Australian Government

Medical Services Advisory Committee

Public Summary Document

Application No. 1377 – Optical Coherence Tomography (OCT) for retinal assessment in the presence of diabetic macular oedema (DMO) for access to treatment with dexamethasone posterior segment drug delivery system

Applicant: **Allergan Australia Pty. Ltd**

Date of MSAC consideration: **MSAC 66th Meeting, 30-31 March 2016**

Context for decision: MSAC makes its advice in accordance with its Terms of Reference, see at www.msac.gov.au

1. Purpose of application and links to other applications

The reapplication sought Medicare Benefits Schedule (MBS) listing of optical coherence tomography (OCT) for the determination of patient eligibility for treatment with the dexamethasone implant based on the previous April 2015 recommendation by MSAC to defer MBS listing of OCT pending a Pharmaceutical Benefits Advisory Committee (PBAC) recommendation to list the dexamethasone implant on the Pharmaceutical Benefits Scheme (PBS). The evidence for a resubmission was received by the Department on 4 November 2015.

2. MSAC's advice to the Minister

After considering the available evidence in relation to safety, clinical effectiveness and cost-effectiveness, MSAC supported listing OCT for retinal assessment in the presence of diabetic macular oedema (DMO) for access to initial treatment with dexamethasone implant, restricted to once per patient per annum. MSAC suggested that a fee of $40 was appropriate.

3. Summary of consideration and rationale for MSAC's advice

MSAC noted that the applicant had resubmitted listing of OCT for retinal assessment in patients with impaired vision due to DMO and with pseudophakia (an artificial lens) for access to treatment with dexamethasone implant. This was coordinated with a separate resubmission for dexamethasone implant to the March 2016 PBAC meeting.

MSAC recalled that it had previously deferred this application at its April 2015 meeting until such time as PBAC made a positive recommendation regarding the corresponding PBS listing

of dexamethasone implant. At its April 2015 meeting, MSAC foreshadowed support for the use of OCT to confirm the presence of macular oedema once a decision to inject dexamethasone implant had been made. The foreshadowed MBS item descriptor allowed for the use of OCT before the initial implant of dexamethasone and prior to each subsequent implant in each case to confirm the presence of oedema and thus, the suitability of proceeding to the injection of the implant. MSAC did not support the repeated use of OCT to monitor post-treatment response, noting that this would be best determined by a visual acuity test with the aid of a Snellen chart. MSAC had also foreshadowed at the time that the MBS fee should be approximately $50.

MSAC noted that PBAC recommended the listing of dexamethasone implant in the PBS at its March 2016 meeting.

In considering this resubmission, MSAC noted that the applicant had updated the proposed MBS item descriptor and amended the item fee in line with MSAC recommendations from the April 2015 meeting. The proposed PBS restriction had been revised, as per PBAC March 2015 recommendations, and was now aligned with those of anti-VEGF treatments (i.e., ranibizumab and aflibercept injections). The proposed treatment algorithm in the resubmission had also been updated with retreatment frequencies for anti-VEGF injections (every 4–8 weeks) and dexamethasone implants (every 4–6 months).

MSAC noted that the resubmission projected that the number of patients with centre-involving DMO would increase from **redacted** in 2016 to **redacted** by 2020, with 30% of these patients estimated to have pseudophakia. The MBS costs associated with dexamethasone implant therapy were estimated to be $**redacted** in year one and increasing to $**redacted** in year five. If restricted to a proposal in which OCT was only funded to confirm the presence of macular oedema in order to initiate dexamethasone therapy, then the MBS costs were estimated to be $**redacted** in year one, increasing to $**redacted** in year five. MSAC noted that costs associated with intravitreal injection of the implant accounted for the majority of the cost to the MBS.

MSAC also noted that the resubmission proposed that the use of dexamethasone implant would offset the use of anti-VEGF injections. Due to the lower frequency of treatment associated with dexamethasone implants compared to anti-VEGF injections, the applicant estimated net cost-savings for the MBS of $**redacted** in year one and $**redacted** in year five. However, MSAC noted that the substitution estimates proposed in the resubmission may not be reached if dexamethasone implant is targeted to patients who cannot tolerate, or who are not responding to anti-VEGF injections. In this case, currently untreated patients would receive treatment at increased rather than decreased costs to the MBS. In light of this, MSAC advised that the savings predicted by the applicant would be unlikely to be realised.

