

7.14 BEVACIZUMAB solution for IV use, 100mg in 4ml and 400mg in 16ml Avastin®, Roche Products Pty Ltd

1 Purpose of Application

- 1.1 The minor re-submission requested a Section 100, Authority Required (STREAMLINED) listing for bevacizumab in combination with platinum-based chemotherapy or topotecan plus paclitaxel for the treatment of persistent, recurrent or metastatic cervical cancer not amenable to curative treatment with surgery and/or radiation.

2 Requested listing

- 2.1 The submission did not explicitly request the same restriction as the November 2015 submission. At the November meeting, the PBAC further considered that the resubmission should define a patient population who would be eligible [for bevacizumab] [November PBAC Public Summary Document, 7.12]. As the minor re-submission did not discuss the patient population, the requested listing was assumed to be that considered at the November 2015 meeting.

3 Background

- 3.1 Bevacizumab received orphan drug designation from the TGA for the treatment of persistent, recurrent or stage IV carcinoma of the cervix in April 2014. The indication recommended at the Advisory Committee on Prescription Medicines (ACPM) meeting on 5 June 2015 is:
- Bevacizumab in combination with paclitaxel and cisplatin is indicated for the treatment of persistent, recurrent or metastatic carcinoma of the cervix.
 - Bevacizumab in combination with paclitaxel and topotecan is an acceptable alternative where cisplatin is not tolerated or not indicated.
 - ARTG registration was granted in October 2015.
- 3.2 This is the second submission for bevacizumab for this indication. The PBAC rejected the request at the November 2015 PBAC to list bevacizumab for the treatment of patients with advanced cervical cancer on the basis of high and unacceptable cost-effectiveness.
- 3.3 The following table provides a summary of the previous submission and the current re-submission.

Table 1: Summary of the previous submission and current re-submission

Component	Bevacizumab November 2015 submission	Current re-submission
Requested PBS listing	The submission proposed that bevacizumab in combination with platinum-based chemotherapy plus paclitaxel or with topotecan plus paclitaxel for the treatment of persistent, recurrent or metastatic	Although not explicitly stated, the Secretariat assumes this to be unchanged from the November 2015 submission.

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Component	Bevacizumab November 2015 submission	Current re-submission
	<p>cervical cancer patients who are not amenable to curative treatment with surgery and/or radiation therapy.</p> <p>PBAC Comment (November 2015 PSD, bevacizumab, paragraph 7.2): “The PBAC accepted the proposed restriction for recurrent, metastatic and persistent disease. The PBAC considered that use with standard platinum-based chemotherapy, either cisplatin (as per TGA approved indication) or carboplatin (current standard of care in Australia) was reasonable. The PBAC noted that topotecan, which was proposed as alternative to platinum-based chemotherapy is only PBS-subsidised for advanced metastatic ovarian cancer.”</p>	<p>The submission does not comment on the use of topotecan for this indication. The TGA indication of some brands included in combination with cisplatin for the treatment of patients with histologically confirmed Stage IV-B, recurrent, or persistent carcinoma of the cervix, which is not amenable to curative treatment with surgery and/or radiation therapy.</p>
Requested price	<p>Ex-manufacturer(ex-man) price: 100 mg \$ [REDACTED] 400 mg \$ [REDACTED] Proposed rebate on ex-man price: [REDACTED]% Effective manufacturer price: 100 mg \$ [REDACTED] 400 mg \$ [REDACTED] Includes a one-off statutory 5% price reduction assumed to be applied from 1 April 2016</p>	<p>Ex-manufacturer(ex-man) price: 100 mg \$ [REDACTED] 400 mg \$ [REDACTED] Proposed rebate on ex-man price: [REDACTED]% Effective manufacturer price: 100 mg \$ [REDACTED] 400 mg \$ [REDACTED] Includes a one-off statutory 5% price reduction assumed to be applied from 1 April 2016</p>
Main comparator	<p>Chemotherapy alone.</p> <p>PBAC Comment (November 2015 PSD, bevacizumab, paragraph 7.4): “7.4 The PBAC agreed that chemotherapy alone (platinum-based chemotherapy plus paclitaxel or topotecan plus paclitaxel for those who are unable to tolerate carboplatin or cisplatin) was the appropriate comparator for bevacizumab in combination with chemotherapy.”</p>	<p>Unchanged from November 2015 submission.</p>
Clinical evidence	<p>Primary clinical study report (GOG 0240) - A randomized phase III trial of cisplatin plus paclitaxel with and without NCI supplied bevacizumab (NSC #704865, IND #113912) versus the non-platinum doublet, topotecan plus paclitaxel, with and without NCI supplied bevacizumab, in Stage IVB, recurrent or persistent carcinoma of the cervix. (n=452).</p> <p>PBAC Comment (November 2015 PSD, bevacizumab, paragraph 7.5): “The PBAC noted the submission presented the results of a head-to-head trial (GOG 0240) comparing bevacizumab in combination with chemotherapy (cisplatin plus paclitaxel or topotecan plus paclitaxel) to chemotherapy alone (n=452).”</p>	<p>Unchanged from November 2015 submission.</p>

