NICE National Institute for Health and Care Excellence

NICE guidance

Dexamethasone intravitreal implant for treating diabetic macular oedema

Technology appraisal guidance
Published: 14 September 2022

www.nice.org.uk/guidance/ta824

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

This guidance replaces TA349.

1 Recommendations

1.1 Dexamethasone intravitreal implant is recommended as an option for treating visual impairment caused by diabetic macular oedema in adults only if their condition has not responded well enough to, or if they cannot have non-corticosteroid therapy.

1.2 This recommendation is not intended to affect treatment with dexamethasone intravitreal implant that was started in the NHS before this guidance was published. Adults 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.

This technology appraisal is a partial review of NICE's technology appraisal guidance on dexamethasone intravitreal implant for treating diabetic macular oedema (TA349) which recommended its use for people who have a pseudophakic (intraocular) lens and whose condition did not respond well enough to, or who could not have non-corticosteroid therapy. This partial review specifically considers people with diabetic macular oedema with a phakic (natural) lens and whose condition did not respond well enough to, or who could not have non-corticosteroid therapy. This final draft guidance from NICE means that dexamethasone intravitreal implant is recommended for treating visual impairment due to diabetic macular oedema only if the diabetic macular oedema has not responded well enough to non-corticosteroids, or non-corticosteroids are unsuitable, irrespective of whether they have a phakic or pseudophakic lens. TA349 has been updated and replaced by this guidance at publication. The considerations below refer only to evidence covered by the partial review.

Why the committee made these recommendations

Standard care for people with diabetic macular oedema who still have a natural lens

(phakic) is anti-vascular endothelial growth factor (anti-VEGF) treatments (such as ranibizumab or aflibercept), or laser monotherapy. If non-corticosteroids do not work well enough, people can keep having anti-VEGFs or laser monotherapy. In people with a phakic lens and diabetic macular oedema who cannot have non-corticosteroid therapy, watch and wait is the only available treatment option.

Clinical trial evidence shows that dexamethasone intravitreal implant is more effective than a sham (inactive) procedure. The sham procedure may be considered as a proxy for continued anti-VEGF therapies. The resulting cost-effectiveness estimates for dexamethasone intravitreal implant compared with anti-VEGF therapy are likely to be within what NICE normally considers an acceptable use of NHS resources. Although no cost-effectiveness evidence was presented for people for whom non-corticosteroids are unsuitable, the committee considered the equalities issues, the unmet need, and the size of the population, and agreed that the risk to the NHS was low, and therefore it is recommended.

2 Information about dexamethasone intravitreal implant

Marketing authorisation indication

2.1 Dexamethasone 700 micrograms intravitreal implant (Ozurdex, AbbVie), is 'indicated for the treatment of adult patients with visual impairment due to diabetic macular oedema who are pseudophakic or who are considered insufficiently responsive to, or unsuitable for non-corticosteroid therapy'.

Dosage in the marketing authorisation

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

Price

2.3 Dexamethasone intravitreal implant costs £870.00 per 700 micrograms (excluding VAT; BNF accessed online July 2022). Costs may vary in different settings because of negotiated procurement discounts.

3 Committee discussion

This appraisal focuses only on the partial review for people who have a phakic (natural) lens. Considerations for people with a pseudophakic (intraocular) lens are still available in the evidence review for NICE's technology appraisal guidance on dexamethasone intravitreal implant for treating diabetic macular oedema (TA349).

The appraisal committee considered evidence submitted by AbbVie, a review of this submission by the evidence review group (ERG), and responses from stakeholders. See the committee papers (TA824) for full details of the evidence for people with a phakic (natural) lens.

The appraisal committee was aware that several issues were resolved during the technical engagement stage.

