NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Final draft guidance

Benralizumab for treating relapsing or refractory eosinophilic granulomatosis with polyangiitis

1 Recommendations

1.1 Benralizumab as an add-on to standard care can be used, within its marketing authorisation, as an option to treat relapsing or refractory eosinophilic granulomatosis with polyangiitis (EGPA) in adults. It can only be used if the company provides it according to the commercial arrangement (see section 2).

1.2 Benralizumab should be stopped after 52 weeks if the EGPA has not responded. Response is:

- a Birmingham Vasculitis Activity Score (BVAS) score of 0, and
- a reduction in oral corticosteroid use, either:
  - by 50% or more since starting benralizumab, or
  - to 7.5 mg or less per day.

1.3 This recommendation is not intended to affect treatment with benralizumab that was started in the NHS before this guidance was published. People having treatment outside this recommendation may continue without change to the funding arrangements in place for them before this guidance was published, until they and their NHS healthcare professional consider it appropriate to stop.

Issue date: August 2025

What this means in practice

Benralizumab must be funded in the NHS in England as an add-on to standard care for relapsing or refractory EGPA in adults, if it is considered the most suitable treatment option. Benralizumab must be funded in England within 90 days of final publication of this guidance.

Benralizumab should be stopped after 52 weeks if the EGPA has not responded.

There is enough evidence to show that benralizumab provides benefits and value for money, so it can be used routinely across the NHS as an add-on to standard care in this population.

Why the committee made these recommendations

Standard care for relapsing or refractory EGPA is oral corticosteroids with or without immunosuppressants.

Benralizumab plus standard care has not been directly compared in a clinical trial with standard care alone. But indirect comparisons suggest that benralizumab plus standard care increases the likelihood of remission (having fewer or no symptoms of EGPA) and reduces relapse (having worse symptoms) compared with standard care alone.

Despite uncertainties in the clinical evidence and in the economic model, the cost-effectiveness estimates are within the range that NICE considers an acceptable use of NHS resources.

In the economic model, people stopped having benralizumab if their condition had not responded after 52 weeks.

So, benralizumab can be used, but should be stopped after 52 weeks if the condition has not responded.

2 Information about Error! Reference source not found.

Marketing authorisation indication

2.1 Benralizumab (Fasenra, AstraZeneca) is indicated 'as an add-on treatment for adult patients with relapsing or refractory eosinophilic granulomatosis with polyangiitis'.

Dosage in the marketing authorisation

2.2 The dosage schedule is available in the summary of product characteristics for benralizumab.

Price

2.3 Benralizumab costs £1,955 for a solution of 30 mg per 1 mg for injection (excluding VAT; BNF online accessed May 2025).

2.4 The company has a commercial arrangement (commercial access agreement). This makes benralizumab available to the NHS with a discount. The size of the discount is commercial in confidence.

Carbon Reduction Plan

2.5 Information on the Carbon Reduction Plan for UK carbon emissions for AstraZeneca will be included here when guidance is published.

3 Committee discussion

The evaluation committee considered evidence submitted by AstraZeneca, a review of this submission by the external assessment group (EAG), and responses from stakeholders. See the committee papers for full details of the evidence.

The condition

Eosinophilic granulomatosis with polyangiitis

3.1 Eosinophilic granulomatosis with polyangiitis (EGPA; previously known as Churg-Strauss syndrome) is a rare, chronic autoimmune condition with

