



Australian Government

Medical Services Advisory Committee

Public Summary Document

Application 1345 – The assessment of Cone Beam Computerised Tomography for dental imaging

Sponsor/Applicant/s: Dental & Medical Diagnostic Imaging (DMDI)

Date of MSAC Meeting: 28 November 2013

1. Purpose of application

A reference requesting consideration of Medicare Benefits Schedule (MBS) listing of Cone Beam Computed Tomography (CBCT) for dental and craniofacial imaging was received by the Department of Health in July 2010. A co-application requesting MBS listing of CBCT for 21 indications reimbursable through four separate MBS descriptors (sinus and facial bones; temporal bones, temporomandibular joint (TMJ) and internal acoustic meatus; dental and sleep apnoea) was submitted by DMDI to the Department in March 2011.

CBCT is a method to acquire 3D images through the use of a rotating gantry to which an x-ray source and detector are fixed. In contrast to the fan shaped beams and multiple detectors used in multi-slice computed tomography (CT), CBCT uses a cone-shaped x-ray beam with a flat panel detector to acquire images. Software programs are applied to these image data to generate a 3D volumetric data set, which can be used to provide reconstructed images in multiple planes (axial, coronal, sagittal, oblique, curved) (White 2008).

Hard structures such as teeth, jaws and skull are visualised well by CBCT due to isotropic and high spatial resolution. However, imaging of soft tissues is relatively poor due to low contrast resolution, with the exception of the visualisation of soft tissue outlines such as the upper airway (Lapp et al 2008; White 2008).

CBCT acquires all images in a single rotation with a scan time between 4.9 and 40 seconds. Some CBCT machines also allow the size of the irradiated area to be reduced through collimation of the primary x-ray beam thereby further reducing the radiation dose to the patient.

CBCT units vary widely in size, cost, radiation dose and parameters such as the “field of view” (imaging volume), which depends on the size and shape of the unit, beam geometry and whether the beam is collimated (American Association of Endodontists & American Academy of Oral and Maxillofacial Radiology 2010). There is a close relationship between the FOV size and the radiation dose received by the patients; therefore it is important that the smallest FOV suitable to capture all the required clinical information is selected for each

patient. Larger field of view CBCT units are currently used in radiology practices and public hospital based dental units whereas smaller field of view CBCT units can be integrated into orthopantomography (OPG) units for use in private dental surgeries and radiology practices which typically are referred to as ‘hybrid’ units.

CBCT scanners are lower cost than conventional CT and suited to office-based and head, neck and dental applications as well as niche uses in radiology and radiation oncology practice.

Currently CBCT is used in Australia in the following settings:

- Dental and craniofacial imaging in radiology practices, public hospitals and private community-based dental and craniofacial specialist practices;
- As an adjunct to treatment planning in radiation oncology practice - CBCT scanners are incorporated into modern linear accelerators;
- As an adjunct to treatment planning in angiography (similar use as linear accelerators); and
- As a transmission source for attenuation correction and anatomic correlation in single photon computed tomography (SPECT) in nuclear medicine.

2. Background

In July 2010, a reference requesting consideration of Medicare Benefits Schedule (MBS) listing of CBCT for dental and craniofacial imaging was received by the Department.

In March 2011, a co-application requesting MBS listing of CBCT for 21 indications reimbursable through four separate MBS descriptors (sinus and facial bones; temporal bones, temporomandibular joint (TMJ) and internal acoustic meatus; dental and sleep apnoea) was submitted by DMDI to the Department.

The final Decision Analytic Protocol (DAP) for the assessment of CBCT was released in September 2012 (MSAC Reference 43). The final DAP was restricted to three dental and surgical indications which were identified as priority areas based on consultation with DOHA, the Royal Australian and New Zealand College of Radiologists (RANZCR) and the Australian and New Zealand Association of Oral and Maxillofacial Surgeons (ANZAOMS). DMDI disagreed with the final DAP and elected to provide an application based assessment report covering the two additional indications of sinuses and bone pathology.

As part of the 2011-12 Budget, the Government announced that it would introduce an MBS interim item from July 2011 for CBCT.

The interim MBS item descriptors for CBCT are shown in the table below. These interim MBS item numbers do not include CBCT of sinuses or of bone structures other than those supporting dentition.

Current MBS Item for Cone Beam Computed Tomography (interim item)

Category 5 – DIAGNOSTIC IMAGING SERVICES
MBS 56025 CONE BEAM COMPUTED TOMOGRAPHY of teeth and supporting bone structures (R) (K) Fee: \$113.15 Benefit: 75% = \$84.90 85% = \$96.20

Current MBS Item for Cone Beam Computed Tomography (interim item)

Category 5 – DIAGNOSTIC IMAGING SERVICES
MBS 56026 CONE BEAM COMPUTED TOMOGRAPHY of teeth and supporting bone structures (R) (NK) Fee: \$56.60 Benefit: 75% = \$42.45 85% = \$48.15

** From 1 July 2011 all services listed in the Diagnostic Imaging Services Table of the MBS, excluding Positron Emission Tomography services, preparation items 60918 and 60927 and MRI modifier items in subgroup 22, will have a mirror NK item (50% of the Schedule Fee) for diagnostic imaging services provided on aged equipment.*

Prior to this, CBCT had been indirectly reimbursed through the MBS using a variety of combinations of item numbers for example: Diagnostic Imaging Services, Category 5, Group I3 - 60100 (tomography) in combination with x-ray items for the head and face (MBS items 57901 to 57945) and OPG MBS items (57960 to 57969).

3. Prerequisites to implementation of any funding advice

CBCT devices vary in terms of capabilities and image quality, and as such are listed accordingly on the Australian Register of Therapeutic Goods (ARTG).

Machines designated as 3D CBCT are registered as either for dental and medical imaging or for dental diagnostic imaging only.

Machines that are 3D or 2D reconstructed hybrid cone beam volumetric tomography with panoramic and cephalometric capabilities are included on the ARTG as panoramic tomography devices with a cephalometric capability for dental use.

Hybrid machines are included on the ARTG as panoramic tomography devices for dental use only.

4. Proposal for public funding

Initially DMDI had requested that CBCT be listed on the MBS under four categories. PASC agreed at its April 2012 meeting that one item descriptor should be developed for CBCT. This is consistent with the TGA listing that notes that CBCT is approved for dental and medical diagnostic imaging (as opposed to specific indications within this category).

Following consultation, PASC determined at its August 2012 meeting that the proposed item should cover CBCT or hybrid machines provided they meet accredited performance characteristics consistent with a dedicated CBCT. PASC also agreed that the item descriptor should be a radiologist performed item and to leave the current ability for dentists (as well as specialist dentists) to refer for CBCT.

PASC proposed MBS item descriptor for CBCT

Category 5 – DIAGNOSTIC IMAGING SERVICES
MBS [item number] CONE BEAM COMPUTED TOMOGRAPHY Dental & temporomandibular joint Imaging for diagnosis and management of mandibular and dento-alveolar fractures, dental implant planning, orthodontics, endodontic, periodontal and temporomandibular joint conditions: without contrast medium NOTE 1: This items covers CBCT, or hybrid machines which meet accredited performance

characteristics consistent with dedicated CBCT

NOTE 2: A CBCT scan may be requested by all medical and dental practitioners but must be performed by or under the professional supervision of a specialist in diagnostic imaging.

Fee: \$288.15 Benefit: 75% = \$216.13 85% = \$244.93

Source: Table 3 p9 of the final DAP for Reference 43

The application requested that the MBS item descriptor be amended to include the wording “sinuses and bone pathology” in the list of indications for CBCT and that all medical practitioners be eligible to refer patients for CBCT imaging.

As per the final DAP for CBCT for dental imaging, patients considered for CBCT would normally have had the following interventions:

- a private dental consultation(s);
- intra-oral radiographs; and/or
- panoramic radiographs (OPG MBS item numbers 57959 - 57969) conducted by a suitably qualified health professional such as a radiologist.

CBCT services are subject to the current professional supervision rules for CT, which state that the service must be performed under the professional supervision of a specialist in the specialty of diagnostic radiology who is available to monitor and influence the conduct of the examination, and to attend to the patient personally if necessary.

5. Consumer Impact Statement

Nil.

6. Proposed intervention’s place in clinical management

CBCT was proposed in addition to clinical assessment with or without two dimensional imaging (e.g. panoramic imaging) and as a replacement to CT. However, the application did not include a clinical management algorithm.

CBCT offers more accurate and detailed imaging over that of 2D imaging however, patients would be exposed to higher radiation doses than under clinical assessment or 2D imaging alone.

As a replacement for CT, CBCT would function as a direct substitute for currently subsidised CT and be used when lower dose conventional dental radiology cannot resolve the clinical questions. For temporomandibular joint imaging, CBCT would replace subsidised CT or MRI.

7. Other options for MSAC consideration

Nil.

8. Comparator to the proposed intervention

The application did not nominate a main comparator.

The application included a limited discussion of CBCT compared to multi-slice CT and suggested that CBCT for sinus and bone pathology could replace existing multi-slice CT MBS items including 56013, 56016, 56022 and 56028. All of these items were listed on the MBS on 1 November 1996.

56013	CT – scan of orbits with or without intravenous contrast medium and with or without brain scan when performed (R) (K) (anaes.)	\$250.0
56016	CT- scan of petrous bones in axial and coronal planes in 1mm or 2mm sections, with or without intravenous contrast medium, with or without scan of brain (R) (K) (Anaes.)	\$290.00
56022	CT – scan of facial bones, para nasal sinuses or both without intravenous (R) (K) (Anaes.)	\$225.00
56028	CT – scan of the facial bones, para nasal sinuses or both with intravenous contrast medium and with any scans of the facial bones, para nasal sinuses or both before intravenous contrast injection, when performed (R) (K) (Anaes.)	\$336.80

9. Comparative safety

The application claimed that CBCT offers a lower dose of radiation exposure compared to multi-slice CT, however did not provide data from any studies or trials to support this claim.

10. Comparative effectiveness

The application included a narrative review of a selection of CBCT literature; however no formal data extraction or synthesis was used to support the application.

11. Economic evaluation

The application did not provide an economic evaluation.

12. Financial/budgetary impacts

The application did not provide a statement about the financial impact of the proposed new indications for CBCT. However, in the response to the critique, the applicant claimed the proposed new indications for CBCT would be cost neutral to the MBS.

In order to evaluate the cost neutral claim, the Department developed three costing options based on three different scheduled fees. All options were based on the assumption that the proposed new indications would substitute for existing CT items 56013, 56016, 56022 and 56028 (nominated comparators), with no displacement of CBCT items 56025 and 56026 and no changes to the number of dental x-ray services.

Option 1: Schedule fee equal to the current CBCT fee which is \$113.15 and a take-up rate of 20 per cent per year over four years (up to 80 per cent). This option represented a saving of \$57 million to the MBS over four years.

Option 2: Schedule fee of \$124.15 which is equal to the current CBCT fee plus 10 per cent which might result if the fee is reviewed. A take-up rate of 20 per cent per year over four years (up to 80 per cent). This option represented a saving of \$52 million to the MBS over four years.

Option 3: Schedule fee of \$288.15, as proposed by the application. With a take-up rate of 80 per cent in the first year as the higher fee would provide a greater incentive for providers to invest in CBCT technology. This option represented an additional cost of \$30 million to the MBS over four years.

The three costing options indicate that CBCT could potentially represent a saving to the MBS, however if the fee proposed by the application was endorsed, it could result in a significant additional cost.

13. Other significant factors

Nil.

14. Key issues for MSAC from ESC

ESC was concerned with reports from the Department of Human Services (DHS) that patients are claiming the interim CBCT item on multiple occasions at the one attendance and agreed that there is no clinical need for multiple scans to be performed at the same attendance.

ESC was concerned that CBCT would substitute for lower radiation dose OPG in dentists' surgeries. ESC was also concerned that dentists would be able to 'self-refer' to perform CBCT with very limited involvement of a radiologist. ESC considered that more detail on the role of the radiologist may be needed in the item descriptor to ensure quality services are provided.

ESC noted that, if CBCT were reimbursed for imaging of the sinuses or bone pathology, the switching from CT to CBCT could be considerable due to the potentially lower radiation dose particularly in children and young adults.

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

MSAC noted that this application for MBS listing of CBCT for imaging of sinuses and bone pathology is to be considered separately to Reference 43 requesting MBS listing of CBCT for three other dental indications and incorporating a review of the interim listed items.

MSAC noted that no comparator was nominated. The application proposes that CBCT is used in addition to clinical assessment with two-dimensional imaging (intra-oral radiography or panoramic imaging [OPG]) and as a replacement for helical multi-detector computed tomography (CT). However, no care pathway or clinical management algorithms were provided in support and there was only a limited discussion included which suggested that CBCT for sinus and bone pathology could replace existing multi-detector CT MBS items.

MSAC was limited in consideration of the available evidence for use of CBCT for imaging sinus and bone pathology as the application only presented a narrative review of a selection of CBCT literature with no formal data extraction or synthesis. The cited studies included cadaveric and phantom studies, and the clinical citations consisted largely of case series. The non-systematic review emphasised incidental findings with no analysis of the implications for management or outcomes. Based on the limited evidence presented, MSAC considered there was only weak safety and effectiveness data for the use of CBCT for imaging sinus and bone pathology.

MSAC was concerned about the potential for CBCT to substitute for lower radiation dose imaging with OPG in dental surgeries, particularly in the absence of high-quality evidence. MSAC noted a recent Australian study (Mathews *et al.* 2013; BMJ 346:12360) which confirms reports of an increased cancer risk among people receiving CT scans in childhood. Unlike past studies assessing radiation risk, which extrapolate data based on cancer rates in atom-bomb survivors, this study examined data from patients who had received CT scans in childhood or adolescence compared with those unexposed.

No economic evaluation or financial implications for listing were provided. The application proposed an increased fee over the current MBS interim item fee and claimed that the proposed new indications for CBCT would be cost neutral to the MBS. MSAC considered that there was no adequate justification provided for the proposed increased fee particularly as no argument was presented stating that the current interim MBS fee is too low. MSAC further considered that the estimate provided by the applicant was likely to result in a significant spend. The Department developed three cost options, two based on the current interim CBCT fee and one based on the fee proposed by the applicant. MSAC noted that for either option based on the current interim MBS fee, CBCT may represent a cost saving to the MBS.

MSAC questioned bulk billing rates and patient co-payments for the interim listed CBCT items. The policy area was not able to comment during the course of the meeting, but have subsequently advised that in 2012/13 the bulk billing rate for the interim items is 60% and the average patient co-payment is \$45.

MSAC was concerned that reports from the Department of Human Services (DHS) indicate that the CBCT interim MBS item is being claimed on multiple occasions at the one attendance. MSAC questioned the clinical need and health implications of this practice, particularly as the patient would receive an increased radiation dose with repeat scans. MSAC suggested deleting 'hybrid machines' from the proposed PASC descriptor as inclusion of the term could increase the likelihood of a patient undergoing multiple scans if a the field of view obtainable with hybrid machine is insufficient. As an additional measure to reduce the likelihood of multiple scans on the one occasion, MSAC suggested limiting Medicare rebates to only one scan per patient per day.

MSAC was also concerned about the potential for dentists to self-refer CBCT, without radiologist involvement and at the patient's expense, while noting that such activity would occur outside the MBS.

MSAC requested that a letter be sent to the Australian Radiation Protection and Nuclear Safety Agency (ARPANSA) seeking their advice in relation to the radiation risks associated with the introduction of CBCT, particularly in relation to dental practices.

MSAC agreed that to address these issues the following notes from the descriptor proposed by PASC should be included in the current interim MBS items for CBCT (56025 and 56026) with the amendment to remove use of hybrid machines:

NOTE 1: Benefits are payable for services rendered on dedicated CBCT equipment only (not hybrid machines).

NOTE 2: A CBCT scan may be requested by specialist dental practitioners and must be performed by or under the professional supervision of a specialist in diagnostic imaging, in an accredited practice.

NOTE 3: Benefits payable once only per patient per day.

MSAC agreed that the current listing helps to maintain a regulated environment for CBCT and emphasised that all MBS-eligible CBCT sites must participate in the Diagnostic Imaging Accreditation Scheme.

Lay summary

Cone beam CT is a medical imaging modality being applied to dental imaging. The conical shape of the x-ray beam distinguishes this technique from helical CT, which uses a fan-shaped beam.

CBCT is currently available on the MBS as interim items for imaging teeth and supporting bone structures. The applicant proposes that CBCT imaging for sinuses and bone pathology be included on the MBS.

MSAC considered that the applicant provided insufficient evidence for assessment of the safety, clinical effectiveness and cost-effectiveness of the proposed services and therefore, MSAC did not support a change in current public funding arrangements. MSAC is seeking advice from the Australian Radiation Protection and Nuclear Safety Agency in relation to potential radiation risks associated with the widespread use of CBCT. MSAC has agreed to modify the current interim MBS item descriptors and maintain the current CBCT fee.

16. MSAC's advice to the Minister

MSAC considered that the strength of the evidence provided in relation to the safety, clinical effectiveness and cost-effectiveness of CBCT for imaging of the sinuses and bone pathology was insufficient and does not support a change to the current interim public funding arrangements for MBS items 56025 and 56026.

However, MSAC supports amending the descriptors for the current MBS items 56025 and 56026 and adding the two proposed notes. MSAC does not support the proposal to increase the MBS fees for these two items.

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

Comment reprinted from MSAC Reference 43 PSD with permission of RANZCR. The Applicant agrees with and supports the RANZCR's comments which are also applicable to this Application 1345.

“RANZCR welcomes the support of MSAC for public funding of CBCT, in particular the requirements for dedicated CBCT equipment and professional supervision by a radiologist in an accredited practice. This maintains arm's length referral for these imaging services, addresses the potential for over servicing, and will deliver expert opinion on the entire volume examined for each patient and avoid unnecessary irradiation. However, there is significant concern with regard to the proposal to exclude Medicare eligibility for requests from “general” dental practitioners. The College estimates that up to 50% of dental implant surgeries in Australia are currently performed by dental practitioners, many of whom have internationally recognised training and experience in implant dentistry or removal of impacted third molars but are not registered as dental “specialists” with the Australian Health Practitioner Regulation Agency (AHPRA). Implant dentistry and the removal of third molars are not restricted to dental specialists in Australia; therefore dental practitioners are performing these procedures within their scope of practice. However, their patients will be denied Medicare funding for the CBCT examination required to support the safety and quality of these procedures, potentially placing patients at an increased risk of permanent nerve damage. These “general” dental practitioners should be eligible to request Medicare funded CBCT examinations as this will often be required to provide guidance on the next appropriate phase of dental health care treatment required for the patient. We also hold genuine concerns that the exclusion of general dental practitioners may lead to a growth in CBCT services using inferior, often high-dose hybrid CBCT units without the expert radiologist involvement required. Medicare eligible CBCT services will be subject to a more appropriate standard of care, creating an issue of inequality for these patients. It is therefore strongly recommended on the basis of safety and quality that Medicare benefits for CBCT continue to be payable for referrals from all suitably credentialed dental practitioners. Finally, we would like to reiterate the case for setting the CBCT rebate to a level closer to

that of CT. The capital expense, radiographer and radiologist time are similar and we are unaware of any economic modelling that supports the current interim rebate.”

18. Context for decision

This advice was made under the MSAC Terms of Reference.

MSAC is to:

Advise the Minister for Health on medical services that involve new or emerging technologies and procedures and, where relevant, amendment to existing MBS items, in relation to:

- the strength of evidence in relation to the comparative safety, effectiveness, cost-effectiveness and total cost of the medical service;
- whether public funding should be supported for the medical service and, if so, the circumstances under which public funding should be supported;
- the proposed Medicare Benefits Schedule (MBS) item descriptor and fee for the service where funding through the MBS is supported;
- the circumstances, where there is uncertainty in relation to the clinical or cost-effectiveness of a service, under which interim public funding of a service should be supported for a specified period, during which defined data collections under agreed clinical protocols would be collected to inform a re-assessment of the service by MSAC at the conclusion of that period;
- other matters related to the public funding of health services referred by the Minister.

Advise the Australian Health Ministers' Advisory Council (AHMAC) on health technology assessments referred under AHMAC arrangements.

MSAC may also establish sub-committees to assist MSAC to effectively undertake its role. MSAC may delegate some of its functions to its Executive sub-committee.

19. Linkages to other documents

MSAC's processes are detailed on the MSAC Website at: www.msac.gov.au.