and budgetary impact (31%) analyses as the most unclear components of the reports. Other benefits and contextual considerations (37%) and ICER's voting questions (33%) were most unclear in 2018. Perceived strengths remained constant over the 2-year period, with payers reporting use of real-world evidence, transparency of methodology, and choice of clinical outcomes as top ICER VAF strengths. Perceived limitations of the ICER VAF evolved over time, with fewer payers citing timeliness of report(s) (45% in 2016; 28% in 2018) and stakeholder engagement (38% in 2016; 26% in 2018) as key limitations of the ICER VAF over the 2-year period. ***Conclusions:*** These results suggest that the impact of ICER in informing payer coverage decisions has increased. Additionally, it appears that updates to ICER's VAF methodology over the past 2 years have addressed some concerns previously noted by payers.

PNS166
CROSS-COUNTRY ICER EVOLUTION: WHAT DOES IT NOW MEAN TO BE COST-EFFECTIVE?

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Objectives: To understand the challenges and similarities in demonstrating cost-effectiveness across CAN (CADTH), GBR (NICE), and in the USA (via the ICER organization). ***Methods:*** The study employed a pragmatic literature, industry, and policy review to understand the challenges faced by manufacturers for therapies in a variety of treatment areas, the differences and similarities of challenges faced in cost-effectiveness assessment across markets, and ways in which CADTH, NICE, and ICER have each contributed to the evolving definition of cost-effectiveness internationally. ***Results:*** CADTH, NICE, and ICER each employ drastically different definitions of cost-effectiveness and make equally divergent usage of their determinations. While CADTH leverages a CAD 20,000-100,000 / QALY threshold (dynamically adjusting based on key factors), NICE employs a lower and less flexible GBP 30,000-50,000 cutoff, and ICER uses a more directional systemic analysis where cost-effectiveness falls in the USD 100,000-150,000 range. Subsequently, CADTH seems to propose discounts that would achieve cost-effectiveness as a leverage bolster for the pan-Canadian Pharmaceutical Alliance payer negotiations, whereas NICE is more firmly committed to recommending reimbursement based on cost-effectiveness, and while ICER has no direct authority, the organization has seen its influence grow with strategic private and public partnerships leveraging its determinations. Despite differences, these three bodies often challenge products' cost-effectiveness claims on similar grounds, with similar shortcomings highlighted by all three. Comparator selection, duration of data, and economic modelling assumptions are all routinely highlighted across these organizations in decisions that rule products to not be cost-effective. These factors contribute to uncertainty in financial calculations and can result in cost-ineffective determinations for even highly effective therapies. ***Conclusions:*** While the definition of cost-effectiveness varies internationally, similar challenges to achieving this status across markets are consistently identified and should be acknowledged and thoroughly assessed by manufacturers of novel therapeutics in their economic modelling.

PNS167
A REVIEW OF EVALUATION CRITERIA AND STRATEGIES FOR INSURANCE COVERAGE OF PERSONALIZED MEDICINE: U.S. PAYER PERSPECTIVES

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Objectives: Personalized medicine (PM) such as pharmacogenomics tests and whole genome sequencing can be used to support treatment decision and improve health outcomes via more accurate risk-stratification and better prevention. The objectives of the study were: 1) Understand payer strategies and evaluation criteria for PM; 2) Identify opportunities and barriers to their coverage. ***Methods:*** A targeted review of the literature was conducted in EMBASE and PubMed. Selection criteria were used to identify payer perspectives and strategies for coverage of PM. Reviews from both public and private payers were included, and name of payer was captured if reported. ***Results:*** 1078 studies were captured by our search strategy and 27 were included for extraction. Overall, 21 studies reported key evaluation criteria for reimbursement from both private and public payers. Payers perceived PM as useful if it allowed targeting responders specifically and reducing costs downstream. They are, however, cautious that this would expand populations for drugs and increase budgets. The top four attributes reportedly used by payers in their decision-making were clinical utility, analytic validity and efficacy, role in medical decision-making as well as cost offsets. One study reported that formulary management varied more among private payers. From the reviews, six studies included payer strategies: two payers offered coverage with evidence development, four offered coverage with conditions, and one payer used external services to price diagnostic tests based on value. ***Conclusions:*** For PM technologies to be adopted by all types of payers, manufacturers need to demonstrate that it accurately informs treatment decisions while showing both clinical and cost benefits. Assessment of the added value of PM remains complex and uncertain. Overall, generating evidence for PM meeting payers' expectations is challenging. Payers, PM manufacturers and other stakeholders ought to collaborate to come up with innovative approaches for coverage, leading to better access for patients.

