on QALY modifiers and cost-effectiveness thresholds if the severity modifier was applied in past appraisals. ***Methods:*** A targeted review of all NICE technology appraisals published in the last five years (June 2017 to May 2022) was conducted. Average age at diagnosis, female/male ratio, and discounted QALYs for standard of care comparators used in the economic analysis were extracted. The absolute and proportional QALY shortfall were calculated to determine severity level for each appraisal, and the relevant QALY modifiers were applied. ***Results:*** A total of 325 NICE appraisals were reviewed, with 106 (33%) appraisals containing sufficient unredacted figures to be included in the analysis. Of the 106 appraisals, a QALY modifier of 1 was applied to 63 (59%) appraisals, a QALY modifier of x1.2 was applied to 30 (28%) appraisals and a QALY modifier of x1.7 was applied to 7 (7%) appraisals. In 6 (6%) appraisals there were multiple QALY modifiers applied across included populations. Of the 7 appraisals where the highest QALY modifier was applied, 6 were in oncology and 1 was in multiple sclerosis. ***Conclusions:*** A review of all NICE technology appraisals with unredacted data over the past 5 years has shown that only a small proportion will have the highest QALY modifier applied, resulting in a £50,000 cost-effectiveness threshold, although this analysis is limited by a high proportion of redacted appraisals.

HTA65
SOCIO-ECONOMIC DETERMINANTS OF HEALTH STATUS DURING COVID-19 PANDEMIC IN HUNGARY

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Objectives: The aim of this study was to analyze socio-economic determinants of health-related quality of life during the COVID-19 pandemic in the general Hungarian population. ***Methods:*** We used data from a large-scale, cross-sectional, online questionnaire survey in which a representative sample of the Hungarian population completed the EQ-5D-5L and answered socio-demographic and the COVID-19 related questions. The Hungarian value set was used to generate utility scores. ***Results:*** Mean age of participants (N=2000) was 47.3 (SD=16.4) years, 46.6% were male, and 17.6% reported previous COVID-19 infection. Mean EQ-5D index was 0.87 (SD= 0.23). Generally, respondents most often reported problems with pain/discomfort (47.4%) and were more likely to have severe problems in the mobility dimension (7.1%). Younger age, higher income and higher education background were associated with higher EQ-5D index (Spearman rho: -0.156, 0.194 and 0.175, $p<0.001$). No significant differences were observed in mean (SD) utility score across quarantine status groups (quarantined 0.86 (0.23) and not quarantined 0.88 (0.23); p=0.827) or vaccination status (vaccinated=0.87 (SD=0.21) and not vaccinated=0.86 (SD=0.25); p=0.339). The mean utility scores of respondents with previous COVID-19 infection and having no, mild, severe symptoms, hospitalized and needed intensive care treatment were 0.93 (0.14), 0.92 (0.14), 0.87 (0.18), 0.69 (0.39) and 0.45 (0.00), respectively. Moreover, respondents who had severe symptoms and hospitalized when they got infected were 4.24 (95% CI, 1.23-14.59) and 17.52 (2.83-108.58) times more likely to report problems with mobility and 3.14 (1.34-7.35) and 5.78 (1.14-29.19) times more likely to report problems with pain/discomfort. ***Conclusions:*** Our results provide valuable inputs into cost-effectiveness analyses of COVID-19 related interventions.

HTA66
PRICE INCREASES OF PRESCRIPTION DRUGS IN SWEDEN – IN WHICH CASES ARE THEY APPROVED?

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Objectives: Price increases for non-generic medicines within the pharmaceutical benefits scheme are only granted in exceptional cases in Sweden. This study assessed price increase decisions for prescription drugs in Sweden and identified relevant factors linked to the decision outcomes. ***Methods:*** The database for reimbursement decisions from the Swedish Dental and Pharmaceutical Benefits Agency was used to identify decisions regarding price increases of prescription drugs between 1 January 2019 and 15 June 2022. The published decision documents were qualitatively assessed, identifying relevant factors for the decision outcome and the relative price increases (pharmacy selling prices) of the approved decisions were quantified. ***Results:*** During the study period, 56 medicines were subject to price increase applications, of which 39 were approved. Medicines included, amongst others, human immunoglobulin therapies, therapies for depression, schizophrenia, and anxiety as well as therapies for patients with high blood pressure. The median price increase was 46% and the largest approved increase was 565%. The relative price increase varied between treatments and indications. Relevant factors regarding the price increase decision were the perceived severity of the condition and potential challenges linked to treatment interruption or switching including the mode of administration, intolerances to treatment alternatives, and side effect profiles. Additionally, risks associated with a diminished supply, the availability of alternative treatment options, and the initial price level in comparison to other European countries and treatment alternatives in Sweden were taken into consideration. ***Conclusions:*** Most of the available price increase applications during the study period resulted in a price increase. While the relative price increase varied between medicines, common factors were identified including the availability of treatment alternatives and potential challenges linked to a diminished supply.

