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Medical Devices Branch
Therapeutic Goods Administration
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Consultation: Proposed reclassification of spinal implantable medical devices

TGA team,

Thank you for the opportunity to provide input to the above consultation on behalf of the Private Health Insurance Industry (PHI) and their peak body Private Healthcare Australia (PHA).

Private health funds are the custodians of members' contributions and these are limited by affordability. As with all health system funding, these funds are a public good and are constrained. Our members expect that medical devices are safe and effective and implicitly place expectations on PHI funds to be a representative for them within health sector delivery. We thank the TGA for recognising this critical issue but also delivering proposed measures that are not onerous on manufacturers and sponsors within the spinal device category.

We support all aspects of this proposed consultation and change. Through this process spinal implants will be appropriately recognised for their risk classification, in particular the longevity of these implants which must be relied upon by patients. This up-classification to Class III will place spine in a matched regulatory status as devices used in joint replacement surgery. Further, this alignment is consistent with the cooperation between Europe via the CE body and the TGA.

The higher level of device recording/reporting associated with class III along with the separately proposed UDI inclusion would significantly reduce time and cost associated with many recalls. Private health insurers would also be in a position to provide greater input on impacted members to the regulator and device companies. Though not specific to this consultation PHA would also like to suggest that greater free access data is published on device performance from the Spine Society Registry as occurs today with the NJRR.

It is critical that device constructs are measured through an independent registry that partners with the TGA to identify devices with higher than anticipated revision rates at either a manufacturer or surgical procedure level. PHA and PHI funds remain concerned that there may be "over servicing" of members in spine surgery due to the funding models in place when compared to other international jurisdictions. From an HTA perspective we want to ensure that low value care is not perpetuated by current reimbursement mechanisms.

In addressing the specific questions provided:

1) *What impacts—including any that are unintended—do you anticipate the proposed reclassification may have for yourself and other stakeholders (such as consumers, healthcare professionals, health organisations, industry etc.)?*

As the peak body for private health insurers the impact to PHA is limited. We support the up-classing of these devices in line with European/TGA harmonisation. As the vast majority of suppliers offer products globally we do not foresee this change as onerous on the manufacturers and sponsors. The inclusion of UPI and ideally UDI will provide greater visibility in cases of device performance and potential product recall.

2) *Are there any further issues and questions we should consider when implementing this change (including areas that can/should be clarified in our guidance)?*

As indicated, introducing agreed device performance analysis and reporting through the Spinal Registry should be considered to time with the proposed changes. The NJRR provides valuable ongoing insight to the TGA in identifying devices with higher than anticipated revision rates. Arguably spinal surgery would be more advantageous to be tracked in this way; not only individual devices would be recorded but categories of surgery could be reviewed for their efficacy.

3) *Do you have any comments/views regarding defining the scope of medical devices that should be covered by the term 'spinal implantable medical device'?*

While PHA support the proposed changes, we note the complexity and criticality of poly axial spinal "screws," which may or not transition to Class III in this process. It would appear they are classified as ancillary devices, yet from our experience are critical to success of the system or surgery.

4) *Do you have any comments regarding exemption of implantable screws, wedges, plates and instruments from the proposed new classification rule?*

Per above, the complexity, cost and load bearing characteristics of modern advanced poly axial screw would indicate they should be considered for inclusion.

5) *Do you have any comments regarding the transitional arrangements proposed in this paper?*

Given the market is predominantly supported by global multinational manufacturers through direct or agency sponsors we would expect these entities are already engaged in the European up classing requirements. We do support from a cost saving perspective the alignment of products/categories with Europe; from prior experience Australian deviations to global requirements are genuinely onerous and often involve specific cost that is passed on in some form to the Australian health system.

Thank you again for the opportunity to contribute to this consultation.

Best Regards

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Craig Moy
Director of Access & Reimbursement
On behalf of Private Healthcare Australia and the Private Health Insurance Industry member funds