

## PP17 Rare Diseases: An Analysis Of Assessments Carried Out By The National Committee For Health Technology Incorporation In Brazilian Public Health System (Conitec)

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**Introduction:** The treatment of rare diseases has been a challenge for the Brazilian Unified Health System. In addition to the high costs of treatments, the characteristics inherent to this type of disease bring weaknesses to the scientific evidence of efficacy and safety. The National Committee for Health Technology Incorporation In Brazilian Public Health System (Conitec) is formed by a plenary of experts who monthly assess demands for incorporation into the public health system.

**Methods:** This exploratory, descriptive, and retrospective study aims to gather qualitative and quantitative data on criteria considered by healthcare decision-makers from Conitec and analyzes which rare diseases were benefited by the commission recommendations. Data from June 2012 to November 2022 were collected from the Conitec website to a specific extraction form and analyzed using descriptive statistics.

**Results:** A total of 763 technologies were evaluated from June 2012 to November 2022, with 158 being drugs for rare diseases. Among these, those with the highest number of diseases benefited were multiple sclerosis 13.3 percent (n=21), cystic fibrosis 6.3 percent (n=10) and pulmonary hypertension 5.7 percent (n=9). About 70 (44.3%) technologies were incorporated into the Unified Health System to treat rare diseases. In these incorporations, 25 technologies initially had an unfavorable recommendation, and only after the public consultation they were recommended for incorporation. Reasons that contributed to this change in recommendation were the new scientific evidence presented (64%), new negotiation of the drug price (28%), and new budgetary impact by revising the calculation of the target population (8%).

**Conclusions:** The criteria for evaluating technologies for rare diseases are similar to those adopted for other clinical conditions. However, it is important to adopt specific criteria in analysis of drugs targeted at diseases considered rare for the population. Negotiating prices with industry is an important factor that was highlighted, potentially favoring access to new treatments that can modify the progress of these diseases.

## PP18 Unlocking The Potential Of Medical Device Reimbursement In India For Better Health Outcomes

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**Introduction:** The Indian healthcare landscape has witnessed several promising changes including the introduction of a comprehensive medical technology inclusion process, Diagnosis-related group (DRG)-pilot and value-based incentives for hospital services under the national public health insurance scheme. Realizing the need for a more patient-centric stance towards improving healthcare outcomes as the way forward, we propose incremental changes including greater participation of public and private care-providers in topic prioritization and the appraisal committee. We also propose a unique evidence-driven approach using reimbursement as a lever for rewarding quality and innovation in medical technologies.

**Methods:** We developed two discussion guides to capture the ideas around deeper involvement of care-providers and patient societies, and introduction of value-based reimbursement for incentivizing high-quality implantable medical devices in India. The guides were prepared using secondary research and key informant interviews. Over 25 key stakeholders representing payers, regulatory agencies, government authorities, clinical experts, and industry players selected through quota sampling participated in a roundtable meeting. Based on the meeting outcomes, key recommendations for leveraging medical device reimbursement for better health outcomes were developed.

**Results:** This qualitative research was carried out with participation of key stakeholders across the medical device reimbursement process. The group proposed recommendations for bringing care-providers closer to the process through a structured and inclusive nomination approach involving therapy users and patient groups at various stages of evaluation. Complementing the existing value-based incentives framework for hospital services, we proposed a similar two-step pathway for incentivizing quality of implantable medical devices. The proposal includes the introduction of certification-based and outcome-based incentives built on a scientific and holistic evaluation criterion.

**Conclusions:** Through this process, we created a pragmatic and concrete call for a stronger voice from care-providers and patient groups in the evaluation process. Consecutively, the proposed innovative framework introducing value-based incentives for implantable medical devices will be instrumental in enabling access to quality health care to poor patients. These strategies follow the principles of value-based care and will go a long way in achieving better health outcomes for the population. The scientific initiative has been made possible with the support of St. Jude Medical India Pvt Ltd. (now Abbott).