regular flare ups and relapse. It involves high levels of eosinophils (a type of white blood cell) in the circulation and tissues. This leads to necrotising inflammation in the small and medium-sized blood vessels (vasculitis), which restricts blood flow to tissues and organs, and damages them. Asthma is one of the main symptoms and can begin many years before other symptoms. Later symptoms include rashes, joint pain and swelling, peripheral neuropathy, abdominal pain, diarrhoea, shortness of breath, arrhythmia, red blood cells in urine, chest pain and heart failure. EGPA can affect every part of the body. Delays in diagnosis can mean worse disease, and more side effects associated with treatment. Relapse means worse symptoms and more organ damage; at least 50% of people have a relapse within 5 years when having standard care (see section 3.2). Refractory is defined as no remission in 6 months, worse symptoms, and a need for high doses of oral corticosteroids. Diagnosis is difficult and can take many years. A patient expert said that late diagnosis can mean irreversible organ damage. Patient experts explained how nerve and joint pain, and asthma symptoms reduce mobility, sometimes to the extent that people have to give up work. People with EGPA can also become isolated because they may avoid other people to reduce the risk of infections. Quality of life is also badly affected by oral corticosteroids, which are the main treatment for EGPA. One patient expert said that oral corticosteroid side effects affected their home and work life, and included feeling "woolly", memory issues, mania, feeling angry, difficulty sleeping and weight gain. They said that within 2 years of taking benralizumab they were able to stop oral corticosteroids altogether, and that they could function "pretty much as well as I used to". The committee concluded that EGPA and the current treatments for it – in particular oral corticosteroids – had a serious impact on people's lives, and that there was a need for a targeted, well-tolerated treatment.

Clinical management

Treatment options

3.2 There are no approved medicines specifically for EGPA in the UK. The main treatment is oral corticosteroids, which are associated with severe side effects including diabetes, cardiovascular disease, osteoporosis, eye problems, peptic ulcers, pneumonia and renal impairment. Immunosuppressants can be added if necessary for relapsing or refractory EGPA. If EGPA is severe (organ or life threatening), cyclophosphamide and rituximab are also options. People who also have severe eosinophilic asthma can have benralizumab (see NICE's technology appraisal guidance on benralizumab for treating severe eosinophilic asthma [TA565]) or mepolizumab (see NICE's technology appraisal guidance on mepolizumab for treating severe eosinophilic asthma).

Comparators

3.3 The company submitted evidence for benralizumab plus standard care compared with standard care alone. Standard care for non-severe, relapsing or refractory EGPA is oral corticosteroids, with immunosuppressants if needed. The company positioned benralizumab for relapsing or refractory EGPA that is not severe (not organ or life threatening). So, it did not submit comparative evidence against cyclophosphamide or rituximab, which are additional options for severe episodes of EGPA (see section 3.6). The clinical experts agreed that standard care with oral corticosteroids, and immunosuppressants if needed, was the appropriate current treatment for people with non-severe relapsing or refractory EGPA. The committee concluded that it was appropriate to compare benralizumab with standard care for this evaluation.

Clinical effectiveness

MANDARA trial

3.4 The MANDARA trial was a phase 3, randomised, double-blind, non-inferiority trial. It compared benralizumab plus oral corticosteroids (with or without immunosuppressants) with mepolizumab plus oral corticosteroids (with or without immunosuppressants). The trial included 140 adults with refractory or relapsing EGPA, 18 of whom were from the UK. Anyone with severe (organ- or life -threatening) EGPA was excluded. The trial lasted for 1 year and the primary outcome was the percentage of people whose condition was in remission at both week 36 and week 48. Remission was defined as a Birmingham Vasculitis Activity Score (BVAS) of 0 and a reduction in oral corticosteroid use to 4 mg per day or less. The trial results showed that benralizumab was non-inferior to mepolizumab, with an adjusted remission rate of 57.7% for benralizumab and 56.5% for mepolizumab (difference 1.2% [95% confidence interval -14.1 to 16.5], p=0.88). The committee concluded that benralizumab is an effective treatment for EGPA.

