Briefing Paper for Surrey Heartlands Integrated Care System (ICS) Area Prescribing Committee (APC)

NICE Technology Appraisals: Local implementation

NICE TA Guidance name and number	Dexamethasone for treating diabetic macular oedema Technology appraisal guidance 824		
Available at	https://www.nice.org.uk/guidance/ta824		
Date of issue	14 September 2022	**Implementation deadline**	30th December 2022

Medicine details[1]	
Name, brand name and manufacturer	Dexamethasone (Ozurdex®) Abbvie
Mode of action	www.medicines.org.uk [accessed on 12/10/2022 at 1452] Dexamethasone, a potent corticosteroid, has been shown to suppress inflammation by inhibiting oedema, fibrin deposition, capillary leakage, and phagocytic migration of the inflammatory response.
Licensed indication	www.medicines.org.uk [accessed on 12/10/2022 at 1630] **4.1 Therapeutic indications** OZURDEX is indicated for the treatment of adult patients with: • visual impairment due to diabetic macular oedema (DME) who are pseudophakic or who are considered insufficiently responsive to, or unsuitable for non-corticosteroid therapy • macular oedema following either Branch Retinal Vein Occlusion (BRVO) or Central Retinal Vein Occlusion (CRVO) (see section 5.1) • inflammation of the posterior segment of the eye presenting as non-infectious uveitis
Formulation	Intravitreal injection.
Usual dosage	www.medicines.org.uk [accessed on 12/10/2022 at 1630] *DME* Patients treated with OZURDEX who have experienced an initial response and in the physician's opinion may benefit from retreatment without being exposed to significant risk should be considered for retreatment. Retreatment may be performed after approximately 6 months if the patient experiences decreased vision and/or an increase in retinal thickness, secondary to recurrent or worsening diabetic macular oedema. There is currently no experience of the efficacy or safety of repeat administrations in DME beyond 7 implants.

	POINT TO NOTE: The Prescribing Clinical Network (previous name of APC) decision of October 2015 was reviewed in May 2018 in regards to frequency of injections and the PCN agreed to the Ophthalmology Network proposal to allow some patients to have injections more frequently than every 6 months (no more frequently than 4 monthly)
Comparison with NICE TA use[2]	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 is the current dose considered by NICE as part of this NICE evaluation. Subsequent changes in the license following NICE publication will need to be considered by the Area Prescribing Committee and **will not be routinely funded** by local commissioners.*

Disease and potential patient group	
Brief description of disease	https://www.moorfields.nhs.uk/sites/default/files/Diabetic%20macular%20oedema.pdf Diabetic eye disease is a leading cause of blindness registration among working age adults in England and Wales. It is caused by changes to the tiny blood vessels of the retina (the light sensitive layer at the back of the eye). In diabetic macular oedema, blood vessels leak fluid into the retina. Vision loss occurs when the fluid reaches the macula (the centre of the retina that provides sharp vision) and builds up, causing swelling. At first, you may not notice changes to your vision. Over time, diabetic macular oedema can cause your central vision to become blurred. A healthy macula is essential for good vision. All people with type 1 and type 2 diabetes are at risk of diabetic macular oedema.
Potential patient numbers per 100,0004	No NICE resource impact statement available **Patient Numbers:** Since dexamethasone NICE was published in 2015. Information on Blueteq shows that notification of treatment initiation with dexamethasone has been given by local trusts for 43 patients.

SUMMARY

Guidance[2]

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.

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.

Other factors e.g. equality issues

There are no equality issues relevant to the recommendations.

Cost implications* [2,3,4]

Cost:
Dexamethasone (Ozurdex) intravitreal implant costs £870 for 1 x 700mcg implant [BNF accessed on 12/10/2022 at 16:46

Resource impact template
No resource impact template has been provided by NICE for this NICE TA

Resource impact statement
No significant resource impact is anticipated

We do not expect this guidance to have a significant impact on resources; that is, the resource impact of implementing the recommendations in England will be less than £5 million per year (or approximately £9,000 per 100,000 population, based on a population for England of 56.3 million people).
This is because the technology is a further treatment option and the overall cost of treatment will be similar.