PNS168
CHALLENGES IN THE DESIGN AND IMPLEMENTATION OF COVERAGE WITH DEVELOPMENT SCHEMES FOR MEDICAL DEVICES

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Objectives: Coverage with evidence development (CED) represents a policy option when there is uncertainty about the costs or benefits of new health technologies. These schemes are particularly relevant for medical devices since clinical and economic data are often limited at launch. This study aims to determine the challenges in the design and implementation of CED schemes for devices, with the objective of facilitating their implementation in the future. ***Methods:*** A systematic review of the literature was conducted to identify existing schemes for devices and the challenges in their design and implementation. Based on the findings of the review, interviews were conducted with decision-makers responsible for the HTA of medical devices in Europe. In addition, data were collected on CED schemes not in the published literature to develop a taxonomy of existing schemes. ***Results:*** Challenges in conducting CED schemes were reported by the majority of the studies. However, mostly all records were on pharmaceuticals, with only 6 studies addressing devices. Based on the results of the review, the challenges explored with decision makers were: determining the eligibility of devices; getting stakeholder agreement; agreeing on funding arrangements; defining appropriate study design and outcomes; dealing with data collection, monitoring and analysis; determining the decision rule at the outset of the scheme, reaching a agreement on price and reimbursement; withdrawing devices if found to be not cost-effective; agreeing on scheme duration; dealing with product modifications, and similar devices entering the market during the scheme. ***Conclusions:*** Several CED schemes for devices exist in Europe and experience with designing and implementing them is being accumulated. However, if use of CED schemes for devices is to be expanded, several of the challenges identified need to be overcome. FUNDING: This research is funded by the EU Horizon 2020 programme, and is undertaken under COMED (Grant number 779306).

PNS169
SIMILARITIES & DIFFERENCES IN GLOBAL VALUE DOSSIER (GVD) AND ACADEMY OF MANAGED CARE PHARMACY (AMCP) DOSSIER DEVELOPMENT

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Objectives: To support product Market Access, organizations will develop a GVD and an AMCP dossier. Both documents require substantial time and effort to develop. This study determined areas of overlap and possible efficiencies when developing GVDs and AMCP dossiers. ***Methods:*** AMCP Format guidelines (version 4.0) and GVD content and best practices were reviewed and compared. Internal process maps for constructing each type of dossier were developed and compared to identify areas of overlap and possible efficiencies. ***Results:*** Areas of overlap exist regarding dossier content:

- Disease Burden: AMCP dossiers require high-level disease descriptions and US-specific burden of disease information. GVDs require the same information, but from a detailed global perspective.
- Clinical Evidence: While both dossiers require clinical study summaries, AMCP study summaries include specific elements and are more detail than GVD study summaries. Additionally, AMCP dossiers require extensive evidence tables; GVDs may not include evidence tables.
- Economic Value: AMCP modeling sections are based on US-specific models; GVDs generally contains the core model(s).
- Other areas of overlap include presentation of relevant treatment guidelines and HTA decisions.

Additionally, it is important to consider the overall focus and "theme" of the dossiers. AMCP dossiers are focused on the product's clinical evidence, organized in a specific format, with limited interpretation of data and no explicit value story. GVDs are built around a specific value story, with flexibility in organization and evidence presentation. While content may overlap, directly transferring text between documents is rarely possible, and content revisions are required to align with the specific type, audience, and messaging/theme of each dossier. ***Conclusions:*** While there are several areas of overlap between the dossiers, specific content must be tailored to different audiences and purposes. Developing a clear plan before beginning work can help identify potential efficiencies, allowing for a more streamlined and perhaps less costly development process.

PNS170
NICE END OF LIFE - SURVIVAL CRITERION: STRICT IMPLEMENTATION OR PRAGMATIC FLEXIBILITY?

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Objectives: The National Institute of Health and Care Excellence (NICE) recommends public reimbursement of health technologies deemed cost-effective at an upper threshold of £20,000-£30,000 per additional Quality Adjusted Life Year (QALY). In