Australian Government

Medical Services Advisory Committee

Public Summary Document

Application No. 1158.1 – Robotic Image-guided stereotactic precise beam radiosurgery and radiotherapy for lung (Cyberknife)

Applicant: **Accuray**

Date of MSAC consideration: **MSAC 65th Meeting, 26 November 2015**

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

A Submission Based Assessment Report for MSAC Application 1158.1 (the resubmission) requesting a separate MBS listing for robotic image-guided stereotactic precise beam radiosurgery and radiotherapy delivered using CyberKnife® (Cyberknife) for primary non-small cell lung cancer (NSCLC) and lung metastases from other primary sites was received from Accuray Incorporated (the Applicant) in October 2014. The applicant subsequently withdrew two indications – operable early stage NSCLC and operable pulmonary metastases. As a result, the resubmission was restricted to stereotactic radiosurgery and radiotherapy delivered with Cyberknife for patients with inoperable stage one NSCLC.

2. MSAC's advice to the Minister

MSAC considered the available evidence for the safety, clinical effectiveness and cost-effectiveness of Cyberknife for treatment of inoperable primary non-small cell lung cancer (NSCLC). MSAC noted the service is funded under existing arrangements and recommended against any increase in public funding for this service due to considerable residual uncertainty in relation to clinical effectiveness and cost effectiveness.

MSAC agreed the application had not established that stereotactic radiosurgery (SRS) and stereotactic body radiotherapy (SBRT) services delivered with Cyberknife were different in outcome to services delivered using three-dimensional conformal radiotherapy (3D-CRT) and Image Guided Radiotherapy (IMRT) (the comparators). MSAC's key concerns were:

- whether there was a distinct clinical need for the proposed service which justified the significant increase in the proposed MBS fee;
- whether it could be demonstrated that the proposed service delivered superior patient outcomes compared to comparator services given the poor quality evidence of safety and effectiveness;

- significant economic uncertainty attributed to the structure of the Markov model, use of uncertain clinical data and extrapolation well beyond the clinical trial follow up; and
- significant financial uncertainty due to epidemiological inputs, the justification of higher fees with evidence, the inclusion of treatment verification as a separate service and the late request for reimbursement of the capital cost of Cyberknife equipment.

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

The application sought:

- an MBS item for SRS/SBRT treatment delivered with Cyberknife with a higher MBS Schedule fee than the comparators or generic stereotactic radiosurgery;
- a separate MBS item for Cyberknife treatment verification with a higher MBS Schedule fee than the current fee for verification of conformal radiotherapy; and
- reimbursement for the capital cost of equipment through the Radiation Oncology Health Program Grants Scheme (ROHPG) with a higher reimbursement rate for the equipment than is currently paid for dual modality linear accelerators.

MSAC noted that SRS services reimbursed under MBS item 15600 include a component for the capital cost of equipment. Therefore, these services do not attract ROHGP payments. However, SBRT services delivered with Cyberknife are claimed under MBS items for 3D-CRT and these do attract ROHGP payments.

MSAC considered that the request for higher fees for treatment with Cyberknife may be being driven by the high cost of Cyberknife equipment and lower patient throughput, rather than improved patient outcomes. While Cyberknife may treat around 250 patients per year, a modified linac may treat around 100 patients requiring SRS/SBRT plus another 200–250 patients requiring conformal radiotherapy per year.

MSAC agreed that the applicant had not established that there was a clinical need for the proposed service at the proposed price point. The Committee also noted that some linacs with capacity to deliver SRS/SBRT may be underutilised at present.

MSAC agreed that with Cyberknife technology, treatment verification is not a separate service. It is part of treatment delivery with continual image guidance allowing for intra-fraction motion tracking and adjustment. MSAC found no justification for the inclusion of a separate, higher MBS fee for treatment verification in association with the proposed service.

MSAC agreed that limiting the comparator to IMRT and 3D-CRT was reasonable but was concerned that the evidence did not demonstrate that Cyberknife provided superior outcomes for patients. MSAC agreed that Cyberknife appeared marginally better than the comparators in terms of effectiveness but was concerned at the poor quality of the evidence. MSAC noted that the applicant had corrected errors relating to the inclusion of Grade 0 adverse events but remained concerned about the exclusion of uncommon adverse events.