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Component	Bevacizumab November 2015 submission	Current re-submission
Key effectiveness data	<p>The addition of Bev + Chemo resulted in a clinically meaningful and statistically significant prolongation of OS (overall survival) compared with Chemo alone (median OS: 12.9 months Chemo alone versus 16.8 months Bev + Chemo; stratified HR=0.74, 95% CI: 0.58, 0.94; p=0.0132).</p> <p>PBAC Comment (November 2015 PSD, bevacizumab, paragraph 7.5): The PBAC noted the primary outcome was overall survival (OS) and progression free survival (PFS) was a secondary outcome. With regards to OS, the results were statistically significant in the ITT analyses, with a HR of 0.74 (95% CI: 0.58, 0.94) at the December 2012 data cut-off and [REDACTED] at the March 2014 data cut-off. With regards to PFS, the results were also statistically significant in the ITT analyses, with a HR of 0.66 (95% CI: [REDACTED]).</p>	Unchanged from November 2015 submission.
Key safety data	<p>Approximately 15 additional patients would experience a serious adverse event, for every 100 patients treated with bevacizumab plus chemotherapy, over a median duration of exposure of [REDACTED] weeks.</p> <p>Approximately 21 additional patients would experience serious adverse events of special interest, for every 100 patients treated with bevacizumab plus chemotherapy, over a median duration of exposure of 20.7 weeks.</p> <p>PBAC Comment (November 2015 PSD, bevacizumab, paragraph 7.6): “The PBAC noted the results of the comparative harms in the evaluation. The PBAC also noted that 15 additional patients would experience a serious adverse event, for every 100 patients treated with bevacizumab plus chemotherapy, over a mean duration of exposure of [REDACTED] weeks. Further, the PBAC were concerned that the rate of non-gastrointestinal (any grade) fistula/abscess were higher in bevacizumab plus chemotherapy ([REDACTED]%) than chemotherapy alone ([REDACTED]%), while the rate of gastrointestinal perforation (any grade) was substantially higher in bevacizumab plus chemotherapy ([REDACTED]%) than chemotherapy alone ([REDACTED]%), as reported in the TGA Clinical Evaluation Report (p40).”</p>	Unchanged from November 2015 submission. The submission does include an additional [REDACTED]% decrement in utility to the PFS values applicable to patients in the bevacizumab treatment arm applied in a sensitivity analysis in the updated economic evaluation.
Clinical claim	<p>Superior efficacy and a manageable and acceptable safety profile compared with chemotherapy alone.</p> <p>PBAC Comment (November 2015 PSD, bevacizumab, paragraph 7.7 & 7.8): “7.7 The PBAC considered the gain in median OS of 3.5 months and the gain in median PFS of 2.3 months associated with bevacizumab were clinically</p>	Unchanged from November 2015 submission.

