikizumab therapy. For patients with current or past corneal or conjunctival eye disease, ocular lubricants or olopatadine eye drops may be required, **please refer to figure 1 for recommended management**. For patients with a significant or severe pre-existing ophthalmic condition (e.g. keratoconus or previous corneal grafts/transplant), consider Ophthalmology review prior to starting a biologic to ensure optimised eye care. For further information and treatment options refer to the British Association of Dermatologist guideline for Dupilumab-related ocular surface disorders; the guidance reported here will be appropriate for management of ocular surface disease associated with these targeted IL-13 therapies; dupilumab, tralokinumab and lebrikizumab.

Patients who develop conjunctivitis that does not resolve following standard treatment (see figure 1 for details) or those who present with severe symptoms (significant conjunctival mucus, severe itch/irritation/watering, worsening conjunctival redness, pain/photophobia and loss of vision) should undergo urgent ophthalmological examination to exclude infective causes or other potential complications. Consider using template letter if a patient requires urgent referral for acute ophthalmological assessment at local Eye Casualty/Ophthalmology service (Appendix 3).

SEL Ocular Surface Disease Management Pathway for Patients on Dupilumab, Tralokinumab and Lebrikizumab

Use in conjunction with the British Association of Dermatologist guideline for Dupilumab-related ocular surface disorders

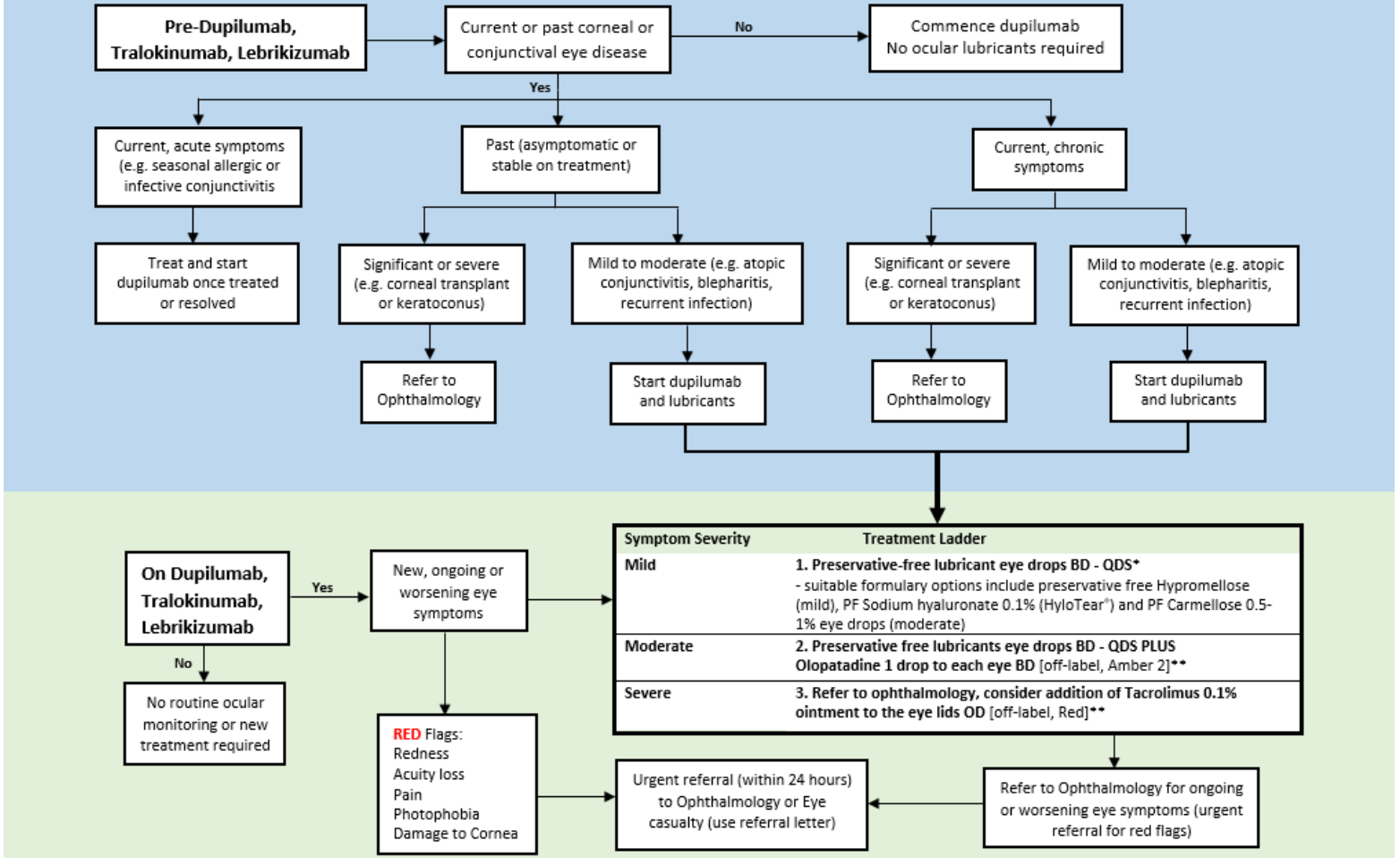


Figure 1: **Management of ocular surface disease disorders related to dupilumab, tralokinumab and lebrikizumab therapy, adapted from figu re 1 of the BAD guideline**
*For full list of preservative free ocular lubricant options refer to Table 2: Ocular lubricants of the British Association of Dermatologist guideline for Dupilumab-related ocular surface disorders
**Refer to Southeast London medicine formulary for off label indication of ocular olopatadine and tacrolimus

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7.2 Biologic therapy and musculoskeletal side effects

Musculoskeletal symptoms are reported as an uncommon side effect of dupilumab therapy (incidence unknown), including arthralgia and joint stiffness. This can be due to inflammatory synovitis and/or enthesitis, with symptoms worse on wakening and lasting more than 30 minutes.

Patients who develop significant musculoskeletal symptoms should undergo rheumatological assessment. Consider urgent referral to a local rheumatology service. The decision to continue dupilumab therapy should be considered on a case-by-case basis.

It is not known if patients on tralokinumab, lebrikizumab and nemolizumab experience musculoskeletal symptoms.

