NICE National Institute for Health and Care Excellence

NICE guidance

Budesonide orodispersible tablet for inducing remission of eosinophilic oesophagitis

Technology appraisal guidance
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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 assess and reduce the environmental impact of implementing NICE recommendations wherever possible.

Contents

1 Recommendations

1.1 Budesonide as an orodispersible tablet (ODT) is recommended as an option for inducing remission of eosinophilic oesophagitis in adults.

1.2 This recommendation is not intended to affect treatment with budesonide ODT 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 clinician consider it appropriate to stop.

Why the committee made these recommendations

Although budesonide ODT has a marketing authorisation for both inducing and maintaining remission in eosinophilic oesophagitis, at the time this appraisal started it was only licensed for induction. So, the company's evidence is for inducing remission only (with treatment of up to 12 weeks) and the committee is unable to make recommendations for maintenance treatment.

There is currently no standard care for inducing remission in eosinophilic oesophagitis. Fluticasone is one treatment option, but it is an asthma treatment that is not easy to use for eosinophilic oesophagitis. Dietary changes are also an option, for example the 6-food elimination diet, which involves cutting out the known allergens milk, eggs, nuts, wheat, soy and seafood from your diet. These treatments can be difficult to access and adhere to. And people often have no treatment at all, so there is an unmet need for this condition.

Clinical trial evidence shows that budesonide ODT improves the signs and symptoms of eosinophilic oesophagitis compared with placebo. There is no direct evidence for budesonide ODT compared with fluticasone or the 6-food elimination diet and the results of an indirect comparison with these treatments are very uncertain.

The cost-effectiveness estimates vary and are also very uncertain. However, the most likely estimates are within what NICE considers a cost-effective use of NHS resources. Therefore, it is recommended for inducing remission in eosinophilic oesophagitis in adults.

2 Information about budesonide orodispersible tablet

Marketing authorisation indication

2.1 Budesonide orodispersible tablet (Jorveza, Dr Falk Pharma UK) is indicated for the treatment of eosinophilic esophagitis in adults.

Dosage in the marketing authorisation

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

Price

2.3 The list price is £323 per pack of 90 one-mg tablets (excluding VAT; BNF online, accessed April 2021). Costs may vary in different settings because of negotiated procurement discounts.

3 Committee discussion

The appraisal committee considered evidence submitted by Dr Falk Pharma UK, a review of this submission by the evidence review group (ERG), NICE's technical report, and responses from stakeholders. See the committee papers for full details of the evidence.

Clinical pathway

Patients need an effective treatment for eosinophilic oesophagitis

3.1 Eosinophilic oesophagitis is a rare, chronic, immune-mediated disease. The body over-produces white blood cells (eosinophils) in the oesophagus, leading to inflammation. Symptoms can be unpleasant and socially embarrassing, and have a significant impact on quality of life. People with eosinophilic oesophagitis can have difficulty swallowing and eating. This can sometimes lead to food becoming stuck in the oesophagus to the point that people cannot even swallow water. People with eosinophilic oesophagitis can also have chest pains, heartburn, upper abdominal pain and food regurgitation. The patient and clinical experts said that one of the biggest challenges of this condition is the lack of a treatment pathway. Treatment includes off-label proton pump inhibitors (such as omeprazole or lansoprazole) and corticosteroids (off-label fluticasone and unlicensed budesonide). People can also try elimination diets such as the 6-food elimination diet (SFED), which involves eliminating the known allergens milk, eggs, nuts, wheat, soy and seafood. Access to treatment varies and the patient and clinical experts explained that even if people can get treatment, it is not always effective. Although proton pump inhibitors can be used for reflux, they are not effective for eosinophilic oesophagitis in most people. Off-label corticosteroids are effective when used properly. But dosing and delivery of off-label corticosteroids is difficult and imprecise because it involves swallowing formulations originally designed for inhalation, which is counterintuitive and poorly understood by patients and clinicians. Dietary interventions are hugely challenging and professional support is often difficult to access. Specialist diets can be expensive so they are not affordable for many people with this disease. The committee concluded

there was an unmet need for a licensed, effective treatment for eosinophilic oesophagitis.