In April 2015, MSAC considered that the MBS fee for this service should be $50. However, in July 2015, MSAC supported listing of another item for OCT to determine eligibility for PBS-subsidised treatments for macular oedema and advised that a fee of $40 would be appropriate for the service. MSAC considered that the MBS fee should be consistent across all OCT items listed to ensure there is no leakage between items. Consequently MSAC revised its advice on the fee for this service and considered an MBS fee of $40 as appropriate.

In considering the broader implications of an MBS item, MSAC reaffirmed that all of the evidence relating to the clinical utility of OCT provided in the resubmission was specific to diagnostic rather than monitoring purposes. MSAC noted that evidence from the MEAD trials and Trial 024, which investigated the efficacy of dexamethasone implant, was presented

in the resubmission. In these studies, central retinal thickness (CRT) assessment by OCT was used only to confirm whether patients had residual macular oedema and therefore, if treatment was indicated. However, assessment of CRT by OCT was not used to determine the extent of response to treatment or to predict treatment outcomes.

MSAC acknowledged that, as retreatment with dexamethasone implant is required every 4–6 months, difficulties may arise in differentiating OCT use associated with diagnosis for the purpose of retreatment as opposed to monitoring. MSAC noted that, while its intention would be for subsequent OCTs to be used to determine ongoing eligibility for treatment, the risk of leakage beyond this scope would be difficult to negate. MSAC suggested that placing a cap on the number of OCTs that could be accessed by patients on an annual basis could help minimise this risk.

MSAC noted that similar difficulties in differentiating diagnosis for the purpose of retreatment from monitoring were evident for the use of OCT in patients receiving anti-VEGF injections. MSAC had previously considered an application for the use of OCT to detect macular oedema to determine eligibility for PBS-subsidised treatment for ranibizumab and aflibercept in July 2015. At the time, MSAC supported public funding of a new MBS item for OCT to determine the presence of macular oedema and thus eligibility for PBS-subsidised therapies indicated for the treatment of all macular conditions and recommended:

- A limit of no more than one OCT service per patient per year.
- The MBS item descriptor should not allow for monitoring with OCT to assess post-treatment response as this could be better determined by performing a visual acuity test.

MSAC emphasised that all of the evidence provided to support the clinical utility of OCT for both dexamethasone implants and anti-VEGF injections related to diagnosis, not monitoring of macular oedema.

MSAC considered whether a separate MBS item should exist for determining PBS eligibility for dexamethasone implant or whether a broader MBS item across different macular oedema causing diseases and associated PBS-listed therapies, as proposed at the July 2015 meeting, would be more appropriate. MSAC advised that the use of a single broader item would allow consistency in the purpose, number of times a patient could receive the service and the fee for the use of OCT across these treatments to be achieved. MSAC therefore concluded that a broader MBS item worded to reflect the use of OCT for the initial diagnosis of macular oedema was appropriate. MSAC advised that the wording of this MBS item descriptor should ensure that the use of OCT is in the initial diagnosis of macular oedema only.

In the context of this resubmission, MSAC reversed its April 2015 foreshadowed advice regarding the establishment of an MBS item that allows OCT use before the initial implant of dexamethasone and before each subsequent implant to confirm the presence of oedema. MSAC was concerned that the risk of leakage to monitoring would be difficult to negate. MSAC emphasised its support for the development of a broader MBS item for the use of OCT to determine the presence of macular oedema, and thus patients' eligibility for PBS-subsidised therapies for the treatment of all relevant macular conditions.

Relevant MSAC advice from additional OCT agenda item at March 2016 meeting

The March 2016 meeting included an agenda item for MSAC to provide advice on the co-ordination of the multiple applications for OCT currently under consideration to ensure consistency across the applications. The three OCT services considered were application 1370, application 1377 and a broad OCT item to determine the presence of macular oedema

and thus eligibility for PBS-subsidised therapies for treatment of all PBS-listed macular conditions. MSAC advised that the evidence supports use of OCT for diagnosis, but not for monitoring. Therefore, MSAC supported the restriction of the OCT service to diagnosis, at no more frequently than once per patient per annum, across all indications involving macular oedema, in order to help determine eligibility to initiate an appropriate PBS-subsidised treatment. However, MSAC did support an additional MBS item following treatment with ocriplasmin to assess whether the vitreomacular adhesion was fully resolved and to rule out the need for vitrectomy. MSAC advised that a $40 fee for all OCT services was appropriate based on evidence of fees used in overseas countries and on the decreasing costs of the equipment required to deliver the service. The positions supported by MSAC during this agenda item were applied to the individual applications 1370 and 1377.

