Australian Government

Department of Health

MSAC Application 1656

Vertebral body tethering for adolescent idiopathic scoliosis

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 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.

Email: hta@health.gov.au
Website: www.msac.gov.au

PART 1 – APPLICANT DETAILS

1. Applicant details (primary and alternative contacts)

Corporation name: Zimmer Biomet Pty Ltd
ABN: 96 096 480 992
Business trading name: Zimmer Biomet

Primary contact name: REDACTED

Alternative contact name: 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?

N/A

PART 2 – INFORMATION ABOUT THE PROPOSED MEDICAL SERVICE

3. Application title

Vertebral body tethering for adolescent idiopathic scoliosis

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

Scoliosis is defined as a lateral S- or C-shaped curvature of the spine in the coronal plane of more than 10°, as measured by the 'Cobb angle' (the angle between the most titled upper and lower vertebrae). In the younger population, 85% of scoliosis cases are idiopathic (of unknown cause) after excluding congenital, syndromic, or neuromuscular causes. The incidence of scoliosis is similar in males and females; however, females have up to a 10-fold greater risk of curve progression. Adolescent idiopathic scoliosis (AIS) refers to scoliosis in patients aged between 10 and 18 years. AIS may cause back pain and is associated with visible deformity, which in turn is associated with emotional distress and diminished self-image Surgery is typically recommended when the major thoracic Cobb angle exceeds 40°. If untreated, these curve progress into adulthood. Severe curvature may lead to respiratory impairment due to rib deformity.

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

Vertebral body tethering (VBT) is a form of scoliosis surgery that aims to preserve spinal mobility. It is a thoracoscopic, minimally-invasive technique in which screws are placed into the vertebral bodies (the thick oval segment of bone forming the front of the vertebra) on the convex side of the coronal deformity. The screws are placed into the middle of the vertebral body with bicortical purchase under fluoroscopic guidance. A high-strength, braided polypropylene tether is then placed into the screw heads and sequentially secured to each screw after segmental compression. The technique achieves immediate post-operative partial correction of the spinal deformity.

The pressure from the tether causes the vertebrae to grow denser and more slowly on the convex side of the curve, whilst the concave side of the spine continues to grow at a normal rate. As such, the spine gradually straightens as the patient grows.

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:

N/A

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

N/A

(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)

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

☐ Yes
☒ No

(g) If yes, please advise:

N/A

7. What is the type of service:

☒ Therapeutic medical service
☐ 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)*:

N/A

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

☐ Pharmaceutical / Biological
☒ Prosthesis or device
☐ 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?

N/A

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

N/A

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

N/A

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

N/A

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

☐ Yes
☒ No

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

N/A

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

☐ Yes
☒ No

(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
☐ No

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

Globus Medical (REFLECT™). However, the REFLECT™ cord (tether) is not on the Prostheses List.

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

Single use consumables: N/A
Multi-use consumables: N/A

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: Vertebral body tethering system (The Tether™)
Manufacturer's name: Zimmer Biomet Spine Inc
Sponsor's name: Zimmer Biomet Pty Ltd

(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
☐ AIMD
☒ N/A

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

☐ Yes (If yes, please provide supporting documentation as an attachment to this application form)
☒ No

(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 (if yes, please provide details below)
☐ No

ARTG listing, registration or inclusion number: 111775
TGA approved indication(s), if applicable: N/A
TGA approved purpose(s), if applicable: Implants used to stabilise, support or correct alignment of spinal vertebrae

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?

N/A

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?

N/A

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.***

The list below includes full papers (no conference abstracts) of VBT studies conducted in more than ten patients that are not superseded by more recent publications.

