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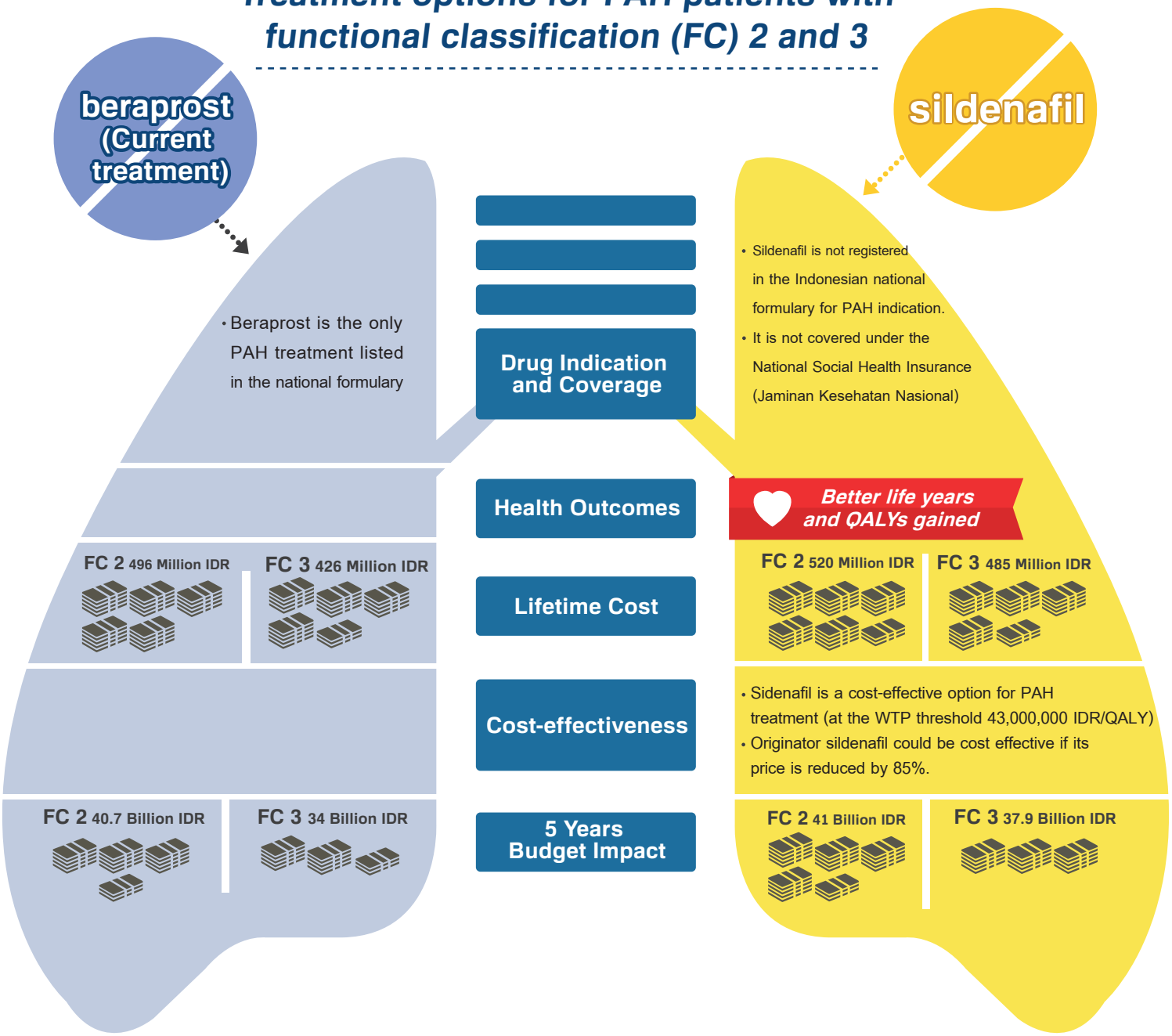
POLICY BRIEF

Health Technology Assessment on Sildenafil as Treatment for Pulmonary Arterial Hypertension (PAH)

Sildenafil is a treatment option for PAH patients that is found to offer an additional 1-3 life years gained for PAH patients compared to beraprost, currently the only treatment available in the benefit package under the National Social Health Insurance (Jaminan Kasehatan Nasional - JKN) of Indonesia. Off-label use of sildenafil for treatment of PAH is recommended to be included in the benefit package. The study results indicate that there is a need for the Ministry of Health in Indonesia to consider the use of off-label medicines in the benefit package given the strong Health Technology Assessment evidence showing the drug's benefit to the Indonesian population.