The condition

There is an unmet need for an effective treatment given less frequently

3.1 The patient expert explained the nature of their experience with current treatment. They explained that the loss of vision has a significant impact on a person's independence and mental health. The patient expert highlighted that having frequent eye injections causes fear, but there is no alternative because laser therapy has not been very effective for them. They emphasised that reducing the number of times they need treatment, especially for an eye injection, would be of huge benefit for their quality of life. They also explained that for this population, there are no other effective treatment options if anti-vascular endothelial growth factor (anti-VEGF) treatments do not work. The patient expert highlighted that although treatments might not improve their diabetic macular oedema, they can stop it from getting worse, which is still very important to people with the condition. The company noted that for people for whom non-corticosteroids are unsuitable, there are no active pharmacological therapy options and watch and wait is the only available

treatment option. Dexamethasone intravitreal implant would therefore provide a pharmacological treatment option for these people. They emphasised that the impact of dexamethasone intravitreal implant would mean less frequent hospital visits and injections compared with anti-VEGF treatments. The committee was aware that some people with diabetic macular oedema may require help from a carer to travel to appointments. The patient expert emphasised that people with diabetic macular oedema may be unsure about using steroids because it could affect their diabetes management. The clinical experts explained that because it is used in small quantities directly into the eye, using dexamethasone should not affect their diabetes management. The committee concluded that there is an unmet need for another treatment option for diabetic macular oedema in people who have a phakic lens. It added that people with diabetic macular oedema and clinicians would welcome an effective new treatment option that is used less frequently.

Having a longer time between treatments will improve outcomes for people with diabetic macular oedema

3.2 The clinical experts emphasised that having a longer time between treatments could benefit both people with diabetic macular oedema and clinicians. They highlighted that people with diabetes often have multiple hospital appointments in different departments. Using dexamethasone intravitreal implant would reduce the number of visits to the eye clinics for follow up or treatment. The clinical experts explained that a longer time between treatments will free up the capacity in the NHS as well as improve quality of life for people with diabetic macular oedema. The clinical experts agreed that the availability of dexamethasone intravitreal implant for this population would change practice. The other treatments do not work well for these people and are only used because clinicians prefer to offer some treatment rather than nothing at all. The clinical experts explained that people with diabetic macular oedema who still have their natural lens are at a significant disadvantage compared with people who have a pseudophakic lens because of the difference in access to dexamethasone. So, they would welcome it as an option to improve the quality of life for people with diabetic macular oedema and their carers. The committee heard from the clinical expert that having a longer time between treatments will free up the capacity in the NHS, but

the committee noted that there was no evidence provided for this. The committee concluded that having a longer time between treatments will improve outcomes for people with diabetic macular oedema who have a natural (phakic) lens.

Treatment pathway and comparators

Anti-VEGFs are the most relevant comparators for people for whom non-corticosteroids do not work well enough

3.3 In its submission, the company compared dexamethasone intravitreal implant with the anti-VEGF therapies ranibizumab and aflibercept. It considered options such as laser photocoagulation alone and bevacizumab. It stated that anti-VEGF therapies would be the most relevant comparators for people for whom non-corticosteroids do not work well enough. It highlighted that bevacizumab does not have a marketing authorisation for this indication and therefore any use would be off-label. The company stated that based on UK clinical feedback, laser photocoagulation is only used in people when the macular oedema does not involve the centre (around 20% of the total diabetic macular oedema population) or in people with diabetic macular oedema with no associated visual impairment, because of concerns around safety and long-term clinical efficacy. For these reasons, laser photocoagulation and bevacizumab were excluded as comparators in the company submission. The committee accepted that anti-VEGFs were the most appropriate comparators for dexamethasone in people for whom non-corticosteroids did not work well enough.

There is a small percentage of people for whom non-corticosteroids are unsuitable and this population can be easily defined in clinical practice

3.4 The committee discussed the treatment pathway and the proposed position of dexamethasone intravitreal implant. The clinical experts highlighted that there is a low proportion of people for whom non-corticosteroids are unsuitable (5% to 10%) such as people who are pregnant, have established allergies to anti-VEGFs, or have had a

cardiovascular event in the past 3 to 6 months (such as a stroke or myocardial infarction). The clinical experts added that people who are unable to have frequent injections because they cannot get to the hospital, their carers cannot bring them, or the hospital is too far would also be unable to have non-corticosteroids. The clinical experts emphasised that although this is a small group, it is important that they have access to treatment that is suitable for them as watch and wait is the only available treatment option. The committee agreed that there is a small percentage of people for whom non-corticosteroids are unsuitable and that this population could be easily defined in clinical practice.