	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.	Observational study (retrospective and prospective)	IDE Study G150001 Food and Drug Administration (2019), The Tether™ - Vertebral Body Tethering System - H190005 – Summary of Safety and Probable Benefit	FDA registration study. Retrospective cohort study of 57 patients in the US with AIS (age ≥10 years), failure of bracing (>5° progression and/or intolerant), Lenke type 1 curve, MT Cobb angle 30-65°, thoracic scoliometer reading ≤20°, thoracic curve corrected to ≤30° pre-operative on supine or standing side bending radiographs, Sanders stage ≤5 or Risser stage ≤3, undergoing VBT. Primary outcome was change in MT Cobb angle. Clinical success defined as major curve Cobb angle ≤40° at 24 months. Follow-up was 2 years.	https://www.accessdata.fda.gov/cdrh_docs/pdf19/H190005b.pdf	August 2019
2.	Observational study (retrospective)	Hoernschemeyer DG, et al, 2020, 'Anterior vertebral body tethering for adolescent scoliosis with growth remaining – a retrospective review of 2 to 5-year postoperative results', J Bone Joint Surg Am; 102: 1169-1176	Retrospective cohort study of 31 patients in the US with AIS undergoing VBT. Primary outcomes were changes in the coronal Cobb angles (proximal thoracic, MT, lumbar). Clinical success defined as Cobb angles ≤30° at skeletal maturity. Mean follow-up was 3.2 years (range: 2 to 5 years).	https://pubmed.ncbi.nlm.nih.gov/32618924/	July 2020
3.	Observational study (retrospective)	Newton PO, et al, 2018, 'Anterior spinal growth tethering for skeletally immature patients with scoliosis – a retrospective look two to four years postoperatively', J Bone Joint Surg Am; 100: 1691-1697	Retrospective cohort study of 17 patients in the US with AIS, Risser stage 0, primary thoracic curve >40°, undergoing VBT. Primary outcomes were changes in the thoracic and lumbar Cobb angle, T2-T12 kyphosis, thoracic and lumbar ATR. Clinical success defined as residual curve <35° and no PSF indicated/performed. Mean follow-up was 2.5 years (range: 2 to 4 years).	https://pubmed.ncbi.nlm.nih.gov/30277999/	October 2018

	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 ***
4.	Observational study (retrospective)	Newton PO, et al, 2020, 'Anterior spinal growth modulation in skeletally immature patients with idiopathic scoliosis – a comparison with posterior spinal fusion at 2 to 5 years postoperatively', J Bone Joint Surg Am; 102: 769-777	Retrospective cohort study and matched cohort analysis of patients in the US with AIS, Risser stage ≤1, and primary thoracic curve 40-67° undergoing VBT (n=23) or PSF (n=26). Primary outcomes were changes in the upper thoracic, MT and lumbar Cobb angle, T2-T12 kyphosis, thoracic and lumbar angle trunk rotation (ATR), coronal imbalance, shoulder height difference, thoracic curve <50°. Clinical success defined as thoracic curve <35° and no PSF indicated/performed. Mean follow-up was 3.4 years (range: 2 to 5 years).	https://pubmed.ncbi.nlm.nih.gov/32379117/	May 2020
5.	Observational study (prospective)	Pehlivanoglu T, et al, 2020, 'Thoracoscopic vertebral body tethering for adolescent idiopathic scoliosis: a minimum of 2 years' results of 21 patients', J Pediatr Orthop; ePub ahead of print	Prospective cohort study of 21 patients in Turkey with AIS (age 9 – 14 years), Risser stage ≤2, Sanders stage ≤4, failure of bracing after ≥6 months, MT curve >35°, minimal curve flexibility 30%, undergoing VBT. Primary outcomes were changes in the major thoracic, proximal thoracic and compensatory lumbar curves. Mean follow-up was 2.3 years (range: 2 to 3.3 years).	https://pubmed.ncbi.nlm.nih.gov/32427800/	May 2020

AIS, adolescent idiopathic scoliosis; ATR, angle trunk rotation; FDA, Food and Drug Administration; IDE, Investigative Drug Exemption; MT, major thoracic; PSF, posterior spinal fusion; US, United States; VBT, vertebral body tethering

** 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.***

None identified

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 statement of clinical relevance from each group nominated):**

    Spine Society of Australia (letter to be forwarded separately)

    Scoliosis Australia

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

    As above

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

    Scoliosis Support Group – Australia (Facebook page)

    Curvy Girls – Australia https://www.curvygirlsscoliosis.com/

    Beyond Scoliosis https://beyondscoliosis.com/

    Setting Scoliosis Straight https://www.settingscoliosisstraight.org/

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

    Globus Medical.

