INTRODUCTION:

The National Institute for Health and Care Excellence (NICE) invited the manufacturer of olaratumab (Lartruvo®), Eli Lilly & Company Limited, to submit evidence for the clinical and cost effectiveness of this drug, in combination with doxorubicin, for advanced soft tissue sarcoma (STS) not amenable to surgery or radiotherapy, as part of the Institute's Single Technology Appraisal. The Peninsula Technology Assessment Group critically reviewed the submitted evidence.

METHODS:

Clinical effectiveness was derived from an open-label, randomized controlled trial, JGDG. The economic analysis was based on a partitioned survival model with a time horizon of 25 years. The perspective was of the UK National Health Service (NHS) and Personal Social Services. Costs and benefits were discounted at 3.5 percent per year. The company's evidence was submitted in anticipation that olaratumab would be considered as an alternative to doxorubicin, which has been used as a first-line treatment for advanced STS. To improve the cost effectiveness of olaratumab, the company offered a discount through a Commercial Access Agreement with the NHS England.

RESULTS:

In the company's submission, the mean base-case and probabilistic incremental cost-effectiveness ratios (ICERs) for olaratumab plus doxorubicin versus doxorubicin alone were GBP 46,076 (USD 61,403) and GBP 47,127 (USD 62,804) per quality-adjusted life-year (QALY) gained, respectively; the probability of this treatment being cost effective at the willingness-to-pay threshold of GBP 50,000 (USD 66,632) per QALY gained, applicable to end-of-life treatments, was 0.54. The respective estimates in our analysis were approximately GBP 60,000 (USD 79,959) per QALY gained, and the probability of cost-effectiveness was 0.21. The increase in the ICERs was primarily due to differences in extrapolation of overall survival, and drug administration costs.

CONCLUSIONS:

Based on the available evidence, olaratumab in combination with doxorubicin improves the survival of patients with advanced STS. However, this treatment is unlikely to be cost-effective. Olaratumab is now recommended for use within the Cancer Drugs Fund.

PP148 Your Money Or Your Life? Are Price Negotiations Health Technology Assessment Best Practice?

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INTRODUCTION:

Many countries use Health Technology Assessment (HTA) organizations to evaluate the clinical and economic impact of new therapeutic interventions. In some markets, HTA outcomes directly link to reimbursement decision-making based on the manufacturer's submitted price (e.g. NICE and SMC [UK]). In others, the HTA outcome leads to price negotiations with manufacturers by a separate body (e.g. HAS/CEPS [France] and G-BA/GKV [Germany]). This research compares major examples of each approach to inform a discussion on whether such price negotiations align with HTA best practice.

METHODS:

Publically-available technology assessment outcomes for G-BA/GKV, NICE and SMC (01/01/2011-31/12/2015) were extracted and compared.

RESULTS:

Of 112 G-BA benefit assessments, 45 percent offered no additional benefit with automatic reference pricing; 55 percent offered additional benefit, qualifying for price negotiations; 77 percent had prices negotiated, 14 percent had price fixed by court, and eight percent withdrew from market. Of 156 NICE Single Technology Appraisals, 51 percent were recommended, 17 percent restricted, 20 percent not recommended, and 12 percent non-submissions. Of 497 SMC appraisals, 35 percent were accepted, 28 percent restricted, 17 percent not recommended and 19 percent non-submissions. Forty-eight percent and 24 percent of NICE and SMC positive appraisals were associated with a Patient Access Scheme (PAS), with 86 percent and 88 percent being simple discounts schemes, respectively.

CONCLUSIONS:

Making reimbursement decisions for new medicines based on a clear set of criteria may be the most objectively fair and transparent method of HTA;

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however, as the NICE and SMC examples show, although strong downward price pressure is exerted (high frequency of PASs), this may come at the cost of many therapies (~33 percent) being denied access. By contrast, the flexibility enabled by a distinct price negotiation phase may enable more therapies access, as shown by the G-BA/GKV example (<10% medicines withdrawn). Nevertheless, the relative effectiveness of the downward price pressures, a key determinant of HTA process effectiveness, cannot be compared due to the confidential nature of UK PAS discounts.

PP149 Features Of Accountable And Reasonable Processes For Coverage Decision-Making

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INTRODUCTION:

The Accountability for Reasonableness (A4R) framework addresses the legitimacy of coverage decision processes by defining four conditions for accountable and reasonable processes: Relevance, Publicity, Appeals, Implementation. Cost-per-quality-adjusted life year (QALY) and multicriteria-centered processes may have distinct implications for meeting A4R conditions. The aim of this study was to reflect on how the diverse features of decision-making processes can be aligned with A4R conditions to guide legitimized decision-making. Rare disease and regenerative therapies (RDRTs) pose special decision-making challenges and offer a useful case study.

METHODS:

To support reflection on how different approaches address the A4R conditions, thirty-four features operationalizing each condition were defined and organized into a matrix. Seven experts from six countries explored and discussed these features during a panel (Chatham House Rule) and provided general and RDRT-specific recommendations for each feature. Responses were analyzed to identify converging and diverging recommendations.

RESULTS:

Regarding Relevance, panelists highlighted the importance of supporting deliberation, stakeholder participation and grounding coverage decision criteria in the legal framework, goals of sustainable healthcare and population values. Among seventeen criteria, thirteen were recommended by more than half of panelists. Although the cost-effectiveness ratio was deemed sometimes useful, the validity of universal thresholds to inform allocative efficiency was challenged. Regarding Publicity, panelists recommended communicating the values underlying a decision in reference to broader societal objectives, and being transparent about value judgements in selecting evidence. For Appeals, recommendations included clear definition of new evidence and revision rules. For Implementation, one recommendation was to perform external quality reviews of decisions. While RDRTs raise issues that may warrant special consideration, rarity should be considered in interaction with other aspects (e.g. disease severity, age, budget impact).

CONCLUSIONS:

Improving coverage decision-making towards accountability and reasonableness involves supporting participation and deliberation, enhancing transparency, and more explicit consideration of multiple decision criteria that reflect normative and societal objectives.

PP151 Comparison Of Patients Undergoing New Technology For Prostate Cancer

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INTRODUCTION:

Prostate neoplasia affects more than one million people worldwide. Surgical treatments have evolved from open or video prostatectomy, up to the High Intensity Focused Ultrasound (HIFU) technique. HIFU studies cite less costs and better quality of life during the first year of follow-up. The objective of this study is to describe a consecutive series of eligible patients, with Gleason score 6 and 7, and compare resources used along those three treatment techniques.

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