




## BSR Guidelines



# Management of foot health in people with inflammatory arthritis: British Society for Rheumatology guideline scope

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The guideline will be developed using the methods and processes outlined in *Creating Clinical Guidelines: Our Protocol* [1]. This development process to produce guidance, advice and recommendations for practice has National Institute for Health and Care Excellence (NICE) accreditation.

### 1 Why the guideline is needed

Foot problems are highly prevalent in adults, children and young people with inflammatory arthritis (IA), but

their burden is often underestimated by health professionals. People with IA are often frustrated that concerns relating to their feet are ignored [2–4]. There are existing guidelines for foot health that may be applicable to IA. A regional podiatry group has developed management guidelines to support non-specialist podiatrists in the management of people with RA and related foot problems [5]. However, these guidelines are now nine years old and, while they are practitioner-facing, they relate only to RA instead of the wider spectrum of IA, do not include children and young people, and are not sensitive to the foot health needs of people from different cultural and religious backgrounds (e.g. footwear and orthotic device appearance and preferences for different materials). There are also standards embedded in the NICE guideline for RA highlighting the need to treat foot pathology [6]. These standards have an underpinning philosophy that encourages empowered self-care, patient involvement in service design, tailoring of services to patients' needs, promotion of informed choice, and



NICE has accredited the process used by BSR to create its clinical guidelines. The term began on 27 February 2012 and the current renewed accreditation is valid until 28 January 2023. More information on accreditation can be viewed at [www.nice.org.uk/accreditation](http://www.nice.org.uk/accreditation).

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timely and appropriate access to services where needed. However, they do not make recommendations about specific aspects of clinical management, such as particular foot problems and different rheumatic diseases. Furthermore, there is limited guidance as to when foot health experts should be consulted and there are no recommendations on which assessments or interventions should be performed. Finally, the Arthritis and Musculoskeletal Alliance (ARMA) have previously produced generic patient-facing Standards of Care for people with musculoskeletal foot health problems [7] and children and young people with JIA [8]. These outlined what patients should expect from services at that time, and the latter recognize the need for specialist podiatry reviews for people with JIA. Despite this, neither provide clinicians with guidance for treatment and both standards are now over a decade old. A survey of non-specialist podiatrists in the UK found that over 95% were unaware of existing guidelines [9]. There is a clear need for a national evidence-based clinical guideline for foot health that is aimed at clinicians and focused on IA more widely.

This new BSR guideline will address the assessment and management of foot health in adults, children and young people with IA and will focus specifically on the healthcare setting in the UK. Clear, culturally sensitive guidance regarding evidence-based strategies for the management of foot problems in people with IA will help all clinicians to provide high-quality care for their patients, service providers, and commissioners, to ensure that adequately resourced foot health services are available to meet the needs of patients. The guideline will provide advice to enable a range of clinicians to provide first-line therapy for foot conditions where access to podiatry is limited, and advise when specialist opinions should be sought.

### Key facts and figures

IA is an umbrella term encompassing a range of chronic, autoimmune conditions characterised by joint inflammation. These include RA, JIA and spondyloarthropathy (SpA) – which encompasses PsA, AS, reactive arthritis, enteropathic arthritis and undifferentiated SpA.

Despite the introduction of aggressive pharmacological therapies, foot problems frequently occur in IA. Around 90% of people with RA experience foot problems during the course of the disease, including rearfoot and forefoot deformity, tibialis posterior dysfunction, peripheral arthritis, and subluxation and dislocation of the MTP joints, leading to pain and reduced walking ability [10]. The foot is also particularly susceptible to damage in JIA. Foot-related impairment and disability has been shown to persist in over 90% of children and young people with the condition, despite intensive pharmacological therapy [11], and foot problems are also common in adults with JIA. In SpA, foot problems also include peripheral arthritis, dactylitis and enthesitis, particularly at the Achilles tendon, plantar fascia and tibialis posterior tendon insertions but also at many other sites. In PsA specifically, forefoot deformity affects

over 90% of people with the condition, while almost two-thirds experience foot pain [12].

Other extra-articular features of IA can manifest in the foot, including peripheral neuropathy and entrapment neuropathies. The risk of peripheral arterial disease is also increased in IA, particularly amongst individuals with a history of steroid use [13]. Long-term steroid use can also contribute to poor tissue viability in the foot, and when combined with joint deformity and poor vascular supply, the risk of tissue breakdown is significantly increased. Foot ulcers are common in IA [14, 15], and in immunosuppressed patients these carry an increased risk of potentially serious infection.

Despite significant advances in the pharmacological management of IA with the advent of whole new classes of medication and a new treatment paradigm, foot problems persist. The impact of foot damage in IA is often underestimated [16] and trivialized, yet people with foot problems consistently report marked reduction in their quality of life, indicating that the impact of foot disorders extends well beyond localized pain and discomfort [17].

### Current practice

A person with IA might present to primary or secondary care with foot problems. In some cases, foot problems precede the diagnosis of IA; 31% of cases are known to have had their first IA symptoms in their feet [18]. After diagnosis, foot problems may be monitored as part of the assessment of overall prognosis and disease activity, potentially with follow-up imaging. Some units run multidisciplinary clinics, but more commonly people with foot problems are seen separately by rheumatology and podiatry, sometimes with additional input from physiotherapy, orthotics, occupational therapy or orthopaedic surgery. The presentation of foot problems in IA is diverse, with some people experiencing problems with general nail and skin care, whereas others have pain and change in foot shape and posture (deformity), making it difficult to walk and find suitable footwear. Such problems can have specific challenges for children and young people as their musculoskeletal system is growing and developing. Others may present with neurological or vascular disease affecting the feet, or with foot ulcers. Treatments for foot pain and deformity can include general nail care, callus debridement, foot orthoses, footwear advice and provision, stretching and strengthening exercises, lifestyle advice and surgery. People with persistent active inflammation in the foot may benefit from corticosteroid injections or a change in systemic treatment.

Variation in practice is widespread and the inadequacies of foot care in the UK are well documented. Although National Early Inflammatory Arthritis Audit (NEIAA) data indicated that 76% of rheumatology departments had podiatry access in 2020 [19], a 2021 BSR rheumatology workforce report highlighted that 80% of departments do not have a podiatrist embedded in their multidisciplinary team [20]. Additionally, a recent clinical audit into the adherence of foot health management standards of RA across six National Health Service

(NHS) Trusts found that only one podiatry department had the facility to see people with RA within six weeks of their initial diagnosis [21], while cross-sectional and longitudinal cohort studies in secondary care frequently report that only 30% to 40% of people with RA access any form of professional foot care or surgery [22–24].

It has been suggested that better integration of foot health services into rheumatology would be beneficial for people with IA [25]. Referral pathways are often unclear, and the lack of podiatrists within specialist teams means many patients seek foot care from the independent sector or non-specialist podiatrists who may not have the specific knowledge to manage their problems. Poor compliance with current foot health standards amongst podiatry departments is prevalent [21].

## 2 Who the guideline is for

This guideline is for

- rheumatologists, general practitioners, orthopaedic surgeons, allied health professionals, and specialist rheumatology nurses involved in the management of people with foot problems in IA;
- people with foot problems in IA and their carers.

Equality considerations

- none known.

## 3 What the guideline will cover

### 3.1 Who is the focus?

*Groups that will be covered*

- Adults with IA affecting the foot;
- Children and young people with IA affecting the foot.

### 3.2 Settings

*Settings that will be covered*

- Primary care and community settings;
- Secondary and tertiary care settings.

### 3.3 Activities, services or aspects of care

*Key areas that will be covered*

We will look at evidence in the areas below when developing the guideline, but it may not be possible to make recommendations in all the areas.