7.3 Biologic therapy and infection risk recommendations

Patients on biologic interventions should be monitored for signs and symptoms of infection throughout treatment.

Consider prophylactic anti-viral therapy in patients with a history of recurrent Herpes simplex prior to commencement of a biologic. Consider checking varicella serology prior to biologic therapy. Patients with absent or low immunity to varicella can consider varicella vaccination although this may not be available via local NHS pathways (as per the Green Book Chapter 28a).

Check travel history prior to initiation of biologic therapy and enquire about prolonged travel in areas endemic for parasitic infections, particularly **helminths**. Investigate as warranted by history, e.g. strongyloides serology, schistosomiasis serology and stool sample for 'ova, cysts & parasites'. If concern, discuss risk assessment on a case-by-case basis with local Infectious Diseases team and, if indicated, treat prior to initiation of biologic therapy. **Note eosinophilia may not be a good marker for helminth infection in this setting**.

If patients become infected with helminth while receiving biologic treatment and do not respond to anti-helminth treatment, treatment with dupilumab, tralokinumab, lebrikizumab should be discontinued until infection resolves. Discuss with local Infectious Diseases team. Nemolizumab does not have any precautions related to helminth infections and is not known to increase the risk.

7.4 Biologic therapy and malignancy risk recommendations

All patients should be fully assessed prior to, and during treatment with biologic therapy with respect to their past or current history of malignancy and/or any future risk of malignancy; the risks and benefits of biologic therapy should be considered in this context.

All patients should be encouraged to participate in national cancer screening programmes appropriate for their age and gender.

Biologic therapy should, whenever possible, be avoided in patients with a current or recent history of malignancy unless the malignancy has been diagnosed and treated more than 5 years previously and/or where the likelihood of cure is high (this includes adequately treated nonmelanoma skin cancer).

Patients who have a more recent history of malignancy should be discussed on a case-by-case basis within the specialist eczema service and with the relevant oncologist, to consider (unknown) risks of biologic therapy in the context of alternative available treatments.

Consider gynaecological review for patients with a history of cervical dysplasia.

Regular comprehensive dermatological assessment for skin cancer is recommended before and at regular intervals during therapy, especially in those patients at increased risk of skin cancer at baseline.

7.5 Biologic therapy with co-morbid asthma

Dupilumab is licensed and a NICE-approved treatment in adults and adolescents ≥12 years as add-on maintenance treatment for severe asthma with type 2 inflammation. **When a patient requires systemic therapy for both asthma and eczema, dupilumab should be considered as first-line treatment.**

Tralokinumab and lebrikizumab have not been shown to be of clear benefit in the treatment of asthma and are not licensed for this indication. Nemolizumab is not licensed for the treatment of asthma and is cautioned in patients with uncontrolled asthma due to absence of clinical data in this population

Important safety information on the discontinuation of dupilumab:

Ensure that the patient's GP and adult asthma service is informed when a patient with severe or unstable co-morbid asthma is commenced on dupilumab, so that a review of the patient may be arranged. Hypereosinophilia was identified in a small number of cases in the phase 3 asthma trials of dupilumab.

A fatal asthma exacerbation occurred in a patient following cessation of dupilumab treatment in the phase 3 atopic dermatitis programme. This was due to the patient stopping their regular maintenance inhaled corticosteroid (ICS) having improved on dupilumab. **For all patients with co-morbid asthma, they should be made aware that their asthma may become more severe at the time of discontinuation of dupilumab. For patients with co-morbid severe or unstable asthma, the asthma service should be informed at the time of discontinuation of dupilumab to arrange additional monitoring within the asthma service.**

7.6 Use of biologic therapy in women planning pregnancy or who are pregnant

Advise women of childbearing potential, who are starting biologic therapy for atopic dermatitis, to use effective contraception and to discuss conception plans with the consultant supervising their care. There are no known interactions between biologic therapies and contraceptive methods.

For women planning conception or who are pregnant, provide information about what is known about the effects of biologic therapy, including:

- there are very limited data on the use of biologics targeting relevant pathways in AD (e.g. IL4/13/31) in pregnant women, which is limited to case reports and a small number of pregnancies in phase 2/3 trials for atopic dermatitis and asthma.
- the available data are too limited and inadequately controlled to comment on the safety of biologics in pregnancy.
- that maternal IgG, and therefore monoclonal antibodies such as dupilumab/ tralokinumab/ lebrikizumab/ nemolizumab, are actively transferred to the developing foetus during the second and third trimester and that the impact of this on neonatal development and risk of infection has not been adequately studied.
- the SPCs for dupilumab, tralokinumab, lebrikizumab and nemolizumab state that 'animal studies do not indicate direct or indirect harmful effects with respect to reproductive toxicity.' Use biologics during pregnancy only if the potential benefit justifies the potential risk to the foetus.
- despite the lack of data regarding biologics, they may be a more appropriate therapy for a woman of childbearing age/ planning pregnancy, since certain standard systemic therapies (methotrexate and mycophenolate mofetil) and oral JAKi are known teratogens.
- if there is a decision to stop treatment, the washout period should be considered to be 12 weeks for dupilumab, 14 weeks for nemolizumab, 16 weeks for tralokinumab and 18 weeks for lebrikizumab.
- that live vaccines must be avoided for the first 6 months of life of infants born to mothers taking biologic therapy beyond 16 weeks' gestation
- relevant patient information resources (SPC).

Discuss the risks and benefits of using biologic therapy in women who are planning conception or who are pregnant. Offer advice on a case-by-case basis by taking into account the woman's views and:

- the available evidence (see above)
- her current disease status
- the course of atopic dermatitis and the fetal outcome during any prior pregnancies

- the risk of severe or unstable atopic dermatitis without biologic therapy
- the importance of controlling severe or unstable atopic dermatitis to maintain maternal health.
- her physical, psychological and social functioning without biologic therapy
- the options for alternative treatment strategies in the event of disease flare

If the decision to use biologic therapy during conception or pregnancy has been made:

- consider stopping biologic therapy in the second/third trimester (e.g. by week 28) to minimize fetal exposure and limit potential risk to neonate, taking into account individual biologics' pharmacokinetics and transfer across the placenta.
- consider using either ciclosporin or prednisolone as first-line options when it is necessary to start a systemic therapy during the second or third trimester.
- that live vaccines must be avoided for the first 6 months of life of infants born to mothers taking biologic therapy beyond 16 weeks' gestation

Consider consultation and information sharing across specialities, including with an obstetrician who has expertise in caring for pregnant women with medical problems. Referrals, including unplanned pregnancies on biologic treatment, should be made to local/regional obstetric medicine service.

