Australian Government
Department of Health, Disability and Ageing

Consultation Paper 10 – General use items utilisation, expenditure and integrity

Stakeholder feedback high level summary

Introduction

The Department of Health and Aged Care (the department) has received a range of stakeholder responses to Consultation Paper 10 – General use items (GUI) utilisation, expenditure and integrity.

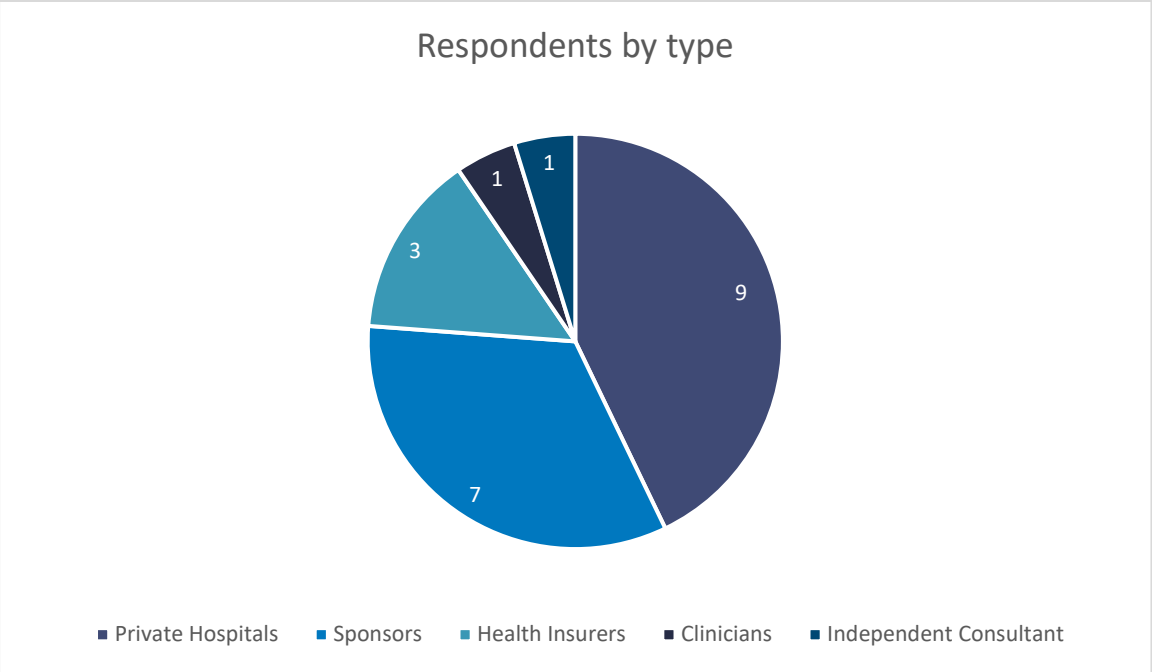
Stakeholders have shared their perspectives on the challenges and opportunities presented by the current PL settings, offering recommendations to ensure that any growth in the use of GUI is aligned with enhanced patient outcomes.

This high-level summary highlights common matters raised by several stakeholders. It is not an analysis of stakeholder submissions but rather provides a high-level summary of the feedback received and should be read in conjunction with the individual submissions on Consultation Hub.

This summary does not reflect the department's position on any of the matters raised nor does it pre-empt any decisions of the department or the government.

This feedback is crucial as we continue to refine our approach to managing GUI, balancing the need for cost-effective healthcare while maintaining the standards of patient care.

Figure 1: Number of respondents to Consultation Paper 10 by stakeholder group



We received a total of 21 submissions to the consultation, from the following stakeholder groups: 9 from private hospitals, 7 from sponsors, 3 from insurers, and 1 each from clinicians and an independent consultant.

Key matters

There are a range of views on the most pressing matters related to integrity, utilisation and expenditure of GUI. A few stakeholders claimed that there is insufficient evidence

demonstrating issues with the current PL settings in relation to GUIs. And that any growth in expenditure and utilisation is due to clinical need.

However, other stakeholders believe that there is uncontrolled increase in GUI utilisation and expenditure with no measurable improvement on patient outcomes.

Engagement with clinicians, education and data accessibility were recognised as the best ways to address concerns of integrity and growth in utilisation and expenditure.

Please note: matters that are not directly related to integrity, usage and expenditure have been considered but are not included in this report.