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**

    Name of expert 2: **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), INTERVENTION, 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:

Scoliosis is defined as a lateral S- or C-shaped curvature of the spine in the coronal plane of more than 10°, as measured by the 'Cobb angle'. In the younger population, 85% of scoliosis cases are idiopathic after excluding congenital, syndromic, or neuromuscular causes. The incidence of scoliosis is similar in males and females; however, females have up to a 10-fold greater risk of curve progression. Adolescent idiopathic scoliosis (AIS) refers to scoliosis first identified in children when they are aged between 10 and 18 years.[1]

Without treatment, there is progression of scoliosis and the extent of spinal curvature, with the rate of progression being greater for more severe curves at the time of diagnosis. Natural history studies have shown that, untreated, thoracic curves greater than 30° progress on average by 19° over a 40-year period[2].

Although AIS may not cause significant pain, it is associated with visible deformity, which is associated with emotional distress and diminished self-image. Detrimental impacts on quality of life have been reported for self-image (and pain) domains for patients who do not undergo surgery for AIS[3]. Severe curvature (Cobb angle ≥40°) may also lead to impaired pulmonary function (shortness of breath) due to rib deformity, which may affect the ability to perform daily activities. There is no evidence of increased mortality with AIS[4].

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:

Patients with AIS are universally defined as having scoliosis (Cobb angle ≥10°) of unknown cause and aged between 10 and 18 years. Surgery – including VBT – is generally recommended for patients with a Cobb angle ≥40° who have failed conservative treatment such as external bracing. In the clinical studies of VBT presented in Part 4 of this Application Form, surgery was performed at a mean age of 12 years. Scoliosis which requires treatment is far less common in boys than in girls (a ratio of about 1 to 10).

The possibility of scoliosis is initially detected via 'outward signs' when the subject is standing, including: head not centred over body; one shoulder higher; one shoulder blade higher and possibly more prominent; unusual gaps between arms and trunk; spine obviously curved; one hip more prominent. The 'forward bend test' is subsequently used to clinically diagnose scoliosis. The adolescent stands with their feet together and parallel, and bends forward as far as they can go with their hands, palms facing each other, pointed between the big toes. With scoliosis, one side of the upper chest (thoracic) region or the lower back (lumbar) region will be more than one centimetre higher than the other.[5]

After a clinical diagnosis of scoliosis, x-ray examinations are performed at regular (e.g., four-monthly) intervals to measure changes in the patient's Cobb angle. External bracing is often used with the aim of maintaining the curve at an acceptable angle during the patient's adolescent growth phase. In suitable candidates who are compliant, the success rate with bracing in avoiding surgery is around 80%. It is

[1] Horne JP, 2014, Am Fam Physician;89(3):193-198
[2] Weinstein SL, 1983, J Bone Joint Surg Am;65(4):447-455.
[3] Rushton PRP, 2013, Spine;38(9):786-794.
[4] Weinstein SL, 2019, J Pediatr Orthop;39:S44-S46.
[5] https://www.scoliosis-australia.org/wp-content/uploads/Self-Detection_FactSheet.pdf

generally agreed that in skeletally immature patients, bracing is purposeful for patients with a Cobb angle between 20° and 40°, and where there is a documented progression of ≥5°. Surgery – including VBT – is indicated where bracing has failed to control curve progression and where the Cobb angle is at least 40°.[6]

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):

As described in Q25 above, the clinical management pathway before patients would be eligible for VBT sequentially involves:

1. Self-detection ('outward signs');
2. Forward standing test (clinical diagnosis);
3. X-ray examination (radiological diagnosis);
4. External bracing (where Cobb angle ≥30°);
5. Surgery (on failure of bracing and where the Cobb angle ≥40°).