Collect pregnancy outcome data for safety registries, for example the UK Teratology Information Service (UKTIS; www.uktis.org) and the A-STAR Registry in the U.K. and Republic of Ireland.

Breast-feeding: Consider continuing or restarting dupilumab, tralokinumab, lebrikizumab, nemolizumab in women wishing to breastfeed. Explain the benefits of breastfeeding and that the small amounts of biologic therapy present in breast milk are unlikely to be absorbed systemically by the infant (refer to drug-specific SPCs).

Men: Animals studies have shown no impairment on fertility for dupilumab, tralokinumab, lebrikizumab and nemolizumab. Based on available data, these drugs do not affect fertility or pregnancy outcomes in men and so therefore no contra-indication to men conceiving whilst on these drugs.

7.7 Use of biologic therapy in the perioperative period for surgery

Although there is no evidence regarding the safe use of biologic therapy peri-operatively, patients are advised to omit the dose of dupilumab, tralokinumab, lebrikizumab and nemolizumab 2 weeks prior to major surgery. Therapy can be restarted post operatively if wound healing is satisfactory and there is no evidence of infection.

If a patient on dupilumab, tralokinumab, lebrikizumab and nemolizumab undergoes emergency major surgery, stop treatment and do not restart until postoperative wound healing is satisfactory and there is no evidence of infection.

7.8 Use of biologic therapy in patients with chronic viral infections

There is insufficient evidence to recommend treatment with biologic therapy in patients with known chronic viral infections especially blood borne viruses, such as HIV and hepatitis B or C. Clinicians should seek specialist advice on a case-by-case basis.

7.9 Biologic therapy and vaccination

Vaccination requirements should be reviewed and brought up to date prior to initiation of biologic therapy with reference to Department of Health Guidance..

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.

Inactivated vaccines are safe to administer concurrently with immunosuppressants; however, where possible, inactivated vaccines should be administered at least **2 weeks** before starting therapy to ensure optimal immune responses.

Consider checking varicella serology prior to biologic therapy. Patients with absent or low immunity to varicella can consider varicella vaccination although this may not be available via local NHS pathways (as per the Green Book Chapter 28a).

While on immunosuppressant therapy, patients should be advised to receive the pneumococcal polysaccharide vaccine (PPV), 'inactivated' influenza vaccine (annual) and Covid-19 vaccine (in line with current guidance; Green Book, Chapter 14). The GP should be asked to ensure that the patient is flagged as being on immunosuppression and requiring vaccination according to Department of Health Guidance.

8. Practical prescribing information specific to JAKi therapy

EMA and MHRA measures to minimise risk of serious side effects with JAK inhibitors (JAKi) for chronic inflammatory disorders:

In line with EMA measures and the April 2023 MHRA drug safety update, to minimise risks of serious/fatal infection, major adverse cardiovascular events, malignancy and venous thromboembolism (VTE), only use JAKis in the following groups of patients when there are no suitable alternatives:

- those aged 65 years or above
- those at increased risk of major cardiovascular problems
- those who smoke or have done so for a long time in the past
- those at increased risk of cancer

Use JAKis with caution in those with risk factors for VTE other than those listed above. Use a lower dose where possible (see specific details in Section 3).

8.1 JAKi therapy and lipid elevations

Clinical trial data show dose dependent increases in blood lipid parameters in patients treated with JAKi compared to placebo. The effect of these lipid parameter elevations on cardiovascular morbidity and mortality has not been determined. Elevations in LDL cholesterol decreased to pre-treatment levels in response to statin therapy.

Assess lipid parameters at approximately 12 weeks following JAKi initiation (the 3 – 4-month clinical review visit is appropriate). Manage hyperlipidaemia in primary care, in the context of overall cardiovascular risk and in line with national clinical guidelines or local clinical guidelines where appropriate (for example SEL Lipid Management Guidance)

Discuss the risk and benefit of continuing JAKi in the context of significant hyperlipidaemia; continuation may be justified where there are limited alternative treatment options. Consider referral to a specialist lipid service such as at Guys' and St Thomas' NHS Foundation Trust for advice.

8.2 JAKi therapy and venous thromboembolism (VTE)

Events of deep venous thrombosis (DVT) and pulmonary embolism (PE) have been reported in patients receiving JAKi, with clinical trial data indicating a higher frequency of VTE with certain JAKi when compared with control populations.

JAKi should be used with caution in patients with additional risk factors for VTE. Risk factors to consider include: older age, 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/m^2 and smoking. Assess these risk factors at baseline and discuss with the patient, explaining their relevance in the context of JAKi related VTE risk and how the risk may be mitigated.

If more specialist input is required, consider referral to a haematology/thrombosis service.

Consider withholding JAKi peri-operatively in those with a significant increased risk of VTE, until this risk is reduced (see also Section 8.6).

Stop therapy and evaluate promptly if clinical features of VTE occur, such as a painful swollen leg, chest pain or shortness of breath.

8.3 JAKi therapy and infection risk

JAKi therapy is associated with an increased rate of infections, such as upper respiratory tract, herpes simplex, herpes zoster, lower respiratory tract infection, cellulitis and urinary tract infections. Refer to individual drug SPCs for specific risks. Serious and sometimes fatal infections have also been reported in patients receiving JAKi. Carefully consider the risks and benefits of treatment with JAKi prior to initiating therapy in patients with active, chronic or recurrent infections, or patients at risk of infection. Monitor for signs and symptoms of infection throughout treatment.

Consider lower dose JAKi in patients with a history of chronic/recurrent infections or underlying condition that may predispose to infection.

If an infection develops, interrupt therapy temporarily if the patient is not responding to standard therapy. Do not resume JAKi treatment until the infection resolves.

Herpes simplex and Herpes zoster:

Cases of herpes virus reactivation (herpes zoster, herpes simplex), have been reported in clinical studies. For patients with a history of recurrent herpes simplex infection consider starting prophylactic anti-viral therapy prior to JAKi therapy. Consider checking varicella serology prior to biologic therapy. Patients with absent or low immunity to varicella can consider varicella vaccination although this may not be available via local NHS pathways (as per the Green Book Chapter 28a).

Refer to Part 1, section 11 for detailed section on reducing risk of VZV reactivation with systemic immunomodulation

Tuberculosis:

Screen for and treat active and latent tuberculosis (TB) before starting JAKi therapy. Be aware of groups at risk for TB and monitor for TB infection throughout JAKi treatment including those who are negative for latent TB prior to initiating JAKi therapy.

8.4 JAKi therapy and malignancy risk

Malignancies were observed in clinical studies of JAKi. Clinical data are insufficient to assess the potential relationship of exposure to JAKi and the development of malignancies. Long term safety evaluations are ongoing.

All patients should be fully assessed prior to, and during treatment with JAKi with respect to their past or current history of malignancy and/or any future risk of malignancy; the risks and benefits of therapy should be considered in this context.

Treatment with JAKi should, whenever possible, be avoided in patients with a current or recent past history of malignancy unless the malignancy has been diagnosed and treated more than 5 years previously and/or where the likelihood of cure is high. Patients who have a more recent history of malignancy should be discussed on a case-by-case basis within the specialist eczema service, and with the relevant oncology team, to consider (unknown) risks of JAKi in the context of alternative available treatments.

All patients should be encouraged to participate in national cancer screening programmes appropriate for their age and gender.

Periodic skin examination is recommended for patients who are at increased risk for skin cancer.

Consider gynaecological review for patients with a history of cervical dysplasia.

8.5 JAKi therapy in women planning pregnancy or who are pregnant and/or breastfeeding

JAKi therapy is contraindicated in pregnancy. When considering treatment with JAKi, women of childbearing potential should be asked about conception plans. **Advise women of childbearing potential to use effective contraception during and for at least one month after taking JAKi**. Contraception Choices provides a useful overview of the different methods available (www.contraceptionchoices.org).

Contraception that contains the hormone oestrogen such as the combined oral contraceptive pill, the patch, and the vaginal ring, carry a small increased risk of blood clots. If these are the preferred or existing methods, patients should speak to their contraception provider to consider their individual risk of blood clots alongside being on a JAK inhibitor.

It is worth noting that long-acting reversible contraception, such as the intrauterine device (also known as the IUD or coil) or contraceptive implant, are the most effective and do not have a reported increased risk of blood clots. These are available via GPs or local sexual and reproductive health clinic. When using other less effective forms of contraception (pills, patches, rings, injections), it is recommended to also use condoms at the same time to prevent pregnancy more effectively.

JAKCONTRACEPTION (EPIC smartphrase) provides a summary of this advice for patient letters (see appendix 5).

Fertility - Studies in animals suggest that treatment with JAKi has the potential to reversibly decrease female fertility while on treatment. There was no effect/is absent data on male spermatogenesis

Breastfeeding - It is unknown if JAKi or their metabolites are excreted in human milk. Available animal data has shown excretion of JAKi in milk, therefore a risk to newborns or infants cannot be excluded and **JAKi are contraindicated during breast-feeding**.

8.6 JAKi therapy in the perioperative period for surgery

There is no evidence regarding the use of JAKi peri-operatively. Consider a break in treatment in the perioperative period on a case-by-case basis and balance against the risk of eczema flare off treatment.

If there is considered significant increased risk of VTE perioperatively, consider withholding JAKi until this risk is reduced.

JAKi have a short half-life (5 – 14 hours – see individual drug SPC) so consider stopping therapy for a period equivalent to 5 half-lives prior to surgery. Therapy can be restarted postoperatively if healing is satisfactory and there is no evidence of infection.

If a patient on a JAKi undergoes emergency major surgery, stop therapy and do not restart until postoperative wound healing is satisfactory and there is no evidence of infection.

8.7 JAKi therapy in patients with chronic viral infections

There is insufficient evidence to recommend treatment with JAKi in patients with known chronic viral infections especially blood borne viruses, such as HIV and hepatitis B. Clinicians should seek specialist advice on a case-by-case basis.

8.8 JAKi therapy and vaccination

Vaccination requirements should be reviewed and brought up to date prior to initiation of JAKi therapy with reference to Department of Health Guidance..

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.

Inactivated vaccines are safe to administer concurrently with immunosuppressants; however, where possible, inactivated vaccines should be administered at least **2 weeks** before starting therapy to ensure optimal immune responses.

Consider checking varicella serology prior to JAKi therapy. Patients with absent or low immunity to varicella can consider varicella although this may not be available via local NHS pathways (as per the Green Book Chapter 28a).

See part 1, section 11 in relation to advice for shingles vaccination and reducing **risk of VZV reactivation with systemic immunomodulation**.

Advise patients to receive the pneumococcal polysaccharide vaccine (PPV), 'inactivated' influenza vaccine (annual) and Covid-19 vaccine (in line with current guidance; Green Book, Chapter 14). Advise the GP to flag that the patient as being on immunosuppression and requiring vaccination according to Department of Health Guidance.

Supporting documents (see relevant local guidelines)

1. GSTT Clinical Guideline: Pathway for managing JAK- inhibitor related risks of HSV/VZV reactivation in people with immune-mediated inflammatory diseases [link accessible by GSTT staff only]
2. GSTT Clinical Guideline: Lymphopenia assessment and onward referral pathway for patients in the Severe Eczema Service [link accessible by GSTT staff only]
3. SEL Lipid Management Guidance

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Appendix 1 – Suggested Specialist Targeted Medication Initiation Patient Pathways

Patient Pathway for Biologic and JAKi Initiation

BASELINE

Consultant decision to initiate biologic for AD

Clinician responsible for assessing treatment eligibility and confirming no cautions / contraindications.

