



Filgotinib for treating moderately to severely active ulcerative colitis

Technology appraisal guidance Published: 1 June 2022

www.nice.org.uk/guidance/ta792

Your responsibility

The recommendations in this guidance represent the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, health professionals are expected to take this guidance fully into account, alongside the individual needs, preferences and values of their patients. The application of the recommendations in this guidance is at the discretion of health professionals and their individual patients and do not override the responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or their carer or guardian.

All problems (adverse events) related to a medicine or medical device used for treatment or in a procedure should be reported to the Medicines and Healthcare products Regulatory Agency using the Yellow Card Scheme.

Commissioners and/or providers have a responsibility to provide the funding required to enable the guidance to be applied when individual health professionals and their patients wish to use it, in accordance with the NHS Constitution. They should do so in light of their duties to have due regard to the need to eliminate unlawful discrimination, to advance equality of opportunity and to reduce health inequalities.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should <u>assess and reduce the environmental</u> impact of implementing NICE recommendations wherever possible.

Contents

1 Recommendations	4
2 Information about filgotinib	5
Marketing authorisation indication	5
Dosage in the marketing authorisation	5
Price	5
3 Committee discussion	6
The condition	6
The treatment pathway	7
Clinical evidence	10
Economic model	13
Cost-effectiveness estimates	18
Innovation	19
Equalities consideration	20
4 Implementation	21
5 Appraisal committee members and NICE project team	22
Appraisal committee members	22
NICE project team	22

1 Recommendations

- 1.1 Filgotinib is recommended, within its marketing authorisation, as an option for treating moderately to severely active ulcerative colitis in adults:
 - when conventional or biological treatment cannot be tolerated, or
 - if the disease has not responded well enough or has stopped responding to these treatments, and
 - if the company provides filgotinib according to the commercial arrangement.

Why the committee made these recommendations

Standard treatments for moderately to severely active ulcerative colitis after conventional treatment are tumour necrosis factor (TNF)-alpha inhibitors (adalimumab, golimumab or infliximab), tofacitinib, ustekinumab or vedolizumab.

Clinical trial evidence shows that filgotinib is more effective than placebo for treating moderately to severely active ulcerative colitis. There is no direct evidence comparing filgotinib with treatments that are offered after conventional treatment. Indirect comparison suggests that filgotinib is likely to be as effective as most of them.

The most likely cost-effectiveness estimates for filgotinib compared with other treatments are within the range NICE normally considers an acceptable use of NHS resources. So filgotinib is recommended.

2 Information about filgotinib

Marketing authorisation indication

2.1 Filgotinib (Jyseleca, Galapagos) is indicated for treating moderately to severely active ulcerative colitis in adults when conventional or biological treatment cannot be tolerated, or the disease has responded inadequately or lost response to treatment.

Dosage in the marketing authorisation

2.2 The dosage schedule is available in the <u>summary of product</u> characteristics for filgotinib.

Price

- 2.3 The price for filgotinib is £863.10 per bottle for thirty 200-mg tablets (BNF online, accessed March 2022). The average cost for each patient per year is estimated at £10,508 based on the list price.
- 2.4 The company has a <u>commercial arrangement</u>. This makes filgotinib available to the NHS with a discount. The size of the discount is commercial in confidence. It is the company's responsibility to let relevant NHS organisations know details of the discount.

3 Committee discussion

The <u>appraisal committee</u> considered evidence submitted by Galapagos, a review of this submission by the evidence review group (ERG), and responses from stakeholders. See the <u>committee papers</u> for full details of the evidence.