MSAC expressed concern that the economic model was biased in support of Cyberknife and:

- that the Markov model did not allow transitions between recurrence health states;
- with the increase in the maximum recurrence time horizon well beyond the clinical trial follow up; and
- that the economic model relied upon a small number of non-comparative case studies.

MSAC noted additional material provided by the applicant had not addressed key issues relating to the sensitivity analysis and the high uncertainty of the clinical data. MSAC agreed the analysis showed Cyberknife to be marginally preferred at low willingness-to-pay thresholds while IMRT is marginally preferred at thresholds above $20,000.

MSAC noted applications for funding of equipment under the ROHPG Scheme are a matter for the Department but agreed the proposed capital reimbursement of Cyberknife through the ROHPG must be factored into the financial model. MSAC also noted the impact of the Extended Medicare Safety Net in funding radiation oncology services. Subject to the passage of legislation, the safety net is expected to be capped from 1 January 2016[1].

MSAC agreed there was uncertainty in relation to: the patient population, epidemiological inputs used, and the applicability of included studies to the Australian context. MSAC noted the total cost of treatment delivered using Cyberknife was estimated at $700,833 in the first year, increasing to $6.9 million in year five. The Committee agreed the additional cost of this proposed service was not justified as the application had not demonstrated the clinical need for the service at the specific price point nor did the evidence support the claim that the service provided superior patient outcomes to the comparators.

4. Background

MSAC considered the original application 1158 for new MBS items with higher Schedule fees for Cyberknife for prostate and lung indications (primary operable and inoperable NSCLC and lung metastases from other primary sites). The clinical claim was that Cyberknife was superior to 3D-CRT, IMRT and surgery. MSAC considered the application in December 2012 and concluded that there was insufficient evidence to support public funding

In October 2014, MSAC received a revised application for Cyberknife for the lung indication only (primary operable and inoperable NSCLC and lung metastases from other primary sites). The clinical claim was that Cyberknife was non-inferior in effectiveness and safety to curative surgery and equivalent in effectiveness and safety to 3D-CRT and IMRT.

In February 2015, the Evaluation Sub-Committee (ESC) considered the revised application, noting the following concerns:

- the MBS descriptor should specify the tumour type and tumour stage;
- fees should be input based;
- inadequate reporting of safety data;
- the outcomes were extrapolated well beyond end of trial follow-up which favours CyberKnife;
- validity of the costings and assumptions;
- the Markov model driven by rate of recurrence and transitioning between disease states is not possible; and
- no evidence presented to support the forecast of the eligible population

After receiving the ESC Report, the Applicant paused the application while developing a response to the issues raised.

[1] On 1 December 2015, the Minister for Health, the Hon Sussan Ley MP announced that the Medicare Safety Net measure would be paused until broader work related to the Medicare and primary care reform package is conducted.

In July 2015, MSAC received a further revised application for Cyberknife for inoperable primary NSCLC only. The clinical claim was that Cyberknife was at least as effective, safe and cost-effective as 3D-CRT and IMRT. The revised application included a response to the February 2015 ESC report and a revised economic model.

5. Prerequisites to implementation of any funding advice

Please see the November 2012 PSD for MSAC Application 1158 for this advice.

6. Proposal for public funding

Between the original application considered by MSAC in November 2012 and the revised submission considered by MSAC in November 2015, the proposal for public funding changed significantly. Table 1 below sets out the PICO and MBS fees proposed at each stage of the application/submission.