Clinical evidence

The results from the MEAD trials are generalisable to UK practice

3.5 The ERG highlighted several differences in the baseline characteristics of people in the pooled MEAD trials compared with UK clinical practice. The previous use of laser, the previous use of anti-VEGF therapy, the proportion of people with baseline cataracts and the proportion of people with baseline best-corrected visual acuity (BCVA) differed from that expected in UK clinical practice. Additionally, in the company submission, the sham arm of MEAD was used as a proxy for continued anti-VEGF use. The committee acknowledged that the MEAD trials most closely represented the group for whom non-corticosteroids do not work well enough, and people for whom non-corticosteroids are unsuitable would not be part of this evidence base. The clinical expert explained that the population in the sham arm of the MEAD trials can be considered comparable to the population expected in clinical practice from a biological point of view, and that the sham arm of the MEAD is a good proxy for anti-VEGF use in the comparison. The company used a last observation carried forward (LOCF) approach to account for missing data. The ERG expressed concerns that a LOCF approach biases the sham and dexamethasone intravitreal implant arms and emphasised that it was not possible to predict the direction of bias. Despite the uncertainties, the committee considered that the MEAD trials represent the most appropriate source of evidence for dexamethasone intravitreal implant for people for whom non-corticosteroids do not work well

enough.

Data from MEAD-010 and MEAD-011 suggests that dexamethasone intravitreal implant is more effective than sham

3.6 The clinical evidence for dexamethasone intravitreal implant came from 2 3-year, phase 3, multicentre, masked, randomised, sham-controlled trials: MEAD-010 and MEAD-011. The trials compared dexamethasone 700 micrograms and dexamethasone 350 micrograms with sham procedure in adults with either pseudophakic or phakic diabetic macular oedema. MEAD-010 included 494 people and took place at 59 study centres in 10 countries. MEAD-011 included 554 people and took place at 72 study centres in 14 countries, with a maximum follow up of 39 months. For this appraisal, only the dexamethasone 700 microgram and sham arms from the phakic (natural lens) subgroups of the trials are relevant. The primary outcome was mean change in BCVA from baseline. BCVA was measured using the Early Treatment Diabetic Retinopathy Study method. The company submission pooled data from MEAD-010 and MEAD-011 for the phakic-only modified ITT (mITT) populations (262 dexamethasone intravitreal implant, 250 sham) and this analysis was used to inform the efficacy of dexamethasone intravitreal implant in the company's base case in their economic model. The sham arm of MEAD was used as a proxy for continued anti-VEGF use. The results from the pooled analysis of the phakic-only populations of the MEAD trials showed that at 39 months, a significantly greater number of people who had dexamethasone intravitreal implant achieved BCVA improvement of at least 10 letters and at least 15 letters from baseline compared with sham (the associated p values are academic in confidence and cannot be presented here). The results for at least a 10-letter improvement in BCVA from baseline were also used in the company's economic model. The committee accepted that it is appropriate for the sham arm of the MEAD trial to be used as a proxy for continued anti-VEGF therapy. The committee concluded that the results from the pooled MEAD trials showed that dexamethasone intravitreal implant is more effective than sham in people with diabetic macular oedema who have a phakic lens.

Dexamethasone intravitreal implant is likely to be clinically

effective in people with phakic diabetic macular oedema for whom non-corticosteroids are unsuitable

3.7 The company had not provided any clinical evidence for people with diabetic macular oedema and a phakic lens for whom non-corticosteroids are unsuitable. They explained that there is no relevant additional evidence available to model this specific population beyond the data that was presented in the evidence review for NICE's technology appraisal guidance on dexamethasone intravitreal implant for treating diabetic macular oedema (TA349). The company submission stated that this population has a high unmet need, and this group is likely to be a small number. The clinical experts explained that there was no biologically plausible reason why dexamethasone intravitreal implant would not be of similar clinical benefit in this group compared with those for whom non-corticosteroids do not work well enough. The committee agreed that although the company provided no evidence for this population, it is expected to be small and can be clearly defined in clinical practice. It concluded that dexamethasone intravitreal implant is likely to be clinically effective in people with diabetic macular oedema and a phakic lens that is unsuitable for non-corticosteroids.