Currently these patients typically undergo spinal fusion as discussed in Part 6c below.

PART 6b – INFORMATION ABOUT THE INTERVENTION

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

Vertebral body tethering to correct AIS is performed by an orthopaedic/spinal surgeon and general (access) surgeon. After the patient is administered general anaesthesia, the surgeons will access the spine through small incisions in the side of the chest. The surgeons then use a fibre-optic video camera to help place titanium screws into the convex side of the vertebrae. A flexible cable made of synthetic polymer ('tether') connects the screws and is secured along the side of the child's vertebrae. The tether is pulled taut, which then guides the child's future growth.

Typically, a patient will spend around one day in the intensive care unit (ICU) and a further four days in hospital before being discharged with oral pain medication.

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

The proposed medical service (VBT) does not include a registered trademark component.

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?

Vertebral body tethering is a less invasive approach to treating AIS compared with spinal fusion, and enables patients to retain a greater range of motion following surgery. Currently, spinal fusion is generally performed for patients with AIS who have failed conservative treatment (external bracing) and have a Cobb angle ≥40°. This is also the intended population for VBT.

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):

VBT is intended for patients who have not yet reached skeletal maturity. In most cases, the implants used in VBT do not need to be removed and remain in the child's spine throughout their lifetime.

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

No other healthcare resources need to be delivered at the same time as VBT.

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

An orthopaedic/spinal surgeon performs the VBT procedure.

[6] https://www.scoliosis-australia.org/about-scoliosis/adolescent-idiopathic-scoliosis

An assisting "access surgeon" may also be required for anterior exposure of the spine. This service is already covered by MBS items 51160 and 51165. The procedure is performed under general anaesthetic – therefore, an anaesthetist will be required (MBS item 20670).

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

The VBT procedure cannot be delegated.

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

There are no limitations on performing VBT beyond being qualified as an orthopaedic/spinal surgeon.

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:

There is no specific training or qualifications for surgeons for performing VBT beyond the general spine fellowship or post-orthopaedic speciality training.

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

- ☒ Inpatient private hospital (admitted patient)
- ☒ Inpatient public hospital (admitted patient)
- ☐ Private outpatient clinic
- ☐ Public outpatient clinic
- ☐ Emergency Department
- ☐ Private consulting rooms - GP
- ☐ Private consulting rooms – specialist
- ☐ Private consulting rooms – other health practitioner (nurse or allied health)
- ☐ Private day surgery clinic (admitted patient)
- ☐ Private day surgery clinic (non-admitted patient)
- ☐ Public day surgery clinic (admitted patient)
- ☐ Public day surgery clinic (non-admitted patient)
- ☐ Residential aged care facility
- ☐ Patient's home
- ☐ Laboratory
- ☐ Other – please specify below

The VBT procedure can only be performed on an admitted/inpatient basis.

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

The VBT procedure may be performed in a public or private hospital.

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

- ☒ Yes
- ☐ No – please specify below

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):

Currently patients in Australia with AIS and a major thoracic Cobb angle ≥40° despite bracing undergo spinal fusion. A bone graft (taken from the patient, bone bank or an artificial bone substitute) is used to fuse the vertebrae together. This is generally performed using the posterior approach (approaching the spine and making an incision in the back) and with pedicle screw instrumentation. Pedicle screws are

used to add extra support and strength to the spinal fusion while it heals, and are placed above and below the fused vertebrae. A rod is used to connect the screws which prevents movement and allows the bone graft to heal. After the fusion is completely healed, the screws and rods can be removed if they cause discomfort. No other healthcare resources need to be delivered at the same time as PSF.