The condition

Living with moderately to severely active ulcerative disease is physically and emotionally challenging

The patient experts explained that the experience of living with 3.1 ulcerative colitis varies on an individual level, but when the disease is active it is extremely challenging. They explained that the symptoms and unpredictable nature of the disease have a profound and devastating impact on all aspects of a person's life. People have abdominal pain and fatigue, frequent diarrhoea and extra-intestinal manifestations such as joint, skin and eye problems. These can lead to an inability to sleep, work, socialise, have a relationship, or look after children. They explained that feeling out of control is an important and common issue for many people with moderately to severely active ulcerative colitis. The committee understood that people with the disease often have difficulty doing day-to-day tasks, have side effects from treatments, fear of having surgery, and difficulties having relationships, and that it affects their selfesteem. The committee concluded that living with moderately to severely active disease is physically and emotionally challenging, and that if medical treatment fails, surgery may be needed.

There is an unmet need for new treatments that induce and maintain remission

The clinical and patient experts explained that there is an unmet need for new treatments that induce and maintain remission. This is because for many people their disease does not respond well to current treatments, or they stop working. The only option for them, other than surgery, is

long-term corticosteroids. This may be associated with extreme side effects including mood changes such as irritability and depression, osteoporosis, cataracts, and risk of steroid dependency and withdrawal. The patient experts explained that if multiple treatments are available early on in the treatment pathway, it allows them to identify the best option as quickly as possible. The clinical experts explained that surgery can be effective for some people, but is left until it is unavoidable. Surgery outcomes vary: there can be a psychological impact both from the surgery and having a stoma, even if it is temporary. Pelvic surgery can also significantly affect sexual and reproductive function. The clinical and patient experts agreed that, because filgotinib is an oral treatment, it may be more convenient than other treatment options. The committee concluded that people with the condition and clinicians would welcome a new treatment option for moderately to severely active ulcerative colitis.

The treatment pathway

Current standard care for people with moderate to severely active disease varies

The clinical experts explained that most people are offered a tumour 3.3 necrosis factor (TNF)-alpha inhibitor first if conventional treatments (aminosalicylates, corticosteroids or thiopurines) cannot be tolerated, or if the disease has not responded well enough or stopped responding to treatment. This is because cheaper biosimilars are available in this class. But they said that TNF-alpha inhibitors are not appropriate for everyone, for example, people with a high risk of heart failure or who are prone to infection. The clinical experts explained that they would usually be offered vedolizumab or ustekinumab instead. If someone has had a TNF-alpha inhibitor and their disease does not respond well enough or stops responding, they are offered a different TNF-alpha inhibitor, or vedolizumab, tofacitinib or ustekinumab. The clinical experts said that treatment is chosen based on factors such as what the person has already tried and the disease's response to these, the safety profile of the drug, and the person's preference. The committee concluded that the most appropriate comparators are TNF-alpha inhibitors, tofacitinib, ustekinumab and vedolizumab, and that in practice the order in which

these are given varies.

Filgotinib could be used at 3 different positions in the treatment pathway

- 3.4 Filgotinib has a marketing authorisation for treating moderately to severely active ulcerative colitis when conventional or biological treatment cannot be tolerated, or if the disease has not responded well enough or stopped responding to treatment. The company's submission presented filgotinib at 3 positions in the treatment pathway:
 - A first-line treatment for the 'biologic-naive' people who have never had a biological treatment (a TNF-alpha inhibitor or vedolizumab) or tofacitinib (a Janus-associated kinase [JAK] inhibitor), but have had conventional treatment and their disease has likely not responded to it or lost response to it.
 - A second-line treatment for 'biologic-experienced' people who have had 1
 biological treatment or tofacitinib and either their disease did not respond to it,
 lost response to it, or they could not tolerate it.

 A third-line treatment for biologic-experienced – people who have had 2 or more biological treatments or tofacitinib and either their disease did not respond or lost an initial response, or they could not tolerate it.

