APACMed Submission

on

NHA Consultation Paper on Payments and Price Setting under Ayushman Bharat PM-JAY Scheme in India

S. No	Section Name	Identified questions (as indicated in the Consultation Paper) on which inputs are sought	Suggestions/ Comments
1.	Provider Payment Mechanisms And PMJAY	Appropriateness of current structure of case-based provider payment system under PM-JAY.	• GST amount on medical devices should be reimbursed separately on top of the current implant prices in AB-PMJAY. • Provision of co-payment for upgrading the implants
2.	International experience of case-base payment schemes and price determination	Suitability of DRG based payment system for PM-JAY to make HBP prices sensitive to patient characteristics such as age, gender, co-morbidity etc.	• The DRGs payment policy in Korea has decreased LOS and readmission rates. These findings support the continued implementation and enlargement of the DRGs payment system. When the DRG system in India is implemented, it could be calibrated using such indices which can encourage technologies which reduce LoS & readmissions and ensure better utilization of healthcare resources. *(Ref: Choi, J.W., Kim, SJ., Park, HK. et al. Effects of a mandatory DRG payment system in South Korea: Analysis of multi-year nationwide hospital claims data. BMC Health Serv Res 19, 776 (2019). https://doi.org/10.1186/s12913-019-4650-8)* • To adjust patient characteristics in the reimbursement pricing, commercial Insurance claims data can also be used as a reference.
3.	Looking To The Longer Term: Diagnosis Related Groups	Willingness/Acceptance for participation among empaneled hospitals for proposed data collection through 'Transaction Management System'.	• There could be a separate WTP for devices in critical patient groups e.g. oncology and transplant similar to end of life care drugs which have indication based pricing/indication specific pricing. • The magnitude of clinical benefit and value of a technology may vary substantially across indications, which can complicate pricing strategies. Healthcare systems that assign a single price for health technologies

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			across all indications and sub-populations of interest, regardless of differences in value, have the potential to discourage development of therapies for high-value areas and increase barriers to treatments. Indication-specific pricing (ISP) of health technologies, however, may better align reimbursement with value.eg: ISP may help healthcare systems better align reimbursement of biopharmaceuticals to their value, but its adoption in key markets is varied. Indication-specific patient registries in Italy allow for differential pricing across indications of a single product. In France, Germany, and the UK, multi-indication products have a single weighted-average price that reflects the product's value across indications. Similar approach is desirable in India for critical innovative products used in multitude of complex indications which are usually carried out in critical care. (Ref: Campbell D. Indication-specific Pricing: What should manufacturers expect in key markets. HTA Quarterly. Winter 2017. Jan. 19, 2017. https://www.xcenda.com/insights/htaq-winter-2017-indication-specific-pricing)
4.	Using Health Technology Assessment for Value-Based Pricing: Health Financing and Technology	1) Proposed framework for value-based pricing of newer packages under PM-JAY	• Principles of value-based pricing of drugs are different from devices. This needs to be identified and included in the guidelines. In devices learning curve, carbon footprint, overall price of therapy of care delivery need to be monetized when the value of products are determined in addition to clinical outcomes and quality of life. Furthermore, resource utilization needs to be taken into account when high end or special medical devices with better features are compared to products which are more affordable but of inferior quality. • The framework spans a broad range of value drivers and does not solely focus on the cost or clinical impacts. The framework takes into account

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	Assessment (Hefta) Unit		four value drivers, including clinical, non-clinical factors important to patients, care delivery economics, and societal impacts. (Ref: https://www2.deloitte.com/us/en/pages/life-sciences-and-health-care/articles/value-framework.html) • Online portal should be established to facilitate proposal submissions to the NHA by healthcare stakeholders. It should also have provisions to expedite the evidence-gathering step by serving as an open, centralized platform for stakeholders to share additional data. • HTA outcomes should be informed to the proposers and there should be a provision of re-application with additional data in case of rejection. • To expedite the evaluation process, HEFTA should consider the HTA reports conducted by the proposer for evaluation/review. The requirement and dossier format should be clearly stated by the payer. • Methodology, clinical inputs, and cost inputs used in the HTA process should be evidence-based and inclusive. • Based on innovation level, medical devices can be classified into three categories: Me-too, incremental innovation, and disruptive innovation. Proposals should be allowed for improved reimbursement under the existing category as well. • The proposed framework appears robust, however a provision for emergency requests or procedure prices which require immediate attention may also be defined.
		2) Process of price negotiation for high end	• **"Special devices"** superior to existing items based on evidence from randomized controlled trials, meta-analyses, or cohort studies may gain up to 40% payment — the highest balance-billing ratio from NHI; however, for cases with only control studies, international conferences with peer reviews, or case series (=10 cases), the balance-billing ratio

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		drugs, consumables and drugs and implants	from NHI is less than 20%. In other words, items supported by more clinically beneficial evidence can receive more health insurance benefits from NHI, resulting in patients paying less, while items with insufficient documentation for clinical effectiveness will remain in self-pay markets. In addition to the clinical evidence submitted by the manufacturer, high-value balance-billing items are evaluated through HTA to ensure their clinical effectiveness and safety while providing patients with cost-effectiveness for special medical device items. (Reference: Tsai, Hsin-Yi, et al. "The reimbursement coverage decisions and pricing rules for medical devices in Taiwan. "GMS Health Innovation and Technologies 16 (2022). • Price negotiation process should be more inclusive with the industry as a key stakeholder and price should not be the only decision criteria for final approval.
		3) Operational framework for inviting nominations, appraisals, timelines for revisions etc.	• Nominations should be in a standardized template for online submission of proposals and a check-point to ensure a proposal meets all requirements before submission to avoid review delays downstream. • Prioritization process should be clearly defined. More preference to be given to the technologies which are well established clinically including life-saving technologies • Evaluation should be on a rolling basis instead of an annual basis. The NHA portal may remain open throughout the review process to allow submitters to upload new or updated data, and to maintain device pertinence during the periodic review of the reimbursement list in subsequent years. • The whole evaluation and subsequent approval should align with the annual health budget allocation process and cycle.

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			• The new unit should ensure a more balanced public and private participation in the evidence synthesis, evaluation, and appraisal of novel therapies. Public stakeholders are understandably cautious about the incremental cost of newer medical technologies, so there needs to be reliance on the private sector to contribute valuable insights on their cost-effectiveness given the sector's tendency for earlier adoption. And clinical societies could be a good alternate and a fair and balanced representation of public and private.
5.	HBP Price Revisions Based on Inflation	Appropriateness of proposed method (or rate) for adjusting the PM-JAY packages prices for inflation.	It is not clear if the revision policy will be applicable to medical technologies also. If yes, NPPA revises the price of selected consumables/drugs/devices based on the wholesale price index every year. The inflation adjustment is not static but varies every year. The same process can be considered by NHA**.**
6.		*General Remarks*	• Lifetime cost of disease burden is directly associated with lifetime cost of treatment including medical devices and therefore it would be a progressive step to look into Health Economics Driven Reimbursement models for medical devices. • Explore and encourage discussions on formulating process and procedure on how to get newer technologies into HTA. • HTA decisions pertaining to technology should reflect broad views of value, as assessed from multiple stakeholders' perspectives and over the entire care continuum. As we experience rapid innovation, our evaluation methodologies need to also evolve to be more pragmatic and adaptive to accommodate future novel technologies.