Indirect treatment comparison

3.5 Because there was no direct evidence comparing benralizumab plus standard care with standard care alone, the company did a Bucher indirect treatment comparison (ITC) and an anchored matching-adjusted indirect comparison (MAIC). Both of these compared MANDARA with the MIRRA trial. MIRRA was the key trial for mepolizumab. It was a phase 3, randomised, double-blind, placebo-controlled trial comparing mepolizumab plus oral corticosteroids (with or without immunosuppressants) with placebo plus oral corticosteroids (with or without immunosuppressants). It included 136 adults with refractory or relapsing EGPA, 13 of whom were from the UK. Anyone with severe (organ- or life-threatening) EGPA was excluded. The trial lasted for 1 year and a primary outcome was the percentage of people whose condition

was in remission both at week 36 and at week 48. The Bucher ITC showed that adding benralizumab to standard care statistically significantly increased the percentage of people whose condition was in remission at both week 36 and week 48. The odds ratio was 17.75 (95% confidence interval 3.33 to 94.67). Adding benralizumab reduced the annualised relapse rate compared with standard care alone, with a rate ratio of 0.57 (95% confidence interval 0.28 to 1.15). The results of the MAIC were similar, but more uncertain. The EAG was satisfied with the company's approach. The committee concluded that the Bucher ITC comparing benralizumab with standard care was appropriate for decision making.

Generalisability to severe EGPA

3.6 The marketing authorisation for benralizumab is as an add-on treatment for relapsing or refractory EGPA. The company submitted evidence for relapsing or refractory EGPA that is not severe, that is, not organ or life threatening. The company said that this was because MANDARA was designed as a non-inferiority trial against mepolizumab. Mepolizumab was expected to be standard care by the time benralizumab was evaluated by NICE. So, the company designed MANDARA to be as similar as possible to the key trial for mepolizumab, MIRRA, which excluded people with severe (organ- or life-threatening) EGPA. But NICE did not evaluate mepolizumab because the company that makes it chose not to submit any evidence for it. The EAG noted that Clinical Practice Research Datalink (CPRD) data showed that around a quarter of people have severe EGPA and so would not be eligible for benralizumab. It said that it had had clinical advice that benralizumab would be a useful treatment option for people with severe EGPA. The clinical experts at the committee meeting explained that severe and non-severe EGPA are not 2 distinct subgroups. They said that people with EGPA can have severe episodes, with organ- or life-threatening symptoms. They will be offered treatment (usually rituximab or cyclophosphamide) to stabilise their condition. The clinical

experts explained that they would not consider benralizumab for a severe episode because there was no evidence to support it – people with severe EGPA were excluded from MANDARA. They added that, once the person's condition is stable, usually after a month or 2 of treatment, their EGPA may then be defined as relapsing or refractory, becoming eligible for benralizumab. The company noted that there were people in MANDARA with a history of severe EGPA, and that they would be able to have benralizumab. The committee concluded that it would consider benralizumab in line with its marketing authorisation. This would mean that people with severe EGPA would not be excluded from treatment with benralizumab. This is because, although the clinical experts suggested that benralizumab would not be used to treat a severe episode of EGPA, people with severe EGPA could become eligible for benralizumab once their EGPA had stabilised.

Economic model

Company's modelling approach

3.7 The company submitted a Markov state-transition model with a 4-week cycle length to estimate the cost effectiveness of benralizumab plus standard care compared with standard care alone. The company also incorporated a sub-model to capture the effect of benralizumab on health-related quality of life and NHS costs, by reducing the acute and chronic adverse events from oral corticosteroids. The Markov model had 4 health states:

- stable disease, divided into:
  - refractory (no remission in the previous 6 months)
  - non-refractory (oral corticosteroid dose stable or tapered in response to reduced EGPA disease activity)
- remission (a BVAS score of 0 and an oral corticosteroid dose of 4 mg per day or less)
- relapse, defined as:

  - active vasculitis (a BVAS score over 0), or
  - active asthma signs or symptoms, or both, with a corresponding worsening in ACQ-6 score, or
  - active nasal or sinus disease, or both, with a corresponding worsening in at least 1 sinonasal symptom question leading to:
    - ◊ an increased dose of oral corticosteroids to over 4 mg per day, or
    - ◊ increased or added immunosuppressant treatment, or
    - ◊ admission to hospital because the EGPA has worsened
- death.

