Private Healthcare Australia
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Reforms to the Prescribed List Part B

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About Private Healthcare Australia

Private Healthcare Australia (PHA) is the Australian private health insurance industry's peak representative body. We have 24 registered health funds throughout Australia as members and collectively represent 98% of people covered by private health insurance. PHA member funds provide healthcare benefits for over 14 million Australians.

Response

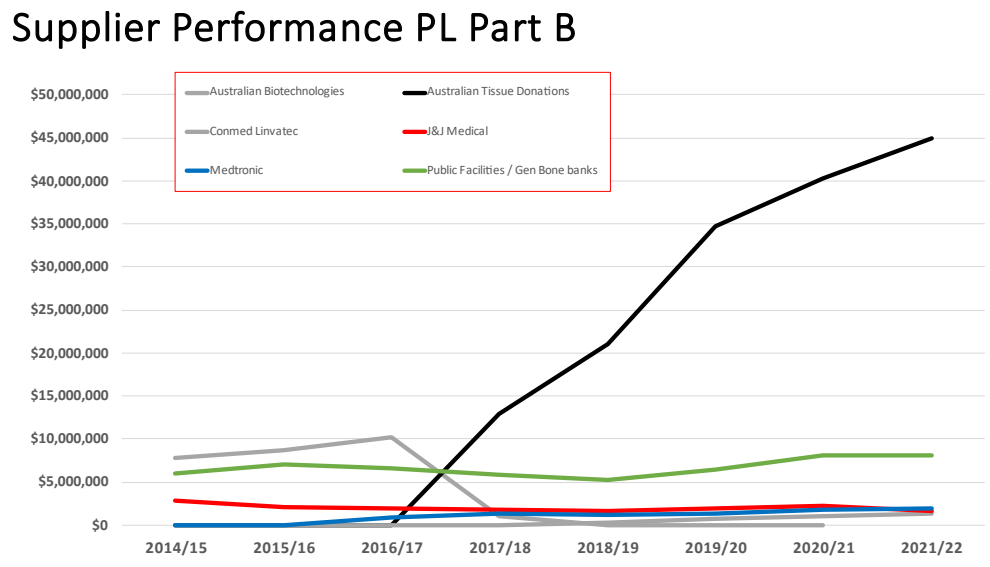
PHA welcomes the opportunity to contribute to the review of Part B of the Prescribed List of Medical Devices and Human Tissue Products.

4. Do you agree with the proposed definition for Part B products? If you DO NOT support Recommendation 1, please explain why. If possible, provide alternative options for definitions.

Yes.

However, highly processed material, which in many cases is imported by a for profit biotech company and delivered through a not for profit (NFP) group such as Australian Tissue Donations Network remains a different type of commercial operation to genuine NFP local tissue banks who seek to support clinical needs.

Commercial processing, distribution and marketing of human tissue products should be treated the same way as other commercial products on the Prescribed List (PL). Over just six years, the billing from commercial operators of human tissue products has grown from less than $10 million to more than $45 million per annum.



Competitive neutrality principles suggest that products supplied by commercial operators should be removed from Part B and considered for inclusion in Part A of the PL. This would likely include a health technology assessment to determine if the massive increase in cost for operations using allograft (predominantly spinal surgery) provide value to the consumer.

5. Do you support Recommendation 2- that the Department consider whether the exemption from fees associated with Part B of the PL be restricted to Sponsors of Class 2 biologicals or Sponsors who are registered as a not-for-profit entity with the Australian Taxation Office? If you DO NOT support Recommendation 2, please explain why. If possible, provide alternative options for exemptions from fees.

Yes, with an amended definition proposed below.

PHA support the delineation between for profit entities and genuine NFP suppliers. We note that one commercial player, Australian Biotechnologies, now owned by EBOS, is invoiced through a NFP group in Australian Tissue Donation Network (ATDN), yet packaging is marked as Australian Biotechnologies. This commercial company is also indicated as the contact with all inquiries relating to invoicing and technical matters, not ATDN.

To ensure proper assessment for exemptions from fees, PHA recommends that sponsors be required to declare that all elements of the supply chain for human tissue products be registered NFL entities.

Under this proposed definition, we suggest that products sponsored by ATDN would be excluded from Part B, and thus assessed through Part A.

6. As per Recommendation 3 – do you agree with the updated structure for Part B products? (see Part B Proposed regrouping structure). If you DO NOT agree with this structure, please explain why. If possible, provide alternative options.

Yes.