Table 1: Summary of revisions associated with MSAC Application 1158.1

	Original Application 1158 MSAC Nov 2012	Submission Based Assessment 1158.1 dated Oct 2014	Formal Response to ESC Feb 2015 dated Jul 2015
Population	1. Prostate cancer 2. Primary operable & inoperable NSCLC 3. Lung metastases when primary tumour is under treatment and control, & lung is sole site of metastatic lesions	1. Primary operable & inoperable NSCLC 2. Lung metastases when primary tumour is under treatment & control, & lung is sole site of metastatic lesions	Primary inoperable NSCLC
Intervention	Robotic, image guided, precise beam SRS & SBRT delivered using Cyberknife		
Comparator	Prostate: 3D-CRT, IMRT, IGRT Lung: surgery, 3D-CRT, IMRT	3D-CRT, IMRT, surgery	3D-CRT, IMRT
Outcomes	Adverse events; Toxicities; Survival; Rate of control (recurrence); Morbidity; Quality of life		
MBS fee	Prostate: $1,582 treatment, $595.78 verification Lung: $2,034 treatment, $766 verification	$2,500 treatment $300 verification	$2,000 treatment $300 verification
ROHPG	Prostate: $559.70 (treatment) Lung: $435.32 (treatment)	$435.32 (treatment)	$505.50 (treatment)

In considering the submission based assessment in February 2015, ESC was concerned that the MBS fees being proposed were not input-based. In addition, ESC noted the proposed fee for the Cyberknife treatment items ($2,500) had increased from the original application, while the proposed fee for treatment verification ($300) had decreased, with no explanation.

In November 2015, MSAC noted further changes to the submission regarding the proposed MBS fee and ROHPG component and rejected the explanation provided by the applicant that the fluidity reflected "*the present team inheriting the submission after substantial work had already been completed without an input-based fee*". MSAC agreed with ESC that the proposed MBS descriptor should specify the clinical indication for treatment as follows:

Proposed MBS item descriptor

Category 3 –Therapeutic procedures
MBS 152XX RADIATION ONCOLOGY TREATMENT, delivered by an image guided robotic stereotactic system – each attendance at which treatment is given – treatment delivered to primary site ~~(lung)~~ for non-small cell lung carcinoma (NSCLC) Stage I. ~~**Fee:** $2,500.00 **Benefit:** 75% = $1,875.00 85% = $2,125.00a~~ **Fee:** $2,000.00 **Benefit:** 75% = $1,500.00 85% = $1,700.00
Category 3 –Therapeutic procedures
MBS 157XX RADIATION ONCOLOGY TREATMENT VERIFICATION - multiple projection acquisition when prescribed and reviewed by a radiation oncologist and not associated with item 15700 or 15705 or 15710 - each attendance (lung). **Fee:** $300.00 **Benefit:** 75% = $225.00 85% = $255.00

7. Summary of Public Consultation Feedback/Consumer Issues

Please see the November 2012 PSD for MSAC Application 1158 for this advice.

8. Proposed intervention's place in clinical management

MSAC noted that SRS and SBRT delivered using Cyberknife receives existing MBS funding under MBS item 15600 for generic stereotactic radiosurgery (SRS with Cyberknife) and relevant MBS items for 3D-CRT (SBRT using Cyberknife).

The enhanced external beam radiotherapy modalities of 3D-CRT and IMRT are also used to treat primary inoperable NSCLC and receive existing MBS funding.

9. Comparator

MSAC agreed that 3D-CRT and IMRT are appropriate comparators. These are enhanced modes of external beam radiotherapy that are used to treat patients with stage I NSCLC who are unsuitable for, or who refuse, surgery. The MBS items for the comparators are MBS 15215, 15230, 15245, 15260 (treatment), 15550 (simulation), 15559, 15562 (dosimetry) and 15705 (treatment verification).

10. Comparative safety

MSAC was concerned about the approach to reporting infrequent adverse events, noting that this issue had been identified by ESC in February 2015. MSAC reiterated the importance of this evidence and rejected the notion that the inclusion of these events could render an assessment of relative safety of the radiotherapy modalities unsuitable.

MSAC noted revised probabilities for acute and late adverse events based on recalculation following the exclusion of Grade 0 events. MSAC agreed the change did not greatly impact the safety data.

11. Comparative effectiveness

MSAC observed the poor quality evidence presented in support of the comparative effectiveness of treatment delivered using Cyberknife. The evidence is limited to 35 single-arm case series. While the applicant provided a list of excluded studies and a quality assessment of the included studies in response to ESC concerns (Table 2), MSAC agreed that excluding the studies only slightly reduced the difference in effectiveness between CyberKnife and the comparators (Table).