Clinician to communicate this clearly to the named CNS in clinic

Clinician

- Ensure all screening tests ordered and physical examination performed
- Document appropriate reference baseline EASI and DLQI
- Document plan for drug transitioning/co-therapy
- Issue prescription for eye care as needed for biologic treatment
- If appropriate, refer to **RESEARCH TEAM** for further information

CNS (same day consult)

- Provide patient with patient information leaflet (PIL)
- With patient discuss PIL, explain next steps of pathway, check/assist with clinician steps to ensure all documented in treatment plan and give CNS contact details
- Book patient into CNS diary to check screening results

↓

When screening results available clinician orders initiation prescription on EPIC, print and sign
Aim to start patient within 2 – 4 weeks
Patient will have drug delivered to home by homecare team.
If for biologic; patient will be taught to self-inject by homecare nurse
If for JAKi; patient will have monitoring blood test 4 weeks after starting treatment

↓

Week 16

NICE Assessment: FACE-TO-FACE review by Clinician

- Confirm correct dosing schedule
- Assess clinical response, including EASI & DLQI, against NICE criteria for eligibility to continue therapy
- Assess adverse events (e.g. eyes and joints) and concomitant medication
- Monitoring blood test for JAKi (routinely not needed for biologics)
- If appropriate, repeat prescription issued and signed

↓

Biologic	**JAKi**
Face-to-face follow up in eczema clinic in **6 months** if stable.	Face-to-face follow up in eczema clinic in **4 months** if stable.
If appropriate, repeat prescription issued and signed at clinic review	

↓

Biologic	**JAKi**
Ongoing eczema clinic follow-up either: • Every **12 months** thereafter* (face-to-face, virtual or digital review if clinically appropriate)	Ongoing eczema clinic follow-up: • Every **4 months** in first treatment year • Every **6 months** thereafter*
If appropriate, repeat prescription issued and signed at clinic review	

*Recommended review interval in stable patient. Consider shorter review interval if clinically indicated.

Appendix 2 – Half Life of Common Treatments

Drug	Half-life	Five half lives
Abrocitinib	5 hours	25 hours (1 day)
Azathioprine	6 hours	30 hours (1.5 days)
Baricitinib	13 hours	65 hours (2.5 days)
Ciclosporin	25 hours	125 hours (5 days)
Dupilumab	-	10 -11 weeks*
Prednisolone	4 hours	20 hours (1 day)
Methotrexate	10 hours	50 hours (2 days)
Mycophenolate Mofetil	18 hours	90 hours (4 days)
Tralokinumab	22 days	110 days (16 weeks)
Upadacitinib	9 – 14 hours	Up to 70 hours (3 days)
Lebrikizumab	24.5 days	122.5 days (18 weeks)
Nemolizumab	18.9 days	94.5 days (13.5 weeks)

**Dupilumab elimination is mediated by parallel linear and nonlinear pathways. After the last steady state dose, the median time for dupilumab concentrations to decrease below the lower limit of detection, estimated by population PK analysis, 10-11 weeks for the 300 mg Q2W regimen.*

When choosing to transition from one therapy to another and whether a therapy washout (or no washout) should be used, take into consideration

- the pharmacology of the drugs that are being started and stopped.
- the person's clinical circumstance.
- the person's views on the risks and benefits of transitioning option(s).

Consider the following strategies when transitioning from standard systemic to biologic or oral JAKi therapy:

- in stable disease, aim **not to overlap** immunosuppressant therapies
- when standard, systemic immunosuppressant therapy cannot be stopped (e.g. prednisolone in people at risk of unstable disease and for whom a disease flare would be severe or hazardous), rationalize use of therapy and aim to stop soon after initiation of new immunosuppressant therapy.

Care should be taken when weaning/discontinuing prednisolone in those on long term therapy or likely to experience a disease flare before biologic or oral JAKi therapy can be initiated – where adrenal insufficiency is suspected and withdrawal of glucocorticoid therapy is being considered refer to local guidance/endocrinology opinion.

Appendix 3 – Suggested Letter Template for Referral to Eye Casualty/Ophthalmology

Severe Eczema Service

URGENT REFERRAL

Date:

Dear Ophthalmology,

I would be most grateful for your assessment of:

Name: **Date of birth:**

Hospital Number: **NHS Number:**

They are on dupilumab/ tralokinumab/ lebrikizumab (anti-IL4/13 receptor monoclonal antibody – *edit as appropriate*) under our severe eczema service. This treatment has been associated with episodes of conjunctivitis on trial.

They have recently developed the following symptoms:

We have/have not held treatment with dupilumab/ tralokinumab/ lebrikizumab. If you have any concerns about their specific ophthalmological presentation in the context of dupilumab/tralokinumab then please liaise with the local corneal service. Yours Sincerely,

Referrer contact details:

Appendix 4 - Key Points for Communication to GP on Initiation of Treatment

As part of the medicines reconciliation process, it is important that GP practices accurately record hospital prescribed and supplied medicines for their patients on their practice system but do not inadvertently issue a prescription for them. This includes targeted immunomodulators used in atopic dermatitis. Local guidance on reconciling hospital only medicines in GP practice electronic record systems can be accessed here.

Initiation of Biologic Therapy:

1. **Do not give live vaccines to people on biologic therapy or to infants (up to 6 months of age) whose mothers have received biologic therapy beyond 16 weeks' gestation.** Inactivated vaccines are safe to administer concurrently with biologic therapy.
   Please ensure that your patient receives the pneumococcal polysaccharide vaccine (PPV), 'inactivated' annual influenza vaccine and the Covid-19 vaccine, in line with current guidance. Please also ensure the patient is flagged as being on immunosuppression and therefore requiring vaccination according to Department of Health Guidance.

2. Patients on biologic therapy are at **an increased risk of infection**, particularly oral herpes. This should be taken into consideration if a patient on treatment with a biologic presents with infective signs and symptoms.

3. Conjunctivitis is a side effect of biologic therapy. Rarely it can be severe and sight threatening. **Any patient on biologic therapy who presents to their GP with new ocular symptoms, must be directed to contact their specialist dermatology team**. As a side effect of biologic therapy, treatment of conjunctivitis should be provided on prescription. For patients with mild conjunctivitis, GPs should prescribe eye lubricants and/or antihistamine eye preparations as per local guidance or formulary. For patients with moderate to severe* conjunctivitis or concerns relating to infection please refer urgently to your local ophthalmology service. *Symptoms to consider: significant conjunctival mucus, severe itch/irritation/watering, worsening conjunctival redness, pain/photophobia and or loss of vision.

Additional points for patients initiated on dupilumab:

4. **Arthralgia/enthesitis is an uncommon side effect** seen with Dupilumab – please advise any patients presenting with these symptoms to contact their dermatology team as soon as symptoms experienced.