HTA67
DO MANUFACTURERS STILL SEE VALUE IN SUBMITTING EVIDENCE FOR A NICE APPRAISAL IN ENGLAND? COMPARING AND CONTRASTING TERMINATED APPRAISALS BETWEEN ONCOLOGY AND NON-ONCOLOGY AND MONOTHERAPIES AND COMBINATION PRODUCTS

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Objectives: A positive NICE assessment is key to funding in NHS England. However, manufacturers are actively foregoing the English market by not submitting an evidence package to NICE resulting in "terminated appraisal". This research is aimed at identifying trends in terminated appraisals in relation to therapeutic area, monotherapy vs combination regimen, and date of termination. ***Methods:*** This study reviewed Single Technology Appraisals (STAs) and Highly Specialised Technologies (HSTs) published in the NICE website from 2017 to June 2022. Appraisals listed as "Terminated appraisal – non submission" were identified and data were extracted on disease area, active substance, (monotherapy vs combination drug), and date of termination. A comparison of the number of terminated appraisals between non-oncology and oncology products and between monotherapies and combination drugs was made. ***Results:*** A total of 358 NICE STAs and HSTs were identified of which 60 (17%) were terminated appraisals. Of these, 72% of were for oncology products, and 35% were for combination drugs. Compared with appraisals for non-oncology products, oncology products were almost twice as likely to result in terminated appraisal (11% vs 21%). A similar situation was also observed for monotherapies and combination drugs (14% vs 26%). The annual proportion of non-submissions was around 20% except for 2018 (4%). ***Conclusions:*** Challenges in generating robust evidence for oncology products are well known and might explain why a decision to not submit the evidence is more likely to be taken for oncology products. The higher likelihood of combination drugs' appraisals to result in terminated appraisal, confirming a 2019 ABPI survey's findings, might be because their added benefit is often not enough to justify their price, and, therefore, access might be particularly challenging in countries relying on cost-effectiveness.

HTA68
DIGITAL HEALTH – WHERE DO WE STAND FROM A MARKET ACCESS PERSPECTIVE IN THE EU-4 AND THE UK?

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Objectives: To assess the market access and pricing processes for digital health applications EU-4 (France, Germany, Italy and Spain) + UK and determine the key decision making criteria. ***Methods:*** National laws and regulations were assessed via targeted literature research, including official health technology/reimbursement agency websites. Additionally, expert interviews were conducted. ***Results:*** In Germany, a new fast-track process was implemented in 2020 in which 130 applications were submitted as of May 2022. 31 were accepted temporarily. The first 5 DiGAs went through price negotiations with agreed discounts of up to 67%. In Spain, some regional health authorities have developed assessment frameworks for mobile applications, such as in Andalusia in whose catalogue 39 applications are included. In Italy, the services provided by the National Health Service (NHS) are only those identified in the "Essential Levels of Care". Some Italian regions recognise "televisits" reimbursement by considering the tariff for F2F visits. In France, there is no specific pricing and reimbursement (P&R) pathway for digital health applications. Since 2020, MOOVECARE® is the only reimbursed digital health app. An important change could be the temporary coverage in the first year of launch after which the standard reimbursement pathway would need to be followed. In the UK, the P&R process for digital health technologies (DHTs) is decentralised, hence their final P&R decisions are made at a clinical commissioning group (CCG) level. The National Institute for Health and Care Excellence (NICE) has developed an evidence standard framework to support the NHS with determining the value of DHTs. ***Conclusions:*** Although there are similarities between the EU4 + UK for the market access of digital health applications, processes vary between countries. As it can be seen in Germany, an improved pathway through a fast-track path can lead to faster and broader market access to patients.