Off-label fluticasone, SFED and no treatment are appropriate comparators for budesonide ODT

3.2 The company expected budesonide orodispersible tablet (ODT) to be used as first-line treatment for eosinophilic oesophagitis, replacing off-label fluticasone and SFED. An unlicensed viscous formulation of budesonide has been used, but the company did not include this as a comparator because most people are treated with off-label fluticasone. A comparison with no treatment was added after technical engagement because fluticasone is used off-label and SFED is not suitable for everyone. The company did not include proton pump inhibitors as a comparator because it expected budesonide ODT to be used after this treatment (see section 3.3). The ERG agreed with the company's choice of comparators. The clinical and patient experts explained that proton pump inhibitors are generally not effective for this population, and off-label corticosteroids and SFED are not suitable for everyone. People can also wait a long time to get treatment. This means that many people with active eosinophilic oesophagitis are not treated and only get care in an emergency like a bolus food impaction (when the oesophagus is obstructed by swallowed food). The committee concluded that off-label fluticasone, SFED and no treatment are appropriate comparators for budesonide ODT.

Population

Adults with active eosinophilic oesophagitis are the relevant population

3.3 The company's key trial (see section 3.5) recruited people whose condition did not respond to treatment with proton pump inhibitors. This was a more limited population than that of the scope, in which the population was adults with active eosinophilic oesophagitis. Although the licence does not include this restriction, the company considered that people are prescribed proton pump inhibitors before they are diagnosed

with eosinophilic oesophagitis, and some may continue on them alongside budesonide ODT. The ERG agreed with the company's approach and also limited the population to people who have already had proton pump inhibitors. The clinical experts explained that, although in practice nearly everyone has proton pump inhibitors before their diagnosis, proton pump inhibitors are not a first-line treatment for eosinophilic oesophagitis. They agreed that limiting the population to people who had tried proton pump inhibitors was not appropriate and could delay treatment. The committee agreed that treatment access was a substantial issue for this population. It noted that, because most people in the NHS are likely to have had proton pump inhibitors before diagnosis, the clinical trial results are likely to be generalisable to NHS practice. The committee concluded that the whole population defined in the scope – adults with active eosinophilic oesophagitis – is the relevant population for this appraisal.

Intervention

Budesonide ODT for inducing remission is the relevant intervention for this appraisal

3.4 The company's submission included evidence only on induction treatment with budesonide ODT and none for maintaining remission. This is because, at the time of the submission, the marketing authorisation was for induction treatment only and no evidence for maintenance treatment was available. The usual duration of induction treatment with budesonide ODT is 6 weeks. If the condition has not appropriately responded after 6 weeks then treatment can be extended for up to 12 weeks. The marketing authorisation was extended in June 2020 to include maintenance treatment (see section 2). The company decided to continue with the appraisal of induction therapy only, rather than start a new appraisal, because it did not want to delay patient access. The company submission included analyses for people having multiple inductions with budesonide ODT for people who relapse after the first induction. The ERG focused on a single induction, but noted that this approach may not apply to clinical practice because budesonide ODT is likely to be used for both induction and maintenance therapy. The clinical

and patient experts confirmed that they would like to use budesonide ODT for both. The clinical experts said that although they would consider a second induction after a relapse, they would generally consider moving to maintenance treatment only if there were multiple relapses. The committee agreed that, because evidence for maintenance treatment had not been submitted, it could not be considered in this appraisal. The committee concluded that budesonide ODT for inducing remission is the relevant intervention for this appraisal.