Table 2: Studies providing efficacy and safety data

Publications		Efficacy	Safety
Cyberknife	Resubmission (14 studies)	6	10
	Formal Response	3	8
IMRT	Resubmission (8 studies)	4	8
	Formal Response	3	7
3DCRT	Resubmission (12 studies)	12	9
	Formal Response	10	9
Surgery	Resubmission (6 studies)	4	4
	Formal Response	0	0

Table 3: Revised clinical outcome parameters (2014 original estimates in black and June 2015 estimates in red)

Clinical Outcome / Modality	Mean Annualized Rate (Yr 1 – 5)	Standard Deviation	Standard Error	Distribution Parameter (α)	Distribution Parameter (β)
Local Recurrence	-	-	-	-	-
CyberKnife	~~5.05%~~ (5.17%)	~~2.32%~~ (3.02%)	~~0.95%~~ (1.74%)	~~26.78~~ (8.30)	~~503.5~~ (152.1)
IMRT	~~13.47%~~ (11.49%)	~~13.20%~~ (15.42%)	~~6.60%~~ (8.90%)	~~3.47~~ (1.36)	~~22.29~~ (10.47)
3DCRT	15.13%	6.62%	2.34%	35.33	198.2
Regional Recurrence	-	-	-	-	-
CyberKnife	~~1.51%~~ (2.02%)	~~0.72%~~ (1.17%)*	~~0.51%~~ (0.67%)*	~~8.62~~ (8.89)	~~562.2~~ (431.1)
IMRT	0.00%	NA	NA	NA	NA
3DCRT	0.00%	NA	NA	NA	NA
Distant Recurrence	-	-	-	-	-
CyberKnife	~~5.24%~~ (5.30%)	~~3.60%~~ (5.09%)	~~2.08%~~ (3.60%)	~~5.96~~ (2.00)	~~107.8~~ (35.70)
IMRT	2.74%	1.88%** (2.63%)**	1.09%** (1.33%)**	6.12 (4.10)	217.2 (145.6)
3DCRT	12.89%	6.34%	2.83%	17.97	121.3
Mortality	-	-	-	-	-
CyberKnife	~~13.63%~~ (18.72%)	~~6.75%~~ (4.50%)	~~2.76%~~ (2.60%)	~~20.98~~ (42.01)	~~133.0~~ (182.4)
IMRT	~~22.24%~~ (21.59%)	~~11.40%~~ (13.86%)	~~5.70%~~ (8.00%)	~~11.63~~ (5.49)	~~40.64~~ (19.93)
3DCRT	~~27.14%~~ (27.11%)	~~5.68%~~ (5.95%)	~~1.64%~~ (1.80%)	~~199.5~~ (165.9)	~~535.4~~ (446.1)

The submission claims that CyberKnife:

- achieves greater local control at 2-3 years follow-up compared to IMRT or 3DCRT, and that similar differences are observable at 4.5-5 years follow-up; and
- may perform slightly better in terms of overall survival than IMRT and substantially better than 3DCRT.

However, MSAC agreed there was considerable variation in study outcomes for each intervention, particularly for the outcome of overall survival, and was concerned about the reliance on single arm case studies.

12. Economic evaluation

During consideration of the submission in February 2015, ESC noted a range of issues with the transformation of clinical evidence into economic and financial models such as:

- use of annualised event rates based on different follow-up durations; and
- extrapolation of clinical outcomes beyond the end of trial follow-up.

The applicant responded to these concerns in the Formal Response by providing additional deterministic and probabilistic sensitivity analyses including:

A. Recalculating the local recurrence rate for CyberKnife using only the 2-year data;
B. Increasing the maximum 10-year recurrence time horizon to 20 years;
C. Increasing the maximum 10-year recurrence time horizon to 20 years, plus setting the recurrence rate reduction beyond 5 years (base case = 75%) to 0% for all 3 modalities;
D. Increasing the maximum 10-year recurrence time horizon to 20 years, plus setting the recurrence rate reduction beyond 5 years (base case = 75%) to 0% for CyberKnife only; and
E. Increasing the standard errors for CyberKnife parameters by a factor of 3.