People entered the model in the stable-disease health state. The company divided stable disease into refractory and non-refractory substates. It said that EGPA is best described by the 4 health states of remission, refractory, non-refractory and relapse. But it said that data limitations in MANDARA meant it was not possible to inform transitions for the refractory and non-refractory states. So, the company treated these 2 health states as substates of stable disease, with constant proportions in each over time. The model had a lifetime time horizon. The EAG was satisfied in general with the model structure, and the clinical experts agreed the model looked appropriate. The committee concluded that the company's model was appropriate for decision making.

Stopping rule

3.8 The marketing authorisation for benralizumab does not specify a stopping rule. But, in the company's model, response to benralizumab was assessed at 52 weeks. Everyone with a response (defined as a BVAS of 0 plus oral corticosteroid dosage of 4 mg per day or less, the primary outcome definition of main remission in MANDARA) kept having benralizumab. Non-response meant that people stopped benralizumab and moved to standard care alone and could not switch back to benralizumab. Everyone who stopped benralizumab was subject to

standard-care transition probabilities. The company said that it chose this stopping rule because it was in line with the:

- length of MANDARA
- recommended use of benralizumab in severe asthma
- anticipated use of benralizumab for EGPA in UK clinical practice.

But the clinical experts explained that the EGPA can respond well, with a BVAS score of 0, and yet people may not be able to reduce their oral corticosteroid use to 4 mg per day or less. The clinical experts noted that some people had doses of oral corticosteroids as high as 40 mg per day before starting benralizumab. The clinical experts said that in practice they use the European League Against Rheumatism (EULAR) criteria, which uses a cut-off of 7.5 mg or less per day. Some of the outcomes in MANDARA also used a remission definition of a BVAS score of 0 plus an oral corticosteroid dosage of 7.5 mg or less per day. The clinical experts suggested that an alternative stopping rule would be a reduction in oral corticosteroids of at least 50% since the start of treatment. The committee concluded that it would prefer a stopping rule in the model that defined response as a BVAS score of 0, with a reduction in oral corticosteroids of either 50% or more since the start of treatment or to 7.5 mg or less per day.

Discontinuation

Benralizumab discontinuation rate

3.9 The company applied a constant discontinuation rate in the model. This accounted for people who stopped benralizumab outside of the stopping rule at 52 weeks (see section 3.8). The company said that the discontinuation rate in MANDARA was unusually low (1.4% per year). In the MANDARA open-label extension trial it was 8% per year, while in TA565 the discontinuation rate was 12% per year. The company chose to assume 5% discontinuation per year in the benralizumab arm of the

model. It said this was a conservative choice and reflected UK clinical practice. The EAG noted the substantial uncertainty around the discontinuation rate. It used the same figure as the company in its base case but explored rates of 1.4% and 8.0% in scenarios. The clinical experts said that a discontinuation rate of between 5% and 8% per year was the most clinically plausible. The committee concluded that the company's base-case assumption of a 5% per year discontinuation rate for benralizumab was acceptable but noted that up to 8% was plausible.

Relationship between benralizumab and oral corticosteroid discontinuation rates

3.10 As noted in section 3.8, the company applied a stopping rule in the model, based on response to benralizumab. The EAG said that, because of the way the company model was set up, 2 assumptions were implied:

- The likelihood of response was the same for people who continued having oral corticosteroids and people who stopped oral corticosteroids while having benralizumab. People whose condition responded continued having benralizumab. The likelihood of benralizumab discontinuation was the same for people who continued having oral corticosteroids and people who stopped oral corticosteroids while having treatment.
- People who stopped oral corticosteroids in the benralizumab arm did not start oral corticosteroids again after stopping benralizumab.