Treatment options for PAH patients with functional classification (FC) 2 and 3



Sildenafil and PAH in Indonesia

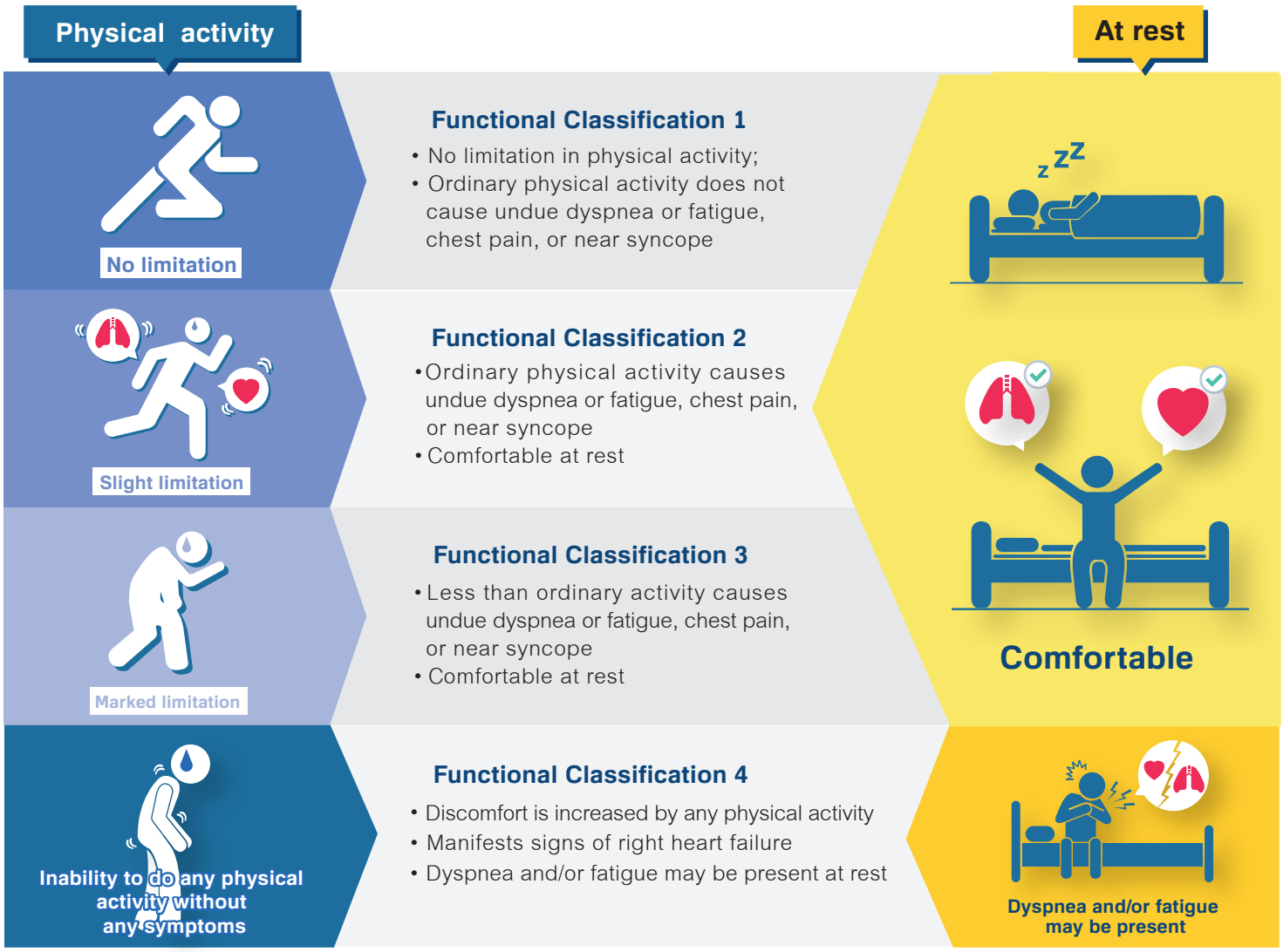
Pulmonary Arterial Hypertension (PAH) is a progressive disease characterized by an increase in pulmonary arterial pressure which can ultimately lead to right heart failure and death. Currently, there is an estimated number of 500 cases in Indonesia. The drug, sildenafil, is regarded by local clinicians as a better treatment than the current available treatment for PAH in the national formulary, beraprost. However, companies have not registered sildenafil with the National Agency of Drug and Food Control (Badan Pengawas Obatdan Makanan - BPOM) for this indication. Several studies have indicated that sildenafil is clinically effective in treating PAH. Additionally, it is not included in the benefits package of the National Social Health Insurance (Jaminan Kasehatan Nasional - JKN). Its use for the PAH indication is off-label as it is only approved for the treatment of erectile dysfunction.