Summary

Consultation Question	Stakeholder Response
1. What do you see are the key areas of concern for the integrity of the PL settings in the context of the GUIs?	The private health insurance (PHI) sector is concerned about the current PL settings for GUIs, claiming they encourage inefficient use of GUIs; "gaming" to maximise the use of higher benefit items; and claiming for unqualified or unused items. As a result, GUIs are excessively utilised, not used efficiently, costly and lacking in transparency. PHIs state that the usage of some items grew suddenly following their listing, suggesting the increase is driven by their availability on the PL rather than clinical need/benefits. They suggest this increase occurred even when surgery rates remain flat, with no measurable improvement in patient outcomes. PHIs also pointed other concerns, including some from the Ernst & Young report (EY report) related to integrity: • utilisation being skewed towards more expensive items, even if cheaper alternatives are clinically sufficient • the risk of claims for GUIs that don't qualify for a PL rebate or weren't used in the related surgery • no limit to the number of GUIs used • no auditable evidence of their use • differences in price do not correspond to quality or features • the process to add or remove items from the PL is complex and challenging • actual data on usage and growth is not transparent or shared, with very little competition among suppliers. Most other stakeholder groups believe that there is insufficient evidence and stakeholder engagement to support claims of system-wide integrity issues. In their view, these claims rely on anecdotal evidence.

Consultation Question	Stakeholder Response
	Private hospitals (hospitals) rejected judging integrity based solely on GUI utilisation and expenditure without clinician input, emphasising that medical practitioners, not hospitals, decide on GUI utilisation. Hospitals' main concern about integrity is with insurers denying funding at the time of claiming for already used GUIs. For example, hospital claim insurers refuse to pay when there are catalogue number mismatches; or insurers having different interpretations of 'acceptability' criteria. Hospitals believe these actions by insurers violate PHI regulations, lack transparency, and increase administrative and financial burdens on hospitals. Sponsors identify the main integrity issues are restrictions on listing new technologies and insurers' refusal to fund PL items.
2. If you were to prioritise options for improved integrity, what order would deliver the most meaningful outcomes?	The key topics identified as a priority for improved integrity to deliver meaningful outcomes were: • increasing transparency • improving data availability (e.g. more data on GUI use and trends per episode of care) • education and guidance (e.g. best practice guidelines; providing feedback to clinicians to help them understand the cost implications of their decisions) • engagement/collaboration with clinicians (e.g. engaging clinical peak bodies to promote resource efficiency; engaging clinicians to understand changes in utilisation). Separately, hospitals argue that payment delays and disputes should be prioritised due to the burden on the system. They point out that GUI use is driven by medical practitioners, not hospitals, and hospitals shouldn't bear the cost. PHIs suggested implementing an enforceable code of conduct for the medical device industry and fixing errors on the PL as a priority to improve integrity.

Consultation Question	Stakeholder Response
	Sponsors believe that there is no evidence to support claims of lack of integrity in clinical decisions, so no action is required.
3. What are some potential system-based actions that could be taken to improve integrity? • By who and when? • How would you suggest the success of these actions is measured? • What are the likely consequences – positive/negative and who would they affect?	There were a few suggestions for system-based actions to improve integrity, including: • implementing audit mechanisms for Medicare Benefits Schedule (MBS) and PL claims • implementing mechanisms to incentivise efficient utilisation and minimising waste • enhancing regulatory oversight by fact-checking advice to insurers and reporting non-payment instances • creating an independent authority to investigate structural issues and handle claims and ensure patient safety • engaging IHACPA to review billing codes annually or periodically • benchmarking annual benefits for GUI items to surgery rates and review PL billing codes • mandating rebate disclosure and annual tendering for equivalent items • conducting price reviews • introducing price/volume agreements for GUIs, based on the Pharmaceutical Benefits Schedule (PBS) model