The company's economic model

The company's economic model structure is consistent with that used in NICE's technology appraisal guidance on dexamethasone intravitreal implant for treating diabetic macular oedema

3.8 The company presented a Markov state transition model, with multiple discrete and independent health states used to capture the treatment of eyes affected with diabetic macular oedema and the progression of visual acuity over time. The ERG agreed that the model structure was consistent with that used in the evidence review for NICE's technology appraisal guidance on dexamethasone intravitreal implant for treating diabetic macular oedema (TA349). The committee agreed that the company's model structure was appropriate for decision making.

Time horizon

Results do not affect the cost effectiveness when adopting a lifetime time horizon or 10-year time horizon

3.9 The company adopted a lifetime time horizon (40 years), saying that this is consistent with that used in NICE's technology appraisal guidance on fluocinolone acetonide intravitreal implant for treating chronic diabetic macular oedema in phakic eyes after an inadequate response to previous therapy and in the evidence review for NICE's technology appraisal guidance on dexamethasone intravitreal implant for treating diabetic macular oedema (TA349). The ERG considered that a shorter time horizon (10 years) should be used because the company's long-term modelling assumptions are too simplistic. The committee noted that the time horizon chosen by the company was the longest seen in eye appraisals to date. It also considered that a shorter time horizon may be more appropriate because it is also consistent with other technology appraisals in this clinical area. The committee considered both time horizons but concluded that the choice of time horizon made little difference to the cost effectiveness, so both were accepted for decision making.

Assumptions about changes in BCVA in years 4 and 5 did not have a substantial effect on the cost-effectiveness results

3.10 In the company's model, the 3-monthly transition probabilities in years 4 and 5 were assumed to equal the last transition probability matrix estimated from MEAD (for both treatment options). The company emphasised that for dexamethasone intravitreal implant there is an upward trend in visual acuity outcomes from the end of MEAD (just over 3 years). The clinical experts highlighted that it is possible to see improvements in the long term in BCVA, although this might only be for a small number of people. The ERG highlighted that the changes in BCVA resulting from dexamethasone intravitreal implant treatment in years 4 and 5 are still a key area of uncertainty and preferred that dexamethasone intravitreal implant maintains vision (no net improvement) in years 4 and 5. The committee noted that this

assumption did not have a big effect on the incremental cost-effectiveness ratio (ICER) or on the overall net monetary benefit. It agreed that it could be optimistic to assume an improvement in visual acuity in years 4 and 5 of the model without further data and if this might only be seen in a small number of people. However, it concluded that the use of different assumptions in the company's and ERG's analyses did not have a substantial effect on the cost-effectiveness results.

Both the ERG and the company's preferred choice of source for the natural history of vision were considered for decision making and neither had a substantial effect on the cost-effectiveness results

3.11 The company's economic model used a 3-month probability of gaining or losing at least 10 letters of BCVA of 2.5% or 3.5% respectively, as reported in NICE's technology appraisal guidance on ranibizumab for treating diabetic macular oedema. The ERG preferred a 3-month probability of gaining or losing at least 10 letters of BCVA of 0% or 3.5% respectively, based on NICE's technology appraisal guidance on fluocinolone acetonide intravitreal implant for treating chronic diabetic macular oedema in phakic eyes after an inadequate response to previous therapy. The ERG highlighted that the choice of source for natural history of vision moved the ICER from the southeast to the southwest quadrant (southwest quadrant ICERs represent costs saved per quality-adjusted life year [QALY] lost, whereas southeast quadrant ICERs represent costs saved per QALY gained). The committee noted that the choice did not have a substantial effect on the overall net monetary benefit result (the actual results are commercial in confidence and cannot be presented here). The committee concluded that without better data for the natural history of vision, both approaches were considered for decision making and neither had a substantial effect on the cost-effectiveness results.