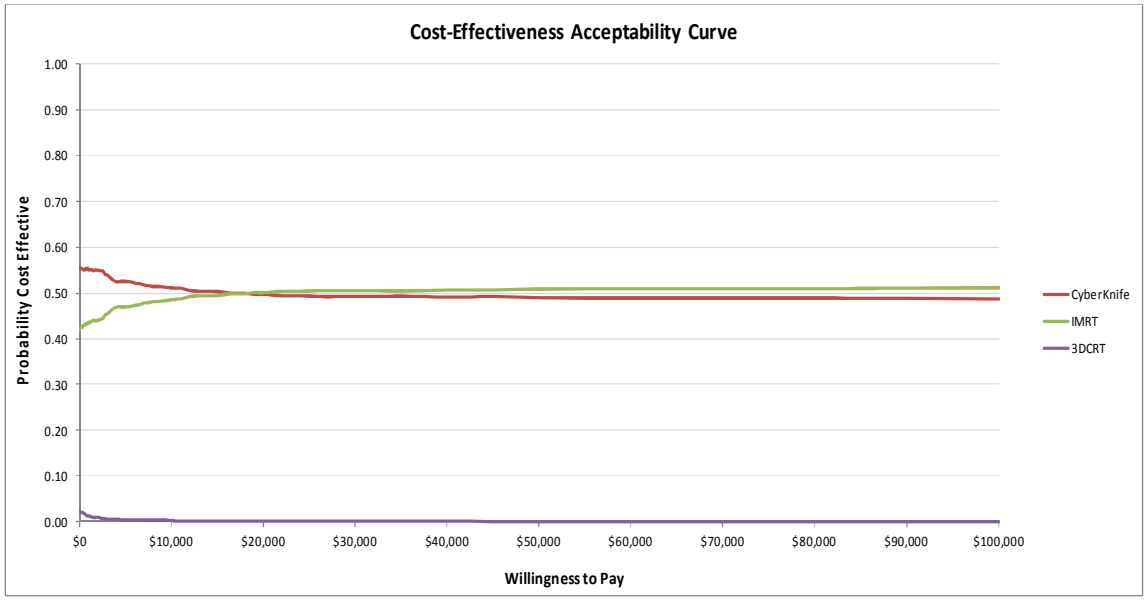
4 and Figure 1 show the results of these analyses from Section EEE of the Addendum.

Table 4: Additional Deterministic Sensitivity Analysis Scenarios and Results

Parameter of Interest (Base Case Value) and Change from Base Case	Total Costs			Total QALYs			CE Ratio 1	CE Ratio 2
-	Cyber-Knife	IMRT	3DCRT	CyberKnife	IMRT	3DCRT	-	-
BASE CASE RESULTS	**$27,536**	**$30,687**	**$35,258**	**4.333**	**4.070**	**2.653**	**CK Dominates***	**CK Dominates†**
RECCURENCE CALCULATION	-	-	-	-	-	-	-	-
Scenario A	$27,960	$30,687	$35,258	4.225	4.070	2.653	CK Dominates*	CK Dominates†
TREATMENT EFFECT; RECURRENCE DURATION	-	-	-	-	-	-	-	-
Scenario B	$28,700	$31,784	$35,887	4.244	3.982	2.591	CK Dominates*	CK Dominates†
Scenario C	$31,313	$34,209	$37,020	3.713	3.480	2.317	CK Dominates*	CK Dominates†
Scenario D	$31,313	$31,784	$35,887	3.713	3.982	2.591	$1,749*	IMRT Dominates§

Source: pg. 20 of the Addendum document
Scenario A: Local recurrence rate calculated using 2-year data only instead of longest available timepoint (base case) for CyberKnife only
Scenario B: Maximum recurrence time horizon increased from 10 years (base case) to 20 years
Scenario C: 20 year maximum recurrence time horizon plus recurrence rate reduction factor increase from 75% (base case) to 0% for all 3 modalities
Scenario D: 20 year maximum recurrence time horizon plus recurrence rate reduction factor increase from 75% (base case) to 0% for CyberKnife only
*IMRT vs. CyberKnife; †3DCRT vs. CyberKnife; §3DCRT vs. IMRT

Figure 1: Additional Probabilistic Sensitivity Analysis Scenario and Result*



Source: pg. 21 of the Addendum document

*Scenario: Local recurrence rate calculated using 2-year data only instead of longest available timepoint (base case) for CyberKnife only with tripled standard error