Policy Implications of Sildenafil for PAH

To assess the cost-effectiveness and budget impact of adopting sildenafil to the benefit package compared to beraprost, this study was commissioned by the Indonesian Health Technology Assessment Committee. Using a societal perspective, a model-based economic evaluation and budget impact analysis of using sildenafil as the first line treatment for PAH patients in Functional Class (FC) 2 and 3 was conducted. The results of this study can be expected to inform the coverage decisions under the National Social Health Insurance (JKN).

Functional Classifications of PAH

The clinical severity of PAH is graded by the functional status of the patient. The grades range from Functional Class (FC) 1 to 4.[1]



[1]The system is developed by the New York Heart Association (NYHA) and modified by the World Health Organization (WHO)

Cost-Utility

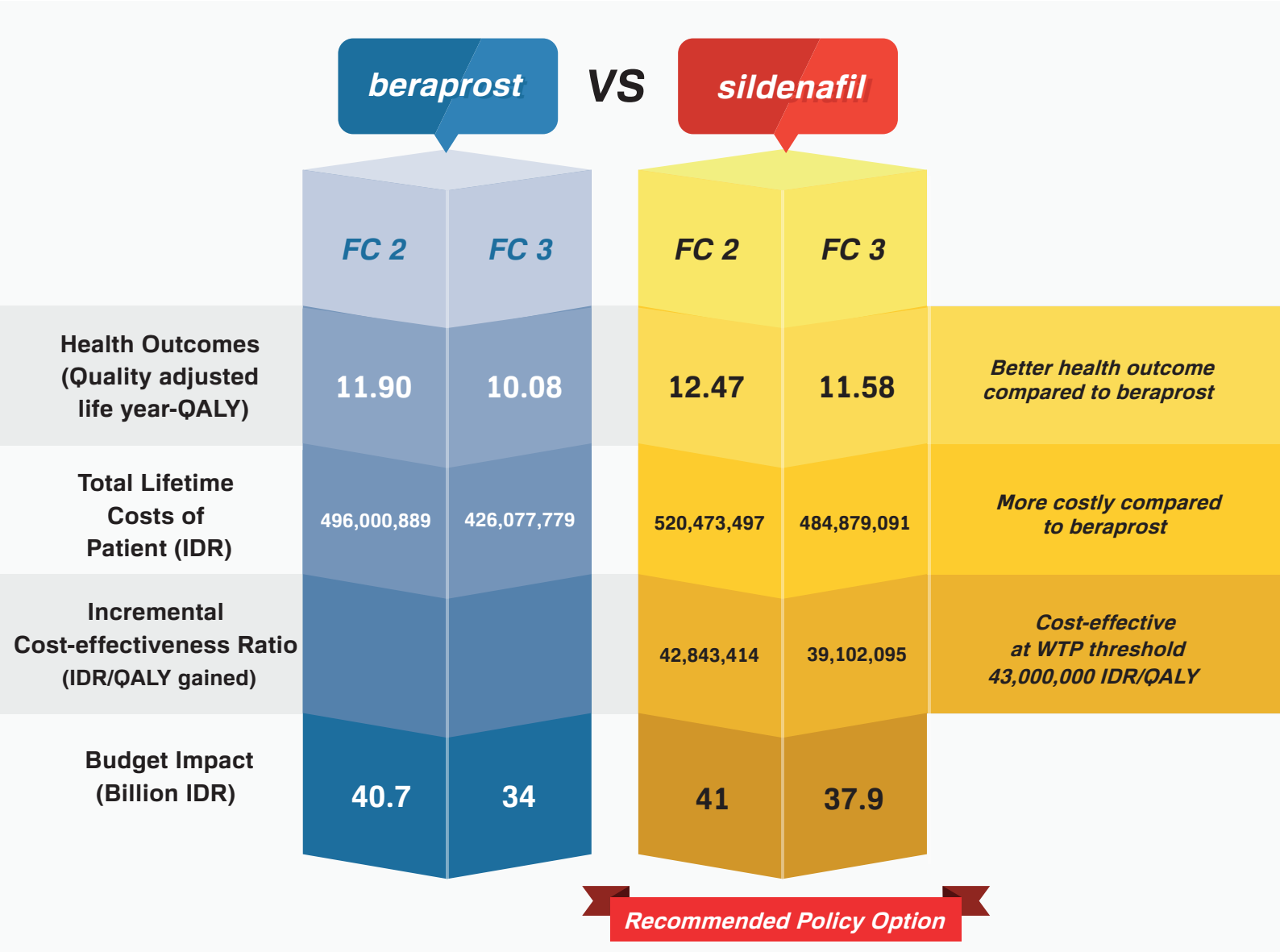
The results indicate that FC 2 patients treated with sildenafil were found to have 0.57 more Quality Adjusted Life Year (QALY) gains compared to beraprost, where one QALY gain entails a one year gain of the patient in perfect health. On the other hand, FC 3 patients treated with sildenafil reported to have 1.51 more QALY gains compared to beraprost.

