Methods. A total of 656 HTA appraisals from 6 European countries were collected for NASs that received regulatory approval between 2012 and 2020. Multivariable logistic (positive and positive with restrictions vs. negative HTA recommendation as dependent variable) and linear regression (rollout time as dependent variable) models examined associations with regulatory orphan designation, expedited process, product type (biotechnological vs chemical), and jurisdiction (France, England, Germany, Poland, Scotland and Sweden). Rollout time was defined as months elapsed from regulatory submission to HTA recommendation (mean± standard deviation).

Results. Multivariable logistic regression analysis identified disparities in HTA recommendations between countries. Every month increase in rollout time conferred a 3 percent reduction in the odds of a positive recommendation (p<0.001). Review and product type did not show associations with HTA recommendation. Interestingly, orphan products showed a 99% increase in the odds of obtaining a positive HTA recommendation compared to non-orphan (p-value=0.003). We found 244 appraisals (37%) assessing an orphan product, of which 202 (83%) received a positive HTA recommendation.

Multivariable linear regression analysis indicated that orphan products presented a 4.4-month rise in rollout time when compared to non-orphan products (p<0.001). The mean rollout time in months for orphan products were 25±12 in France, 30±15 in England, 21±9.1 in Germany, 37±16 in Poland, 25±12 in Scotland and 27±14 in Sweden.

Conclusions. Orphan designated products showed greater odds of receiving a positive HTA recommendation compared with non-orphan. A more detailed review of orphan products could result in their longer rollout time compared with non-orphan counterparts. Considerable differences were found between HTA recommendations and rollout times between jurisdictions.

PD48 Does Unmet Need Influence The Scottish Medicines Consortium Health Technology Assessment Decisions For Rare Disease Conditions?

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Introduction. The Scottish Medicines Consortium (SMC) defines end-of-life medicines as drugs used for treating conditions that usually lead to death within three years using currently available treatments. Orphan medicines are drugs used for the treatment of very rare conditions and ultra-orphan drugs are used for the treatment of extremely rare conditions. The objective of this study is to determine the influence of unmet need on SMC health technology assessment (HTA) decisions for rare disease conditions.

Methods. The reimbursement data between 2004 and 2021 from SMC for rare disease conditions were included. These data were categorized based on the presence of an unmet need, that is, drugs considered under the orphan or ultra-orphan process, or those that fulfilled SMC end-of-life criteria. A chi square test was conducted to determine an association between the presence of an unmet need and the HTA decision. HTAs without a decision were excluded.

Results. A total of 91 HTAs were included in the analysis of which, 57.1 percent (n = 52) were recommended, and 42.9 percent (n = 39) were not recommended. Out of the recommended reviews, 32.7 percent (n = 17) addressed an unmet need and 67.3 percent (n = 35) did not. Recommended drugs had positive clinical evidence and high cost-effectiveness or the submission of a patient access scheme while negative decisions were associated with lower or uncertain cost-effectiveness. The chi square test result showed no association between the presence of an unmet need and the HTA decision (p = 0.315).

Conclusions. Unmet need does not influence the SMC HTA decisions for rare disease conditions. Economic elements were the driving factors in the decision-making process.

PD49 Burden And Cost Of Anterior Cruciate Ligament Reconstruction And Reimbursement Of Its Treatment In Indonesia: An Observational Study

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Introduction. The number of anterior cruciate ligament reconstruction (ACLR) procedures is increasing. However, the likelihood of not allocating sufficient funds for the ACLR procedure in a developing country, especially in Indonesia, is high. This study aimed to analyze costs for ACLR procedures in Indonesia's resource-limited context, determine the burden of ACLR, and propose national prices for ACLR reimbursement.

Methods. A retrospective observational study was conducted on the cost of ACLR from a payer perspective using inpatient billing records from 1 January 2019 to 31 December 2019 from four hospitals. The national burden of ACLR was calculated and national prices for reimbursement were developed.

Results. Of the 80 ACLRs performed, 53 (66%) were isolated ACLRs and 27 (34%) were combined with meniscus treatment. The mean hospital costs incurred per ACLR procedure were USD 2,853 (IDR 40.4 million), which was mainly attributed to the orthopedic implants (USD 1,387; IDR 19.6 million). The costs of ACLR with combined meniscus treatment were estimated to be 35 percent higher than for isolated ACLR. The national burden of ACLR revealed a total budget of USD 367.4 million (IDR 5.2 trillion) per 100,000 patients for ACLR with additional meniscus treatment and USD 271.3 million (IDR 3.8 trillion) per 100,000 patients for the isolated ACLR procedure.