MSAC agreed that in Scenarios B and C, the same reduction to rates is applied across all three modalities in the model, and this has the effect of maintaining the benefit of CyberKnife over the comparators. However, in Scenario D, IMRT dominated 3DCRT and was cost-effective compared to CyberKnife, with an ICER of $1,749/QALY. MSAC agreed that for Scenario E, the revised recurrence rates and standard errors for CyberKnife contribute to a probabilistic sensitivity analysis in which CyberKnife would be the preferred option at low willingness-to-pay thresholds, with IMRT marginally more preferred at thresholds over $20,000.

MSAC agreed that Scenarios D and E highlighted the sensitivity in the model and high level of uncertainty in the clinical data, particularly between IMRT and Cyberknife. MSAC considered that the inputs to the model should be viewed with caution as all rely on a small number of non-comparative case series.

MSAC was concerned about whether the studies were conducted in healthcare systems that are applicable to the Australian context. The Formal Response indicated that half of the studies were conducted in the United States, with one conducted in Australia, and that CyberKnife clinical protocols do not vary significantly in different geographies. However, MSAC remained concerned about whether patients in the included studies represented the proposed population for this application.

The base case for the revised economic model included:

- Revised estimate for clinical inputs following quality assessment and error correction;
- New proposed MBS fees for CyberKnife; and
- Addition of ROHPG fees for all radiotherapy modalities.

The revised base case analysis included small increases in the total cost for all three modalities.

Table 5: Results of the respecified economic evaluation in the Formal Response

Outcome	CyberKnife	IMRT	Incremental	3DCRT	Incremental
Costs	~~$26,619~~ $27,536	~~$30,345~~ $30,687	~~$3,726~~ -$3,151	~~$34,157~~ $35,258	~~$7,538~~ -$7,722
QALYs	~~4.436~~ 4.333	~~3.801~~ 4.070	~~0.634~~ -0.263	~~2.653~~ 2.653	~~1.782~~ -1.680
ICER	**-**	**-**	**Dominated**	**-**	**Dominated**

Abbreviations: ICER = Incremental cost-effectiveness ratio; QALY = Quality-adjusted life-years.
Sources: pg. 84 of the October 2014 submission & pg. 27 of the Addendum document

MSAC agreed that there was no change to the outcome for 3DCRT in the revised probabilistic sensitivity analysis and that 3DCRT was unlikely to be the preferred option at any willingness-to-pay threshold. However, the results for CyberKnife and IMRT changed considerably. CyberKnife was only slightly more likely to be preferred over a wide range of thresholds compared to IMRT (53% vs. 47% respectively).

13. Financial/budgetary impacts

MSAC noted the revised financial impact of CyberKnife which incorporated changes to the proposed fee for treatment and included a ROHPG rate of $505.50 per attendance. The revised cost of CyberKnife treatment, including verification, was estimated to be $700,833 in Year 1, rising to $6,939,525 in Year 5 (Table 6). Disaggregated costs for all MBS items associated with the CyberKnife listing (7) showed lower costs of $572,300 in Year 1 rising to $5,646,692 in Year 4. No reason for the difference in cost was provided, although the disaggregated costs appeared to exclude ROHPG funding. MSAC observed that the estimates did not include offsets from the replacement of IMRT and 3DCRT services.

Table 6: Aggregated cost for the likely use of providing CyberKnife treatment and verification services

	2015	2016	2017	2018	2019	Total (2015-2019)
NSW				$2,261,178	$2,336,217	$4,597,396
Vic			$1,695,792	$1,753,999	$1,812,207	$5,261,998
QLD			$0	$1,420,797	$1,467,947	$2,888,745
SA	$0	$0	$0	$0	$524,886	$524,886
WA *	$700,833	$723,055	$746,986	$772,626	$798,266	$3,741,766
Tasmania	$0	$0	$0	$0	$0	$0
Northern Territory	$0	$0	$0	$0	$0	$0
Australian Capital Territory	$0	$0	$0	$0	$0	$0
Cost of CyberKnife Treatments and Verification	$700,833	$723,055	$2,442,777	$6,208,601	$6,939,525	$17,014,791

* in operation at Sir Charles Gairdner Hospital Cancer Centre since 7th April 2014.