Clinical evidence

Budesonide ODT improves remission rates compared with placebo

3.5 The key evidence was from BUL-1/EEA, a double-blind, multicentre, placebo-controlled study. It compared induction treatment with budesonide ODT with placebo in 88 people with active eosinophilic oesophagitis whose condition was refractory to proton pump inhibitors. Induction treatment with budesonide ODT was given for 6 weeks and if the condition did not go into remission it was extended for another 6 weeks. The mean age in the trial was 37 years. The primary outcome was clinico-histological remission. This combined:

- endoscopy-measured histological remission, defined as a peak eosinophil count of under 16 eos/mm^2 hpf (eosinophils per millimetre squared high-power field), **and**
- symptom resolution, defined as a severity of 2 points or less on 0 to 10 dysphagia (difficulty swallowing) and odynophagia (pain during swallowing) scales.

Clinico-histological remission was seen in 57.6% of patients (34 out of 59) who had budesonide ODT, and none of the 29 patients on placebo ($p<0.0001$). Similarly, histological remission was seen in 93.2% of patients (55 out of 59) who had budesonide ODT, and none of the patients on placebo ($p<0.0001$). Evidence from a 2-week trial of induction with budesonide ODT (BUU-2/EEA) and from 6 weeks of open-label treatment with budesonide ODT (BUL-2/EER)

also supports its efficacy. The committee concluded that induction treatment with budesonide ODT increases the rate of histologic and clinico-histologic remission compared with placebo.

Indirect treatment comparison

The studies included are small, have different designs and have no UK patients

3.6 No trial compared budesonide ODT with off-label use of corticosteroids formulated for inhalation or dietary treatment. The company did an indirect comparison using data for histological remission from 5 trials: the budesonide trials BUL-1/EEA and BUU-2/EEA (see section 3.5), and Alexander et al. (2012), Philpott et al. (2016) and Dellon et al. (2017). Alexander et al. compared fluticasone with placebo in 42 patients with eosinophilic oesophagitis in the US. Philpott et al. (2016) compared SFED (alongside proton pump inhibitors) with budesonide (viscous formulation) in an observational Australian study of 56 people with eosinophilic oesophagitis whose condition was refractory to proton pump inhibitors. Dellon et al. compared off-label budesonide with placebo in 100 patients with eosinophilic oesophagitis in the US. None of the studies included UK patients. All the studies were small, had different designs and recruited people with different baseline characteristics.

The results of both the company's and the ERG's indirect comparisons are very uncertain

3.7 For its indirect treatment comparisons, the company used a Bayesian random effects network meta-analysis without a continuity correction for zero events in the placebo arm. The high number of zero events was one of the drivers of the very wide credible intervals in the company's model. The company provided a Bayesian model with a continuity correction during clarification, but the ERG found that this version of the model did not work properly when different inputs were used. Instead, the ERG used a frequentist random effects model, which automatically adds a continuity correction for the zero events. Despite this correction, both analyses still had very wide credible intervals (company) and confidence

intervals (ERG), indicating substantial uncertainty in the results. The company's analyses suggested a response rate per 12-week cycle of 68% for fluticasone and 18% for SFED. The ERG's analyses suggested a response rate per cycle of 73% for fluticasone and 44% for SFED. Both analyses suggested a response rate per cycle of 95% for budesonide ODT and 4% for no treatment. The clinical experts considered the ERG's SFED estimates to be more plausible. The patient expert noted the particularly challenging nature of SFED, which can be expensive and require professional support (see section 3.1). For fluticasone, the clinical and patient experts considered the company's estimates to be more plausible because of the difficulty in administering it and adherence to treatment among patients (see section 3.1). The committee noted that the impact of effect-modifying variables in the analyses was unknown and concluded that both the company's and ERG's results were very uncertain.

