EUnetHTA JA3 WP4 - Other technologies, OTCA25

External review by external experts and factual accuracy check by manufacturers of the 2nd draft assessment on [Stereotactic Body Radiation Therapy (SBRT) for lung, prostate and liver cancer]

Comment from	Page number	Line or section number	Description of factual inaccuracy and proposed amendment	Character of comment • 'major'[a] =1 • 'minor'[b] = 2 • 'linguistic'[c] =3	Authors' reply
Varian Medical System	3	46	Please correct spelling of „Hilary"	2	Corrected
Varian Medical System	11	255	Add Clinac IX machine	1	Added
Varian Medical System	21	748	**LUNG** • 2012 white paper shows 5-year survival with EBRT @ 13% vs 56% for SBRT. (based on JAMA 2010 confirms at 55.8% survival; 98% local control) • First Timmerman paper was in 2003 in CHEST (a pulmonology journal) show trend and is first to use term radioablation. • Haasbeck paper definitely shows that NO TREATMENT, is much worse than RT (which in this case means SBRT) for those that are older. While this early paper shows that 85 y/o do better with Surgery than RT, it also points out that most of those >=85 are NON-SURGICAL Candidates for comorbid reasons. Referenced Study: Timmerman, Robert, et al. "Stereotactic body radiation therapy for inoperable early stage lung cancer." Jama 303.11 (2010): 1070-1076. Timmerman, Robert, et al. "Extracranial stereotactic radioablation: results of a phase I study in medically inoperable stage I non-small cell lung cancer." Chest 124.5 (2003): 1946-1955.	1	All of the quoted studies were published before the publication dates of interest determined in the project plan, that is 01/01/2015.

Please add extra rows as needed.

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			Haasbeek, Cornelis JA, et al. "Stage I non-small cell lung cancer in patients aged≥ 75 years: outcomes after stereotactic radiotherapy." Cancer: Interdisciplinary International Journal of the American Cancer Society 116.2 (2010): 406-414.		
Varian Medical System	21	757	**Prostate** • A paper that was published in JAMA (Journal of the American Medical Association) in February 2019, for which Dr. Kishan served as lead author, assessed long-term outcomes after SBRT for low-risk and intermediate-risk prostate cancer, following the outcomes of 2142 patients. The study concluded that prostate SBRT "for low-risk and intermediate-risk disease was associated with low rates of severe toxic events and high rates of biochemical control." This further "suggests that SBRT is an appropriate definitive treatment modality for low-risk and intermediate-risk prostate cancer." • Another paper, published five months later in the International Journal of Radiation Oncology, Biology & Physics (RED journal), reported on an impressive 6116 patients, analyzing survival rates, toxicity, and outcomes after prostate SBRT. Results showed a 7-year biochemical disease-free survival rate of 93.7 percent. They concluded that Prostate SBRT "has sufficient evidence to be supported as a standard treatment option for localized prostate cancer while ongoing trials assess its potential superiority." This is based on "substantial prospective evidence supporting its use, with favorable tumor control, patient-reported quality of life, and levels of toxicity."	1	Thank you for the additional literature. We explain below why these papers were not eligible for the present assessment: • **Kishan et al., Jackson et al., Jiang et al., Dang et al.:** The first four studies were excluded because of the lack of a comparator. These studies do not allow a direct comparison of outcomes after SBRT with those after other radiotherapy modalities. • **Greco et al.**: In this study, SBRT is compared with Single Dose Radiotherapy (SDRT). SDRT entails the administration of a single dose of 24Gy in one session. This comparator is out of the scope of the

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			• Regarding treatment effectiveness and durability, a third paper published in the RED journal in November 2019 showed how prostate SBRT eliminates evidence of disease as defined by decreasing PSA to normal levels. "In this multi-institutional cohort of patients with long-term follow-up, we found that SBRT led to low nPSAs (PSA nadirs = low values). In turn, lower nPSAs are associated with reduced incidence of, and longer time to, biochemical failure." A figure within this paper shows the median PSA to be in the range of 0.2 ng/ml at 7 years post treatment. • Gantry-based SBRT for prostate cancer is associated with a favorable safety and efficacy profile, despite variable intrafractional motion management techniques. These findings suggest that multiple treatment platforms can be used to safely deliver prostate SBRT. Additionally, the reference study mentions that "Gantry-mounted prostate SBRT seems to be safe and effective in a multi-institutional setting" "Thus, prostate SBRT need not be anchored to any particular treatment platform." (Dang Study). • "This study offers encouraging perspectives on the feasibility and safety of 24 Gy SDRT in organ-confined prostate cancer...In this randomized clinical trial among patients with intermediate-risk prostate cancer, SDRT was safe and associated with low toxicity, and the tumor control and quality-of-life end points closely match the SBRT arm outcomes" (Greco study)		present assessment; instead, we include conventional ratiotherapy consisting of 8 or more fractions.