HTA69
DELAY OF INNOVATIVE ONCOLOGY TREATMENTS - CASE FROM BULGARIA

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Objectives: In Bulgaria health technology assessment (HTA) was introduced in late 2015. Ministerial Order N9 was issued and legally framed the process – all new drugs

must go under HTA procedure if applied for Positive drug list (PDL) inclusion, which grants reimbursement by the National Health Insurance Fund (NHIF). In April 2019 the legislation was amended and HTA regulation have become part of Medicinal Products In Human Medicine Act. The aim of this study is to provide a better understanding of the timeliness of HTA processes in Bulgaria. ***Methods:*** Outcomes of HTA appraisals and supplementary documents issued and uploaded on website of the National Council on Prices and Reimbursement of Medicinal Products (NCPRMP) between 1 January, 2016 and 31 December, 2021 were reviewed. The HTA appraisals for oncology drugs were identified and the EMA marketing authorization information was reviewed and included. ***Results:*** From 152 HTA appraisals 52 (34%) were selected as treatments in oncology – 42 drugs and 2 diagnostic kits; 48 indications; 3 negative decisions for PDL inclusion. The therapeutic area with the highest proportion was leukemia (18%, n=9), followed by carcinoma, non-small-cell lung (18%, n=9) and breast cancer (14%, n=7). The median time from EMA authorization to HTA application was 634.5 days (min=50 days; max=4864 days). The median length of the HTA procedure was 185.5 days (180 days by regulation) (min=82 days; max=651 days). The median time taken from HTA application to PDL inclusion was 225.5 days (min=44 days; max=955 days). The overall median duration from EMA authorization to PDL inclusion was estimated to be – 1040 days (min=383 days; max=3397 days). ***Conclusions:*** Positive HTA recommendations facilitate market access of innovative drugs. In Bulgaria, part of the observed delay in patient access is induced by legislative barriers – finalized HTA process and positive recommendations in UK, France, Germany, and Sweden.

HTA70
FOUR IS THE NEW SEVEN: THE APPLICATION OF NEW ROUTING CRITERIA FOR NICE'S HIGHLY SPECIALISED TECHNOLOGY PROGRAMME

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Objectives: NICE updated the scoping criteria for the highly specialised technology (HST) programme in 2022 following consultation with stakeholders. The seven previous criteria were streamlined to four, with the aim to make the "routing decision clearer, consistent, more transparent and precise to provide greater clarity, precision and predictability for the routing of topics". This study analysed products that were accepted to HST previously, against the new criteria, to test the hypothesis that the new criteria enable greater predictability for the routing of topics. ***Methods:*** Drugs assessed via HST prior to the change in scoping criteria were assessed against the previous and new criteria to assess whether any would fare differently within the new routing system. Two approaches were used; one applying a stringent interpretation of criteria and one applying a less stringent interpretation, to account for subjectivity in the application of each of the criteria. ***Results:*** Twenty HST appraisals have been completed for 19 unique products. When applying each set of criteria stringently, only 9 of 20 (45%) appraisals met all old criteria, vs 17 of 20 (85%) meeting new criteria. When applied less stringently, this changes to 16 of 20 (80%) meeting old criteria, vs 19 of 20 (95%) meeting new criteria. ***Conclusions:*** The new HST routing criteria reflect actual decision making from NICE more consistently than the old criteria. Therefore, the new criteria which will be used going forward are a more accurate reflection of routing for HST.

HTA71
WILL THE NEW EU HTA REGULATIONS INCREASE THE METHODOLOGICAL REQUIREMENTS TO CONDUCTING SYSTEMATIC LITERATURE REVIEWS OF CLINICAL EVIDENCE?

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Objectives: Health technology assessment (HTA) bodies across the European Union (EU) have different systematic literature review (SLR) methodology requirements. The recently announced pan-EU HTA regulation will establish a new set of evidence requirements for the joint clinical assessment (JCA), which will attempt aligning the evidence requirement of all EU Member States. To understand what the evidence requirements for a pan-EU JCA might entail, we compared the methodological requirements for clinical SLRs across EU country-level HTA bodies. ***Methods:*** Pending guidance from EUnetHTA 21, the most up-to-date clinical SLR requirements issued by France (HAS), Ireland (NCPE), Sweden (TLV) Germany (G-BA) were reviewed. Requirements of EUnetHTA were included to reflect past centralised EU processes. The following methodological requirements were extracted: search strategy, search time-period, study design, databases, study selection process, quality assessment and language. ***Results:*** All agencies included in this review, except TLV, provide guidance on search time-period and study design. The search time-period should not be restricted and should be undertaken within 3-6 months prior to HTA. All agencies require inclusion of randomised controlled trials (RCTs). Evidence from non-RCTs and observational studies are accepted by NCPE, HAS, EUnetHTA, but rarely by G-BA and can only be justified in exceptional cases. HAS, G-BA and EUnetHTA prescribe specific search databases, with MEDLINE®, Embase® and Cochrane® being most common. Along with English language searches, non-English language searches are recommended by NCPE and G-BA. ***Conclusions:*** SLR requirements at pan-EU HTA level are likely to be rather broad to satisfy what is acceptable across EU HTA agencies. We anticipate a pan-EU SLR to be conducted within previous 3 months of submission, include RCTs and in specific cases non-RCTs and observational studies, and review of English and certain non-English articles. Such a broad scope will need to be factored into sponsors' timelines to ensure timely preparation for a pan-EU JCA process.