Cost-effectiveness estimates

Dexamethasone intravitreal implant is cost effective compared with anti-VEGFs for people for whom non-corticosteroids do not

work well enough

3.12 The company compared dexamethasone intravitreal implant with a composite comparator consisting of anti-VEGF treatments (aflibercept and ranibizumab). The company's base-case deterministic ICER for dexamethasone intravitreal implant dominates (that is, works better and costs less than) anti-VEGFs when the list price of anti-VEGFs is used (incremental costs -£6,969; incremental QALYs 0.114). The corresponding probabilistic ICER (generated by the ERG) for dexamethasone intravitreal implant also dominated anti-VEGFs when the list price of anti-VEGFs was used (incremental costs -£7,024; incremental QALYs 0.123). Additionally for the results using a 100% aflibercept comparator, the company's ICER for dexamethasone intravitreal implant dominated aflibercept when the list price of aflibercept was used (incremental costs -£9,549; incremental QALYs 0.114). When using a 100% ranibizumab comparator, the company's ICER for dexamethasone intravitreal implant also dominated ranibizumab when the list price of ranibizumab was used (incremental costs -£2,581; incremental QALYs 0.114). Taking into account confidential prices for anti-VEGFs, dexamethasone intravitreal implant still dominated anti-VEGFs (exact ICERs are confidential and cannot be reported here). The committee noted that the ERG's cost-effectiveness base case estimated that dexamethasone intravitreal implant was associated with a small loss in QALYs compared with anti-VEGFs. Therefore, the ERG's cost-effectiveness base-case ICER was in the southwest quadrant of the cost-effectiveness plane. It was noted that in situations in which an ICER is estimated for a technology that is less effective and less costly than its comparator, the commonly assumed decision rule of accepting ICERs below a given threshold is reversed. So, the higher the ICER, the more cost effective a treatment becomes. The ERG's base-case cost-effectiveness analysis showed dexamethasone intravitreal implant was associated with cost savings per QALY lost compared with anti-VEGFs when the list price of anti-VEGFs was used. The ERG's deterministic ICER was £1,040,800 (southwest) per QALY lost (incremental costs -£6.333; incremental QALYs -0.006). The corresponding probabilistic ICER was £2,267,457 (southwest) per QALY lost (incremental costs -£6,322; incremental QALYs -0.0033). The ERG replicated the company analyses using the confidential discount for anti-VEGFs (exact ICERs are

confidential and cannot be reported here). Dexamethasone intravitreal implant remained associated with cost savings per QALY lost in the ERG's base case and these ICERs were above £30,000 per QALY lost. Overall, the committee concluded that dexamethasone intravitreal implant was likely to be cost-effective compared with anti-VEGFs.

Dexamethasone intravitreal implant is a cost-effective use of NHS resources when using the net monetary benefit approach compared with anti-VEGFs

3.13 The committee also considered the incremental net monetary benefit to compare dexamethasone intravitreal implant with anti-VEGFs to support decision making. An advantage of the net monetary benefit is that it allows the cost of an error to be quantified. A positive net monetary benefit implies that the intervention is cost effective compared with the alternative at the given cost-effectiveness threshold. In analyses that included the confidential discount for anti-VEGFs, the net monetary benefit results were found to stay positive at thresholds of £20,000 and £30,000 per QALY gained for both the company base case and the ERG's base case. Given that any differences in QALYs between dexamethasone intravitreal implant and anti-VEGFs are small, the committee concluded that dexamethasone intravitreal implant is a cost-effective use of NHS resources when using the net monetary benefit approach compared with anti-VEGFs.

Although no cost-effectiveness results were presented for people with phakic diabetic macular oedema that is unsuitable for non-corticosteroids, the risk to the NHS would be low

3.14 The committee noted that the company provided no cost-effectiveness evidence for people for whom non-corticosteroids are unsuitable. The committee recalled the views of the company and the clinical experts that they expected that dexamethasone intravitreal implant would be of similar clinical benefit in this group compared with those for whom non-corticosteroids do not work well enough (see section 3.7). The committee noted that the comparator for people with diabetic macular oedema that is unsuitable for non-corticosteroids would be watch and

wait rather than continued use of anti-VEGFs. The company submission highlighted that because this population is expected to be small, it would not have a substantial impact on the overall cost effectiveness. The committee noted that this group has no available pharmacotherapy treatment options. It was also mindful that it would need to consider relevant factors such as equalities issues in making its decision (see section 3.15). It agreed that dexamethasone was likely to be similarly effective in this population and since the population is expected to be small, the risk to the NHS would be low if approved.

