

Public Summary Document

Application No. 1370.1 – Ocriplasmin for symptomatic vitreomacular adhesion (VMA) including macular hole

Applicant: Alcon Laboratories (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 ocriplasmin based on the previous November 2014 recommendation by MSAC to defer MBS listing of OCT pending a Pharmaceutical Benefits Advisory Committee (PBAC) recommendation to list ocriplasmin on the Pharmaceutical Benefits Scheme (PBS).

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 confirming the diagnosis of vitreomacular traction (VMT) with or without macular hole (MH) to inform treatment with PBS subsidised ocriplasmin. MSAC advised that patients treated with ocriplasmin would be eligible for two OCT services, one prior to treatment and another three months later to ensure the adhesion was fully resolved and to rule out the need for vitrectomy. MSAC suggested a fee of \$40 was appropriate. MSAC considered that potential over use of MBS subsidised OCT could be monitored by comparing the number of MBS claims for OCT in people with VMT with the number of PBS claims for ocriplasmin.

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

MSAC recalled that this application to list OCT on the MBS is part of an integrated codependent submission, which also requested that PBAC consider PBS listing ocriplasmin to treat VMT. MSAC deferred the application in November 2014 until such time as PBAC recommended the corresponding PBS listing of ocriplasmin. A resubmission to list ocriplasmin on the PBS was considered at the March 2016 PBAC meeting, where it received a positive recommendation. No new submission was provided to MSAC so it was assumed that the application was the same as that considered at the November 2014 MSAC meeting.

MSAC recalled that, in July 2015, a separate application for the use of OCT to detect macular oedema in order to access PBS-subsidised treatment for macular conditions was considered. It was recommend that there be a limit of no more than one OCT service per patient per year and no additional monitoring with OCT to assess post-treatment response, noting this was better determined by a visual acuity test. However, MSAC noted that patients with VMT are a different and distinct population to the patients included in the macular oedema application. MSAC advised that in patients with VMT, a second OCT service (three months post-treatment) was necessary to assess the need for further treatment following ocriplasmin, to ensure that any adhesion had been fully resolved and to rule out the need for vitrectomy.

At the November 2014 meeting, MSAC indicated that the estimated MBS cost for OCT services (less than \$500,000 per annum) was likely to be an underestimate, as it did not take into account patients who are identified as being ineligible for ocriplasmin treatment once an OCT has been conducted (e.g. because OCT indicates there is no VMT or the MH is too large) and because of a risk that the term 'suspected VMT' would be interpreted broadly to justify billing the OCT service to the MBS even when other ocular conditions may be more likely. However, MSAC noted that it would be possible to identify overuse of OCT for suspected VMT given its link to the PBS listing for subsidised ocriplasmin, as OCT usage that is considerably higher than the number of PBS claims for ocriplasmin would be highly likely to be leakage.

The MBS costs in the application were calculated on a cost of \$91.75 per OCT service. 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.

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 coordination 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

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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

The original submission details can be found in the Public Summary Document for Application 1370, http://www.msac.gov.au/internet/msac/publishing.nsf/Content/1370-public

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

The applicant had no comments.

6. Further information on MSAC

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