determine any trends and drivers of local decision-making. **RESULTS:** As expected, there was variation across CCGs in funding decisions. However, there was only a limited correlation between funding decisions and CCG priorities or performance. It became evident that there were no strong discernible trends or drivers for local funding decisions on these products. **CONCLUSIONS:** Unlike the national level assessments undertaken by NICE, the drivers of local formulary decisions on new pharmacotherapies are difficult to establish and vary across CCG, making it difficult for pharmaceutical companies to obtain access for their medicines using a "one size fits all" approach. Thus, pharmaceutical companies need to engage more closely with CCGs to better understand their needs (including beyond-the-pill) and demonstrate the 'localised' value of pharmacotherapies.

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THE GERMAN AMNOG DRUG REIMBURSEMENT PROCESS: FACTORS ASSOCIATED WITH GBA-DECISIONS ABOUT THE ADDITIONAL BENEFIT

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OBJECTIVES: Since the introduction of the AMNOG in January 2011, an early benefit assessment by the German G-BA is required for all new drugs in Germany. Objective of our study was to identify any predictors of G-BA decisions. **METHODS:** All G-BA decisions up to 04/2015 were analyzed; basic characteristics of each drug as well as of each decision were documented. A multivariate ordinal regression analysis, using given additional benefit classification (ranging from 1 for major additional benefit to 5 for no additional benefit) as dependent variable, was conducted. **RESULTS:** 130 completed G-BA assessment procedures were evaluated. Within these, G-BA decisions were as follows: 16.9% of the drugs received considerable additional benefit (for at least one patient subgroup), 23.1% received a minor additional benefit, 10.0% received a non-quantifiable additional benefit, and 50.0% received no additional benefit. Due to the specifics of German value assessment, orphan drugs automatically receive an additional benefit, but 39.1% of the assessed drugs received a non-quantifiable additional benefit (lowest possible assessment). Our multivariate regression analysis showed that the strongest predictors for an above-average benefit ranking were proven advantages in mortality ($p<0.001$) or morbidity ($p=0.001$). Additionally, products for use in malignant ($p=0.013$) or infectious diseases ($p<0.001$) as well as orphan treatments ($p=0.027$) were more likely to reach a better benefit rating. Furthermore, any evidence of a favorable safety profile of a treatment is associated with a better ranking ($p=0.10$). **CONCLUSIONS:** Key factors for positive G-BA decisions seem to be a proven superiority in mortality or morbidity against the standard treatment as defined by the German G-BA. However, this is difficult to prove in specific chronic disease areas, especially if surrogate outcomes are not widely accepted. This may explain why, for example, 80% of the assessed diabetes drugs did not receive any additional benefit in Germany.

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OVERVIEW OF NUB PROCESS FOR IN-PATIENT DRUGS AND DEVICES IN GERMAN

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OBJECTIVES: In Germany, the reimbursement and pricing of innovative in-patient drugs and devices is managed through the NUB application process. These applications are submitted by the hospital stakeholder and are approved or rejected by the Institute for the Hospital Remuneration System (InEK). The objective of this research was to assess the NUB trends in Germany in 2012-2014. **METHODS:** We developed a database of NUB approvals and rejections based on the Institute for the Hospital Remuneration System's (InEK)'s reports. All information was extracted into Excel format. The following data was extracted: product name, indication, year of submission, number of NUB applications submitted, status score, type of evidence available and lack of evidence for NUB rejection. Additionally, the number of re-applications and re-rejections were also analyzed. **RESULTS:** In 2013 and 2014, a total of 21264 and 25634 NUB applications were submitted for 612 and 613 medical products, respectively. Of these applications in 2013 and 2014, 10% and 16% were approved for NUB (as Status 1) and 82% and 75% were rejected (as Status 2), respectively. In 2014, the median number of hospital applications for NUBs with Status 1 and Status 2 were 37 and 3, demonstrating the importance of hospital participation for seeking NUB approval. Among approved NUBs, 37% of the applications were for drugs and 63% were for devices. Interestingly, the median NUB hospital applications for approved drugs was 192, while for devices, the median was 9 applications. In 2014, 447 NUB applications for products were re-submitted, of which 5 were approved and the remaining were re-rejected. The evidence requirements analysis suggests the need for hospital focused economic data. **CONCLUSIONS:** The NUB process plays a critical role in market access for in-patient drugs and devices. For approval, two key components are: hospital focused economic evidence and provider stakeholder involvement.