Consultation Question	Stakeholder Response
	• introducing an activity-based funding model, where GUI are included only if they provide real clinical value, with annual adjustments to keep spending aligned with surgery levels • an expenditure cap for hospitals with high GUI usage unless certified necessary by a doctor • reviewing price differentials and adjusting prices when the gap between volume and surgery rates widens. The department was recognised as the main driver of system-based actions. Clinicians, including those from the AMA, were identified as the main sources of data and clinical insights. MDHTAC was proposed to lead a governance group, with the Australian Commission on Safety and Quality in Health Care (ACSQHC) helping to gather evidence. It was also suggested that insurers contribute by reporting issues and sharing data. The positive consequences of implementing some of the suggested system-based actions are enhanced trust and collaboration among stakeholders. And a reduced risk of fraudulent claims and misuse of PL benefits. On the other hand, these actions could result in administrative burdens and costs for stakeholders. And potential unintended consequences if any action is implemented without careful consideration. Any system-based action may increase workload for the department, insurers, and suppliers, leading to a heavier reliance on the public health system. Success could be measured through effective monitoring, transparency in rebates, and competitive pricing. As well as reduced payment delays and fewer payment rejections. Some stakeholders indicated that system-based actions to improve integrity are not required. Because there is insufficient evidence that there are system-wide issues with integrity related to GUI utilisation.
4. Are there specific sub-categories of GUIs on the PL that represent concerning areas of	Insurers identified specific sub-categories of GUIs where utilisation growth exceeds the underlying surgery rate, with no clear clinical benefit. These include haemostatic devices,

Consultation Question	Stakeholder Response
growth in utilisation per episode of care that are driving increases in benefit expenditure?	internal adhesives, adhesion barriers, staples & tackers, infusion pumps, and dura defect repair items. Insurers claim that this growth is often driven by their availability on the PL rather than changes in clinical needs, leading to higher costs without corresponding clinical benefits. Some statistics PHIs use to support their claims include a 12.9% volume growth in GUIs in 2017/18 despite flat surgery volumes. Insurers also note the cost of some GUI use has doubled over a five-year period. For example, internal adhesives, including skin glues and matrix products, rose from $27.2 million in 2014 to $73.3 million in 2019. There's no evidence that patient outcomes improved during this time. There is also a claim that utilisation for GUIs that are not implantable or cannot be seen on an x-ray have increased over the last decade. This increase does not match the growth in surgery rates. A separate claim is that GUI that can be used for several purposes, come in various forms, and don't have clear or detailed records of how they're used, are more likely to be overused and wasted. Neither sponsors nor hospital groups identified subcategories of GUIs as having concerning growth in utilisation. They both argue that changes in clinical practices and adoption of new technology that improve patient outcomes are generally the drivers of growth in utilisation. There was a claim that while the Australian Prudential Regulation Authority (APRA) data shows an increase in GUI utilisation per episode of care, the overall amount paid in benefits for these items by insurers has fallen 17.8% since 2017. Sponsors also noted that IHACPA's report of December 2022 showed that for staples & tackers, benefits per episode increased by ~1.5% annually, benefits per item by ~0.5%, and items per episode by ~0.9% over a four-year period. In their view, this data suggests concerns about increasing use are unfounded. Both sponsors and hospitals agree that any increase in utilisation and expenditure should be clinically warranted. They indicated their willingness to work with the department to address instances where this is not the case.

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	A hospital group noted that data previously released by the department showed a downward trend in both GUI utilisation and benefit paid per episode of care. For instance, from 2019 to 2022, GUI utilisation per episode of care decreased from 2.90 to 2.64, and the benefit paid per episode of care dropped from $635.58 to $557.77. These figures contradict claims of increased utilisation and wastage. Additionally, some stakeholders highlighted they lack data and/or expertise to be able to assess changes in GUI utilisation patterns by sub-category and provide meaningful insights.
5. Are there specific types of procedures/episodes of care that represent higher growth in utilisation based on standard of care/clinical practices?	Stakeholders provided examples of procedures for which growth in utilisation was a result of changes in clinical practice: • the trend in bariatric procedures shifting to sleeve gastrectomy, which is now the standard of care, meant a switch from gastric bands to staples, haemostats and sealants, increasing their utilisation • colorectal surgery clinical guidelines support laparoscopic colorectal resections due to better patient outcomes. This has resulted in increased use of cannula tubes, special surgical tools and staples and sutures • the Enhanced Recovery After Surgery (ERAS) protocols, which aim to improve surgical outcomes and speed up recovery, have led to higher utilisation of staples & tackers • the National Bowel Screening Program, which has increased diagnostic procedures, patient complexity and new surgical techniques has contributed to increased GUI utilisation • gastroenterology uses a significant number of GUIs, such as haemostatic clips during polyp removal procedures • insurers implementation of penalties for adverse events and re-admissions led to an increase in use of haemostats and sealants