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			Referenced Studies Kishan AU, Dang A, Katz AJ, Mantz CA, Collins SP, Aghdam N, Chu FI, Kaplan ID, Appelbaum L, Fuller DB, Meier RM, Loblaw DA, Cheung P, Pham HT, Shaverdian N, Jiang N, Yuan Y, Bagshaw H, Prionas N, Buyyounouski MK, Spratt DE, Linson PW, Hong RL, Nickols NG, Steinberg ML, Kupelian PA, King CR. Long-term Outcomes of Stereotactic Body Radiotherapy for Low-Risk and Intermediate-Risk Prostate Cancer. JAMA Netw Open. 2019 Feb 1;2(2):e188006 Jackson WC, Silva J, Hartman HE, Dess RT, Kishan AU, Beeler WH, Gharzai LA, Jaworski EM, Mehra R, Hearn JWD, Morgan TM, Salami SS, Cooperberg MR, Mahal BA, Soni PD, Kaffenberger S, Nguyen PL, Desai N, Feng FY, Zumsteg ZS, Spratt DE. Stereotactic Body Radiation Therapy for Localized Prostate Cancer: A Systematic Review and Meta-Analysis of Over 6,000 Patients Treated On Prospective Studies. Int J Radiat Oncol Biol Phys. 2019 Jul 15;104(4):778-789 Jiang NY, Dang AT, Yuan Y, Chu FI, Shabsovich D, King CR, Collins SP, Aghdam N, Suy S, Mantz CA, Miszczyk L, Napieralska A, Namysl-Kaletka A, Bagshaw H, Prionas N, Buyyounouski MK, Jackson WC, Spratt DE, Nickols NG, Steinberg ML, Kupelian PA, Kishan AU. Multi-Institutional Analysis of Prostate-Specific Antigen Kinetics After Stereotactic Body Radiation Therapy. Int J Radiat Oncol Biol Phys. 2019 Nov 1;105(3):628-636. Dang, Audrey T., et al. "Gantry-mounted linear accelerator–based stereotactic body radiation therapy for low-and intermediate-risk prostate cancer." Advances in radiation oncology 5.3 (2020): 404-411.		

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			Greco, Carlo, et al. "Safety and Efficacy of Virtual Prostatectomy With Single-Dose Radiotherapy in Patients With Intermediate-Risk Prostate Cancer: Results From the PROSINT Phase 2 Randomized Clinical Trial." JAMA oncology (2021).		
Varian Medical System	21	776	**Liver** Conclusion from study: "In summary, small HCC tumors appear to be good candidates for SBRT, though larger (over 1000 cc) tumors have been successfully treated as well."- Rosenzweig, Kenneth. Referenced Study: Schulz, R. A., et al. "Stereotactic body radiation therapy (SBRT) for early-stage primary liver cancer (HCC)." Appl Rad Oncol (2013): 12-8.	1	The suggested study (**Schulez RA et al**) was published in 2013. According to the inclusion/exclusion criteria of the project plan, studies published before 1st January 2015 do not match the inclusion criteria and are considered as excluded.
Varian Medical System	58	1378	Assuming we are listing all of our linacs in this table and not just those considered in this study, the report is missing Edge (previously mentioned in the report) and Halcyon Halcyon- same specs as Ethos and please make the following changes for both Ethos and Halcyon - 2 imaging detectors for Ethos and Halcyon Edge- All of the same specs as Truebeam NA on ultrasound for all products	1	Modified

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			Please note that while Varian is no longer manufacturing Trilogy and Clinac iX, they are still functioning in the market Note about multi-leaf collimation- please see specific detail about leaves here: https://www.oncologysystems.com/resources/linear-accelerator-guides/varian-high-energy-linear-accelerators-comparison-chart		
Varian Medical System	294	4583	Again, missing Halcyon, Ethos, Clinac IX - Halcyon and Ethos- Yes for all columns except SRS - Halcyon CE mark 2017 and Ethos- 2021 Clinac IX- Yes for all columns, approved 2005	1	Added
Varian Medical System	295	4588	- For Germany, there is still no dedicated code exclusively for SBRT but there are flat fees for SBRT in combination with IGRT and IMRT as well as for the planning. - Based on IPAAC 2020 publication „Tackling reimbursement for radiation oncology and cancer surgery: challenges and options"- Lithuania states no RT reimbursement	2	The responses received from the Institute for Quality and Efficiency in Health Care (Germany) and the State Agency for Health Care Accreditation (Lithuania) regarding the reimbursement of SBRT for the indications studied have been reviewed. Table A17 reflects their responses. We do not make changes.