*Treatment of people*

Foot problems (including pain, deformity, nail and skin pathologies, ulceration, reduced circulation and neuropathy) in people with the following rheumatic diseases:

- RA;
- SpA, including PsA, AS, enteropathic arthritis, reactive arthritis and undifferentiated SpA;

- JIA.

*Assessment and diagnosis*

- Assessments;
- Imaging;
- Referral to specialist foot services.

*Treatment strategy*

- personalized care;
- orthotic devices;
- footwear;
- targeted exercises and gait rehabilitation;
- nail and skin care;
- wound management;
- targeted injection therapy;
- reviewing systemic disease control;
- surgical referral;
- follow-up and monitoring.

*Secondary prevention*

- physical activity;
- smoking;
- weight loss.

*Areas that will not be covered*

- Surgical procedures;
- Treatment of traumatic foot injuries;
- Systemic drug therapy.

*Related guidance*

- The North West Podiatry Services Clinical Effectiveness Group's 2010 rheumatology guidelines for the management of foot health for people with rheumatoid arthritis [5];
- NICE guideline [NG100] for rheumatoid arthritis in adults: management in 2018 [6];
- ARMA Standards of Care for People with Musculoskeletal Foot Health Problems in 2008 [7];
- ARMA Standards of Care for Children and Young People with Juvenile Idiopathic Arthritis in 2010 [8].

### 3.4 Key issues and draft questions

While writing this scope, we have identified the following key issues and draft questions related to them. The key issues and draft questions will be used to develop more detailed review questions, which guide the systematic review of the literature.

*Assessment and diagnosis*

#### Assessments

1. In adults or children and young people with suspected or confirmed IA, what clinical assessments should be undertaken when assessing foot health and disease activity, and how often?

#### Imaging

2. In adults or children and young people with suspected or confirmed IA, what imaging should be requested

when assessing foot health, and when should imaging be requested?

#### Referral to specialist foot services

- When should adults or children and young people with suspected or confirmed IA be referred to specialist foot services, e.g. podiatry?

#### Treatment strategy

##### Personalised care

- In adults or children and young people with foot problems in IA, what personalised care (e.g. support for self-management, activation, shared decision making and culturally-sensitive education) relating to foot health, and considering a person's wider biopsychosocial health determinants, should be provided and when?

##### Orthotic devices

- In adults or children and young people with foot problems in IA, are orthotic devices effective, when are they indicated, and which types of orthotic devices are effective?

##### Footwear

- In adults or children and young people with foot problems in IA, what types of footwear are effective?

##### Targeted exercises, gait rehabilitation and electro-physical therapies

- In adults or children and young people with foot problems in IA, what frequency, intensity, type and time (duration) of exercises, gait rehabilitation and electro-physical therapies is effective?

##### Nail and skin care

- In adults or children and young people with common toenail pathologies in IA, what conservative treatments are effective, and when should abnormal nails be surgically removed?
- In adults or children and young people with common skin pathologies (e.g. callus) in IA, what treatments are effective?

##### Wound management

- In adults or children and young people with foot ulceration in IA, including infected foot ulcers, what treatments are effective?

##### Targeted injection therapy

- In adults or children and young people with foot problems in IA, are local corticosteroid injections safe and effective, and if so, when should these be offered?

##### Reviewing systemic disease control

- When should local foot symptoms prompt a review of systemic disease control in adults or children and young people with IA?

#### Surgical referral

- In adults or children and young people with foot problems in IA, when should a surgical referral be considered?
- In patients requiring foot and ankle surgical procedures, including nail surgery, should biologics/DMARDs be stopped, when should they be stopped, and for how long?

#### Follow-up and monitoring

- How often should foot health be reassessed in adults or children and young people with IA?
- In young people with IA who are transitioning from paediatric to adult care, how should foot health be incorporated?

#### Secondary prevention

##### Physical activity

- In adults or children and young people with foot problems in IA, what is the clinical effectiveness of physical activity?