Although sildenafil is reported to have better health outcomes, the study also indicates that it is more costly than beraprost. Despite this, the incremental cost of providing sildenafil as first line therapy when compared to beraprost is only by a margin of IDR 24 Million for FC 2 and IDR 59 Million for FC 3. Therefore, the measure used for cost-utility, which is the incremental cost-effectiveness ratio (ICER) value or the incremental cost associated with one additional unit of QALY for sildenafil compared to beraprost, is found to be IDR 42,843,414 and IDR 39,102,095 for FC 2 and FC 3 patients respectively.

To assess whether the cost can be absorbed by the health system, the willingness to pay (WTP) per QALY gained is used as a threshold of cost-effectiveness. Given that Indonesia is yet to establish a threshold, the study used the value of one GDP or IDR 43,000,000 per QALY gained as the WTP threshold. The ICER for both FC 2 and FC 3 patients are below the WTP threshold and as such, sildenafil becomes cost-effective.

Budget Impact

The study also analyzed the budget expenditure required in the future if sildenafil at the generic drug price were to be included in the benefit package under the JKN. Given a five-year projection, it is determined that IDR 41 Billion and IDR 37.9 Billion will be the total cost for FC 2 and FC 3, respectively. When compared to beraprost, the incremental budget is only by a margin of IDR 300 Million and IDR 3.9 Billion for FC 2 and FC 3 patients, respectively.



Policy Recommendations

- The Healthcare and Social Security Agency (Badan Penyelenggara Jaminan Sosial Kesehatan - BPJS Kesehatan) should include sildenafil as the first line treatment for PAH in FC 2 and FC 3 in the benefit package.
- The Ministry of Health should request local and international pharmaceutical companies to provide 20mg tablet of sildenafil to be available in Indonesia (instead of only 100mg tablet, which is used for other indications).
- The case of sildenafil can be used to reexamine the inclusion of off-label medications to the benefit package. Given strong HTA evidence that the drug is highly beneficial to the Indonesian population, then its inclusion in the benefit package should be strongly considered.

Policy Impact

After the completion of the study and consideration of high-level stakeholders and officials, sildenafil went through rapid approval from the pharmaceutical regulatory agency, Badan Pengawas Obat dan Makanan or Badan POM (Indonesia's National Agency of Food and Drug Control), to be registered for the PAH indication in Indonesia. Sildenafil is now part of the national formulary and can be reimbursed through the universal healthcare coverage scheme. However, off-label medicine use in Indonesia remains a policy issue and iDSI and ADP are supporting local scholars to find a long-term policy solution.

Acknowledgement

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For more information on this study, please go to *www.globalhitap.net/projects/idsi-indonesia*

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