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	• the COVID-19 pandemic was recognised as a source of irregular changes in utilisation patterns through surgery delays and workforce changes Some stakeholders noted that other factors besides the relationship between type of procedure and growth in utilisation should be considered. For example: ageing population, changing patient complexity, higher incidence of conditions, better diagnostics, technological advancements, shorter surgeries and early discharges. They believe the current PL settings provide flexibility for optimal patient outcomes as clinical practices evolve. Additionally, some stakeholders highlighted they lack data and/or expertise to be able to assess changes in GUI utilisation patterns by type of procedure and provide meaningful insights.
6. If there are concerns that the growth in utilisation is not related to clinical need, how is this determined/measured? Who can validate this?	Data analysis and engagement with clinicians were identified as the main ways to determine/validate growths in utilisation not related to clinical need. Growth could be measured by looking at use metrics, clinical outcomes, and costs. And by comparing growth, benchmarking, and looking at international use trends. Organisations like IHACPA, healthcare providers (e.g. clinicians), regulatory bodies, and research institutions could help validate the assumptions and facts. Another suggestion was to publish volume data by PL billing code, similar to the statistics provided by Services Australia for the MBS and the PBS. There was a proposal to establish an independent authority to investigate claims of inappropriate use or wastage. And another proposal to introduce routine monitoring at both the hospital and procedure levels to review the behaviour of sponsors and hospitals. In terms of engagement, hospitals mentioned that GUI utilisation is a clinician decision, and can vary depending on the practitioner, location, and speciality. So, any concerns need to be addressed directly with the clinicians and their representative bodies. A few

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	stakeholders agree that any review of increased utilisation should involve clinicians, to understand whether utilisation is clinically justified. Insurers note that the EY report is substantial enough to warrant an investigation into whether the use of GUI is always driven by clinical needs. However, other stakeholders argue that this report is outdated and, in some cases, unsubstantiated claims of overutilisation.
7. What system-based mechanisms are either in place or need to be put in place to address this problem? • Would these mechanisms be different if there was a demonstrated clinical need? • Would a national index that benchmarks the usage per episode of care (based on the IHACPA bundled benefit work) provide a reasonable measure from which to determine actions to adjust the PL benefits per grouping?	Education and data availability were recognised as tools that could help address concerns in this area. Education could come in the form of developing clinical guidelines for GUI use based on best practices. And by providing ongoing education and training for healthcare providers on GUI utilisation. In terms of data availability, most stakeholders agree that increasing data transparency would benefit all stakeholders, as current data is not sufficient or available. For instance, currently, HCP data is not shared, and APRA data is difficult to interpret because of historical issues with the 'Other' category. Stakeholders also suggest that data could be made available to hospitals and clinicians to improve education and behaviour. There was a suggestion to publish average GUI utilisation data by episode type, jurisdiction, hospital type, and specialty. This would help identify and discuss above-average use with clinicians and could encourage behavioural change without pressure. Other system-based mechanisms suggested included: • implementing transparency in the Health Products Portal (HPP) to show what items are covered by PL rebate codes • designing a mechanism whereby if the number of GUIs increases faster than the number of surgeries, the price of GUIs should be reduced accordingly • establishing robust utilisation review processes

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	• creating a mechanism to lower GUI prices if the gap between surgery rates and volume widens too much, regularly review GUI use to ensure it meets clinical needs and benchmarks and establish a collaborative governance group • introducing price/volume agreements for general use items, like the PBS model. If item use increases by more than 10% in a year (adjusted for surgery volume), reduce the price by 10%. In terms of a national index, some stakeholders agree it could be a measure used to determine actions. The index could also be provided to hospitals and clinical societies to improve education. However, its success would depend on the factors considered to calculate it. Stakeholders noted the index should focus on patient outcomes and informed decisions. Another view is that a national index would only work if its goal were to achieve efficient procurement and reduce surgical waste. Other stakeholders argue that benchmarking utilisation per episode of care could lead to access and equity issues due to variations in clinical practices. It would impose limits on utilisation that could risk patient outcomes. Also, while benchmarks can highlight anomalies, they do not account for the unique circumstances clinicians may face during surgery.
8. How would you suggest the success of these actions are measured?	Hospitals believe the focus should be on tracking utilisation and making data-driven policy decisions. Beyond this, they believe measuring success is challenging due to evolving practices and technologies. They suggest a start would be by benchmarking GUI data and identifying best practices. Research papers on appropriate GUI utilisation, especially for new items, can be very helpful. Implementing plans with clear KPIs and milestones, and comparing GUI utilisation quarterly, could provide valuable insights. Using a uniform data set to track utilisation and costs is also important. Other suggestions include:

Consultation Question	Stakeholder Response
	• ensuring GUI items remain on the PL guarantees access to the best outcomes. Maintaining PL rebate codes ensures traceability and transparent billing, and including part numbers in these codes aligns with ARTG requirements • transparency can be improved by providing volume data by PL billing code, like MBS and PBS • creating a live reporting system to monitor usage patterns. An independent clinical body could review this data to identify low-value care and exclude it from funding • invest in uplifting and maintaining the PL and comparing GUI volume growth with surgery growth rates • all price increases should demonstrate a public benefit case and clinicians should be informed of common PL item prices to help them make cost-aware decisions • if hospitals use GUI much more than peers, full rebates should only be given if doctors certify the use is reasonable.
9. What are the likely consequences – positive/negative and who would they affect?	Negative consequences of implementing system-based actions include increased administrative burdens and higher costs for hospitals. Excessive compliance could undermine clinical needs and increase costs for patients. Private hospitals might struggle to serve the sickest patients due to negative cost recovery, increasing reliance on public health system. Complications of clinicians not using GUIs due to policy limitations would place strain on the public sector as these patients would most likely return to public hospitals. Sponsors and hospitals believe that the current PL settings benefit insurers through reduced length of stay, reduced post-operative complications and patient satisfaction due to private hospitals using available best outcome items. Any introduced limitations could restrict clinician choices, harm patient care, and raise out-of-pocket costs, making private health insurance less valuable. This might lead to more people dropping their coverage.

Consultation Question	Stakeholder Response
	Stakeholders also noted that reopening GUI reform could divert attention from more pressing issues. Some of the positive consequences of implementing some of the system-based mechanisms suggested by stakeholders include better financial agreements, improved data collection, better patient outcomes and transparent billing. Additionally, appropriate and efficient GUI utilisation would reduce waste and optimise resource allocation. Stakeholders identified other specific positive consequences for specific system-based mechanisms suggested.
10. Are there other areas of concern with the retention of GUIs on the PL that need to be considered?	There were a few other matters raised by stakeholders. Sponsors noted that restrictions on including new groupings on Part D hinder the introduction of innovative items that could improve costs and patient outcomes. They emphasise the need for flexibility in applications for Part D listings to allow for innovation and new technology. Otherwise, they believe Australian private patients are at risk of being left behind. Sponsors and hospitals emphasised that the appropriate use of medical technology, including GUI should be at the clinician's discretion. They argue that limits on GUI utilisation and expenditure should not be decided or imposed by non-clinical organisations, as they could jeopardise patient outcomes. Hospitals reiterated that capping or bundling GUIs is not practical. Hospitals highlighted the lack of data transparency from insurers, which hinders the identification of significant growth areas. They call for insurers to provide proper evidence of integrity issues before any action is taken. Hospitals argue that high utilisation rates can be justified if they lead to better health outcomes and cost savings in the long run. Hospitals mention the importance of retaining GUIs on the PL as they are not covered by the national procedure banding schedule and are not used in every procedure.

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	Hospitals believe there are positive impacts of retaining GUIs on the PL and this should be highlighted through an impact analysis. Some stakeholders highlighted issues with the definition of GUI. The fact that there is no consistent definition of GUI in Australia's health system leads to different interpretations. Hospitals also mention the lack of certainty about government policy on GUIs as an integrity concern, highlighting risks to clinical utilisation and patient care due to health insurers' record profits. There was mention that the PL is not an appropriate mechanism to introduce utilisation controls on medical devices. There was a request to revisit the review of staples & tackers, directly consulting with relevant clinical societies and MBS data to inform their specific use.

Next Steps

After considering all matters raised by different stakeholder groups, there is no substantive evidence to merit implementation of system-based mechanisms. However, there were some clear actions that can positively influence integrity:

- improve data accessibility and transparency
- education on GUI utilisation and waste management

We will explore implementation of these two actions.

Additionally, we will investigate addressing concerns of growth at the grouping level, engaging clinicians to understand whether the growth is clinically warranted.

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All information in this publication is correct as of April 2025