##### Smoking

- In adults or children and young people with foot problems in IA who smoke, what is the clinical effectiveness of giving up smoking?

##### Weight loss

- In adults or children and young people with foot problems in IA who are overweight or obese, what is the clinical effectiveness of weight loss?

The guideline is expected to be published in 2023.

## 4 Guideline working group constituency

Edward Roddy (WG lead) – Rheumatologist  
 Mike Backhouse (WG deputy lead) – Podiatrist  
 Lara Chapman (lead author) – Podiatrist  
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 Jasmine Davey – Lay member  
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 Rachel Ferguson – Paediatric Podiatrist  
 Gavin Cleary – Paediatric Rheumatologist  
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 Lindsey Cherry – Podiatrist  
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## Data availability statement

No new data were generated or analysed in support of this research.

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# A 2nd generation, JAK1 preferential inhibitor for moderate to severe RA<sup>1-6</sup>

While 1st generation JAK inhibitors are relatively non-selective,<sup>2-6</sup> JYSELECA has over 5x greater potency for JAK1 over JAK2/3 and TYK2<sup>1\*</sup>


Balancing sustained efficacy<sup>7-11</sup> with acceptable tolerability<sup>1,12</sup>

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\*From biochemical assays, the clinical relevance of which is uncertain. JAK, Janus kinase; RA, rheumatoid arthritis; TYK, tyrosine kinase.

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Refer to Summary of Product Characteristics (SmPC) before prescribing, and for full prescribing information.

**JYSELECA**  filgotinib 100 mg or 200 mg film-coated tablets.  
**Indication:** Jyseleca is indicated for the treatment of moderate to severe active rheumatoid arthritis in adult patients who have responded inadequately to, or who are intolerant to one or more disease modifying anti-rheumatic drugs (DMARDs). Jyseleca may be used as monotherapy or in combination with methotrexate (MTX). **Dosage: Adults:** 200 mg once daily. Taken orally with/without food. It is recommended that tablets are swallowed whole. **Laboratory Monitoring:** Refer to the SmPC for information regarding laboratory monitoring and dose initiation or interruption. **Elderly:** A starting dose of 100 mg once daily is recommended for patients aged 75 years and older as clinical experience is limited. **Renal impairment:** No dose adjustment required in patients with estimated creatinine clearance (CrCl)  $\geq 60$  mL/min. A dose of 100 mg of filgotinib once daily is recommended for patients with moderate or severe renal impairment (CrCl 15 to  $< 60$  mL/min). Not recommended in patients with CrCl  $< 15$  mL/min. **Hepatic impairment:** Mild/moderate hepatic impairment: no dose adjustment required. Severe hepatic impairment: not recommended. **Children (< 18 years):** Safety and efficacy not yet established. **Contraindications:** Hypersensitivity to the active substance or to any of the excipients. Active tuberculosis (TB) or active serious infections. **Pregnancy/Precautions:** See SmPC for full information. **Immunosuppression:** Combination use with immunosuppressants e.g. ciclosporin, tacrolimus, biologics or other Janus kinase (JAK) inhibitors is not recommended as a risk of additive immunosuppression cannot be excluded. **Infections:** Infections, including serious infections such as pneumonia and opportunistic infections e.g. tuberculosis (TB), oesophageal candidiasis, and cryptococcosis have been reported. Risk benefit should be assessed prior to initiating in patients with risk factors for infections (see SmPC). Patients should be closely monitored for the development of signs and symptoms of infections during and after filgotinib treatment. Treatment should be interrupted if the patient