The result of these 2 assumptions was that the proportion of people having standard care who had oral corticosteroids as part of standard care after stopping benralizumab decreased continually over time. This meant that a third implicit assumption in the company model was that standard care without oral corticosteroids was equally effective as standard care with oral corticosteroids. The transition probabilities for standard care were the same regardless of the proportion of people

having oral corticosteroids. This assumption meant that, as the discontinuation rate for benralizumab increased, its incremental cost-effectiveness ratio (ICER) decreased. This was because, with no side effects from oral corticosteroids, standard care after benralizumab was associated with higher quality-adjusted life years (QALYs) and lower costs than standard care alone. The EAG explored these assumptions through the following scenarios:

- standard care with oral corticosteroids has better efficacy than standard care without oral corticosteroids
- if someone stops oral corticosteroids, they do not stop benralizumab
- if someone stops oral corticosteroids while having benralizumab, but goes on to stop benralizumab, they start oral corticosteroids again.

The clinical experts said there was limited evidence that benralizumab was a disease-modifying treatment. So once people stopped benralizumab, their condition would revert to how it was before. They said that this meant that people would need to restart oral corticosteroids if they stopped benralizumab. The clinical experts confirmed that oral corticosteroids were the mainstay of standard care for EGPA. The committee concluded that it preferred the EAG's scenario in which everyone who stops oral corticosteroids while having benralizumab starts oral corticosteroids again after stopping benralizumab.

Oral corticosteroid discontinuation in the benralizumab arm

3.11 The company model assumed that in the standard-care arm the percentage of people having oral corticosteroids was constant over time at 86.2% (based on CPRD data). In the benralizumab arm, the rate of oral corticosteroid discontinuation was 38% per year indefinitely (derived from MANDARA). The EAG said there was no evidence that oral corticosteroid discontinuation in the benralizumab arm would continue at the same rate

indefinitely beyond 1 year. It noted that the change in average dose over 52 weeks for everyone in MANDARA suggested that the constant discontinuation rate may not persist forever. The EAG suggested that most of the benefit of benralizumab would be at the beginning of treatment, and so the highest rate of oral corticosteroid discontinuation would also be around this time. In its base case, the EAG assumed that the 38% annual discontinuation rate declined linearly to 0% at 5 years. It also explored a scenario in which it was 0% at 1 year. The clinical experts agreed that the rate of oral corticosteroid discontinuation would not be linear in clinical practice. They did not think it would drop to 0% at 1 year but agreed that it would plateau with time. The company said that oral corticosteroid discontinuation rate at 52 weeks was 41% in MANDARA, and 43% after a further 1 year in the open-label extension of MANDARA. The committee noted that this implied that the rate did drop to around 0% at 1 year. One of the patient experts said that they were able to completely stop taking oral corticosteroids during their second year of benralizumab treatment. The committee thought that the most appropriate assumption was likely to be a linear reduction in oral corticosteroid discontinuation from 38% in the first year to 0% at some point between years 1 and 5. It noted that assuming either 1 year or 5 years had a minimal effect on the ICER. The committee concluded it would prefer a scenario showing a linear reduction to 0% by 2 years.

Treatment-effect waning

3.12 The company did not incorporate treatment-effect waning into its model. That is, the effect of benralizumab was assumed to continue at the same level while people were having treatment. The treatment effect stopped when benralizumab was stopped. The company said that this was in line with TA565, which assumed no treatment-effect waning. It also said its clinical experts agreed this was reasonable. With no evidence to the contrary, the EAG also assumed no treatment-effect waning in its base case, but noted that any changes to the assumption would significantly

increase the ICER. The clinical experts said that if the EGPA stopped responding to benralizumab, then benralizumab treatment would be stopped. So, the committee concluded that any loss of treatment effect was likely to be captured in the discontinuation rate and the response-based stopping rule, and that treatment-effect waning did not apply.