5. Please monitor any co-morbid atopic disease (e.g. asthma) and adjust therapy as required. **Dupilumab also has a beneficial effect in asthma, and any changes to or cessation of dupilumab therapy may adversely affect the patient's asthma control.** Patients may need to increase asthma therapy if stopping dupilumab.

Initiation of JAKi Therapy:

1. **Do not give live vaccines to people taking JAKi therapy or to infants (up to 6 months of age) whose mothers have received biologic therapy beyond 16 weeks' gestation.** Inactivated vaccines are safe to administer concurrently with biologic therapy.
   Please ensure that your patient receives the pneumococcal polysaccharide vaccine (PPV), 'inactivated' annual influenza vaccine and the Covid-19 vaccine, in line with current guidance. Please also ensure the patient is flagged as being on immunosuppression and therefore requiring vaccination according to Department of Health Guidance.

2. Patients taking JAKi 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 an JAKi presents with infective signs and symptoms that are not responding to standard treatment, please contact the patient's specialist dermatology team for advice.

3. **Events of DVT and PE have been reported in patients taking JAKi therapy**. 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 JAKi therapy and consider alternative treatment options.

4. **Increases in blood lipid parameters** have been observed in patients treated with JAKi. The effect of these lipid parameters on cardiovascular morbidity and mortality has not been determined. Following initiation, the patient's specialist dermatology team will monitor their lipid parameters. Patients should subsequently be managed according to **national or local clinical guidelines for hyperlipidaemia where appropriate (for example** SEL Lipid Management Guidance**)**. This will be primarily following assessment by their GP in context of overall cardiovascular risk. Significant hyperlipidaemia should be discussed with the patient's specialist dermatology team.

5. Cases of **diverticulitis and gastrointestinal perforation** have been reported in patients taking JAKi. Patients presenting with new onset abdominal signs and symptoms, especially pain accompanied by fever, nausea and vomiting, should be evaluated promptly for early identification of diverticulitis or gastrointestinal perforation. The majority of reported cases occurred in patients with **pre-existing diverticular disease or those on long-term concomitant medicines associated with an increased risk of diverticulitis** such as NSAIDs, corticosteroids and opiates. If prescribing these types of medication to a patient on an JAKi, this risk should be considered.

Appendix 5 – Suggested Dermatology Specific EPIC User Smartphrases

EPIC User SmartPhrase – JAKINHIBITORCHECKLIST

ASSESSMENT CONSIDERATIONS BEFORE STARTING JAK inhibitor	
Risk factors for malignancy	
Age over 65yrs	Yes ☐ No ☐
Current or previous history of cancer	Yes ☐ No ☐
More than 200 PUVA or more than 350 UVB phototherapy sessions or sunbed use	Yes ☐ No ☐
Risk factors for infection	
Previous chickenpox	Yes ☐ No☐ VZV IgG titre=
Previous shingles*	Yes ☐ No☐
Previous Shingrix vaccine	Yes ☐ No☐
Previous HSV infections**	Yes ☐ No☐
Seasonal vaccines up to date (COVID and flu)	Yes ☐ No☐
Previous pneumococcal vaccine (within last 5 years)	Yes ☐ No☐
History of chronic or recurrent infection	Yes ☐ No☐
Risk factors for cardiovascular disease	
Ischaemic heart disease, peripheral vascular disease or stroke	Yes ☐ No☐
Obesity	Yes ☐ No☐
Hypertension	Yes ☐ No☐
Hypercholesterolaemia	Yes ☐ No☐
Diabetes	Yes ☐ No☐
Risk factors for VTE	
Previous DVT or PE	Yes ☐ No☐
Smoking	Yes ☐ No☐
Coagulation disorder	Yes ☐ No☐
Recent surgery or immobilisation	Yes ☐ No☐
Severe varicose veins	Yes ☐ No☐
Hormone therapy (HRT or OCP)	Yes ☐ No☐
Other	
Strong family history of stroke/DVT/PE, malignancy, or cardiovascular disease	Yes ☐ No☐
Renal impairment	Yes ☐ No☐ Consider dose reduction if CrCl 30-60 ml/min
Relevant only for Baricitinib and Abrocitinib: Concomitant use of OAT1/3 inhibitors (e.g. Angiotensin Receptor Blockers such as Valsartan; furosemide, aspirin, pantoprazole, mefenamic acid, Pioglitazone, Probenecid, Rifampicin, Novobiocin, Cabotegravir, Terifluonomide, P-aminohippuric acid (PAH), Leflunomide)	Yes ☐ No☐ If 'Yes', consider dose reduction
Relevant only for Upadacitinib and Abrocitinib: Concomitant use of strong inhibitors of CYP2C19/CYP2C9/CYP3A4 e.g. grapefruit juice, clarithromycin, itraconazole, amiodarone, fluconazole, fluoxetine, metronidazole, isoniazid, ritonavir,trimethoprim/sulfamethoxazole Concomitant use of strong inducers of CYP2C19/ CYP2C9/CYP3A4 eg carbamazepine, phenobarbital, phenytoin, rifampicin	Yes ☐ No☐ If 'Yes', consider dose reduction Yes ☐ No☐ If 'Yes', consider alternative/monitor efficacy
History of diverticular disease***	Yes ☐ No☐

If answer of 'Yes' to the above except for any of the questions linked to vaccination history where if the answer is 'No' then carefully assess the patient's suitability for JAK inhibitors, consider alternative treatments, and involve a Consultant if indicated.
*Consider Shingrix vaccine
**Consider anti-viral prophylaxis if relevant infection risks
***Diverticular disease risk applies only to Baricitinib

EPIC User SmartPhrase – Drug Fact Boxes

User SmartPhrase – DUPILUMABFACTBOX

Kindly note the following information about dupilumab (Dupixent):

Around 58 out of every 100 people are clear or nearly clear of eczema by 3-4 months of treatment with dupilumab.

Around 20 out of every 100 people may experience conjunctivitis. Around 6 out of every 100 people may experience arthritis. Around 1 out of every 20 people may experience worsening of their face and neck eczema. Around 1 in 1000 people taking dupilumab may experience a serious side effect such as a severe allergic reaction. Asthma may improve when on dupilumab. For this reason, if dupilumab needs to be stopped for any reason, asthma may recur and need treatment.