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Accuray	55	1280	Comment: Stereotactic radiotherapy doses usually delivered in maximum 10 fractions		The source from which this information was extracted has been revised (ref 2) and there it is indicated that the maximum is 12. No changes are made.
Accuray	56	1323	non-isocentric non coplanar FFF		The source from which this information was extracted has been reviewed (ref 81) and there the concept of non-isocentric FFF-beam delivery is exclusively indicated. No changes are made.
Accuray	56	1336	robotic and image-guided CyberKnife® SBRT delivery		Added
Accuray	56	1337	the inherent flexibility of the robotic manipulator of CyberKnife® enables a truly 3D workspace (many independently targeted treatment beams, i.e. multiple isocenters) allowing to treat complex tumors		The source from which this information was extracted has been reviewed (ref 81) and although the CyberKnife has these characteristics, they are not included in the description of the consulted article. No changes are made.

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Accuray	56	1349	**Below are suggestions to complement the short paragraph dedicated to CyberKnife:** The treatment delivery is facilitated by a lightweight linear accelerator mounted on a robotic manipulator capable of performing movements with 6 degrees of freedom to deliver many independently targeted (non-isocentric) and non-coplanar treatment beams (photon beams delivered in an infinite number of positions). This configuration coupled with intrafraction image guidance allows for the delivery of frameless radiosurgery treatments anywhere in the body with submillimeter accuracy (mechanical precision of the robot is 0.12 mm) *Moutsatsos A, Pantelis E, © Springer Nature Switzerland AG 2020 A. Conti et al. (eds.), CyberKnife NeuroRadiosurgery, https://doi.org/10.1007/978-3-030-50668-1_3*	1	Thank you for the information provided to complete the description of the CyberKnife. However, its inclusion would decompensate the information provided for the other models. It is not included.
Accuray	56	1351	thanks to real-time artifical intelligence – driven motion synchronization using image-guided tracking algorithms. Several dedicated image-guided algorithms can be used depending upon the type of lesion tissue and density. For example, for lung, a dedicated lung tracking with respiratory modelling algorithm, the Xsight® Lung, is commonly used. In combination with the tracking method, the Synchrony® motion tracking module is used for moving targets using an optical camera monitoring the position of markers placed on the patient surface, on a special vest. *Moutsatsos A, Pantelis E, © Springer Nature Switzerland AG 2020 A. Conti et al. (eds.), CyberKnife NeuroRadiosurgery, https://doi.org/10.1007/978-3-030-50668-1_3*	1	Thank you for the information provided to complete the description of the CyberKnife. However, its inclusion would decompensate the information provided for the other models. It is not included.

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Accuray	56	1352	without having to reposition or to immobilize the patient who can breathe freely and is not restrained in any way	1	Thank you for the information provided to complete the description of the CyberKnife. However, its inclusion would decompensate the information provided for the other models. It is not included.
Accuray	56	1355	There are three collimation systems defining the geometric characteristics of the treatment beam delivered to the patient used and creating highly conformed dose distributions with sharp dose gradients: 12 fixed conical collimators, with diameters ranging from 5 to 60 mm; the Iris™ Variable Aperture Collimators achieving the same set of circular field sizes as those obtained with the fixed collimators; the InCise™ 2 multi leaf collimator, each leaf being driven independently. The InCise MLC allows the delivery of irregularly shaped and larger radiation fields using fewer beams as compared to other collimators. Therefore, a treatment time reduction of 30-35% has been reported along with a better dose gradient. Collimators can be exchanged using an automatic and pneumatic tool-changing mechanism. *Moutsatsos A, Pantelis E, © Springer Nature Switzerland AG 2020 A. Conti et al. (eds.), CyberKnife NeuroRadiosurgery, https://doi.org/10.1007/978-3-030-50668-1_3* *Calusi S et al, Physica Medica 71 (2020) 31–38*	1	Thank you for the information provided to complete the description of the CyberKnife. However, its inclusion would decompensate the information provided for the other models. It is not included.