The company clarified that in the biologic-experienced subgroup it assumed the same efficacy for filgotinib as a second or third-line treatment because of the lack of evidence. The ERG noted that efficacy reduces when moving from the first biologic to a second or third biologic when the disease does not respond adequately or loses response. It explained that in the SELECTION trial (see section 3.6) remission at 10 weeks reduced from 16.3% in people taking their second biologic to 7.4% in people taking their third biologic. The clinical experts explained that they would expect efficacy to reduce when moving from second to third-line treatment because of previous drug exposure or because people needing further treatments have disease that is more difficult to treat. The clinical and patient experts agreed with the company's positioning of filgotinib because it would offer an additional choice at each line of treatment. The committee noted it was not presented with evidence of filgotinib's effectiveness specifically as a third-line treatment. The committee considered that the company's assumption that filgotinib would have the same efficacy, regardless of how many biologics treatments people had previously, was unlikely and optimistic. But it noted that this applies to all treatments and not just filgotinib. The committee considered that having another option at each of the 3 positions in the pathway offers people more choice, and agreed with the company's positioning.

Conventional treatment is not an appropriate comparator for filgotinib

3.5 The NICE scope included conventional treatment, infliximab, adalimumab, golimumab, tofacitinib, ustekinumab and vedolizumab as comparators. The company explained that it considered conventional treatment as a relevant comparator in line with the NICE scope and NICE's technology appraisal guidance on tofacitinib and ustekinumab. The ERG noted that the population under consideration was: people with moderately to severely active ulcerative colitis whose disease has not responded well enough, or has stopped responding to, or could not tolerate conventional or biologic treatment – that is, people who had already had conventional treatment. Therefore, the ERG did not

consider conventional treatment a relevant comparator. The clinical experts agreed that filgotinib will only be used after conventional treatment. The committee concluded that conventional treatment is not an appropriate comparator for filgotinib.

Clinical evidence

The SELECTION trial is broadly generalisable to UK clinical practice

- 3.6 SELECTION was a phase 2b/3 randomised, double-blind, multicentre trial comparing filgotinib 200 mg, filgotinib 100 mg and placebo. It included adults with moderately to severely active ulcerative colitis, defined by a Mayo clinic score of between 6 and 12, and component subscores of at least 1 for stool frequency and rectal bleeding and at least 2 for endoscopic findings and physicians' global assessment. It had an induction and a maintenance phase:
 - Induction phase: included 2 cohorts, biologic-naive (n=659) and biologic-experienced (n=689). Participants were randomised to filgotinib 200 mg or 100 mg, or placebo. The primary outcome was the proportion of people who had remission from endoscopy, bleeding or stool frequency (EBS). The main secondary outcomes were the Mayo clinic score for remission and response, mucosal healing, an endoscopic subscore of 0, and histologic remission. All outcomes were measured at the end of week 10.

• Maintenance phase: the 664 participants whose disease responded after 10 weeks of induction treatment were re-randomised to maintenance treatment of filgotinib 200 mg or 100 mg, or placebo. Participants having filgotinib during the induction phase could be randomised to the dose of filgotinib they had during induction, or placebo. Participants whose disease responded to placebo during the induction phase continued on placebo. The primary outcome was the proportion of people with EBS remission. The main secondary outcomes were the Mayo clinic score for remission and response, mucosal healing, an endoscopic subscore of 0, histologic remission, sustained EBS remission and 6-month corticosteroid-free remission. All outcomes were measured up to week 58.

The clinical experts explained that the population in SELECTION was broadly generalisable to the people who would have filgotinib in clinical practice. However, they noted that the biologic-naive subgroup of the induction phase included more women and non-US people having filgotinib than placebo. The committee considered that a greater proportion of US people could have a minor influence on disease severity and concomitant treatment use. It concluded that SELECTION is broadly generalisable to NHS practice and is suitable for decision making.

Filgotinib is more effective than placebo at inducing and maintaining remission

In the induction phase of the SELECTION trial, the rate of EBS remission in biologic-naive participants was statistically significantly higher in the filgotinib arm at 26.1% (95% confidence interval [CI] 20.4% to 31.8%) than the placebo arm at 15.3% (95% CI 8.9% to 21.7%). Similarly, rates of EBS remission were also statistically significantly higher in the filgotinib arm at 11.5% (95% CI 7.4% to 15.5%) than the placebo arm at 4.2% (95% CI 0.6 to 7.9%) for the biologic-experienced subgroup in the induction phase. At week 58 of the maintenance phase, a statistically significantly higher proportion of people who had filgotinib were in EBS remission at 37.2% (95% CI 30.2% to 44.2%) than people who had placebo at 11.2% (95% CI 4.5% to 18.0%). The committee concluded that filgotinib is more effective than placebo for inducing and maintaining remission for people with moderately to severely active ulcerative colitis.

Filgotinib is likely to be as effective as most comparators in the induction phase

- There was no head-to-head evidence comparing filgotinib against the comparators in the NICE scope (see section 3.5). Therefore, the company did network meta-analyses (NMAs) to allow for indirect treatment comparisons with them. It presented NMAs according to previous biologic use for induction and for maintenance treatment with filgotinib. Analyses were of clinical response, clinical remission and mucosal healing:
 - The biologic-naive subgroup included people who had not had a biologic. The analysis estimated the relative efficacy of filgotinib compared with adalimumab, golimumab, infliximab, tofacitinib, ustekinumab and vedolizumab.
 - The biologic-experienced subgroup included people who had had a biologic.
 The analysis estimated the relative efficacy of filgotinib with adalimumab, tofacitinib, ustekinumab and vedolizumab.

The results of the company's induction NMAs showed that filgotinib is likely to be as effective as the comparators in the biologic-naive and biologic-experienced subgroups. The results are academic in confidence and cannot be presented here. The ERG considered that the company's induction phase NMAs were methodologically robust and were a suitable source of clinical data for its model. The committee noted that the trials included in the NMAs had different designs, but concluded that the company's induction phase NMAs were appropriate.

Filgotinib's effectiveness in the maintenance phase is uncertain

3.9 The company's maintenance phase NMAs estimated values to populate the longer-term effectiveness of each treatment for the cost-effectiveness model. They estimated that filgotinib is likely to be as effective as most comparators in biologic-naive and biologic-experienced subgroups. The results are academic in confidence and cannot be presented here. The ERG noted that the results of the maintenance phase NMAs were invalid because people in the maintenance phase represent the population whose disease has

responded to the different induction treatments, which varied between trials. The ERG explained that the company's NMAs used placebo as a common comparator, but what constituted the 'placebo group' varied between trials. The company's NMAs included participants whose disease responded to filgotinib who were then re-randomised to placebo. Other studies included participants whose disease responded to comparator treatments who were then re-randomised to placebo, thus disconnecting the network and making the results invalid. The ERG explained that in clinical practice people entering the maintenance phase either continue the induction treatment that their disease responded to or stop it. At this point there is no option to switch to another treatment without first being inducted onto that treatment. Therefore, the ERG preferred to calculate 50-week probabilities of no response, response without remission and remission conditional on having the response at 10 weeks at the end of induction. It used these values to replace the values from the maintenance phase NMAs in its base case. The committee noted that the re-randomisation of people in trials at the start of the maintenance phase made judging the relative effectiveness of treatments beyond the induction period difficult. It also noted that neither the company nor the ERG had explored adjusting for differences in baseline risks in the maintenance part of the NMAs. It would have preferred to see a maintenance phase NMA that included only trial participants who remained on active treatment or placebo for the duration of the trial or participants randomised to active treatment or placebo for both the induction and maintenance phase. However, the committee noted that, because of the trial's design, this would still only include people whose disease responded during the induction phase. The committee considered that both the company's and ERG's approaches were biased. However, the committee noted that using either approach had a minimal effect on the cost-effectiveness results. The committee concluded that it had concerns about the methodology of the maintenance NMAs and that the effectiveness of filgotinib in the maintenance phase was uncertain.