Availability of PAS and details (if appropriate):
Dexamethasone was included in the national procurement process for retinal services

Availability of homecare service (if appropriate

No

Alternative treatments and cost per patient per year

Other NICE recommended products: (listed in order of cost

Anti VEGF treatment

- Ranibizumab biosimilar (anti-VEGF)
- Aflibercept (anti-VEGF)
- Brolucizumab (anti-VEGF)
- Ranibizumab originator (anti-VEGF)
- Faricimab (anti-VEGF)

Intravitreal Corticosteroids

- Dexamethasone Intravitreal implant (Ozurdex®) – for use when DMO does not respond to non-corticosteroid treatment, or such treatment is unsuitable.
- Fluocinolone acetonide intravitreal implant (Iluvien®) - for use when DMO is insufficiently responsive to available therapies

Options not reviewed by NICE but used in standard practice:

None

Impact to patients

- There is an unmet need for an effective treatment given less frequently for patients with a phakic lens (previously dexamethasone was NICE approved for patients with pseudophakic lenses.

Impact to primary care prescribers

- This is a National Tariff excluded high-cost drug and is commissioned by integrated care systems (ICS) for use in secondary care. There should be no prescribing in primary care.
- Primary care prescribers should be aware that their patient is receiving this medicine and ensure that this is recorded in the patient's notes to be alert to potential side-effects and interactions with other medicines prescribed in primary care. This will also ensure that GP records, which are accessed by other healthcare providers, are a true and accurate reflection of the patient's medication.

Impact to secondary care

- Providers are NHS hospital trusts.
- The initiation, administration and on-going treatment is managed by secondary care.
- An additional treatment option would be valued by clinicians.

Impact to commissioners

- The technology is commissioned by ICBs and they are required to comply with the recommendations in a NICE TA within 90 days of its date of publication.

Implementation

- Blueteq forms to be developed.
- Trusts to follow internal governance procedures to add to their formulary.
- Pathway has been discussed at Ophthalmology Medicines Network and place in therapy considered

<u>Area Prescribing Committee – Decision making criteria</u>

National Guidance and priorities

- NICE published this Technology Appraisal (TA824) on 14th September 2022 with a 90 day implementation deadline. Surrey Heartlands ICB is mandated to fund this treatment.

Clinical Effectiveness

- 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.

Patient Safety

- Potent corticosteroid (special warnings as per SPC (www.medicines.org.uk)
- Safety and efficacy of ozurdex® administered in both eyes concurrently is not recommended (www.medicines.org.uk)

Patient Factors

- An additional treatment option in patients with phakic lenses would be valued by patients.
- Suitable for patients unable to get to the hospital to have frequent injections, their carers cannot bring them, or the hospital is too far away.

Environmental impact

- Patients will be required to attend a clinic setting to receive the injection.
- NICE committee was aware that some people with diabetic macular oedema may require help from a carer to travel to appointments. (carbon footprint)

Equality and diversity

- The [NICE] committee did not identify any equality issues.

Place in therapy relative to available treatments

- 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

Stakeholder views

- The Ophthalmology Medicines Network will receive this paper for comments during the wider APC consultation process.

Cost effectiveness

- We do not expect this guidance to have a significant impact on resources; that is, the resource impact of implementing the recommendations in England will be less than £5 million per year (or approximately £9,000 per 100,000 population, based on a population for England of 56.3 million people).

Additional funding required

- Anticipated cost is expected to be less than £100k/Place/annum financial threshold for APC decisions.

Identified implementation issues

- Drug should be identified as RED (hospital use only).
- GPs should continue to ensure patient practice records are kept up to date.

Recommendation to APC

- National Tariff excluded high-cost drug: Yes
- Agree Blueteq tick box forms as presented

References:

Declaration of interest: None

Explanation of declaration of interest: None.

Version control sheet: