



Australian Government
Department of Health

Application Form
(New and Amended
Requests for Public Funding)
(Version 0.1)

This application form is to be completed for new and amended requests for public funding (including but not limited to the Medicare Benefits Schedule (MBS)). It describes the detailed information that the Australian Government Department of Health requires in order to determine whether a proposed medical service is suitable.

Please use this template, along with the associated Application Form Guidelines to prepare your application. Please complete all questions that are applicable to the proposed service, providing relevant information only. Applications not completed in full will not be accepted.

Should you require any further assistance, departmental staff are available through the Health Technology Assessment Team (HTA Team) on the contact numbers and email below to discuss the application form, or any other component of the Medical Services Advisory Committee process.

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Website: <http://www.msac.gov.au>

PART 1 – APPLICANT DETAILS

1. Applicant details (primary and alternative contacts)

Corporation / partnership details <i>(where relevant):</i> Corporation name: ABN: Business trading name:	Interventional Radiology Society of Australasia REDACTED REDACTED REDACTED
Primary contact name:	REDACTED
Primary contact numbers: Business: Mobile: Email:	REDACTED REDACTED REDACTED
Alternative contact name:	REDACTED
Alternative contact numbers: Business: Mobile: Email:	REDACTED REDACTED REDACTED

2. (a) Are you a lobbyist acting on behalf of an Applicant?

Yes:

No:

(b) If yes, are you listed on the Register of Lobbyists?

Yes:

No:

PART 2 – INFORMATION ABOUT THE PROPOSED MEDICAL SERVICE

3. Application title

Vertebroplasty for severely painful osteoporotic vertebral fractures of less than 6 weeks duration

4. Provide a succinct description of the medical condition relevant to the proposed service (*no more than 150 words – further information will be requested in Part 6 of the Application Form*)

Osteoporotic vertebral fractures are increasingly prevalent as the population ages. Most osteoporotic vertebral fractures cause mild or moderate symptoms and do not require intervention. A small but significant subset of patients experience severe pain and loss of function following the fracture. This can cause loss of independence and hospitalisation. Vertebroplasty can be used to provide pain relief when the pain is severe and poorly controlled by medication, and when the fracture is less than 6 weeks in duration. The alternative, larger dose of opiate analgesics causes many side effects in this patient group including delirium, nausea, constipation and increased propensity to falls. This patient group includes both outpatients and inpatients. The assumption that pain due to osteoporotic spinal fractures is self-limiting is incorrect in this patient sub-group with poor outcomes at 6 months in the placebo group of the VAPOUR trial.

5. Provide a succinct description of the proposed medical service (*no more than 150 words – further information will be requested in Part 6 of the Application Form*)

The procedure is performed in an Interventional Radiology suite using local anaesthesia. High quality fluoroscopic imaging is required. A needle is passed through the skin of the back and into the fractured vertebral body. The trabecular space of the vertebral body is progressively filled with polymethyl methacrylate (PMMA) using fluoroscopic imaging to guide the injection. The procedure is terminated when the vertebral body has an adequate distribution of PMMA to stabilise the fractured vertebral body (distribution from superior to inferior endplate and anterior cortex to posterior third of vertebral body in lateral projection and from pedicle to pedicle in frontal projection), or if PMMA begins to extravasate outside of the bone. The patient can be mobilised after 2 hours and outpatients can be discharged home at this time.

6. (a) Is this a request for MBS funding?

Yes:
No:

(b) If yes, is the medical service(s) proposed to be covered under an existing MBS item number(s) or is a new MBS item(s) being sought altogether?

Amendment to existing MBS item(s):
New MBS item(s):

(c) If an amendment to an existing item(s) is being sought, please list the relevant MBS item number(s) that are to be amended to include the proposed medical service:

(d) If an amendment to an existing item(s) is being sought, what is the nature of the amendment(s)?

- i. An amendment to the way the service is clinically delivered under the existing item(s)
- ii. An amendment to the patient population under the existing item(s)
- iii. An amendment to the schedule fee of the existing item(s)
- iv. An amendment to the time and complexity of an existing item(s)
- v. Access to an existing item(s) by a different health practitioner group
- vi. Minor amendments to the item descriptor that does not affect how the service is delivered
- vii. An amendment to an existing specific single consultation item
- viii. An amendment to an existing global consultation item(s)
- ix. Other (please describe below)

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(e) If a new item(s) is being requested, what is the nature of the change to the MBS being sought?

- i. A new item which also seeks to allow access to the MBS for a specific health practitioner group
- ii. A new item that is proposing a way of clinically delivering a service that is new to the MBS (in terms of new technology and / or population)
- iii. A new item for a specific single consultation item
- iv. A new item for a global consultation item(s)

x

(f) Is the proposed service seeking public funding other than the MBS?

Yes:

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No:

x

(g) If yes, please advise:

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7. What is the type of service:

Therapeutic medical service	x
Investigative medical service	
Single consultation medical service	
Global consultation medical service	
Allied health service	
Co-dependent technology	
Hybrid health technology	

8. For investigative services, advise the specific purpose of performing the service (which could be one or more of the following):

- i. To be used as a screening tool in asymptomatic populations
- ii. Assists in establishing a diagnosis in symptomatic patients
- iii. Provides information about prognosis

- iv. Identifies a patient as suitable for therapy by predicting a variation in the effect of the therapy
- v. Monitors a patient over time to assess treatment response and guide subsequent treatment decisions

9. Does your service rely on another medical product to achieve or to enhance its intended effect?

Pharmaceutical / Biological	
Prosthesis or device	x
No	

10. (a) If the proposed service has a pharmaceutical component to it, is it already covered under an existing Pharmaceutical Benefits Scheme (PBS) listing?

Yes	
No	

(b) If yes, please list the relevant PBS item code(s)?

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(c) If no, is an application (submission) in the process of being considered by the Pharmaceutical Benefits Advisory Committee (PBAC)?

Yes (please provide PBAC submission item number below)	
No	

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(d) If you are seeking both MBS and PBS listing, what is the trade name and generic name of the pharmaceutical?

Trade name	
Generic name	

11. (a) If the proposed service is dependent on the use of a prosthesis, is it already included on the Prostheses List?

Yes	x
No	

(b) If yes, please provide the following information (where relevant):

Billing code(s)	OH503, OH171, JJ609, SY429, HW577
Trade name of prostheses	G21Kit, Mendec Kit, vertebroplasty system, Vertecem, Avamax Kit
Clinical name of prostheses	PMMA with complex delivery system
Other device components delivered as part of the service	These are appropriate PMMA kits for vertebroplasty which are already listed

(c) If no, is an application in the process of being considered by a Clinical Advisory Group or the Protheses List Advisory Committee (PLAC)?

Yes	<input type="checkbox"/>
No	<input type="checkbox"/>

(d) Are there any other sponsor(s) and / or manufacturer(s) that have a similar prosthesis or device component in the Australian market place which this application is relevant to?

Yes	<input type="checkbox"/>
No	<input checked="" type="checkbox"/>

(e) If yes, please provide the name(s) of the sponsor(s) and / or manufacturer(s).

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12. Please identify any single and / or multi-use consumables delivered as part of the service?

Single use consumables
Multi-use consumables

Skin antiseptic, sterile drapes, sterile gown and gloves for operator

PART 3 – INFORMATION ABOUT REGULATORY REQUIREMENTS

13. (a) If the proposed medical service involves the use of a medical device, in-vitro diagnostic test, pharmaceutical product, radioactive tracer or any other type of therapeutic good, please provide the following details:

Type of therapeutic good	PMMA cement with complex delivery system
Manufacturer's name	
Sponsor's name	Orthotec, Johnsons and Johnson T/A DePuy Synthes , Stryker

(b) Is the medical device classified by the TGA as either a Class III or Active Implantable Medical Device (AIMD) against the TGA regulatory scheme for devices?

Class III	<input type="checkbox"/>
AIMD	<input type="checkbox"/>
N/A	<input checked="" type="checkbox"/>

14. (a) Is the therapeutic good to be used in the service exempt from the regulatory requirements of the *Therapeutic Goods Act 1989*?

Yes	<input type="checkbox"/>	If yes, please provide supporting documentation as an attachment to this application form
No	<input checked="" type="checkbox"/>	

(b) If no, has it been listed or registered or included in the Australian Register of Therapeutic Goods (ARTG) by the Therapeutic Goods Administration (TGA)?

Yes (please provide details below)	<input checked="" type="checkbox"/>
No	<input type="checkbox"/>

ARTG listing, registration or inclusion number:	177835,141428,119643,98843,235604
TGA approved indication(s), if applicable:	
TGA approved purpose(s), if applicable:	

15. If the therapeutic good has not been listed, registered or included in the ARTG, is the therapeutic good in the process of being considered for inclusion by the TGA?

Yes (please provide details below)	<input type="checkbox"/>
No	<input checked="" type="checkbox"/>

Date of submission to TGA	
Estimated date by which TGA approval can be expected	
TGA Application ID	
TGA approved indication(s), if applicable	
TGA approved purpose(s), if applicable	

16. If the therapeutic good is not in the process of being considered for listing, registration or inclusion by the TGA, is an application to the TGA being prepared?

Yes (please provide details below)

No

Estimated date of submission to TGA

Proposed indication(s), if applicable

Proposed purpose(s), if applicable

PART 4 – SUMMARY OF EVIDENCE

17. Provide an overview of all key journal articles or research published in the public domain related to the proposed service that is for your application (limiting these to the English language only). *Please do not attach full text articles, this is just intended to be a summary.*

	Type of study design *	Title of journal article or research project (including any trial identifier or study lead if relevant)	Short description of research (max 50 words)**	Website link to journal article or research (if available)	Date of publication***
1	Blinded RCT	Safety and efficacy of vertebroplasty for acute painful osteoporotic fractures (VAPOUR): a multicentre, randomised, double-blind, placebo-controlled trial. (Clark et al Lancet 2016)	The VAPOUR trial was specifically designed to address a recommendation in the 2011 MSAC report. This trial targeted a subgroup of elderly patients with severe pain due to osteoporotic fractures of less than 6 weeks duration. A majority were hospital inpatients. NRS Pain entry score $\geq 7/10$.	http://www.thelancet.com/journals/lancet/article/PIIS0140-6736(16)31341-1/abstract	August 2016
2	Blinded RCT	A randomized trial of vertebroplasty for painful osteoporotic vertebral fractures. (Buchbinder et al NEJM, 2009)	Blinded placebo controlled trial of vertebroplasty for painful vertebral fractures up to 12 months old in outpatients only. NRS Pain entry score requirement not defined.	www.nejm.org/doi/full/10.1056/NEJMoa0900429	August 2009

	Type of study design *	Title of journal article or research project (including any trial identifier or study lead if relevant)	Short description of research (max 50 words)**	Website link to journal article or research (if available)	Date of publication***
3	Blinded RCT	A Randomized Trial of Vertebroplasty for Osteoporotic Spinal Fractures. (Kallmes et al, NEJM<2009)	Blinded placebo controlled trial of vertebroplasty for painful vertebral fractures up to 12 months old. Outpatients only. NRS Pain entry score $\geq 3/10$.	http://www.nejm.org/doi/full/10.1056/NEJMoa0900563	August 2009
4	Open label RCT	Vertebroplasty versus conservative treatment in acute osteoporotic vertebral compression fractures (Vertos II): an open-label randomised trial. (Klazen et al, Lancet 2010)	Open label RCT comparing vertebroplasty to conservative therapy for fracture less than 6 weeks duration. Outpatients only. NRS Pain entry score $\geq 5/10$.	http://dx.doi.org/10.1016/S0140-6736(10)60954-3	September 2010
5	Other studies have been summarised in MSAC 27.1 assessment	MSAC 27.1 assessment	Other trials not considered relevant to conclusions in MSAC 27.1 assessment	http://webarchive.nla.gov.au/gov/20160615053438/http://www.msac.gov.au/internet/msac/publishing.nsf/Content/27.1-public	Nov 2011
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11					

	Type of study design *	Title of journal article or research project (including any trial identifier or study lead if relevant)	Short description of research (max 50 words)**	Website link to journal article or research (if available)	Date of publication***
1 2 .					
1 3 .					
1 4 .					
1 5 .					

* Categorise study design, for example meta-analysis, randomised trials, non-randomised trial or observational study, study of diagnostic accuracy, etc.

**Provide high level information including population numbers and whether patients are being recruited or in post-recruitment, including providing the trial registration number to allow for tracking purposes.

*** If the publication is a follow-up to an initial publication, please advise.

18. Identify yet to be published research that may have results available in the near future that could be relevant in the consideration of your application by MSAC (limiting these to the English language only). Please do not attach full text articles, this is just intended to be a summary.

	Type of study design*	Title of research (including any trial identifier if relevant)	Short description of research (max 50 words)**	Website link to research (if available)	Date***
1.	Blinded RCT	VERTOS4	Blinded, placebo controlled trial of vertebroplasty for patients with painful vertebral fractures less than 6 weeks duration at time of enrolment. Outpatients only. NRS pain entry $\geq 5/10$. Recruitment completed.	https://www.ncbi.nlm.nih.gov/pubmed/21466679	Don't know
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* Categorise study design, for example meta-analysis, randomised trials, non-randomised trial or observational study, study of diagnostic accuracy, etc.

**Provide high level information including population numbers and whether patients are being recruited or in post-recruitment.

***Date of when results will be made available (to the best of your knowledge).

PART 5 – CLINICAL ENDORSEMENT AND CONSUMER INFORMATION

19. List all appropriate professional bodies / organisations representing the group(s) of health professionals who provide the service (please attach a letter of support for each group nominated).

Interventional Radiologists (letter from Interventional Radiology Society of Australasia attached)

20. List any professional bodies / organisations that may be impacted by this medical service (i.e. those who provide the comparator service).

Aside from vertebroplasty, only intensified and extended conservative medical measures are usually considered for the management of painful vertebral fractures that are unresponsive to initial medical management. This may involve medical therapy directed by Aged Care physicians, General Practitioners, Rheumatologists, Endocrinologist or spine surgeons. Physiotherapy may assist in the rehabilitation phase. This may involve prolonged hospitalisation.

21. List the relevant consumer organisations relevant to the proposed medical service (please attach a letter of support for each consumer organisation nominated).

Osteoporosis Sydney Support Group (letter has been requested and will be forwarded to MSAC). Please do not wait for this letter before processing this application.

22. List the relevant sponsor(s) and / or manufacturer(s) who produce similar products relevant to the proposed medical service.

Sponsors manufacturing appropriate products listed in answer to Question 11 and Question 13.

23. Nominate two experts who could be approached about the proposed medical service and the current clinical management of the service(s):

Name of expert 1	REDACTED
Telephone number(s)	REDACTED
Email address	REDACTED
Justification of expertise	REDACTED
Name of expert 2	REDACTED
Telephone number(s)	REDACTED
Email address	REDACTED
Justification of expertise	REDACTED

Please note that the Department may also consult with other referrers, proceduralists and disease specialists to obtain their insight.

PART 6 – POPULATION (AND PRIOR TESTS), INDICATION, COMPARATOR, OUTCOME (PICO)

PART 6a – INFORMATION ABOUT THE PROPOSED POPULATION

- 24. Define the medical condition, including providing information on the natural history of the condition and a high level summary of associated burden of disease in terms of both morbidity and mortality.**

Osteoporotic vertebral fractures affect an estimated 1.4 million patients in the world annually (Johnell et al 2006). Although many patients with vertebral fractures experience mild symptoms, a subset of patients develop significant disability and complications due to pain and some require hospitalisation (Jacobsen et al, 1992). Standard therapy, comprising rest, analgesia and mobilisation is often poorly tolerated in the elderly with the adverse effects of analgesia and immobilisation leading to additional health problems including poor cognition, increased risk of falls, constipation and nausea (Goldstein et al 2015).

The overall burden of osteoporotic vertebral fractures including those with minimal symptoms, was described in the MSAC 2011 vertebroplasty assessment 27.1, page 24, thus:

“Vertebral fracture occurs in a broad demographic of patients with clinical presentation that is highly varied, ranging from asymptomatic to life-threatening or disabling. Consequently, epidemiological evaluation of the burden of this condition is fraught with difficulty. Vertebral fractures are associated with both a short-term and potentially long-term reduction in QOL (Lips et al. 1999) and a modest increase in mortality, which is most pronounced in the first year after fracture (Johnell et al. 2004), but equates to about a 5 per cent increase in 5-year mortality (Woolf & Pfleger 2003). As well as acute pain, vertebral fractures can lead to chronic pain, immobility, depression and impaired respiratory function (Lips et al. 1999). Having experienced at least one (prevalent) vertebral fracture is associated with a significantly increased risk of subsequent fractures, comparable to the risk implied by osteoporosis itself (Pasco et al.2006). When kyphotic deformity is present, the effect of vertebral fracture can become severe or critical. Compression of the spinal cord may occur, indicating the need for open surgical decompression. In the absence of neurological compromise, kyphosis may impair biomechanical or respiratory function (Lombardi Jr et al. 2005).Risk of vertebral fracture is higher in women than in men, and increases exponentially with age (Sanders et al. 1999b). The lifetime risk of osteoporotic fracture is estimated at 1 in 2 in Australian women and 1 in 3 in Australian men (Access Economics Pty Limited 2001). Vertebral fracture represents 46 per cent of diagnosed osteoporotic fractures. The most significant risk factor for vertebral fracture is osteoporosis; the presence of vertebral fracture is sometimes used as a definition of ‘clinical osteoporosis’ (Lips et al. 1999).Estimating the burden of disease associated with vertebral fracture is hampered by the notion that not all clinically significant vertebral fractures are diagnosed and not all diagnosed vertebral fractures are clinically significant (It is estimated that 50 to 75 per cent of vertebral fractures are asymptomatic (Cummings & Melton 2002), although they are regularly diagnosed through incidental radiographic findings (Sanders et al. 1999b). There is also evidence of systematic underestimation of the incidence and burden relating to clinical vertebral fracture, owing to patients’ reluctance to seek clinical evaluation of lower back pain (Nevitt et al. 1998). Also negatively biasing the estimates of the incidence or prevalence of vertebral fracture is the fact that radiographic confirmation of mild to moderate fracture will not alter management, and hence radiographic confirmation of a clinical diagnosis of vertebral fracture is not routine in healthier patients.”

This current application is only concerned with the subgroup of patients with osteoporotic fractures who have age >60 years, severe pain (NRS pain score \geq 7/10) which is not adequately controlled by medical therapy, fracture duration less than 6 weeks duration. This group includes both hospital inpatients and outpatients. The only randomised controlled trial to collect data on the natural history of this severely afflicted patient subgroup is the VAPOUR trial. The control group of 59 patients in this trial had mean age 80, severe osteoporosis (mean QCT T score Lumbar spine of -4.5), mean baseline NRS pain score of 8.6/10 and mean baseline Roland Morris Disability score of 19.8/24. 57% of the group were inpatients. The median duration of hospital stay was 22.6 days (range 6 to 71). At the final data collection time of 6 months, 3 patients had died and another 2 had developed spinal cord compression (one managed with surgical decompression and spinal fusion and the other developing paraplegia). At 6 months, 53% still had moderate or severe pain and 76% were still using analgesics. There was a mean 63% vertebral body height loss in the fracture at 6 months in the control group with 16% mean additional collapse since baseline.

- 25. Specify any characteristics of patients with the medical condition, or suspected of, who are proposed to be eligible for the proposed medical service, including any details of how a patient would be investigated, managed and referred within the Australian health care system in the lead up to being considered eligible for the service.**

The eligible patient population are patients greater than 60 years of age, with acute, severe back due to one or two osteoporotic vertebral fractures within 6 weeks of fracture onset. The symptoms of pain should be severe (estimated at greater than or equal to 7 out of 10 on an NRS pain scale), and poorly controlled by oral analgesics. Most patients with severely painful acute fractures are seen by their general practitioner or alternatively present by ambulance to the emergency room of hospitals and are hospitalised. Medical specialists particularly aged care physicians, rheumatologists, endocrinologists, and spine surgeons may also consult the patient in this acute, early fracture phase. The patient should have a spinal radiograph to confirm a fracture. The patient should be referred to Interventional Radiology for assessment of vertebroplasty. The patient will need an MRI to confirm recent fracture consistent with the location of the acute pain. The MRI is arranged by either the Interventional radiologist or the referring physician. If MRI is contra-indicated, SPECT-CT nuclear medicine imaging should be obtained.

If the MRI confirms a suitable fracture and the patient's symptoms are severe and of less than 6 weeks duration, then vertebroplasty should be offered to the patient without delay. The more quickly the procedure is performed the better the technical and clinical outcome.

- 26. Define and summarise the current clinical management pathway *before* patients would be eligible for the proposed medical service (supplement this summary with an easy to follow flowchart [as an attachment to the Application Form] depicting the current clinical management pathway up to this point).**

This application is for patients meeting eligibility criteria of age >60, vertebral fracture on x-ray, pain of severe level (NRS pain $\geq 7/10$) and duration for less than 6 weeks. First line treatment is medical therapy: analgesics including simple analgesics \pm opiates, rest followed by assisted mobilisation \pm physiotherapy. Some patients cope with the symptoms at home and others are hospitalised for pain control or due to loss of function. If symptoms are adequately controlled with medical therapy then vertebroplasty is not required. If patient's symptoms are not well controlled with medical therapy then they are candidates for vertebroplasty. They should undergo either MRI or SPECT-CT imaging (If MRI contraindicated). If they are still considered appropriate for vertebroplasty after this further imaging then the intervention should be offered to the patient without delay, as the outcomes are better the earlier the intervention. If MRI precludes vertebroplasty then the patient remains on medical therapy alone unless there is a complication such as spinal cord compression requiring open, decompressive surgery.

PART 6b – INFORMATION ABOUT THE INTERVENTION

- 27. Describe the key components and clinical steps involved in delivering the proposed medical service.**

1. Trial of conservative therapy by primary physician
- 2..Referral of suitable patients to an interventional Radiologist for assessment
3. MRI to confirm appropriate fracture
4. Vertebroplasty performed in an Interventional radiology suite either as an inpatient (If patient hospitalised already) or as an outpatient as a day surgery procedure.

28. Does the proposed medical service include a registered trademark component with characteristics that distinguishes it from other similar health components?

No

29. If the proposed medical service has a prosthesis or device component to it, does it involve a new approach towards managing a particular sub-group of the population with the specific medical condition?

Yes it involves using PMMA kits with complex delivery systems that are already listed on the prostheses schedule, to treat severely painful, acute osteoporotic vertebral fractures less than 6 weeks duration.

30. If applicable, are there any limitations on the provision of the proposed medical service delivered to the patient (i.e. accessibility, dosage, quantity, duration or frequency).

The patient should not have more than three vertebral levels treated at a single treatment session, for safety reasons. It is rare to have more than 2 acute (less than 6 weeks) vertebral fractures so few patients should require more than 2 levels injected anyway.

31. If applicable, identify any healthcare resources or other medical services that would need to be delivered at the same time as the proposed medical service.

Conscious sedation may be administered by the Interventional Radiologist if required

32. If applicable, advise which health professionals will primarily deliver the proposed service.

Interventional Radiologists

33. If applicable, advise whether the proposed medical service could be delegated or referred to another professional for delivery.

No

34. If applicable, specify any proposed limitations on who might deliver the proposed medical service, or who might provide a referral for it.

Providers should be restricted to Interventional Radiologists trained for Tier B procedures as per IRSA and RANZCR guidelines, including training in vertebroplasty. Rarely, other specialist such as pain physicians or spinal surgeons who can demonstrate training in Interventional Radiology spinal techniques, including vertebroplasty. Referrals should come from from a medical practitioner including General Practitioners who most frequently manage these patients in the acute phase.

35. If applicable, advise what type of training or qualifications would be required to perform the proposed service as well as any accreditation requirements to support service delivery.

Training in Interventional Radiology Tier B techniques (IRSA and RANZCR guidelines) including training in vertebroplasty.

36. (a) Indicate the proposed setting(s) in which the proposed medical service will be delivered (select all relevant settings)

Inpatient private hospital	<input checked="" type="checkbox"/>
Inpatient public hospital	<input checked="" type="checkbox"/>
Outpatient clinic	<input type="checkbox"/>
Emergency Department	<input type="checkbox"/>
Consulting rooms	<input type="checkbox"/>
Day surgery centre	<input checked="" type="checkbox"/>
Residential aged care facility	<input type="checkbox"/>
Patient's home	<input type="checkbox"/>
Laboratory	<input type="checkbox"/>
Other – please specify	<input type="checkbox"/>

(b) Where the proposed medical service is provided in more than one setting, please describe the rationale related to each.

Can be performed as an inpatient for patient's already hospitalised prior to referral for vertebroplasty or in a day surgery setting for outpatients. The Day Surgery centre would need to be equipped with a fluoroscopic Interventional radiology suite and these are usually only found in larger hospitals.

37. Is the proposed medical service intended to be entirely rendered in Australia?

Yes

X

No (please specify below)

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PART 6c – INFORMATION ABOUT THE COMPARATOR(S)

38. Nominate the appropriate comparator(s) for the proposed medical service, i.e. how is the proposed population currently managed in the absence of the proposed medical service being available in the Australian health care system (including identifying health care resources that are needed to be delivered at the same time as the comparator service).

Aside from vertebroplasty, only intensified and extended conservative medical measures are usually considered for the management of painful vertebral fractures that are unresponsive to initial medical management. For patients with osteoporotic fractures, conservative second-line management may include extended hospitalisation, increased dose of narcotic analgesics, imaging guided spinal injections of facet joints, muscle relaxants, heat treatments, anti-resorptive agents, falls prevention strategies, or bed rest followed by early mobilisation. Back bracing is rarely used in this fragile, often disabled population of patients. Physiotherapy is often used in the rehabilitation phase as the patient learns to gain confidence mobilising again particularly after prolonged bed rest.
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39. Does the medical service that has been nominated as the comparator have an existing MBS item number(s)?

Yes (please provide all relevant MBS numbers below)

X

No

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40. Define and summarise the current clinical management pathways that patients may follow *after* they receive the medical service that has been nominated as the comparator (supplement this summary with an easy to follow flowchart [as an attachment to the Application Form] depicting the current clinical management pathway that patients may follow from the point of receiving the comparator onwards including health care resources).

This application is for patients meeting eligibility criteria of age>60, vertebral fracture on x-ray, pain of severe level (NRS pain $\geq 7/10$) and duration for less than 6 weeks. First line treatment is medical therapy: analgesics including simple analgesics \pm opiates, rest followed by assisted mobilisation \pm physiotherapy. Some patients cope with the symptoms at home and others are hospitalised for pain control or due to loss of function. If symptoms are not adequately controlled with first line medical therapy then the dose of narcotic analgesic medication would be increased and if the patient is not coping at home, the patient may be hospitalised for pain relief and support. This can include hospitalisation of the partner if the afflicted patient is the carer. Referral to a specialist physician may occur. Early mobilisation is attempted often with the supervision of physiotherapy. Once the patient is able to start mobilising again, rehabilitation may commence to facilitate confidence with mobilisation and independence before discharge home. This may involve transfer of the patient to a specialist rehabilitation hospital.

If spinal cord compression occurs due to uncontrolled collapse of the fracture, then decompressive surgery may be required.

41. (a) Will the proposed medical service be used in addition to, or instead of, the nominated comparator(s)?

Yes	X
No	

(b) If yes, please outline the extent of which the current service/comparator is expected to be substituted.

Vertebroplasty will be used in addition to the current comparator of medical therapy. It may result in reduced duration of hospitalisation and analgesic use.

42. Define and summarise how current clinical management pathways (from the point of service delivery onwards) are expected to change as a consequence of introducing the proposed medical service including variation in health care resources (Refer to Question 39 as baseline).

The addition of vertebroplasty to usual medical therapy will add another potential therapy for patients with severe, uncontrolled (despite medical therapy) back pain due to acute (<6/52) osteoporotic fractures. This subgroup of elderly patients should be referred for consideration of vertebroplasty, undergo MRI imaging and if appropriate be offered vertebroplasty.

Vertebroplasty adds the procedure costs to the conservative clinical pathway. Vertebroplasty results in improved clinical outcomes in this patient group, causing reduced duration of hospitalisation (for patients hospitalised at the time of referral), causing a saving in health expenditures. There is also some reduction in analgesic use following vertebroplasty.

PART 6d – INFORMATION ABOUT THE CLINICAL OUTCOME

43. Summarise the clinical claims for the proposed medical service against the appropriate comparator(s), in terms of consequences for health outcomes (comparative benefits and harms).

The VAPOUR trial examined this directly on the advice of MSAC assessment 27.1 which described the requirement for such a trial. It shows clinically significant improvement in pain reduction, disability reduction, anatomic deformity of the fracture, and the duration of hospital stay for the defined subgroup of patients with severe pain treated with vertebroplasty within 6 weeks of fracture onset.

44. Please advise if the overall clinical claim is for:

Superiority	x
Non-inferiority	

45. List the key health outcomes (major and minor – prioritising major key health outcomes first) that will need to be specifically measured in assessing the clinical claim of the proposed medical service versus the comparator:

Safety Outcomes
Mortality is either reduced or equal with vertebroplasty (conflicting publications)
New fracture incidence is equal in conservative vs vertebroplasty
Risk of complication due to either natural history of fracture collapse (conservative therapy risk) and procedural complication (vertebroplasty group) is balanced
Clinical Effectiveness Outcomes
Reduced pain in vertebroplasty group at all time points from 3 days to 6 months
Reduced disability in vertebroplasty group at 1 month, 3 months and 6 months post intervention
Trend toward improved quality of life scores in vertebroplasty group
Reduced fracture deformity by 36% of vertebral height in the vertebroplasty group
Reduced duration of median hospital stay by 5.5 days in vertebroplasty group
Reduced analgesic use at 3 months and 6 months post vertebroplasty

PART 7 – INFORMATION ABOUT ESTIMATED UTILISATION

46. Estimate the prevalence and/or incidence of the proposed population.

This is a relatively small subgroup in the large population of patients with osteoporotic vertebral fractures. The prevalence is small but significant and includes most patients hospitalised with acute osteoporotic spinal fractures, and an almost equal number of outpatients.

47. Estimate the number of times the proposed medical service(s) would be delivered to a patient per year.

The majority of patients would require one vertebroplasty, but a minority will sustain another vertebral fracture in the same year. Some of these will not suffer severe pain with the new fracture but others will, so perhaps 10-15% of patients may benefit from another vertebroplasty in the same year.

48. How many years would the proposed medical service(s) be required for the patient?

It is a lifetime intervention for a particular episode, or fracture. It may need to be repeated in another vertebral level, were the patient to sustain another severely painful fracture in the future. Patients having sustained one painful vertebral fracture are at increased risk of future vertebral fractures although these may or may not present clinically with severe pain.

49. Estimate the projected number of patients who will utilise the proposed medical service(s) for the first full year.

Prior to removal of the interim MBS item number 35400 for vertebroplasty in November 2011, the MBS item number 35400 was used 667 times in Australia between July 2008 and June 2009 and 645 times between July 2010 and June 2011. As the current application targets a smaller sub-group of patients, with both severe pain (NRS pain $\geq 7/10$) and fractures less than 6 weeks duration, we would estimate annual use of MBS item number to be less than this, probably about 400-500 cases per year.

50. Estimate the anticipated uptake of the proposed medical service over the next three years factoring in any constraints in the health system in meeting the needs of the proposed population (such as supply and demand factors) as well as provide commentary on risk of 'leakage' to populations not targeted by the service.

The uptake would be estimated as above, 400-500 cases per year. These cases are already occurring in both the public and private hospitals. The public hospital patients can access the treatment for free due to Medicare not affecting public hospital practice. In the private hospitals, the patients are required to pay for the procedure themselves due to the link between Medicare and the health Funds. There is no difficulty in the system meeting these demand because it is already happening, and all necessary infrastructure is in place. Chance of leakage to non-targeted population is small given the history of modest usage of vertebroplasty when Medicare funding was available.

PART 8 – COST INFORMATION

51. Indicate the likely cost of providing the proposed medical service. Where possible, please provide overall cost and breakdown.

Additional work up imaging MRI spine schedules cost \$358. Procedure including prosthesis (\$500) and Medicare schedule fees (proposed Vertebroplasty fee of \$700 plus imaging fee MBS item 61109 of \$258.90), and theatre cost for one hour (estimate \$1,000), would be \$2,418/procedure. So total cost for vertebroplasty including work up imaging is \$2733. Likely saving of 5.5 hospital days for inpatients (estimated bed fees \$850/night) is \$4675. There are probably further savings in this inpatient group due to reduced imaging, medication, physiotherapy and ancillary costs inevitably accumulating for inpatients. Reduction in costs caused by spinal cord compression in the conservative group. Reduction in analgesic costs in vertebroplasty group.

Overall expenditure would be reduced for inpatients and there would be modest expenditure increase for outpatients. Overall projection of cost to the health system is roughly revenue neutral.

52. Specify how long the proposed medical service typically takes to perform.

Approximately one hour from patient entering the IR suite to leaving the suite.

53. If public funding is sought through the MBS, please draft a proposed MBS item descriptor to define the population and medical service usage characteristics that would define eligibility for MBS funding.

Category 3-therapeutic procedures
<p>Proposed item descriptor VERTEBROPLASTY, for the treatment of a painful osteoporotic vertebral compression fracture, where Patient aged >60 Pain is severe (numeric rated pain score ≥ 7 out of 10) Symptoms poorly controlled by analgesic therapy Severe pain duration <6 weeks MRI (or SPECT_CT if MRI unavailable) evidence of acute vertebral fracture</p>
<p>Fee: \$(700)</p>
<p>The fee has been calculated from previous fee prior to removal in 2011 plus CPI increase since then.</p>

PART 9 – FEEDBACK

The Department is interested in your feedback.

54. How long did it take to complete the Application Form?

Very time consuming to complete. Longwinded and lacking clarity. It could be abbreviated and more focused.

55. (a) Was the Application Form clear and easy to complete?

Yes

No

X

(b) If no, provide areas of concern.

It has redundant sections and tends to ask for the same information in different questions.

56. (a) Are the associated Guidelines to the Application Form useful?

Yes

No

X

(b) If no, what areas did you find not to be useful?

The explanation of the question most often just paraphrases the same question, adding no clarification

57. (a) Is there any information that the Department should consider in the future relating to the questions within the Application Form that is not contained in the Application Form?

Yes

No

X

(b) If yes, please advise:

1. Has this therapy been the subject of previous MSAC applications? In this case, vertebroplasty has been the subject of two prior vertebroplasty assessments. The latter actually gave rise to the VAPOUR trial which prompted this application, but it is impossible to mention that in this format.

2. Has the procedure been assessed by Health Technology Assessments in other countries (eg NICE guidance)