is not responding to antimicrobial therapy, until infection is controlled. There is a higher incidence of serious infections in the elderly aged 75 years and older, caution should be used when treating this population. **Tuberculosis:** Patients should be screened for TB before initiating filgotinib, and filgotinib should not be administered to patients with active TB. **Viral reactivation:** Cases of herpes virus reactivation (e.g., herpes zoster) were reported in clinical studies (see SmPC). If a patient develops herpes zoster filgotinib treatment should be temporarily interrupted until the episode resolves. Screening for viral hepatitis and monitoring for reactivation should be performed. **Malignancy:** Immunomodulatory medicinal products may increase the risk of malignancies. Malignancies were observed in clinical studies (see SmPC). **Fertility:** In animal studies, decreased fertility, impaired spermatogenesis, and histopathological effects on male reproductive organs were observed (see SmPC). The potential effect of filgotinib on sperm production and male fertility in humans is currently unknown. **Haematological abnormalities:** Do not start therapy, or temporarily stop, if Absolute Neutrophil Count (ANC)  $< 1 \times 10^9$  cells/L, ALC  $< 0.5 \times 10^9$  cells/L or haemoglobin  $< 8$  g/dL. Temporarily stop therapy if these values are observed during routine patient management. **Vaccinations:** Use of live vaccines during, or immediately prior to, filgotinib treatment is not recommended. **Lipids:** Treatment with filgotinib was associated with dose dependent increases in lipid parameters, including total cholesterol, and high-density lipoprotein (HDL) levels, while low density lipoprotein (LDL) levels were slightly increased (see SmPC). **Cardiovascular risk:** Rheumatoid arthritis patients have an increased risk for cardiovascular disorders. Patients should have risk factors (e.g., hypertension, hyperlipidaemia) managed as part of usual standard of care. **Venous thromboembolism:** Events of deep venous thrombosis (DVT) and pulmonary embolism (PE) have been reported in patients receiving JAK inhibitors including filgotinib. Caution should be used in patients with risk factors for DVT/PE, such as older age, obesity, a medical history of DVT/PE, or patients undergoing surgery, and prolonged

immobilisation. **Lactose content:** Contains lactose; patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption should not take filgotinib. **Pregnancy/Lactation:** Filgotinib is contraindicated in pregnancy. Filgotinib should not be used during breast-feeding. Women of childbearing potential must use effective contraception during and for at least 1 week after cessation of treatment. **Driving/Using machinery:** No or negligible influence, however dizziness has been reported. **Side effects:** See SmPC for full information. **Common ( $\geq 1/100$  to  $< 1/10$ ):** nausea, upper respiratory tract infection, urinary tract infection and dizziness. **Uncommon ( $\geq 1/1000$  to  $< 1/100$ ):** herpes zoster, pneumonia, neutropenia, hypercholesterolaemia and blood creatine phosphokinase increase. **Serious side effects:** See SmPC for full information. **Legal category:** POM **Pack:** 30 film-coated tablets/bottle **Price:** UK Basic NHS cost: £863.10 **Marketing authorisation number(s):** Great Britain Jyseleca 100mg film-coated tablets PLGB 42147/0001 Jyseleca 200mg film-coated tablets PLGB 42147/0002 Northern Ireland Jyseleca 100mg film-coated tablets EU/1/20/1480/001 EU/1/20/1480/002 Jyseleca 200mg film-coated tablets EU/1/20/1480/003 EU/1/20/1480/004 **Further information:** Galapagos UK, Belmont House, 148 Belmont Road, Uxbridge UB8 1QS, United Kingdom 00800 7878 1345 [medicalinfo@glpg.com](mailto:medicalinfo@glpg.com) Jyseleca® is a trademark. **Date of Preparation:** January 2022 UK-RA-FIL-202201-00019  Additional monitoring required

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**For Great Britain and Northern Ireland, reporting forms and information can be found at [yellowcard.mhra.gov.uk](http://yellowcard.mhra.gov.uk) or via the Yellow Card app (download from the Apple App Store or Google Play Store).**  
**Adverse events should also be reported to Galapagos via email to [DrugSafety.UK.Ireland@glpg.com](mailto:DrugSafety.UK.Ireland@glpg.com) or 00800 7878 1345**

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