The following proposed MBS item descriptors were developed based on these outcomes:

Category 2 – DIAGNOSTIC PROCEDURES AND INVESTIGATIONS Group D1 – MISCELLANEOUS DIAGNOSTIC PROCEDURES AND INVESTIGATIONS Subgroup 2 - OPHTHALMOLOGY
MBS [item number (Note: this will be assigned by the Department if listed on the MBS)] OPTICAL COHERENCE TOMOGRAPHY to determine if the requirements relating to: a) age-related macular degeneration for access to initial treatment with ranibizumab or aflibercept, OR b) diabetic macular oedema for access to initial treatment with ranibizumab, aflibercept or dexamethasone, OR c) central or branch retinal vein occlusion for access to initial treatment with ranibizumab or aflibercept*, OR d) vitreomacular traction for access to initial treatment with ocriplasmin, under the Pharmaceutical Benefits Scheme (PBS) are fulfilled. Limited to one service per annum, unilateral or bilateral. Fee: $40.00

*point c) is written in reflection of the PBAC recommendation to add BRVO to the aflibercept listing

Category 2 – DIAGNOSTIC PROCEDURES AND INVESTIGATIONS Group D1 – MISCELLANEOUS DIAGNOSTIC PROCEDURES AND INVESTIGATIONS Subgroup 2 - OPHTHALMOLOGY
MBS [item number (Note: this will be assigned by the Department if listed on the MBS)] OPTICAL COHERENCE TOMOGRAPHY for the assessment of the need for further treatment following PBS-subsidised ocriplasmin, claimable only once per eye per lifetime. Fee: $40.00

4. Background

At the April 2015 meeting, MSAC deferred application 1377 until such time as PBAC made a positive recommendation regarding the corresponding PBS listing of dexamethasone implant.

See Public Summary Document at
http://www.msac.gov.au/internet/msac/publishing.nsf/Content/1377-public

5. Proposal for public funding

The applicant proposed a revised MBS item descriptor for OCT for retinal assessment in patients with DMO and pseudophakia (artificial lens post cataract surgery), or those scheduled for cataract surgery, for access to treatment with dexamethasone implant. The applicant noted that the final wording of the MBS item descriptor may need to be revised to align with the PBS restriction, when finalised.

Re-treatment frequencies were added to the proposed treatment algorithm, anti-VEGF: every 4-8 weeks and dexamethasone implant: every 4-6 months.

6. Financial/budgetary impacts

The likely utilisation and costs associated with the proposed MBS item for OCT and the co-dependent PBS listing of dexamethasone implant were estimated using an epidemiological approach.

The estimated number of patients eligible for treatment from the reapplication is shown in Table 1.

Table 1 Number of eligible DMO patients under the proposed restriction

	2016	2017	2018	2019	2020
Australian adult population[a]	**redacted**	**redacted**	**redacted**	**redacted**	**redacted**
Prevalence of DM in Australia (7.22%)[b]	**redacted**	**redacted**	**redacted**	**redacted**	**redacted**
Proportion with centre-involving DMO (5.7%)[c]	**redacted**	**redacted**	**redacted**	**redacted**	**redacted**
Proportion of pseudophakia among patients with centre-involving DMO (30%)[d]	**redacted**	**redacted**	**redacted**	**redacted**	**redacted**

[a] Based on population projections from the Australian Bureau of Statistics from 2016 to 2020. (http://www.ausstats.abs.gov.au/Ausstats/subscriber.nsf/0/0E09CCC14E4C94F6CA2574B9001626FE/$File/32220_2006%20to%202101.pdf)
[b] Deloitte Access Economics 2015
[c] Literature search per PBAC submission
[d] Weighted proportions from pivotal DMO trials (024, Campochiaro 2011, DRCR.net 2010, 2015, Gillies et al. 2014, MEAD)

The estimated net cost to the MBS associated with dexamethasone implant ranges from $**redacted** in Year 1 to $**redacted** in Year 5.

Due to the lower treatment frequency of dexamethasone implant compared with the anti-VEGF injections the reapplication estimated that there would be net cost-savings for the MBS of $**redacted** in Year 1, decreasing to $**redacted** in Year 5.

7. Applicant's comments on MSAC's Public Summary Document

Allergan welcomes the recommendation from MSAC.

8. Further information on MSAC

MSAC Terms of Reference and other information are available on the MSAC Website at: www.msac.gov.au.