Utility values

Source of utility values

3.13 MANDARA (n=140) used the SF-36 to collect health-state utility data. The company mapped this to the EQ-5D, in line with the NICE reference case. But it chose not to use this health-related quality-of-life data in the model because it said it was not consistent with insights from the company's patient and clinical expert interviews. Firstly, the trial utility values in the remission and relapse states were similar. But the patient and clinical experts said health-related quality of life was much better in remission than when relapsed because symptoms were reduced, and less medication was needed. Secondly, the refractory health state did not have the lowest utility value in the trial. The patient and clinical experts said the refractory state is the worst in terms of health-related quality of life. This is because severe symptoms, plus the despair, anxiety and frustration at not having had any remission for 6 months, means a significant worsening of wellbeing. The company also cited evidence that it suggested showed the SF-36 may not accurately capture health-related quality of life in EGPA, for example that BVAS scores may not correlate well with it.

Instead, the company did 2 real-world studies – the Adelphi Real World Disease Specific Programme (DSP; 177 people with EGPA, 9 from the UK), and a UK-specific vignette study (300 people from the general public and 21 people with EGPA). In both of them, people filled out EQ-5D-5L questionnaires, which were mapped to the EQ-5D-3L. The company chose to use results from Adelphi DSP because it provided EQ-5D data

for all 4 health states, had the larger number of people with EGPA, and mapped utilities using a UK value set. It also noted that the values for the refractory state in the vignette study were unusually low. The EAG agreed that Adelphi DSP was the best source of evidence for the cost-effectiveness analysis. The patient and clinical experts also agreed that the MANDARA health-related quality-of-life data did not reflect their real-world experience, and that the data collected in Adelphi DSP was more realistic. The committee considered the concerns around the validity of the SF-36 but was not convinced they were supported by the available evidence. It noted that it was a commonly used measure in other conditions, and that, because BVAS was a disease-activity score, rather than a health-related quality-of-life measure, it would not necessarily be expected to correlate with the SF-36. It considered that it was reasonable to use the SF-36 to measure health-related quality of life in people with EGPA. But it agreed that the specific values from MANDARA lacked face validity (that is, were unexpected in this patient group). The committee concluded that it would have preferred to use data on health-related quality of life from the main trial. But it acknowledged in this case that the data was not reliable, so accepted that the data collected in Adelphi DSP was appropriate for decision making.

Refractory and relapse states

3.14 The company applied utility decrements in the model for acute and chronic adverse events related to oral corticosteroids, using an oral corticosteroid sub-model (see section 3.7). The EAG was concerned this risked double counting the negative effect of oral corticosteroid-related adverse events. This is because a large proportion of the people in Adelphi DSP, used to inform the health-state utility values, had organ damage, which could be related to oral corticosteroids. So, the utility values used for the health states may already have captured oral corticosteroid-related adverse events to an extent. The EAG was concerned about applying utility decrements for oral corticosteroid-related

adverse events on top. It thought that this may result in the utility values for the refractory and relapse states being underestimated, assuming that these states had more oral corticosteroid-related adverse events than the non-refractory and remission states. The EAG adjusted its base case to avoid double counting by increasing the utility values used in the refractory and relapse states. The company accepted that this was a reasonable, if more conservative, approach. It confirmed that it had not been able to analyse whether organ damage in Adelphi DSP was attributable to oral corticosteroids or to the EGPA itself. The committee concluded that it preferred the EAG's base case, in which the utility value in the refractory and relapse model health states was adjusted to account for the potential double counting of oral corticosteroid-related adverse events.

Other factors

Equality

3.15 The committee noted issues raised around socioeconomic disparities in education level, healthcare literacy and access to healthcare resources, and cultural and language barriers. It noted that these factors can affect the ability to manage subcutaneous treatments like benralizumab at home. But because its recommendation does not restrict access to treatment for some people over others, the committee agreed this was not a potential equality issue. The committee also noted concerns raised around restricting benralizumab to non-severe EGPA. But, as noted in section 3.6, benralizumab may be available to these people once their condition has stabilised, so the committee agreed that this was also not an equality issue.

Uncaptured benefits

3.16 The committee considered whether there were any uncaptured benefits of **Error! Reference source not found.**. It noted the serious harms to people with EGPA from the effects of standard care with oral

corticosteroids. It noted that benralizumab is an innovative treatment that specifically targets EGPA, which current treatment does not. The committee concluded that there might be some uncaptured benefits, but most benefits had already been captured in the QALY calculation.

Cost-effectiveness estimates

Company and EAG cost-effectiveness estimates

3.17 NICE's manual on health technology evaluations notes that, above a most plausible ICER of £20,000 per QALY gained, judgements about the acceptability of a technology as an effective use of NHS resources will take into account the degree of certainty around the ICER. The committee will be more cautious about recommending a technology if it is less certain about the ICERs presented. But it will also take into account other aspects including uncaptured health benefits. The committee recalled the statements from the patient and clinical experts about the need for a targeted and well-tolerated treatment for EGPA that reduced the need for oral corticosteroids. It noted that EGPA is a rare condition and that benralizumab is an innovative technology. It noted that NICE's manual on health technology evaluations says that committees may be able to accept a higher degree of uncertainty when evidence generation is particularly difficult because of this rarity. So, the committee concluded that an acceptable ICER would be towards the upper end of the range NICE considers a cost-effective use of NHS resources (£20,000 to £30,000 per QALY gained).

The committee's preferred assumptions

3.18 Because of benralizumab's confidential commercial arrangement, the exact cost-effectiveness estimate is confidential and cannot be reported here. The committee's preferred model assumptions were:

- stopping criteria assessed at 52 weeks using response defined as:
  - a BVAS score of 0, and

  - a reduction in oral corticosteroid dose of 50% or more since the start of treatment, or to 7.5 mg or less per day (see section 3.8)
- utility values as per the EAG base case, from the Adelphi DSP study with an adjustment for potential double counting of oral corticosteroid-related adverse events (see sections 3.13 and 3.14)
- benralizumab discontinuation rate as per the company and EAG base cases (5% per year; see section 3.9)
- if someone stops oral corticosteroids while having benralizumab, they start them again after stopping benralizumab, as per the EAG scenario (see section 3.10)
- oral corticosteroid discontinuation in the benralizumab arm starts at a 38% annual rate and declines linearly to 0% at 2 years (see section 3.11)
- no treatment-effect waning if EGPA responds to treatment (see section 3.12).

With these assumptions the probabilistic base-case ICER was below the range specified in section 3.17.

Conclusion

Recommendation

3.19 Using the committee's preferred assumptions, the ICER was within the range that NICE considers a cost-effective use of NHS resources. So, benralizumab can be used in the NHS.

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 integrated care boards, NHS England and, with respect to their public health functions, local

authorities to comply with the recommendations in this evaluation within 90 days of its date of publication.

4.2 Section 4f of The Innovative Medicines Fund Principles states that a discretionary source of early funding (from the overall Innovative Medicines Fund budget) is available for certain medicines recommended by NICE. In this instance, interim funding has been agreed for benralizumab. Interim funding will end 90 days after positive final guidance is published (or 30 days in the case of drugs with an Early Access to Medicines Scheme designation or cost comparison evaluation), at which point funding will switch to routine commissioning budgets.

4.3 The Welsh ministers have issued directions to the NHS in Wales on implementing NICE technology appraisal guidance. When a NICE technology appraisal guidance recommends the use of a drug or treatment, or other technology, the NHS in Wales must usually provide funding and resources for it within 60 days of the first publication of the final draft guidance.

4.4 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 relapsing or refractory EGPA and the healthcare professional responsible for their care thinks that benralizumab is the right treatment, it should be available for use, in line with NICE's recommendations.

5 Evaluation committee members and NICE project team

Evaluation 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 being evaluated. If it is considered there is a conflict of interest, the member is excluded from participating further in that evaluation.

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

Chair

Charles Crawley
Chair, technology appraisal committee B

NICE project team

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

Emilene Coventry
Technical lead

Michelle Green
Technical adviser

Vonda Murray
Project manager

Richard Diaz
Associate director

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