incorporating headroom analysis, return on investment, one-way sensitivity analysis and scenario analyses using data from secondary sources.

Results. The review of the literature, focus groups with CKD patients, and qualitative interviews with technology developers helped to understand relevant characteristics of WDHT and user preferences helped inform the next R&D iteration. Compared to the standard care, WDHT that support stage ≥3 CKD patients self-management at home by measuring blood pressure and monitor mobility has the potential to be cost-effective at conventional cost-effectiveness threshold levels. From the headroom analysis, novel WDHT can be priced up to GBP280 (EUR315, USD360) and still be cost-effective compared to standard home blood pressure monitoring.

Conclusions. Our study provides valuable information for the further development of the WDHT, such as defining a go/no-go decision, as well as providing a template for performing early HTA of Digital Health Interventions.

OP437 Use Of Real-World Evidence In Survival Analysis Adjusting For Treatment Crossover In Cutaneous T-Cell Lymphoma

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Real-World Evidence is useful for validating crossover adjustment approaches, particularly when the adjustment is required because a trial does not accurately reflect a health technology assessment (HTA)-relevant population. We use the MAVORIC trial advanced stage mycosis fungoides and Sézary syndrome cutaneous T-cell lymphoma population and data from the Hospital Episodes Statistics to explore and validate crossover adjustment methods.

Introduction. The MAVORIC trial compared mogamulizumab to vorinostat in patients with mycosis fungoides (MF) or Sézary syndrome (SS), subtypes of cutaneous T-cell lymphoma. However, the treatment comparison within MAVORIC may not represent an HTA relevant population from a UK perspective: (i) 72.6 percent of patients randomized to vorinostat switched to mogamulizumab and (ii) vorinostat is not used in current clinical practice in the UK. This study explores methods to adjust treatment effect estimates using different crossover adjustment methods and Real-World Evidence.

This medicine is subject to additional monitoring. This will allow quick identification of new safety information. See www.mhra.gov.uk/yellowcard for how to report side effects.

Methods. An advanced stage (stage ≥IIB MF and all SS) population was included. Three methods were considered for treatment crossover adjustment. A synthetic control arm was created using the Hospital Episodes Statistics (HES) dataset. Predicted survival for the MAVORIC control arm, post-crossover adjustment, was compared to the HES to inform the selection of the appropriate methods for adjustment. A direct comparison between mogamulizumab (reweighted to represent the distribution of MF/SS patients in the HES) and the synthetic control was also conducted.

Results. Following crossover adjustment of the vorinostat arm, using the inverse probability of censoring weighting method, the overall survival (OS) hazard ratio (HR) estimate for mogamulizumab vs. vorinostat was 0.45 (95% confidence interval (CI): 0.19, 1.07). This adjustment method was considered the most appropriate based on an assessment of assumptions and a comparison of OS between the adjusted vorinostat data and the HES data. The OS HR estimate for reweighted mogamulizumab vs. synthetic control from HES was 0.33 (CI: 0.21, 0.50).

Conclusions. Real World Evidence from the HES database can be used to validate crossover adjustment methods and to better reflect current clinical practice in the UK. Results using both methods support each other.

OP440 Comparison Of Evidence Supporting Cancer Drug Approvals And Prices In The US And Brazil

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Introduction. Cancer drug prices are high on the policy agenda worldwide. Previous research found no association between cancer drug benefits and prices at the time of regulatory approval. Drugs approved in the US with uncertain benefits may have spillover effects in other settings. Our objective was to compare the evidence supporting cancer drug approvals in the US and Brazil, and to examine the association between cancer drug prices and availability of added therapeutic benefit.

Methods. We matched all novel cancer drugs approved in the US from 2010–2019 to approvals in Brazil. We extracted data on pivotal study design characteristics and outcomes in the US and Brazil, and evidence supporting price approval in Brazil, including availability of added therapeutic benefit.

Results. From 2010–2019, fifty-six cancer drugs with matching indications were approved in US and Brazil and had their prices authorized in Brazil by December 2020. Drug were available in Brazil following a median 522 days after US approval (IQR: 351–932). In the US, thirty-four (60.7 percent) of the drugs had pivotal randomized controlled trials (RCTs) and Twelve (21.4 percent) had overall survival benefit. By the time of Brazilian approval, forty-one (73.2 percent) drugs had pivotal RCTs and twenty-two (39.3 percent) had overall survival benefit. A total of twenty-eight (50 percent) drugs did not demonstrate added therapeutic benefit over other authorized drugs for the same indication and had a median reduction from requested to approved price of 6.1 percent (IQR: 0–27.8 percent) in Brazil. The twenty-seven (48.2 percent) drugs with added therapeutic benefit had a median price reduction of 2.0 percent (IQR: 0–9.2 percent).

Conclusions. Half of new cancer drugs approved in Brazil failed to demonstrate added therapeutic benefit. The Brazilian pricing system secured considerable price reductions, ensuring that prices for

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