Model structure

The model structure is appropriate

3.8 The company used a Markov model with 3 health states: active eosinophilic oesophagitis, remission with maintenance, and remission without maintenance, plus a death state. After technical engagement, the company modelled multiple inductions with budesonide ODT for people with eosinophilic oesophagitis whose disease relapses after the initial induction. Maintenance for budesonide ODT was not modelled, but it was included for comparators. The ERG used the version of the company's model from before technical engagement because it allowed a longer time horizon. Both models had the same structure, but not all inputs could be set in the same way, so the 2 models could not provide the same results. The ERG modelled a single induction with budesonide ODT. Maintenance for budesonide ODT was not modelled. The clinical experts agreed that the 3 health states were appropriate for this disease area. They repeated that an ideal model of clinical practice would include budesonide ODT as both induction and maintenance treatment (see section 3.4), and said that they hoped for a future appraisal of budesonide ODT as maintenance treatment. The committee concluded

that the model structure was appropriate.

The company's and the ERG's approach to modelling are both suitable for decision making

3.9 The company's multiple inductions model explored a 1-year and 2-year time horizon and included maintenance treatment for comparators. It assumed that the rate of response to budesonide remains the same for all inductions (rates of response to fluticasone were also assumed to be the same for all inductions). However, the ERG noted that the company had not presented any evidence on the response rates for subsequent inductions in relation to the initial induction. The ERG's single induction model used a 5-year time horizon for a scenario modelling maintenance treatment for comparators and a 3-year horizon for a scenario without maintenance treatment for comparators. Both the company and ERG agreed that a longer time horizon would be needed for a model that includes maintenance treatment with budesonide ODT. The clinical experts said that although eosinophilic oesophagitis is a chronic condition, a shorter time horizon is acceptable to model induction. The clinical experts explained that they would consider re-induction but noted that the treatment protocol with budesonide ODT was yet to be established. The committee agreed that the way the induction treatment would be used was uncertain and concluded that it would consider both the company's and the ERG's approach to modelling.

Remission rates

The company's and the ERG's assumptions about remission are both suitable for decision making

3.10 Remission rates were based on the results of the indirect treatment comparison. The committee had already concluded that the company's and the ERG's results were very uncertain (see section 3.7). Only data for histological remission were analysed by the company. Remission states in the model therefore included people in histological remission regardless of whether their clinical symptoms were resolved. The clinical experts explained that some people who have histological remission will

still have clinical symptoms. In the key trial, the primary outcome was clinico-histological remission, which combined resolution of inflammation (endoscopy-measured histological remission) and clinical symptoms (dysphagia and odynophagia reported by patients). The rates of clinico-histological remission were lower than the rates of histological remission (see section 3.5). The company also assumed that people who are in remission at 1 year will remain in remission. The ERG assumed that people who remain in remission at 1 year will continue to relapse. The clinical experts agreed that there may be a proportion of people who would remain in a long remission after a successful treatment but they were unable to confirm whether the company's assumption was appropriate or not. The committee concluded that the assumption about long-term remission was uncertain and concluded that it would consider both the company's and the ERG's approach in its decision making.

Relapse rates

The company's and the ERG's approach to relapse rates are both suitable for decision making

3.11 Relapse rates were not collected in the company's trials. The company assumed the following rates per 12-week cycle:

- 41%, based on the rates in the placebo group of BUL-2/EER, for the first 4 cycles used for no treatment and all active treatments (budesonide ODT, fluticasone and SFED)
- 15.3% for fluticasone when used for maintenance
- 50% for SFED at 1 year because of non-adherence (based on Lucendo et al. 2013).

The ERG used the following rates per 12-week cycle:

- 31.5% for no treatment and all active treatments, based on Dellon et al. (2019)
- 11.7% for fluticasone and SFED when used for maintenance, based on a review of maintenance studies.

The clinical experts agreed that that all the proposed rates were uncertain. But they considered the relapse rates for no treatment from BUL-2/EER to be more appropriate because it was a higher quality study than Dellon et al. (2019). The committee concluded that both approaches to relapse rates were uncertain and that it would consider both the company's and the ERG's approach in its decision making.