Economic model

The company's economic model is appropriate for decision

making

The company used a Markov model to estimate the cost effectiveness of filgotinib compared with adalimumab, golimumab, infliximab, tofacitinib, ustekinumab and vedolizumab. The company's model structure was similar to those used in previous ulcerative colitis technology appraisals. It included health states defined by the type of treatment (advanced treatment, conventional treatment, surgery, post-surgery), as well as degree of disease control (remission or response without remission) to replicate the relapsing and remitting nature of ulcerative colitis. The Markov model had a lifetime horizon and a cycle length of 10 weeks and included clinical response, clinical remission and serious infections. The ERG agreed that the company captured all relevant health states and that its approach was appropriate. The committee concluded that the company's model was appropriate for its decision making.

Cardiovascular adverse events should have been included in the model

3.11 The company's model only included serious infections. It excluded all other adverse events associated with filgotinib. The ERG considered that the company's approach was appropriate and in line with NICE's technology appraisal guidance on tofacitinib and ustekinumab. However, the committee was aware of the association between the JAK inhibitor tofacitinib and incidence of cardiovascular events and malignancies shown in a safety study of people over 50 with rheumatoid arthritis and at least 1 additional cardiovascular risk factor. It was also aware of broader ongoing investigations of JAK inhibitors. The committee questioned if filgotinib would also be associated with increased cardiovascular risk in people with ulcerative colitis. The clinical experts pointed out that people with ulcerative colitis are much younger and may have a different risk profile than people with rheumatoid arthritis. The committee concluded that it was concerned that people having filgotinib were likely to have an increased risk of cardiovascular events, and that balancing the benefit and risks before starting filgotinib was essential. It also agreed that cardiovascular adverse events should have been included in the model.

Long-term loss of response in the model should have been different in people in the 'response without remission' and 'remission' health states

3.12 Ulcerative colitis is not always active. Many people with the disease have periods of response and loss of response. In its model, the company estimated long-term loss of response from its NMAs and used the same value for the 'response without remission' and 'remission' health states. The company explained that, if the disease responded to treatment, it would not expect this response to wane over time. So, it considered that using the same loss of response for both health states was appropriate. The ERG explained that remission is harder to achieve than response without remission. But once it is achieved it is more stable. It said that the company's approach is inconsistent with this and favours filgotinib. The ERG noted that it could not adjust the model for differential loss of response. The clinical experts agreed with the ERG, saying loss of response was less likely in people whose disease is in remission than in people whose disease has only responded. The committee concluded that it would have been more appropriate to use a differential loss of response for each health state.

Loss of response is unlikely to be constant over time

3.13 In its model, the company assumed a constant loss of response for the 'remission' and 'response without remission' health states. The company considered that its assumption that loss of response is constant over time was likely to be an overestimate. The company also explained that the constant loss of response rates would likely underestimate the average duration of treatment. It provided a scenario analysis assuming a 25% reduction in the loss of response rate after the first year of maintenance. The clinical experts considered this scenario to be appropriate. However, the ERG explained that a 25% reduction refers to the reduction in loss of response rate not to the loss of response rate. The committee was aware that NICE's technology appraisal guidance on ustekinumab used a 25% reduction after the first 2 years of treatment. It noted that the company's scenario had a minimal effect on costeffectiveness results. The committee concluded that, because of the lack of long-term efficacy data, it was not clear if loss of response would be

constant over time, and it considered the company's scenario in its decision making.

The health state utility values for people with active ulcerative colitis are uncertain

3.14 The company and the ERG used health state utility values based on the SELECTION trial in their base cases. The company used utility values collected at baseline for the 'active ulcerative colitis' health state and utility values collected at 10 weeks for the 'response without remission' and 'remission' health states. It applied the same values for the full duration of the model. The utility values are academic in confidence and cannot be presented here. The ERG agreed with the company's utility values, except for the 'active ulcerative colitis' health state. The ERG preferred to use the utility values collected at 10 weeks, which were specific to non-responders, and for consistency with the other health states. The ERG asked the company to provide scenarios exploring utility values specific to biologic-naive and experienced people, and specific to people in the induction and maintenance phase. The committee was disappointed that the company did not provide these scenarios. It was also aware that considerably lower utility values for active ulcerative colitis were used in NICE's technology appraisal guidance on tofacitinib and ustekinumab. In the absence of additional scenarios, the committee concluded that the ERG's approach was reasonable, but recognised that the quality of life of people with active ulcerative colitis in the analysis was uncertain.