We have provided detailed information on dupilumab here:

British Association of Dermatologists patient information leaflet on dupilumab

https://www.bad.org.uk/pils/dupilumab/

Dupilumab manufacturer patient information leaflet

874476 G,028,V86,DUPIXENT 150MG LI AAB,,GEF (Folder 4228807) (medicines.org.uk)

User SmartPhrase – TRALOKINUMABFACTBOX

Kindly note the following information about tralokinumab (Adtralza)

Around 56 out of every 100 people are clear or nearly clear of eczema by 3-4 months of treatment with tralokinumab. Around 5 in every 100 people may experience conjunctivitis. Around 1 in 1000 people taking tralokinumab may experience a serious side effect such as a severe allergic reaction.

We have provided detailed information on tralokinumab here:

Adtralza manufacturer patient information leafle

Adtralza PIL (medicines.org.uk)

User SmartPhrase – LEBRIKIZUMABFACTBOX

Kindly note the following information about lebrikizumab (Ebglyss)

Around 69 out of every 100 people are clear or nearly clear of eczema by 3-4 months of treatment with lebrikizumab.

Around 6 to 7 out of every 100 people may experience conjunctivitis. Around 1 in 200 people taking lebrikizumab might get a serious infection such as shingles.

We have provided detailed information on Lebrikizumab here:

Lebrikizumab manufacturer patient information leaflet

uk-pl-pfp.pdf (medicines.org.uk)

User SmartPhrase – NEMOLIZUMABFACTBOX

Kindly note the following information about nemolizumab (Nemluvio) today

Around 44 out of every 100 people are clear or nearly clear of eczema by 3-4 months of treatment with nemolizumab.

Up to 1 in every 10 people taking nemolizumab might get a mild side effect such as headache. Less than 1 in 100 patients report uncommon allergic reactions to the medication.

You may find further information about nemolizumab therapy here:

Nemolizumab patient information leaflet: https://www.medicines.org.uk/emc/files/pil.100635.pdf

User SmartPhrase – ABROCITINIBFACTBOX

Kindly note the following information about abrocitinib (Cibinqo):

Around 70 out of every 100 people are clear or nearly clear of eczema by 3-4 months of treatment with abrocitinib.

About 1-2 out of a 100 people taking abrocitinib might get a serious infection such as shingles and about 1 out of a 1000 people taking abrocitinib might get a serious side effect such as pneumonia, blood clots in the lungs or the legs, heart attack or stroke.

You may find further information about abrocitinib therapy here:

Abrocitinib patient information leaflet:

QRD Human Product Information Template (medicines.org.uk)

User SmartPhrase – BARICITINIBDRUGFACTBOX

Kindly note the following information about baricitinib (Olumiant) today

Around 48 out of every 100 people are clear or nearly clear of eczema by 3-4 months of treatment with baricitinib.

Around 1 in every 100 people taking baricitinib might get a serious side effect such as shingles or pneumonia. Around 1 to 2 out of every 1000 people taking baricitinib might get a serious side effect such as blood clots in the lungs or the legs, heart attack or stroke.

You may find further information about baricitinib therapy here:

Baricitinib patient information leaflet:

Microsoft Word - Olumiant_PIL_OL034_Mar23_GB_annotated - Copy (medicines.org.uk)

User SmartPhrase – UPADACITINIBFACTBOX

We have discussed the following information about upadacitinib (Rinvoq) today

Around 77 out of every 100 people are clear or nearly clear of eczema by 3-4 months of treatment with upadacitinib.

Around 1 in every 100 people taking upadacitinib might get a serious side effect such as shingles or pneumonia. Around 1 to 2 out of every 1000 people taking upadacitinib might get a serious side effect such as blood clots in the lungs or the legs, heart attack, stroke, infection in the blood (sepsis) and severe allergic reactions which may affect breathing.

You may find further information about upadacitinib therapy here:

Upadacitinib patient information Leaflet:

Rinvoq, INN-Upadacitinib (medicines.org.uk)

EPIC User SmartPhrase – Pregnancy and Contraception Advice

User SmartPhrase – BIOLOGICSECZEMAPREGNANCY

I have explained overall safety unknown as data is limited and new drug. Biologic may be used if benefits outweigh risks in pregnancy. Decisions made on a case by case basis. Doesn't cross placenta in early pregnancy, and we would ideally stop it at start of 3rd trimester (last dose 26 weeks) to avoid transplacental transfer of antibodies (including the drug) which is highest in the 3rd trimester. We arrange a review around this time. Can restart once recovers from delivery (safe with breastfeeding). If biologic is continued beyond week 16 of pregnancy, live vaccines must be avoided for the first 6 months of life of neonate

User SmartPhrase – JAKCONTRACEPTION

If you are taking or considering a JAK inhibitor tablet for your eczema it is important for you to know that these tablets are not advised in pregnancy as they could harm the baby's growth in the womb, in particular the baby's bone development. It is important to be on a reliable form of contraception whilst on this treatment. If you are not sure about which contraception is right for you, your GP or local sexual and reproductive health clinic can discuss this further with you, and this website provides a good overview of the different methods (www.contraceptionchoices.org).

JAK inhibitor tablets carry a warning regarding a potential increase in the risk of blood clots. Contraception that contains the hormone oestrogen such as the combined oral contraceptive pill, the patch, and the vaginal ring, also carry a small increased risk of blood clots. If these are your preferred or existing methods you should speak to your contraception provider to consider your individual risk of blood clots.

It is worth noting that long-acting reversible contraception, such as the intrauterine device (also known as the IUD or coil) or contraceptive implant, are the most effective and do not have a reported increased risk of blood clots. These are available via your GP or local sexual and reproductive health clinic. When using other less effective forms of contraception (pills, patches, rings, injections), it is recommended to also use condoms at the same time to prevent pregnancy more effectively.

Decision aid for biologic therapy and oral JAK inhibitors for atopic dermatitis

This is a decision aid to help clinicians and patients decide their treatment choice and not a comprehensive data source or replacement for the individual Drug Summary of Product Characteristics.