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Component	Bevacizumab November 2015 submission	Current re-submission
	<p>modest, especially in view of significant adverse events including the clinically significant higher incidence of fistula.</p> <p>7.8 The PBAC considered this claim was adequately supported for superior comparative effectiveness in terms of OS and PFS compared with chemotherapy alone. However, the claim of manageable and acceptable safety profile was not adequately supported. While bevacizumab has some clinical benefits to patients, these may be counter-balanced by clinical harms.”</p>	
Economic evaluation	<p>•Cost-utility model with cost/QALY \$75,000/QALY - \$105,000/QALY (this included the submission’s proposed █% rebate on ex manufacturer price).</p> <p>PBAC Comment (November 2015 PSD, bevacizumab, paragraph 7.9): “The PBAC noted the cost utility analysis presented in the submission resulted in an ICER of greater than \$75,000/QALY - \$105,000/QALY. The PBAC, noting the clinical outcomes, considered that this base case ICER/QALY was unacceptably high and was based on QALYs gained resulting from parametric extrapolation of OS and PFS that could not be relied upon. The PBAC noted that base-case ICER/QALY value was much higher than the range of ICER that the Committee has considered cost-effective for treatments of cancer. Further, the PBAC agreed with the ESC that the base case ICER/QALY likely represents a lower boundary of a plausible range of cost-effectiveness. The PBAC noted that the ICER was sensitive to the extrapolation from a median follow-up of 14.1 months to a time horizon of 7 years. The PBAC questioned that trial data was available to 55.9 months however, the submission chose not to incorporate data beyond 14.1 months. The PBAC noted the results of the sensitivity analyses and that the ICER increases to \$105,000/QALY - \$200,000/QALY using the trial OS data up to 55.9 months.”</p>	<p>•Cost-utility model with cost/QALY \$45,000 - \$75,000.</p> <p>The base case was updated to incorporate a █% rebate, rather than the █% rebate proposed in the November 2015 submission and the truncation point was extended to 55.9 months. In sensitivity analysis, a █% decrement in utility to the PFS values applied to patients in the bevacizumab treatment arm was applied results in ICER of \$45,000/QALY - \$75,000/QALY</p> <p>The ICERs increased when the preparation fee includes TGA licensed compounders fee (\$█) rather than the non-TGA licensed compounders fee (\$█), see below for more information.</p>
Number of patients	<p>•█ in Year 1 decreasing to █ in Year 5.</p> <p>PBAC Comment (November 2015 PSD, bevacizumab, paragraph 7.11): “The PBAC noted that the estimates of utilisation of bevacizumab were uncertain and the financial estimates were likely overestimated. The PBAC recommended that the sponsor consider obtaining estimates of the cumulative number of cervical cancer deaths in the next 5-10 years taking into account the change in Human papillomavirus (HPV) testing in 2017 and the impact of the HPV vaccine on the National</p>	Unchanged from November 2015 submission.

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Component	Bevacizumab November 2015 submission	Current re-submission
	Immunisation Program. Also some justification should be provided in relation to the uptake rates of bevacizumab.”	
Estimated cost to PBS	Less than \$10 million in Year 1 decreasing to less than \$10 million in Year 5 for a total of \$20 - \$30 million over the first 5 years of listing. PBAC Comment: As above.	Less than \$10 million Year 1 decreasing to less than \$10 million in Year 5 for a total of \$20 - \$30 million over the first 5 years of listing.
PBAC decision	Reject PBAC Comment (November 2015 PSD, bevacizumab, paragraph 7.1): “The PBAC rejected the request to list bevacizumab for the treatment of patients with advanced cervical cancer on the basis of high and unacceptable cost-effectiveness.”	-

Source: Compiled during the minor overview

4 Clinical place for the proposed therapy

- 4.1 The PBAC accepted the proposed restriction for recurrent, metastatic and persistent disease. The PBAC considered that use with standard platinum-based chemotherapy, either cisplatin (as per TGA approved indication) or carboplatin (current standard of care in Australia) was reasonable. The PBAC noted that topotecan, which was proposed as alternative to platinum-based chemotherapy is only PBS-subsidised for advanced metastatic ovarian cancer.
- 4.2 The PBAC accepted the clinical place for bevacizumab for advanced cervical cancer.

5 Comparator

- 5.1 The previous major submission considered by the PBAC in November 2015 nominated chemotherapy alone. This was unchanged.
- 5.2 The PBAC agreed that chemotherapy alone (platinum-based chemotherapy plus paclitaxel or topotecan plus paclitaxel for those who are unable to tolerate carboplatin or cisplatin) was the appropriate comparator for bevacizumab in combination with chemotherapy.

6 Consideration of the evidence

Sponsor hearing

- 6.1 There was no hearing for this item as it was a minor submission.

Consumer comments

- 6.2 The PBAC noted and welcomed the input from two organisations (Medical Oncology Group of Australia and Rare Cancers Australia) via the Consumer Comments facility on the PBS website. The comments described the survival benefits of treatment with bevacizumab.

Clinical trials

- 6.3 No additional clinical trials or clinical evidence were presented in the minor re-submission.