Comparator treatment sequences used in the NHS vary

3.15 The ERG noted that the company's model included relevant comparators and some treatment sequences used in NHS clinical practice. However, it also noted that the company could have explored additional treatment sequences. The clinical experts explained that in clinical practice if people with the disease have a loss of response and have produced antibodies on 1 TNF-alpha inhibitor, they would often be offered another TNF-alpha inhibitor. Therefore, a treatment sequence of infliximab followed by another TNF-alpha inhibitor (for example, adalimumab) and other combinations of anti-TNFs should be considered. The clinical

experts said that the company's modelled treatment sequences did not fully reflect clinical practice, and some were less plausible (for example, using tofacitinib after vedolizumab). The committee was aware that ulcerative colitis is a heterogeneous disease and treatment choices are influenced by many factors. It was pleased that the company attempted to model treatment sequences and recognised that, because of the large number of possible treatment sequences, it was not practical to model them all. The committee noted that the company's choice of treatment sequences had a minimal effect on cost-effectiveness results. It concluded that a range of treatment sequences for moderately to severely active ulcerative colitis are plausible, and the company's modelled treatment sequences do not fully reflect clinical practice.

The cost of dose escalation for comparators should only be included if the clinical benefit is also included

3.16 In its model, the company used dose escalation for some comparators but not filgotinib. It clarified that dose escalation for filgotinib is not appropriate because there are only 2 approved doses, 200 mg and 100 mg, and filgotinib 100 mg is only approved for ulcerative colitis with moderate to severe renal impairment. The company explained that the dose of comparators is commonly escalated in NHS clinical practice, if allowed by the marketing authorisation. The ERG explained that the proportion of people who have dose escalation and the time to escalation is not certain. It noted that the company's approach was inconsistent because it applied additional costs for escalated doses, but not the additional clinical benefits associated with dose escalation. This favoured filgotinib. Therefore, the ERG considered that it was not appropriate to include the cost of dose escalation in its base case. The clinical experts explained that dose escalation is common to try to achieve remission or regain partially lost response. The committee recalled that it was not appropriate to include dose escalation for filgotinib and that it was not used in clinical trials of comparator treatments. The committee considered the ERG's approach more appropriate for decision making. It considered that, if the cost of dose escalation is included, its clinical benefit should also be included.

The ERG's approach of a consistent probability and quality of life impact of chronic pouchitis is appropriate

The company estimated the rates of long-term complications after 3.17 surgery from Ferrante et al. (2012), in line with the approach in NICE's technology appraisal guidance on tofacitinib. Ferrante et al. reported that 46% of people developed at least 1 episode of acute pouchitis and 19% developed chronic pouchitis. The company used the 46% figure to calculate the 10-weekly constant probability of developing post-surgery complications for the 'post-surgery complications' health state, and assigned a lower utility score for the remainder of their lifetime in its model. The ERG explained that most people do not develop chronic pouchitis, and that acute pouchitis can be treated. Therefore, the ERG considered that 46% was not a correct estimate of the probability of developing chronic complications. Instead it used the value of 19%, which was consistent with the impact on quality of life applied in the model. The committee concluded that the ERG's approach of using the probability of chronic pouchitis was more appropriate for decision making.