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REIMBURSEMENT OF ORPHAN AND EXPENSIVE DRUGS IN THE NETHERLANDS: EXPLORATION OF ESSENTIAL CRITERIA IN THE DECISION MAKING PROCESS

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OBJECTIVES: The aim of this study is to (i) review the methodological quality of pharmacoeconomic evaluations of orphan and expensive drugs that applied for reimbursement in The Netherlands, and (ii) explore essential criteria in the reimbursement recommendations made by The Dutch National Healthcare Institute (ZINL). **METHODS:** Data were extracted from pharmacoeconomic reports published by ZINL between 1 January 2006 and 31 December 2013 using a data extraction form. Compliance to pharmacoeconomic guidelines was determined by evaluating deviations in the pharmacoeconomic reports from the list of provided items in the guidelines. Multiple variables (i.e. drug safety, efficacy, therapeutic value, and cost-effectiveness) were investigated regarding their influence on the reimbursement recommendation by performing the Pearson's Chi-squared test, Kolmogorov-Smirnov test, and Wilcoxon rank sum test. **RESULTS:** In total, 53 pharmacoeconomic evaluations were included in this study. Of these, 16 concerned orphan drugs, while 37 evaluated high cost- drugs. Of the 53 pharmaceutical compounds evaluated in this study, 39 (73.6%) received a positive reimbursement advice, 11 (20.8%) received a negative reimbursement advice, and 3 drugs were not assessed for reimbursement through either the outpatient reimbursement system nor the intramural high cost reimbursement system (5.7%). In total, 277 deviations from the pharmacoeconomic guidelines were observed, but no single item was found to have a statistically significant effect on the reimbursement recommendation. In contrast to drug safety and cost-effectiveness outcomes, both drug efficacy and therapeutic value showed to have statistically significant impact on the reimbursement decision. **CONCLUSIONS:** In The Netherlands, drug efficacy and therapeutic value can be considered as essential criteria in the reimbursement decision of orphan and expensive pharmaceuticals, resulting in a reimbursement system being centered on clinical value. Even though cost-effectiveness does not have a significant impact on the decision, compliance in the reimbursement dossiers by manufacturers to the Dutch Guidelines for Pharmacoeconomic research can be further improved.

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PERFORMANCE OF DRG-BASED REIMBURSEMENT POLICY IN NATIONAL HEALTH INSURANCE : EIGHT YEARS' EXPERIENCES

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OBJECTIVES: The diagnosis-related group (DRG) based reimbursement system has been voluntarily applied to inpatients with seven diseases in the Korean national health insurance since 2002, and was mandatory for all health-care institutions from July 1, 2013. The main purpose of this study was to evaluate the performance of DRG-based reimbursement in health care expenditure and to propose alternative policies. **METHODS:** A non-equivalent control group pretest-posttest design with a difference-in-difference approach was adopted to compare changes in medical service utilization and physician's behavior between DRG-based reimbursement(experimental group) and fee-for-service reimbursement(control group). Seven diseases to which DRG-based reimbursement was applied included tonsillectomy, cataract surgery, appendectomy, herniotomy, hemorrhoidectomy, hysterectomy, and Caesarean section. The panel data were produced from year 2004~2011 medical claims database of the National Health Insurance, which covered a total of 1,119,028 cases per year. **RESULTS:** From 2004 to 2011, surgical operations in institution reimbursed by DRG have been significantly increased more than those in institutions reimbursed by fee-for-service. The results showed that the DRG-based payment has reduced the length of stay in seven diseases, while it has changed physician's behavior to charge DRG-code upward and shift medical tests and expensive antibiotics from inpatients to outpatients because DRG was applied to inpatient only. The DRG-based payment in seven diseases has consistently increased medical expenditure as well as medication expenses more than fee-for-service, partly due to no global budget in the Korean national health insurance. **CONCLUSIONS:** Challenges and future issues to expand the DRG-based reimbursement system to all diseases for inpatients should be considered such as monitoring service quality, strategic plans to control physicians' behavior, limiting the number of DRG classifications, and the introduction of global budgeting.

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IMPACT OF ESSENTIAL HEALTH BENEFIT BENCHMARK PLANS ON US MARKET ACCESS

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OBJECTIVES: Beginning in 2014, the Affordable Care Act requires new health plans to cover essential health benefits (EHB), including pharmaceutical products, according to the state level benchmark plans. The objectives of this analysis were to understand state level variations in design of plans, access to drugs and likely impact on patient choice and health outcomes. **METHODS:** Benchmark plans for the top five states (i.e., FL, IL, NY, TX and CA), covering ~116 million lives, were obtained from the CMS. For each plan, the categories, classes and number of covered drugs was collected and pooled into one database. Analysis was conducted at the entire population level, state-level and for top classes of drugs. The comments from patient groups were reviewed to understand the impact of EHB on patient choice and health outcomes. **RESULTS:** Benchmark plans for the top five states provide coverage of 4215 drugs belonging to 158 classes as defined by USP. While four states (FL, IL, NY and TX) had a similar number of covered drugs (median of 892 drugs), CA had a significantly lower number of covered drugs, amounting to 28% less than the other four states. On average, 10% of the drugs were in the class called "No USP Class", highlighting the limitation of CMS designated USP classification system for the new plans. In CA, FL, IL, NY and TX there were 18, 7, 8, 11 and 8 classes, respectively, for which only 1 was covered. In CA, top 8 classes were identified for which patients had a 75% lower choice than other states, and these included indications such as Anti-Diabetics and Pain medications. **CONCLUSIONS:** Review of new benchmark plans shows some states can have a significantly lower patient choice of therapies. There is a need for new policy measures to ensure that all patients have equal access to new treatments.

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A SIMULATION ANALYSIS USING THE ORANGE PRICE REFERENCE TOOL

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OBJECTIVES: International Reference Pricing (IRP) is a key cost-containment tool for health care payers across the world. IRP may apply either fixed or flexible