Utilities

The company's and the ERG's approach to utilities are both suitable for decision making

3.12 The company and the ERG both used age-adjusted UK population norms to calculate a utility of 0.93 for EQ-5D for remission of eosinophilic oesophagitis. For active eosinophilic oesophagitis, the company applied a disutility of 0.15 for gastro-oesophageal reflux disease (which the company considered to be a proxy for eosinophilic oesophagitis) from Kartman et al. (2004; n=1,011). The ERG used a disutility of 0.07 for eosinophilic oesophagitis based on Hewett et al. (2017; n=44). The utilities for active disease were 0.78 using the company's and 0.86 using the ERG's approach. The company noted that the Hewett et al. study included patients with active eosinophilic oesophagitis and patients in remission. The ERG agreed that this introduced additional uncertainty, but it explained that another study, by Larsson et al. (2015) in 47 people with eosinophilic oesophagitis, reported similar results. The clinical and patient experts said that, although there were some similarities between gastro-oesophageal reflux disease and eosinophilic oesophagitis (they both include breakthrough symptoms and treatment breaks), there were differences. For example, a major issue with gastro-oesophageal reflux disease is sleep disturbance, whereas with eosinophilic oesophagitis it is food disturbance. However, they would not expect utilities for active eosinophilic oesophagitis to be higher than utilities for gastro-oesophageal reflux disease. Overall, the clinical experts agreed that gastro-oesophageal reflux utilities could be used as a proxy for eosinophilic oesophagitis. They also noted that some patients in the remission state may still have clinical symptoms, so using the UK

population norms may be an overestimate. The committee agreed that the utilities were uncertain, but it noted that proxy utilities are usually considered only when disease-specific utilities are not available. The committee concluded that it would consider both the company's and the ERG's approach in its decision making.

Costs

The induction dose for off-label fluticasone is 2 mg per day and wastage for budesonide ODT should be included

3.13 The company used a 2 mg per day induction dose for fluticasone based on Butz et al. (2017). For budesonide ODT it did not include wastage because it assumed multiple inductions in its base case. The ERG used a 1.5 mg per day induction dose for fluticasone based on Lucendo et al. (2020). For budesonide ODT it included wastage because 84 one-mg tablets would be needed for 6 weeks of induction treatment, and a pack contains 90 tablets. Another pack of 90 tablets would be used if induction was extended to 12 weeks. The clinical and patient experts agreed that wastage for budesonide should be included. They considered the company's estimate of the fluticasone dosage to be more plausible. The committee concluded that the more likely induction dose for off-label fluticasone was 2 mg per day and that wastage for budesonide ODT should be included in the model.

The committee prefers the company's approach to follow-up and monitoring costs

3.14 The company assumed 1 gastroenterologist visit and 0.5 of an endoscopy visit per 12-week cycle for budesonide ODT and fluticasone. For no treatment it assumed half of the follow-up and monitoring costs of budesonide ODT and fluticasone. For SFED it assumed 1 gastroenterologist visit, 1.3 endoscopy visits and 1.8 dietitian visits per cycle. The ERG considered the company's assumption to be appropriate, but assumed no follow-up and monitoring costs for no treatment. The clinical and patient experts agreed that assuming no cost for patients on no treatment was not realistic because they would still need NHS

services such as endoscopies and admissions to A&E for food bolus obstruction. They therefore preferred the company's approach. The committee concluded that it was likely that people having no treatment would still need some healthcare services, and they therefore preferred the company's approach.

The company's and the ERG's assumptions about endoscopic interventions are both suitable for decision making

3.15 The company assumed the following endoscopic dilation rates per 12-week cycle:

- 12.5% for active disease with no treatment (based on Shoepfer et al. 2010)
- 6% for disease in remission with no treatment (half of the active disease rate)
- 6% for active disease with treatment (half of the active disease rate with no treatment)
- 3% for disease in remission with treatment (half of the active disease rate).