Clinical claim

- 6.4 The original submission claimed that the addition of bevacizumab to chemotherapy alone as superior in terms of comparative effectiveness over chemotherapy alone and with a “manageable and acceptable safety profile”, in patients with advanced cervical cancer. The PBAC considered this claim was adequately supported for superior comparative effectiveness in terms of OS and PFS compared with chemotherapy alone. However, the claim of manageable and acceptable safety profile was not adequately supported. While bevacizumab has some clinical benefits to patients, these may be counter-balanced by clinical harms. [November PBAC PSD, 7.8]

Economic analysis

- 6.5 In the previous major submission considered by PBAC in November 2015, the submission presented a cost utility analysis against chemotherapy alone.
- 6.6 The minor re-submission did not alter the economic model structure from November 2015 but changed three inputs in the model (price, the truncation point for OS, and adverse event-related disutilities).
- 6.7 As raised in the evaluation of the November 2015 submission, preparation fee paid to TGA licensed compounders (\$██████) and non-TGA licensed compounders (\$██████) are different. As the majority of chemotherapy preparations are compounded in settings where the \$██████ fee applies, this fee should continue to be used in PBAC submissions.
- 6.8 At the November 2015 meeting, PBAC noted the cost utility analysis presented in the submission resulted in an ICER of greater than \$75,000/QALY - \$105,000/QALY. The PBAC, noting the clinical outcomes, considered that this base case ICER/QALY was unacceptably high and was based on QALYs gained resulting from parametric extrapolation of OS and PFS that could not be relied upon. The PBAC noted that base-case ICER/QALY value was much higher than the range of ICER that the Committee has considered cost-effective for treatments of cancer. Further, the PBAC agreed with the ESC that the base case ICER/QALY likely represents a lower boundary of a plausible range of cost-effectiveness. The PBAC noted that the ICER was sensitive to the extrapolation from a median follow-up of 14.1 months to a time horizon of 7 years. The PBAC questioned that trial data was available to 55.9 months; however, the submission chose not to incorporate data beyond 14.1 months. The minor re-submission modified the proposed price and the truncation point for OS in the economic model, from 14.1 months used in the base-case economic

evaluation in the previous submission to 55.9 months. The ICER is \$45,000/QALY - \$75,000/QALY gained. This ICER was independently verified. When additional \$█ fee is included in the cost of bevacizumab, the ICER is \$45,000/QALY - \$75,000/QALY gained.

- 6.9 At the November 2015 meeting, the PBAC considered that future economic analysis should take into account the adverse event related disutilities. In the minor re-submission, the sponsor maintains that the utilities applied in the base case economic model are informed by trial data specific to each treatment arm and therefore account for the impact of adverse events related to bevacizumab on quality of life. The sponsor accepted that there is uncertainty associated with mapping FACT G data to EQ 5D values, and therefore an additional █% decrement in utility to the PFS values applicable to patients in the bevacizumab treatment arm has been applied in a sensitivity analysis in the updated economic evaluation. This sensitivity analysis resulted in an ICER of \$45,000/QALY - \$75,000/QALY gained (or \$45,000/QALY - \$75,000/QALY gained, when additional \$█ fee is included). This ICER was independently verified.

Drug cost/patient/course: \$█

- 6.10 The average drug cost per patient per course was estimated: 1) assuming a treatment duration of █ cycles (based on the time to off-treatment (TTOT) estimates from the GOG 0240 trial); 2) assuming 54.4% of prescriptions being dispensed in public settings and 45.6% in private settings; and 3) incorporating an expected one-off statutory 5% price reduction (to be applied from 1 April 2016), including preparation fee of \$█ and the proposed █% rebate on the ex-manufacturer price for bevacizumab (Source: Updated Economic Evaluation.xlsx).

Estimated PBS usage & financial implications

- 6.11 The minor submission estimated a net cost to the PBS of less than \$10 million in Year 5 of listing, with a total net cost to the PBS of \$10 - \$20 million per year and net cost to government of \$20 - \$30 million per year over the first 5 years of listing. This is summarised in the table below as well as the expected patient/prescription numbers, which are unchanged from the November 2015 submission.
- 6.12 At the November 2015 meeting, the PBAC noted that the estimates of utilisation of bevacizumab were uncertain and the financial estimates were likely overestimated in the November 2015 submission. The PBAC recommended that the sponsor consider obtaining estimates of the cumulative number of cervical cancer deaths in the next 5-10 years taking into account the change in Human papillomavirus (HPV) testing in 2017 and the impact of the HPV vaccine on the National Immunisation Program. Also some justification should be provided in relation to the uptake rates of bevacizumab.
- 6.13 The minor re-submission stated: In 2007, the National HPV Vaccination Program commenced to protect young Australian women against infection with HPV and reduce cervical cancer incidence. In addition to the ongoing program for girls aged 12–13 years, a catch up program provided the HPV vaccine for women aged 13–18 years in schools and 18–26 years in the community. Since the average age of diagnosis of cervical cancer in Australia is 51 years, the impact of the HPV vaccination program on the incidence of cervical cancer will not be evident for some