39. Does the medical service (that has been nominated as the comparator) have an existing MBS item number(s)?

☒ Yes (please list all relevant MBS item numbers below)
☐ No

The MBS items for performing PSF in patients with AIS are:

MBS item # 50644

SPINE, bone graft to, for a child or adolescent, associated with surgery for correction of scoliosis or kyphosis or both

Fee: $2,174.85

MBS item # 50608

SCOLIOSIS OR KYPHOSIS, in a child or adolescent, treatment by segmental instrumentation and fusion of the spine

Fee: $3,534.05

MBS item # 50604

Scoliosis or kyphosis, in a child or adolescent, spinal fusion for (without instrumentation)

Fee: $1,902.65

MBS item # 50640

SCOLIOSIS, in a child or adolescent, congenital, resection and fusion of abnormal vertebra via an anterior or posterior approach

Fee: $2,254.05

40. Define and summarise the current clinical management pathway/s 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):

Following PSF, patients are typically discharged from hospital after five to seven days. These patients receive oral pain medication and typically have follow-up appointments at six, 12, 24 and 48 weeks (with further appointments as required to assess changes in scoliosis until the child stops growing). Some patients require a re-operation, primarily due to infection, symptomatic implants, pseudoarthrosis (failure of fusion), pedicle screw misplacement, or progressive deformity[7].

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

☐ In addition to (i.e. it is an add-on service)
☒ Instead of (i.e. it is a replacement or alternative)

(b) If instead of (i.e. alternative service), please outline the extent to which the current service/comparator is expected to be substituted:

Redacted

[7] Mignemi M, 2018, Spine Deformity;6:409-416.

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 clinical management pathway is expected to be similar following VBT compared to PSF. However, recovery time is expected to be quicker since the procedure is less invasive. Some patients may require a revision of their VBT procedure in the future to remove, replace or tighten screws, or to replace or adjust the tether. Patients who undergo VBT may eventually require spinal fusion if the initial procedure is not deemed to be successful (see Q41b).

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):

VBT is non-inferior to PSF for the management of AIS in terms of spinal curvature correction. VBT also has similar safety (adverse event rates) compared with PSF. However, quality of life is superior with VBT compared with PSF.

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

☒ Superiority
☐ Non-inferiority

45. Below, 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:
Overall adverse events (AEs) (rate)
Serious AEs (rate)
Infections (rate)
Neurological complications (rate)
Clinical Effectiveness Outcomes:
Absolute change in major thoracic (MT) Cobb angle (degrees)
Proportional change in MT Cobb angle ('correction', percentage)
Clinical success (as defined in each study, rate)
Change in proximal (upper) thoracic curve (degrees)
Change in lumbar (thoracolumbar) curve (degrees)
Thoracic angle of trunk rotation (ATR, degrees)
Lumbar ATR (degrees)
Healthcare Resources:
Surgical time (minutes)
Length of stay (days)
Secondary surgeries, including VBT re-operations and spinal fusions (rates)

PART 7 – INFORMATION ABOUT ESTIMATED UTILISATION

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

A review of 20 published studies from various countries in the Northern Hemisphere reports the prevalence of AIS (defined by Cobb angle ≥10°) amongst girls aged 10 to 14 years to be between 2% and 3%[8]. Scoliosis Australia also report this prevalence rate but also state that the prevalence of severe AIS (Cobb angle ≥40°) is only 0.1%[9].

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

It is anticipated that the VBT procedure would only be delivered once per patient. However, revisions to the index VBT procedure may be required in order to replace/tighten/remove screws or adjust the cord.

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

As noted above, it is anticipated that the VBT procedure would only be delivered once per patient. However, revisions to the index VBT procedure (e.g., cord or screw adjustments/replacement) may be performed up to the age at which the patient reaches skeletal maturity. Potentially, if there is substantial curve progression, a surgeon may remove the VBT construct and proceed to spinal fusion. It is also possible that the VBT construct may be removed after the patient reached skeletal maturity if the tether breaks, for example.

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

The number of PSF procedures for scoliosis claimed under the MBS can be used to estimate the number of patients who would be eligible for the proposed VBT service. In 2019, MBS items for spinal fusion of scoliosis were claimed 397 times as shown in the table below. Based on the five-year average service volumes for these MBS items, it is estimated that 471 patients would be eligible for the proposed VBT service in 2022. This may be an overestimate since the MBS volumes will include some repeat fusion procedures for the same patient.