Other factors

Recommending dexamethasone intravitreal implant would address many of the important equalities issues identified

3.15 The company submission noted that no equality considerations relating to using dexamethasone intravitreal implant were identified or anticipated. At scoping it was raised that if a person is registered as blind or partially sighted, it is considered a disability, as stated in the Equality Act 2010. Therefore, the committee noted the patient population addressed in this appraisal is a protected group under this act. The patient expert emphasised that there is a high prevalence of diabetes among people with a learning disability. They highlighted there are challenges in providing treatments and routine eye tests for people with a learning disability and that anything to help improve that access and reduce health inequality is worth considering. The committee noted that people with a learning disability could benefit from a treatment involving fewer injections and fewer visits to the clinic for treatment. The committee considered that a difference in prevalence between different groups was not considered an equalities issue that could be addressed through a technology appraisal. It was satisfied that these groups would have appropriate access to treatments such as dexamethasone intravitreal implant if it was recommended. The committee concluded that recommending dexamethasone intravitreal implant would address many of the important equalities issues identified.

Innovation

Dexamethasone intravitreal implant will reduce the number of treatment visits and improve quality of life for people with diabetic macular oedema

3.16 The company considered dexamethasone to be innovative. This is because it addresses a substantial unmet clinical need for people with phakic eyes for whom non-corticosteroids do not work well enough or are unsuitable. The company highlighted that dexamethasone intravitreal implant offers a treatment option that improves patient outcomes and decreases the burden on patients and healthcare systems. The clinical experts highlighted that dexamethasone needs less frequent injections compared with anti-VEGFs, and might address some of the capacity issues that they currently face in clinical practice. The committee noted that these benefits were likely to be captured in the QALY and concluded that dexamethasone intravitreal implant would reduce the number of treatment visits and improve quality of life for people with diabetic macular oedema.

Conclusion

Dexamethasone intravitreal implant is recommended for treating diabetic macular oedema in people with a phakic lens

3.17 Each of the plausible analyses for dexamethasone compared with anti-VEGFs in the population with phakic eyes when non-corticosteroids do not work well enough resulted in ICERs showing that dexamethasone dominated anti-VEGFs, or that dexamethasone was associated with cost savings per QALY lost in the range normally considered a cost-effective use of NHS resources. The committee noted that the company provided no evidence for people for whom non-corticosteroids are unsuitable. However, based on the feedback from the clinical experts, the committee added that they would expect clinical effectiveness to be similar in this group (see section 3.7). The committee was satisfied that this group can be clearly defined in clinical practice and that the group is very small

meaning that the risk to the NHS would be low (see section 3.14). It agreed that recommending dexamethasone intravitreal implant in this group could address some important equalities issues (see section 3.15). Overall, the committee agreed that dexamethasone intravitreal implant is recommended for treating diabetic macular oedema in people with a phakic lens for whom non-corticosteroids do not work well enough or are unsuitable. This recommendation from NICE means that dexamethasone intravitreal implant is recommended for treating visual impairment due to diabetic macular oedema only if the diabetic macular oedema has not responded well enough to non-corticosteroids, or non-corticosteroids are unsuitable, irrespective of whether they have a phakic or pseudophakic lens. NICE's technology appraisal guidance on dexamethasone intravitreal implant for treating diabetic macular oedema (TA349) has been updated and replaced by this guidance at publication. Considerations for people with a pseudophakic (intraocular) lens are still available in the evidence review for NICE's technology appraisal guidance on dexamethasone intravitreal implant for treating diabetic macular oedema (TA349).

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.

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 person has diabetic macular oedema and the doctor responsible for their care thinks that dexamethasone intravitreal implant 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 C.

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.

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Accreditation