The ERG used a similar approach, but assumed different rates:

- 4% for active disease with no treatment (based on clinical advice)
- 2% for disease in remission with no treatment (half of the active disease rate)
- 2% for active disease with treatment (based on Runge et al. 2016)
- 1% for disease in remission with treatment (half of the active disease rate).

The clinical experts agreed that the most plausible rates were somewhere between the company's and ERG's estimates. The committee agreed with the experts and concluded that it would consider both the company's and ERG's approach in its decision making.

Cost-effectiveness estimate

The cost-effectiveness estimates are uncertain and sensitive to

even very small changes in the model's inputs

3.16 In the company's analyses of multiple inductions, budesonide ODT was the most expensive treatment and provided the most quality-adjusted life years (QALYs). The fully incremental ICER (incremental cost-effectiveness ratio) for budesonide ODT was £1,958 per QALY gained when compared with no treatment in the 2-year horizon model, and £4,780 per QALY gained when compared with fluticasone in the 1-year horizon model. The company did not provide any probabilistic results exploring the inherent uncertainty. The analyses were sensitive to changes in assumptions and when all the ERG's assumptions were applied, some pairwise ICERs were higher than £30,000 per QALY gained. In the ERG's analysis of a single induction with maintenance treatment for comparators (5-year horizon), budesonide ODT was the second cheapest treatment after no treatment, but it did not provide the most QALYs (fluticasone was the most expensive treatment with the most QALYs). The fully incremental ICER for fluticasone was £14,012 per QALY gained when compared with budesonide ODT. However, in the ERG's analysis of a single induction without maintenance treatment for comparators (3-year horizon), budesonide ODT was the most expensive treatment with the most QALYs. The fully incremental ICER for budesonide ODT was £27,078 per QALY gained when compared with fluticasone. The committee noted the differences in the total cost of budesonide ODT based on the modelling approach and agreed that this, together with the very small QALY gains, means that the results are sensitive to even very small changes in the model's inputs.

The most likely estimate is within the range NICE considers a cost-effective use of NHS resources

3.17 The committee made the following conclusions about the key model inputs.

- Remission rates (section 3.10): both the company's and the ERG's approaches were uncertain, and both were considered for decision making.
- Relapse rates (section 3.11): both the company's and the ERG's approaches were uncertain, and both were considered for decision making.

- Utilities (section 3.12): both the company's and the ERG's approaches were uncertain, and both were considered for decision making.
- Treatment cost (section 3.13): the induction dose for off-label fluticasone should be 2 mg per day and wastage for budesonide ODT should be included.
- Follow-up and monitoring costs (section 3.14): both the company's and the ERG's approaches were uncertain, but the company's approach was preferred.
- Endoscopic dilation (section 3.15): both the company's and the ERG's approaches were uncertain, and both were considered for decision making.

  The committee noted the high level of uncertainty in the model inputs. However, because of the challenges with using off-label corticosteroids and dietary interventions outside clinical trials, the committee agreed that the comparative effectiveness of budesonide ODT was likely to have been underestimated. Therefore, the cost-effectiveness estimates were likely to be biased against it. The committee also agreed that budesonide ODT is a licensed treatment option for people with eosinophilic oesophagitis who had few other treatment options. Taking all this into account, the committee concluded that the most likely ICER would be within the range normally considered a cost-effective use of NHS resources (£20,000 to £30,000 per QALY gained).

Conclusion

Budesonide ODT is recommended for routine use

3.18 The committee concluded that the most plausible estimates were within the range NICE considers a cost-effective use of NHS resources. Therefore, it recommended budesonide ODT for inducing remission in adults with eosinophilic oesophagitis.

4 Implementation

4.1 Section 7(6) 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.

4.2 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 eosinophilic oesophagitis and the doctor responsible for their care thinks that budesonide orodispersible tablet 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 A.

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 minutes of each appraisal committee meeting, 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.

Marcela Haasova
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