Table 7: Disaggregated Costs Over 5 Years for Treatment of Early Stage Inoperable NSCLC by CyberKnife

Parameter	EARLY STAGE INOPERABLE NSCLC Treatment by CyberKnife				
Patients Treated (Reference: Table E.2.1.5)	75	77	261	662	740
	2015	2016	2017	2018	2019
MBS and DRG Codes					
152XX: [new proposed MBS code/fee for CyberKnife; each attendance for treatment delivered to primary site]	$382,500	$392,700	$1,331,100	$3,376,200	$3,774,000
15215: Radiation oncology treatment [1 field/initial field; single photon]	$0	$0	$0	$0	$0
15230: Radiation oncology treatment [per each additional field, 2-5 fields; single photon]	$0	$0	$0	$0	$0
15245: Radiation oncology treatment [1 field/initial field; dual photon]	$0	$0	$0	$0	$0
15260: Radiation oncology treatment [per each additional field, 2-5 fields; dual photon]	$0	$0	$0	$0	$0
15550: Simulation (3D without contrast)	$41,986	$43,105	$146,110	$370,594	$414,259
15559: Dosimetry	$0	$0	$0	$0	$0
15562 (3WS): Dosimetry (≤3 workstations)	$71,448	$73,353	$248,639	$630,648	$704,954
15562 (4WS): Dosimetry (≥4 workstations)	$0	$0	$0	$0	$0
157XX: Radiation oncology treatment verification [new proposed MBS code/fee for CyberKnife]	$57,375	$58,905	$199,665	$506,430	$566,100
15705: Radiation oncology treatment verification (multiple projection acquisition)	$0	$0	$0	$0	$0
20520: Initiation of management of anaesthesia for all closed chest procedures (including bronchoscopy) [for fiducial marker insertion]	$5,680	$5,832	$19,767	$50,137	$56,044
23010: Anaesthesia, perfusion or assistance at anaesthesia for a period of 26-30 minutes	$1,893	$1,944	$6,589	$16,712	$18,681
30710: Endobronchial ultrasound guided biopsy [if tumor is biopsied during marker insertion]	$0	$0	$0	$0	$0
41889: Bronchoscopy [for fiducial marker insertion]	$8,513	$8,740	$29,625	$75,140	$83,994
56301: Computed tomography scan of chest without contrast [to assess fiducial marker position post-insertion]	$0	$0	$0	$0	$0
58506: Radiographic examination of chest (lung fields) [to assess fiducial marker position during insertion]	$2,905	$2,982	$10,109	$25,639	$28,660
ANNUAL COST for TREATMENT by CYBERKNIFE	**$572,300**	**$587,561**	**$1,991,604**	**$5,051,500**	**$5,646,692**
Treatment cost per patient	$7,630.67	$7,630.67	$7,630.67	$7,630.67	$7,630.67

14. Key issues from ESC for MSAC

Since previous consideration of this application by MSAC (Nov 2012) and then ESC (Feb 2015), significant changes have been made to the patient population, comparators, proposed MBS fees, proposed ROHPG funding and the economic and financial model (refer to background and table of changes below)

The MSAC Public Summary Document for Application 1158 (December 2012 http://www.msac.gov.au/internet/msac/publishing.nsf/Content/1158-public) provided for a resubmission to be lodged through ESC if the applicant could differentiate robotic image-guided stereotactic precise beam radiosurgery and radiotherapy from other image-guided radiotherapies, plus address deficiencies in the submission. ESC advised that a clear distinction had still not been made between services provided with Cyberknife technology and those covered by existing stereotactic radiosurgery MBS items.

ESC agreed that the structure of the economic model was biased in favour of Cyberknife, with 3-5 year data for survival extrapolated to 20 years, and questionable epidemiological inputs.

15. Other significant factors

MSAC noted that the application sought partial funding for Cyberknife through the Radiation Oncology Health Program Grants (ROHPG) Scheme and that this was a matter for the Department.

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

The applicant had no comment.

17. Further information on MSAC

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