7. Do you support Recommendation 4- that the Department establish a regular review process of the Part B groupings? If you DO NOT support Recommendation 4, please explain why. If possible, provide suggestions for a review process.

Yes.

8. Do you support Recommendation 5- that the Department proceed with implementing the three assessment pathways which mirror the pathways for Parts A and C of the PL? If you DO NOT support Recommendation 5, please explain why and, if possible, provide alternative assessment options.

Yes.

Genuine donor centre tissue labs have traditionally offered support on tissue they generate, often on demand, to meet a unique patient need. Donor labs are unlikely ever to be able to deliver the documentation and HTA analysis required to submit adequate evidence for a Tier 2 or Tier 3 application.

By contrast commercial operators generating substantial revenue through Part B with a trading entity of a NFP or are part of large global organisations that often have substantial Part A listings are suitably geared to completing these applications. Should the Department agree that Part B be reserved for genuine NFPs throughout the supply chain, then consideration should be given to providing a lighter touch approach to assessment pathways for Part B.

9. Do you support Recommendation 6- that the Department provide additional support and guidance for Sponsors of Class 2 biologicals to navigate HTA pathways? If you DO NOT support Recommendation 6, please explain why. If possible, provide suggestions of the type of support and guidance that you would find useful.

Yes, with caveats.

Health funds want to ensure products used by members have had appropriate clinical review consistent to their application and risk. However, the Department should not be assisting global multinationals that are likely to be conducting similar assessments in multiple jurisdictions, nor local for-profit entities even when associated with a NFP donor centre for transactional purposes. Again, ensuring Part B is reserved for products where the entire supply chain is not for profit.

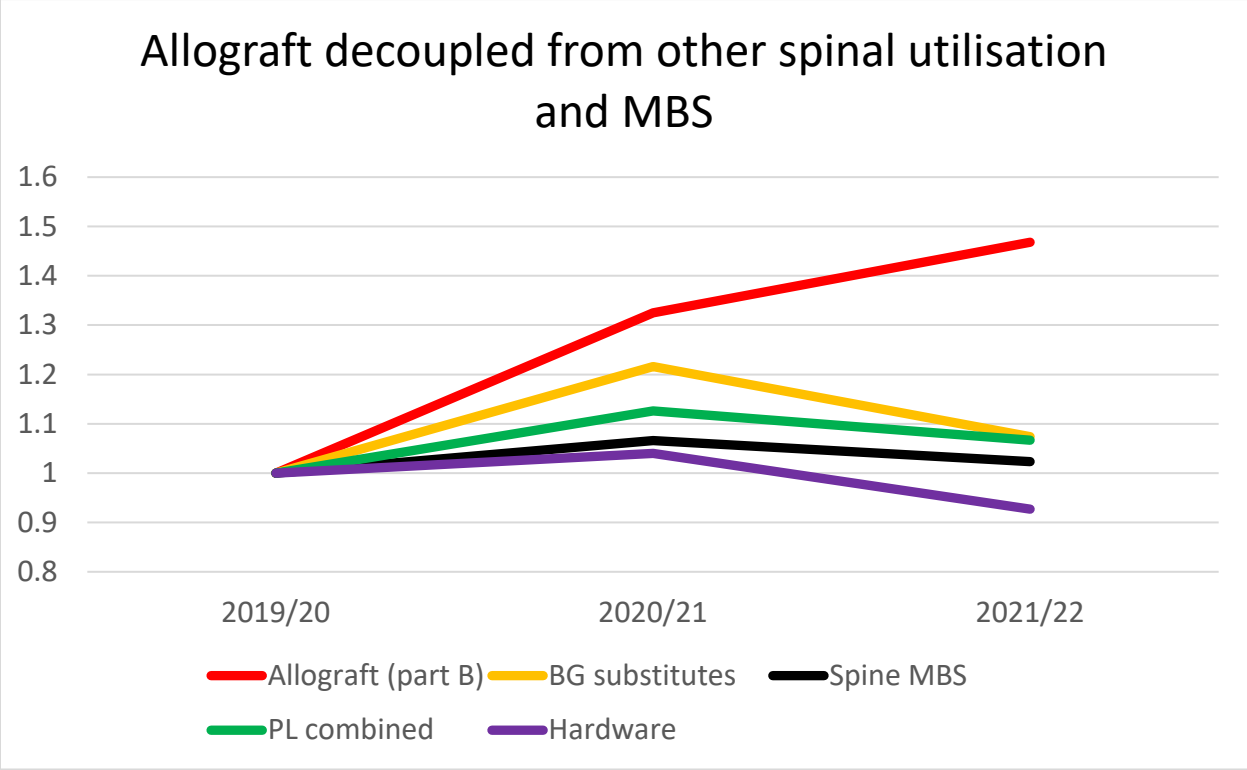
10. Do you support Recommendation 7- that the Department undertake further work on the methodology for pricing including the development of costing standards? If you DO NOT support Recommendation 7, please explain why. If possible, provide suggestions for a methodology for pricing.