HTA72
EXAMINING THE EFFECTIVENESS OF THE CANCER DRUGS FUND: ARE DATA COLLECTION PLANS WORKING AS INTENDED?

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Objectives: The Cancer Drugs Fund (CDF) in England enables early access to promising new cancer technologies, conditional on additional evidence collection to address any clinical uncertainty. This research reviewed NICE CDF exit evaluations to identify whether the data collection plans were met and whether these sufficiently addressed the uncertainty raised in the original NICE evaluation. ***Methods:*** Technologies that exited the CDF between 1 October 2016 and 15 June 2022 were identified. NICE Committee papers and final appraisal documents from both the original and CDF exit evaluations were reviewed. Key issues of uncertainty in the original evaluation were extracted alongside details of the data collection plan and the data actually collected by the time of the CDF exit evaluation to compare if these matched and whether the Appraisal Committee considered the uncertainty to be resolved. ***Results:*** Excluding one terminated evaluation, 20 technologies were identified as having exited the CDF, with only one of these technologies not recommended following CDF exit evaluation. Median time between CDF entry and exit was 35 months. Overall, 6/20 (30.0%) CDF exit evaluations presented data that did not align with the original data collection plan, mainly due to trial data remaining immature or the Systemic Anti-Cancer Therapy dataset failing to collect the appropriate data. Despite ultimately being recommended, 12/20 (60.0%) CDF exit evaluations did not fully resolve the uncertainty from the original evaluation. Of the 14 CDF exit evaluations that presented data aligned with the original data collection plan, only 7 of these (50.0%) fully addressed the uncertainty from the original evaluation. ***Conclusions:*** The data collected within the CDF period did not always align with the original data collection plan and most CDF exit evaluations did not fully address the clinical uncertainty identified in the original evaluation. Despite this, recommendation rates of technologies exiting the CDF were found to be high.

HTA73
EVALUATION OF NICE SEVERITY MODIFIERS

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Background: The National Institute for Health and Care Excellence (NICE) updated their health technology evaluation methods in January 2022. NICE replaced the end of life (EOL) criteria, which allowed a recommendation with an incremental cost-effectiveness ratio (ICER) of up to £50,000 per quality-adjusted life year (QALY), with a new severity modifier. This new approach considers absolute QALY shortfalls (AS) and proportional QALY shortfalls (PS) to determine relevant QALY weights and the willingness to pay (WTP) threshold to be applied. ***Objectives:*** This study aimed to analyse technologies that were accepted with the EOL criteria and assess whether they would still receive additional QALY weighting if evaluated using the new criteria. ***Methods:*** NICE single technology appraisals (STA) between 2015 and 2021 were reviewed to identify technologies that were accepted for EOL criteria. Data required to estimate AS and PS were identified from company submissions. AS and PS weights were estimated using a published QALY Shortfall Calculator tool. ***Results:*** In total, 324 STAs with a positive recommendation conducted between 2015 and 2021 were screened. Of 72 STAs meeting EOL criteria, 32 submissions provided data required to estimate AS and PS. Reasons for exclusion included, confidential data (72.5%), missing data (20.0%), and inappropriate comparator (5.0%). Using the QALY Shortfall Calculator tool, 20 (62.5%) were found to be eligible for an additional 1.2x QALY weighting (WTP of £36,000/QALY), and 7 (21.9%) were found to be eligible for an additional 1.7x QALY weighting (WTP of £50,000/QALY) under the new severity modifier criteria. ***Conclusions:*** The results of this study indicate that technologies previously eligible for EOL criteria are unlikely to receive the same benefits under the new severity modifier, with only 21.9% of technologies still able to receive a WTP of £50,000/QALY. Future research should focus on the appraisals that are now likely to be eligible for a severity modifier.

HTA74
NOVEL APPROACH TO DECISION MAKING FOR ORPHAN DRUGS

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Objectives: This policy perspective presents a unique pricing and reimbursement (P&R) system for orphan medicinal products (OMP) recently adopted in Czechia. ***Methods:*** The updated legislation follows the recommendations for value assessment and funding processes for rare diseases (ORPH-VAL). It also incorporates additional elements of value defined by ISPOR Special Task Force. ***Results:*** Out of 185