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			Recently a novel optimization algorithm (VOLO™) was introduced in the Accuray Precision™ treatment planning system and demonstrated significantly improved planning and treatment efficiencies: reduced delivery time for IRIS-based and improved quality of dose distribution for MLC-based plans versus previous sequential optimizer, which may generate increased patient throughput. *Zeverino M et al, Physica Medica 64 (2019) 230-237* *Schüler E, J Appl Clin Med Phys 2020; 1–10*		
Accuray	57	1364	Comment: Is Edge actually non-ionizing?		Yes, according to the information provided by its manufacturer (Varian)
Accuray	58	1378	**Additional column:** Accuray Inc (USA) CyberKnife® (latest generation is CyberKnife® S7™) TYPE: Linear accelerator Photons: Yes (single energy) Electrons: No MICROWAVE POWER: Source: Magnetron Power: 6 MV GANTRY: Rotation range: NA. Movement with 6 degrees of freedom COLLIMATION: 3 collimation systems - 12 fixed conical collimators; diameters from 5 to 60 mm - Iris™ variable aperture collimators achieving the same set of circular field sizes (5 to 60 mm) - Multileaf: 52 (26 tungsten leaf pairs)	1	Added

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			IMAGING: N° of detectors: 2 Ultrasound: NA RESPIRATORY GATING: No. Synchrony® motion tracking and synchronization enabling personalized, real-time adaptive delivery DOSIMETRY SYSTEM: Display accumulated dose: Yes		
Accuray	64	1696	*Comment: no manufacturer should be able at this point in time to address the requirement for on-board CT*		As indicated in the report, they are consensus recommendations formulated by two German scientific societies, although in their preparation they have taken into account previous guidelines from other European and American societies. No changes are made.
Accuray	294	4583	**CyberKnife: Date of approval** **Comments**: over time, there have been several CE-marking obtained for the successive versions of CyberKnife. Very first CyberKnife® version was approved in 2002. In 2010: CyberKnife® VSI In 2013: CyberKnife® M6™	1	Added

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			In 2017: CyberKnife® M6™ with Accuray Precision® treatment planning system and IDMS® data management system In 2020: CyberKnife® S7™ Accuray Precision® and IDMS® system Note: both M6™ and S7™ versions are currently available for sale		
Accuray	295	4588	SWITZERLAND: Reimbursed **Comments:** According to the Switzerland "principle of trust", all procedures performed by physicians at hospitals are considered eligible for coverage within the mandatory health insurance system. SBRT not being part of the health benefits list (KLV) that includes technologies that have been questioned by health insurance companies or hospitals and evaluated (HTA process) by the Federal Office for Public Health (FOPH) to review their eligibility for national coverage, there should be no restriction to their use. In outpatient settings, TARMED fee-for-service model. In hospitals, DRG system. Source: MTRC report 2018, attached herewith	1	The response received from Swiss Network for Health Technology Assessment (Switzerland) on the reimbursement of SBRT for the indications studied has been reviewed. Table A17 reflects their response. We do not make changes.
Accuray	19	645-646	**Comment:** we don't understand the sentence "Condition the offer of surgery in case of a shortage of accredited surgeons for SBRT" as radiotherapy is not practiced by surgeons (except for neuro-radio-surgeons for intracranial or spine applications) but by radiation oncologists instead, as well as medical physicists and radiation therapists.	2	Thanks for the observation. After reviewing the answer, we have written again hoping that it is clearer and more precise. The new text is on page 19 and point 2.2 of appendix 3:

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			Is radiotherapy for prostate delivered by urology surgeons, for example, in some countries?		New text: It could modify the volume of surgical activity if SBRT is implemented as an alternative technology to surgery for resectable tumors of the lung, prostate and liver.
MD, PhD Adam Maciejczyk Director of Wroclaw Comprehensive Cancer Center, Wrocław, Poland; Department of Oncology, Wroclaw Medical University, Poland	--	--	He reviewed the 2nd draft assessment report, but he has not considered neccesary to provide any comments on the document	--	--
Begoña Barragán García Grupo Español de Pacientes	--	--	She reviewed the 2nd draft assessment report, but she has not considered neccesary to provide any comments on the document	--	--

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con Cáncer GEPAC, Spain)(patient representative)					

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