time and is not captured in the current AIHW incidence projections. Additionally, no change in the incidence of advanced cervical cancer in the five year financial estimates is expected with the changes in HPV testing from 2017.

- 6.14 As raised in the evaluation of the November 2015 submission, preparation fee paid to TGA licensed compounders (\$██████) and non-TGA licensed compounders (\$██████) are different. As the majority of chemotherapy preparations are compounded in settings where the \$██████ fee applies, this fee should continue to be used in PBAC submissions. The minor submission included the preparation fee applicable to non-TGA licenced compounders (\$██████). A sensitivity analysis of the financial estimates was presented in the pre-PBAC response assuming the preparation fee for TGA licenced compounders applies (\$██████). The impact of this change on the financial estimates was minimal (total net cost to the PBS/RPBS at effective price (patient co-payments removed) of less than \$10 million in year 5 of listing in sensitivity analysis compared with less than \$10 million in year 5 in the base case).

Table 2: Overall cost to Government of by year of PBS listing of bevacizumab

	Year 1	Year 2	Year 3	Year 4	Year 5
Number of advanced cervical cancer patients treated with bevacizumab	██████	██████	██████	██████	██████
Net cost to PBS/RPBS at published price (patient co-payments removed)	\$██████	\$██████	\$██████	\$██████	\$██████
Net cost to PBS/RPBS at effective price (patient co-payments removed)	\$██████	\$██████	\$██████	\$██████	\$██████
Overall net cost to Government Health Budget of listing bevacizumab at published price	\$██████	\$██████	\$██████	\$██████	\$██████
Overall net cost to Government Health Budget of listing bevacizumab at effective price	\$██████	\$██████	\$██████	\$██████	\$██████
Net 5 year cost to Government Health Budget of listing bevacizumab at effective price					\$██████

Source: Updated Financial Cost to PBS.xlsx

The redacted table shows that at year 5, the estimated number of patients was less than 10,000 per year and the net cost to the PBS would be \$20 - \$30 million per year.

- 6.15 At the November 2015, the PBAC considered that some justification should be provided in relation to the uptake rates of bevacizumab and a resubmission should define a patient population who would be eligible and have access to treatment. While not directly addressed in the minor submission, the pre-PBAC response presented a sensitivity analysis to the financial estimates increasing the uptake rate of bevacizumab in advanced cervical cancer from ██████% (based on expert opinion) to ██████%. In this scenario, the estimated net cost to the PBS was \$10 - \$20 million in Year 5 of listing, with a total net cost to the PBS of \$20 - \$30 million per year and net cost to government of \$20 - \$30 million per year over the first 5 years of listing.

Table 3: Sensitivity analysis – overall cost to Government by year of PBS listing of bevacizumab in advanced cervical cancer assuming █% uptake rate and preparation fee for TGA licenced compounds applies in public hospital setting

	Year 1	Year 2	Year 3	Year 4	Year 5
Number of advanced cervical cancer patients treated with bevacizumab	█	█	█	█	█
Net cost to PBS/RPBS at effective price (patient co-payments removed)	\$█	\$█	\$█	\$█	\$█
Overall net cost to Government Health Budget of listing bevacizumab at effective price	\$█	\$█	\$█	\$█	\$█

The redacted table shows that at year 5, the estimated number of patients was less than 10,000 per year and the net cost to the PBS would be less than \$10 million per year.