Descriptor	MBS Item Number	2015	2016	2017	2018	2019
SPINE, bone graft to, for a child or adolescent, associated with surgery for correction of scoliosis or kyphosis or both	50644	298	257	287	260	224
SCOLIOSIS OR KYPHOSIS, in a child or adolescent, treatment by segmental instrumentation and fusion of the spine	50608	229	189	224	201	171
Scoliosis or kyphosis, in a child or adolescent, spinal fusion for (without instrumentation)	50604	2	2	0	1	0
SCOLIOSIS, in a child or adolescent, congenital, resection and fusion of abnormal vertebra via an anterior or posterior approach	50640	3	3	1	2	2
Total		532	451	512	464	397

Source: Services Australia (http://medicarestatistics.humanservices.gov.au/statistics/mbs_item.jsp, accessed 14 October 2020)

[8] Grivas TB, 2006, Scoliosis;1:9.

[9] https://www.scoliosis-australia.org/policies-programs/role-of-the-family-doctor

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:

Redacted. The eligible population in each year – defined by patients who currently undergo PSF (see above) – is assumed to increase in line with the underlying Australian population aged 12 years (mean age for performing VBT in patients with AIS). The underlying prevalence rate of AIS is not assumed to change over time. Redacted.

Year	2022 (Y1)	2023 (Y2)	2024 (Y3)
Eligible population	Redacted	Redacted	Redacted
Uptake rate	Redacted	Redacted	Redacted
VBT procedures	Redacted	Redacted	Redacted

Source: ABS population projections, Australia (Series B)

It is possible that there may be some leakage to of the service to children with early onset scoliosis (age <10 years) or to adolescents with Cobb angles less severe than those typically indicated for surgery (e.g. less than 40°) given the less invasive nature of VBT relative to spinal fusion.

PART 8 – COST INFORMATION

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

The estimated cost of the VBT procedure is provided in the tables below, which are separated into the MBS fees for the procedure (total = $4,923) and the proposed costs of the equipment (total = $42,571). The overall cost is therefore $47,494.

Cost Item	MBS Item #	100% MBS Fee	75% Benefit
VBT procedure (proposed fee)	TBC	$3,534.05	$2,650.54
Assistant*	51303	$706.81	$530.11
INITIATION OF MANAGEMENT OF ANAESTHESIA for extensive spine and/or spinal cord procedures	20670	$261.30	$195.98
Anaesthesia Time Units 3:11 to 3:20 hours	23116	$321.60	$241.20
FLUOROSCOPY using a mobile image intensifier, in conjunction with a surgical procedure lasting 1 hour or more	60509	$98.90	$74.18
Total		$4,922.66	$3,692.00

*Costs calculated from 20% of the fee of the VBT procedure

Description	Unit cost	Quantity*	Total cost
Vertebral body screws	Redacted	Redacted	Redacted
Anchor	Redacted	Redacted	Redacted
Cord	Redacted	1	Redacted
Total			Redacted

*Redacted.

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

The VBT procedure typically takes 3 – 3.5 hours[10].

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.

The proposed item descriptor for the VBT procedure is provided below.

Category 3 – Therapeutic Procedures – Surgical Operations
Proposed item descriptor: SCOLIOSIS, in a child or adolescent, anterior correction of, with vertebral body tethering Proposed fee: $3,534.05

The existing MBS item 50616 is believed to already cover revisions to the index VBT procedure. However, a proposed item descriptor (a modification of MBS item 501616 with the same fee) is provided below if required.

Category 3 – Therapeutic Procedures – Surgical Operations
Proposed item descriptor: SCOLIOSIS, in a child or adolescent, re-exploration for adjustment or removal of ~~segmental instrumentation~~ vertebral body tethering instrumentation used for correction of spine deformity Proposed fee: $3,534.05

[10] Newton PO, 2020, J Bone Joint Surg Am;102:769-777.