Questions you might want to ask	How do I take it?		How many people were clear or nearly clear after 3-4 months of treatment?	Roughly what proportion of people stops their treatment in the first 3-4 months due to unwanted effects?	Is there anything else to consider?	
	How do I take it? How often do I need to inject / take the treatment?	How long has this treatment been around? *			What are some of the conditions that would make your doctor hesitant about giving the treatment?	Is this medication also used for other medical conditions?
Biologic therapies						
Dupilumab (Dupixent®)	1 injection, under the skin every other week	NICE TA Aug 2018	 58%[23]	 3%[23]	-Severe conjunctivitis and keratitis § -Helminth infection ‡	Add on treatment for selected patients with severe asthma ¥ Add on treatment for selected patients with chronic rhinosinusitis with nasal polyposis
Tralokinumab (Adtralza®)	1 injection for pre-filled pen (2 injections for pre-filled syringe) under the skin every other week 4 weekly dosing may be considered after 16 weeks of treatment	NICE TA Aug 2022	 56%[24]	 2%[24]	-Severe conjunctivitis and keratitis § -Helminth infection ‡	Not indicated for asthma
Lebrikizumab (Ebglyss®)	1 injection under the skin every other week 4 weekly dosing may be considered after 16 to 24 weeks of treatment	NICE TA Oct 2024	 69%[27]	 2%[27]	-Severe conjunctivitis and keratitis § -Helminth infection ‡	Not indicated for asthma
Nemolizumab (Nemluvio®)	1 injection under the skin every 4 weeks until week 16 then every 8 weeks	NICE TA July 2025	 44%[28]	 1.4%[28]	-Uncontrolled asthma	Not indicated for asthma

Oral JAK inhibitors						
Abrocitinib (Cibinqo®)	One tablet once daily	NICE TA Aug 2022	 59-70%[23]	 2.5-4%[23]	-Abnormalities in blood count ^ -Chronic or recurrent infection -Increased risk of blood clots (DVT/ PE) ^^ -Increased risk of cardiovascular problems ^^ -Significant smoking history (past/current) ^^ -Increased risk of cancer ^^ -Age ≥ 65 years ^^ -Severe renal impairment -Pregnancy and breast feeding	
Baricitinib (Olumiant®)	One tablet once daily	NICE TA March 2021	 43-48%[25]	 0-5%[25]	-Abnormalities in blood count^ -Chronic or recurrent infection -Increased risk of blood clots (DVT/ PE) ^^ -Increased risk of cardiovascular problems ^^ -Significant smoking history (past/current) ^^ -Increased risk of cancer ^^ -Age ≥65 years ^^ -Renal impairment -Diverticular disease -Pregnancy and breast feeding	Rheumatoid arthritis Alopecia areata
Upadacitinib (Rinvoq®)	One tablet once daily	NICE TA Aug 2022	 65-77%[26]	 1-1%[26]	-Abnormalities in blood count ^ -Chronic or recurrent infection -Increased risk of blood clots (DVT/ PE) ^^ -Increased risk of cardiovascular problems ^^ -Significant smoking history (past/current) ^^ -Increased risk of cancer ^^ -Age ≥65 years ^^ -Severe renal impairment -Diverticular disease -Pregnancy and breast feeding	Rheumatoid arthritis Psoriatic arthritis Ankylosing spondylitis Ulcerative colitis

¥ Dupilumab and Asthma : Dupilumab is indicated in adults and adolescents 12 years and older as add-on maintenance treatment for severe asthma with type 2 inflammation characterised by raised blood eosinophils and / or raised fraction of exhaled nitric oxide (FeNO), who are inadequately controlled with high dose inhaled corticosteroids plus another medicinal product for maintenance treatment. Monitor patients with comorbid asthma carefully following discontinuation of dupilumab.
§ Advise patients to report new onset or worsening eye symptoms.
‡ Treat patients with helminth infections before initiating dupilumab, tralokinumab or Lebrikizumab.

^ Haematological abnormalities. Absolute Neutrophil Count (ANC) < 1 x 109 cells/L and Absolute Lymphocyte Count (ALC) < 0.5 x 109 cells/L were reported in clinical trials. Haemoglobin < 8 g/dL was reported in rheumatoid arthritis clinical trials. Do not initiate treatment (or if already on treatment, temporarily interrupt treatment) if the absolute neutrophil count < 1 x 109 cells/L, absolute lymphocyte count < 0.5 x 109 cells/L or haemoglobin < 8 g/dL. The risk of lymphocytosis is increased in elderly patients with rheumatoid arthritis. Rare cases of lymphoproliferative disorders have been reported.
^^Only use JAK inhibitors if there are no suitable alternative treatments in people: aged 65 years or above, at increased risk of major cardiovascular problems (such as heart attack or stroke), who smoke or have done so for a long time in the past, at increased risk of cancer. Use JAK inhibitors with caution in people with risk factors for VTE other than those listed above. When possible, use a lower dose in people at risk of VTE, cancer or major cardiovascular problems.

Drug Acquisition Costs

Drug costs, including administration costs, dosage, price per dose and commercial arrangements, should be one of the factors considered when initiating, switching or escalating the dose of biologic/oral JAK Inhibitor therapy. The cost of the first year of treatment will vary depending on loading dose schedules and commercial arrangements/short-term free of charge supplies. An average annual cost for the first 3 years of treatment has been used to account for this in the following table. Prices for all drugs include homecare services and exclude VAT.

Drug	Mode of action	Route of administration	Maintenance Dose	Cost Tier
Abrocitinib (Cibinqo®)	JAK inhibitor	Oral	100mg or 200mg once daily	£
Baricitinib (Olumiant®)	JAK inhibitor	Oral	2mg or 4mg once daily	£
Upadacitinib (Rinvoq®)	JAK inhibitor	Oral	15mg once daily	£
Upadacitinib (Rinvoq®)	JAK inhibitor	Oral	30mg once daily	££
Dupilumab (Dupixent®)	IL-13/IL-4 inhibitor	Subcutaneous	300mg every other week	££
Lebrikizumab (Ebglyss®)	IL-13 inhibitor	Subcutaneous	250mg every four weeks	££
Tralokinumab (Adtralza®)	IL-13 inhibitor	Subcutaneous	300mg every other week	££
Nemolizumab (Nemluvio®)	IL-31 inhibitor	Subcutaneous	30mg every eight weeks	££

Prices are correct as of July 2025 and may be subject to change

Drugs listed in alphabetical order within each cost tier