7 PBAC Outcome

- 7.1 The PBAC recommended the Section 100 Authority Required (STREAMLINED) listing for bevacizumab in combination with platinum-based chemotherapy plus paclitaxel for the treatment of persistent, recurrent or metastatic cervical cancer not amenable to curative treatment with surgery and/or radiation. The recommendation was made on the basis of the cost-effectiveness of bevacizumab with chemotherapy over chemotherapy alone.
- 7.2 The PBAC accepted the proposed restriction for recurrent, metastatic and persistent disease. The PBAC noted that November 2015 submission estimated that in August 2016 approximately █ patients would be accessing bevacizumab in the Roche Medicines Assistance Program and would not meet the initial criteria of the proposed listing. The PBAC considered that use with standard platinum-based chemotherapy, either cisplatin (as per TGA approved indication) or carboplatin (current standard of care in Australia) was reasonable.
- 7.3 The submission proposed (and reaffirmed in the pre-PBAC response) the use of bevacizumab in combination with topotecan plus paclitaxel for patients unable to tolerate platinum-based chemotherapy, as in the pivotal phase III trial (GOG-0240) The PBAC noted that topotecan is only PBS-subsidised for advanced metastatic ovarian cancer and that only some brands of PBS-listed topotecan are registered for use in combination with cisplatin for the treatment of patients with histologically confirmed Stage IV-B, recurrent, or persistent carcinoma of the cervix, which is not amenable to curative treatment with surgery and/or radiation therapy. The PBAC considered that the circumstances of a PBS-listing of topotecan for cervical cancer had not been yet established in Australia. The PBAC would welcome a submission supporting such a listing.
- 7.4 The PBAC reiterated their view that chemotherapy alone (platinum-based chemotherapy plus paclitaxel or topotecan plus paclitaxel for those who are unable to tolerate carboplatin or cisplatin) was the appropriate comparator for bevacizumab in combination with chemotherapy.
- 7.5 The PBAC noted that there is a clinical need for treatment options for patients with persistent, recurrent or metastatic cervical cancer. The PBAC reiterated their view

that the gain in median OS of 3.5 months and the gain in median PFS of 2.3 months associated with bevacizumab were clinically modest, especially in view of significant adverse events including the clinically significant higher incidence of fistula.

- 7.6 The PBAC noted that minor re-submission did not alter the economic model structure from November 2015 but changed three inputs in the model (price, the truncation point for OS, and adverse event-related disutilities). The PBAC considered these changes were informative for assessing the cost-effectiveness of the treatment and noted that the ICER ranged from \$45,000/QALY - \$75,000/QALY gained to \$45,000/QALY - \$75,000/QALY gained.
- 7.7 The PBAC considered that the ICER was at the high end of what would be considered cost effective, but that this was acceptable in the context of a relatively small population with a high clinical need for treatments for this patient population.
- 7.8 The PBAC recalled that the estimates of utilisation of bevacizumab in the November 2015 submission were uncertain and the financial estimates were likely overestimated. The PBAC noted that, in the highly conservative scenario increasing the uptake rate of bevacizumab to ■■■%, the estimated net cost to the PBS was less than \$10 million in Year 5 of listing.
- 7.9 The PBAC advised that under subsection 101 (3BA) of the National Health Act 1953, that bevacizumab should not be treated as interchangeable on an individual patient basis with any other drug.
- 7.10 The PBAC advised that bevacizumab is not suitable for inclusion in the PBS medicines for prescribing by nurse practitioners as chemotherapy agents are currently considered to be out of scope for prescribing by nurse practitioners.
- 7.11 The PBAC recommended that the Early Supply Rule should not apply.
- 7.12 The submission is not eligible for an Independent Review, because the PBAC has made a positive recommendation.

Outcome:

Recommended

8 Recommended listing

8.1 Amend existing listing as follows:

Name, Restriction, Manner of administration and form	Max. Amount	No. of Rpts	Proprietary Name and Manufacturer	
BEVACIZUMAB bevacizumab, 100 mg/4 mL injection, 1 x 4 mL vial bevacizumab 400 mg/16 mL injection, 1 x 16 mL vial	1,800mg	7	Avastin	Roche Products Pty Limited