Yes.

There has been a fundamental change in the use of human tissue products in Australia, concurrent with the rise of ATDN/ Australian Biotechnologies/EBOS as a dominant supplier in the market since 2016.

More people are receiving human tissue products, and many people are receiving very large volumes of human tissue products as part of their procedure.

With flat to declining spinal and orthopaedic procedures over this time, the Department needs to investigate why the use of human tissue products has grown so quickly. PHA have been unable to locate specific clinical guidelines or studies (such as Cochrane Reviews) that would have so rapidly changed clinical practice.



This rapid change in clinical practice means the cost-benefit analysis for human tissue products must have changed. PHA recommends that any supplier with for-profit elements in the supply chain be removed from Part B of the PL and assessed through Part A. Given the very large volumes of human tissue products used and the very high consumer cost, this is likely to involve Medicare Benefits Advisory Council (MSAC) assessment.

Although spinal registries remain underdeveloped compared to others, there should be enough evidence on procedures such as spinal fusions between public and private cases (and within private cases) to determine the cost effective value of the substantive levels of bone graft in use, and whether the varying volume quantities and spend added real value for patients. For example, understanding the difference in spend on bone graft and bone graft substitutes within the private sector for a category of spinal version compared to the same category of spinal fusion (i.e. single level / two level) between public and private may be illustrative.

11. Do you support Recommendation 8- that the Department undertake a review of state and federal legislative requirements which prohibit trading in human tissue and its application to determining benefits for Part B? If you DO NOT support Recommendation 8, please explain why.

Yes.

PHA support the decision by the Department to look into the legislation at state and federal level in trading of human tissue. The rapid rise in trading of human tissue products raises a range of concerns, particularly if for-profit entities are sourcing product from overseas.

12. Do you support Recommendation 9- that the Department retain the PL items for autologous skull flaps and femoral heads? If you DO NOT support Recommendation 9, please explain why.

No.

We do not support this in principle. While we note there is a cost in taking in an autologous skin flap and retaining it, this is not a prostheses or a third party tissue item, and as such should be funded outside the PL. The PL should not be used to support funding for harvesting a patient's own tissue. This does not meet the definition of the PL and creates a precedent that would be difficult to contain.

13. Do you support Recommendation 10- that the Department does not pursue restricting the use of Part B items to specific MBS items at this time? If you DO NOT support Recommendation 10, please explain why.

No.

The Australian Government restricts the use of Medicare, of pharmaceuticals and other products to clinically relevant and cost-effective indications. There is no policy justification for treating medical devices differently to pharmaceuticals.

The Australian Government has taken a greater interest in addressing low value care in recent years, including a 2023-24 Budget initiative to improve the integrity of the Medicare Benefits Schedule. It is incongruous to aggressively target low value care in some areas but not others.

14. Do you support the proposed restructure of Part B (attached)? If you DO NOT support the proposed restructure of Part B, please explain why and, if possible, suggest alternative options.

Yes.

15. Any additional comments on the PwC report (optional)

We thank the department for extending its Prescribed List review to include Part B. However, we are not convinced the approach taken by PwC and the Department in this review is fully cognisant of the massive change in clinical practice in this area. This change in clinical practice seems associated with the growth of one specific supplier entity, and the use of human tissue products has become decoupled from the surgeries that they are involved with. This would appear to be creating further low value care in spinal surgery, a surgical discipline that already has less consistent outcomes to many other surgical disciplines.

The trade in human tissue products in Australia has changed, with very large sums of money involved – taken from consumers through legislated benefits through the Prescribed List. Income for one entity has increased from less than $10 million per annum to over $45 million, with no oversight of the commercialisation of the supply chain, where the human tissue product is coming from, and where the money is going.

Meanwhile, patients are being given much more human tissue product in aggregate, and some individual patients are being given very large quantities of human tissue products in their procedures. Clinical guidelines have not changed, but clinical practice has.

The rise of a new commercial model has been associated with large changes in clinical practice, which have the potential to increase low value care, to endanger patients and corrupt the traditional market of not-for-profit tissue banks.