Cost-effectiveness estimates

The most likely cost-effectiveness estimates are lower than those normally considered an acceptable use of NHS resources

- 3.18 Cost effectiveness was assessed by calculating net health benefit, because there were multiple comparators for each subgroup. The incremental net health benefit of filgotinib was compared with each comparator at a threshold of £20,000 and £30,000 per quality-adjusted life year (QALY) gained for each subgroup. The company's and ERG's base case results included the confidential commercial discounts, which means they cannot be reported here. However, the committee recalled that there were several uncertainties in the company's approach, specifically:
 - no evidence was presented for efficacy estimates for filgotinib at third-line for the biologic-experienced subgroup (see section 3.4)

- the results of the maintenance phase NMAs (see section 3.9)
- equal loss of response for the 'remission' and 'response without remission' health states (see <u>section 3.12</u>)
- uncertainty in quality-of-life estimates (see <u>section 3.14</u>)
- the comparator treatment sequences did not fully reflect clinical practice (see section 3.15)
- the application of dose escalation (see section 3.16).

The committee noted that most of the uncertainties had minimal effect on cost-effectiveness results. It considered the biologic-naive and biologic-experienced subgroups separately. It concluded that, taking into account the uncertainty, the cost-effectiveness estimates for filgotinib compared with other treatments for moderately to severely active ulcerative colitis were below what NICE normally considers an acceptable use of NHS resources.

Innovation

The benefits of filgotinib are adequately captured in the costeffectiveness analysis

3.19 The company considered filgotinib to be innovative because it is a second-generation JAK inhibitor that is a preferential and reversible inhibitor of JAK1. It explained that targeted inhibition of JAK1 could reduce inflammatory cytokine signalling in ulcerative colitis. Filgotinib is administered orally so there will be no additional costs associated with its use. The clinical experts noted that other treatments with similar class and efficacy are available. The committee acknowledged the benefits offered by filgotinib and that people value an oral treatment, but it noted that it had not been presented with evidence of any additional benefits that were not captured in the QALY measurements. The committee concluded that the benefits of filgotinib were adequately captured in the model.

Equalities consideration

There are no equalities issues relevant to the recommendations

3.20 The patient experts explained that for certain faith groups the impact of active disease and the effects of surgery may interfere with religious practices and cause distress. The committee did not consider this an equality issue that could be resolved by this appraisal. No other equality or social value judgement issues were identified.

4 Implementation

- 4.1 Section 7 of the National Institute for Health and Care Excellence
 (Constitution and Functions) and the Health and Social Care Information
 Centre (Functions) Regulations 2013 requires clinical commissioning
 groups, NHS England and, with respect to their public health functions,
 local authorities to comply with the recommendations in this appraisal
 within 3 months of its date of publication.
- The Welsh ministers have issued directions to the NHS in Wales on implementing NICE technology appraisal guidance. When a NICE technology appraisal recommends the use of a drug or treatment, or other technology, the NHS in Wales must usually provide funding and resources for it within 2 months of the first publication of the final appraisal document.
- 4.3 When NICE recommends a treatment 'as an option', the NHS must make sure it is available within the period set out in the paragraphs above. This means that, if a patient has moderately to severely active ulcerative colitis and the doctor responsible for their care thinks that filgotinib is the right treatment, it should be available for use, in line with NICE's recommendations.

5 Appraisal committee members and NICE project team

Appraisal committee members

The 4 technology appraisal committees are standing advisory committees of NICE. This topic was considered by committee B.

Committee members are asked to declare any interests in the technology to be appraised. If it is considered there is a conflict of interest, the member is excluded from participating further in that appraisal.

The <u>minutes of each appraisal committee meeting</u>, which include the names of the members who attended and their declarations of interests, are posted on the NICE website.

NICE project team

Each technology appraisal is assigned to a team consisting of 1 or more health technology analysts (who act as technical leads for the appraisal), a technical adviser and a project manager.

Harsimran Sarpal

Technical lead

Michelle Green

Technical adviser

Jeremy Powell

Project manager

ISBN: 978-1-4731-4585-6

Accreditation