Category / Program	Section 100 – Efficient Funding of Chemotherapy Private Hospital/Private Clinic Authority Required (STREAMLINED) Public Hospital Authority Required (STREAMLINED)
Prescriber type:	<input type="checkbox"/> Dental <input checked="" type="checkbox"/> Medical Practitioners <input type="checkbox"/> Nurse practitioners <input type="checkbox"/> Optometrists <input type="checkbox"/> Midwives
Severity:	Advanced
Condition:	Carcinoma of cervix
PBS Indication:	Advanced carcinoma of cervix
Treatment phase:	Initial treatment
Restriction Level / Method:	<input type="checkbox"/> Restricted benefit <input type="checkbox"/> Authority Required - In Writing <input type="checkbox"/> Authority Required - Telephone <input type="checkbox"/> Authority Required – Emergency <input type="checkbox"/> Authority Required - Electronic <input checked="" type="checkbox"/> Streamlined
Clinical criteria:	Patient must have a GOG performance status of 0 or 1; AND The condition must not be amenable to curative treatment with surgery, OR The condition must not be amenable to curative radiation therapy; AND The condition must be previously untreated with this drug AND Patient must not have prior chemotherapy treatment; OR Patient must have received prior chemotherapy with radiation therapy; AND The treatment must be in combination with platinum-based chemotherapy plus paclitaxel
Prescriber Instructions	Advanced carcinoma of the cervix is defined as persistent carcinoma, recurrent carcinoma or metastatic carcinoma of the cervix. The patient's Gynaecologic Oncology Group (GOG) performance status and body weight must be documented in the patient's medical records at the time the treatment cycle is initiated.
Administrative Advice	Special Pricing Arrangements apply.

Category / Program	Section 100 – Efficient Funding of Chemotherapy Private Hospital/Private Clinic Authority Required (STREAMLINED) Public Hospital Authority Required (STREAMLINED)
Prescriber type:	<input type="checkbox"/> Dental <input checked="" type="checkbox"/> Medical Practitioners <input type="checkbox"/> Nurse practitioners <input type="checkbox"/> Optometrists <input type="checkbox"/> Midwives

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Severity:	Advanced
Condition:	Carcinoma of cervix
PBS Indication:	Advanced carcinoma of cervix
Treatment phase:	Continuing treatment
Restriction Level / Method:	<input type="checkbox"/> Restricted benefit <input type="checkbox"/> Authority Required - In Writing <input type="checkbox"/> Authority Required - Telephone <input type="checkbox"/> Authority Required – Emergency <input type="checkbox"/> Authority Required - Electronic <input checked="" type="checkbox"/> Streamlined
Clinical criteria:	Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must not have progressive disease; AND The treatment must be in combination with platinum-based chemotherapy plus paclitaxel
Prescriber Instructions	Advanced carcinoma of the cervix is defined as persistent carcinoma, recurrent carcinoma or metastatic carcinoma of the cervix.
Administrative Advice	Special Pricing Arrangements apply.

Category / Program	Section 100 – Efficient Funding of Chemotherapy Private Hospital/Private Clinic Authority Required (STREAMLINED) Public Hospital Authority Required (STREAMLINED)
Prescriber type:	<input type="checkbox"/> Dental <input checked="" type="checkbox"/> Medical Practitioners <input type="checkbox"/> Nurse practitioners <input type="checkbox"/> Optometrists <input type="checkbox"/> Midwives
Severity:	Advanced
Condition:	Carcinoma of cervix
PBS Indication:	Advanced carcinoma of cervix
Treatment phase:	Grandfathering treatment
Restriction Level / Method:	<input type="checkbox"/> Restricted benefit <input type="checkbox"/> Authority Required - In Writing <input type="checkbox"/> Authority Required - Telephone <input type="checkbox"/> Authority Required – Emergency <input type="checkbox"/> Authority Required - Electronic <input checked="" type="checkbox"/> Streamlined
Clinical criteria:	Patient must have previously received non-PBS-subsidised therapy with this drug for this condition prior to xx/Month/Year; AND Patient must not have progressive disease; AND The treatment must be in combination with platinum-based chemotherapy plus paclitaxel
Prescriber Instructions	Advanced carcinoma of the cervix is defined as persistent carcinoma, recurrent carcinoma or metastatic carcinoma of the cervix. The patient's Gynaecologic Oncology Group (GOG) performance status and body weight must be documented in the patient's medical records at the time the treatment cycle is initiated.

Administrative Advice	Special Pricing Arrangements apply.
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9 Context for Decision

The PBAC helps decide whether and, if so, how medicines should be subsidised in Australia. It considers submissions in this context. A PBAC decision not to recommend listing or not to recommend changing a listing does not represent a final PBAC view about the merits of the medicine. A company can resubmit to the PBAC or seek independent review of the PBAC decision.

10 Sponsor's Comment

The PBAC's decision to recommend bevacizumab for PBS listing is welcome news for patients with advanced cervical cancer.