payers. **OBJECTIVES:** To better understand the current and evolving roles of CoI and national disease registries in the EU, including implications on the pricing and management of orphan drugs, and to identify implications for future evolution of rare disease specialty centers in the US. The trends on the EU development of CoI and national rare disease registries will be reviewed and expert opinion will be consulted. **RESULTS:** Tools and data that will be available to both the payer bodies and the EU payers. **CONCLUSIONS:** In general, examples of influence of CoI and disease registries on the pricing and reimbursement of orphan drugs (e.g. CoI in France, cancer registries in Italy) will be described. Implications of the use of this information and data will be explored for EU payers. **CONCLUSIONS:** EU payer bodies will gain increasing information and data necessary to further scrutinize the price and reimbursement opportunity for orphan drugs, through the use of registries and evaluation by CoI. Manufacturers should be prepared to understand and consider partnerships with CoI in EU.

**PHP105**

**A REVIEW OF DIFFERENT APPROACHES PROPOSED FOR VALUE BASED PRICING**

**Udupa DN1, Janodia M2, Muragundi PM1**

**OBJECTIVES:** To identify and assess the different options which the Centers for Medicare & Medicaid Services (CMS) has to review new drugs and biologics under its National Coverage Determination (NCD) process, and conduct such review in the wake of its recent NCD for sipuleucel-T. This analysis seeks to better understand if CMS will employ NCD’s to centralize its control over drug coverage. **METHODS:** The net benefit approach was applied to drugs and biologics that have been approved previously which could result in product misuse. Such misuse may lead to unwanted use, use that increases costs without commensurate outcomes, us that may impact patient safety or use outside of indication that is not deemed reasonable and necessary. **RESULTS:** The review of the most recent CMS NCD covering sipuleucel-T provides some indication as to how CMS may use its NCD authority to control product coverage.

**CONCLUSIONS:** Using CMS’s sipuleucel-T NCD as a potential predictor of future NCD actions, CMS may continue to make overall coverage decisions regarding labeled indications, but defer offer label coverage determinations to individual contractors.

**PHP106**

**PRIORITY SETTING FOR HEALTH TECHNOLOGY ASSESSMENT IN UKRAINE**

**Pariv Y1, Stepanenko A2, Mandrić O3, Zalis’ka O4**

**OBJECTIVES:** To review the various options that the Centers for Medicare & Medicaid Services (CMS) has to review new drugs and biologics under its National Coverage Determination (NCD) process, and conduct such reviews in the wake of its recent NCD for sipuleucel-T. This analysis seeks to better understand if CMS will employ NCD’s to centralize its control over drug coverage. **METHODS:** The net benefit approach was applied to drugs and biologics that have been approved previously which could result in product misuse. Such misuse may lead to unwanted use, use that increases costs without commensurate outcomes, us that may impact patient safety or use outside of indication that is not deemed reasonable and necessary. **RESULTS:** The review of the most recent CMS NCD covering sipuleucel-T provides some indication as to how CMS may use its NCD authority to control product coverage. **CONCLUSIONS:** Using CMS’s sipuleucel-T NCD as a potential predictor of future NCD actions, CMS may continue to make overall coverage decisions regarding labeled indications, but defer offer label coverage determinations to individual contractors.

**PHP107**

**NEED AND IMPORTANCE OF PHARMACOECONOMIC GUIDELINES IN INDIA**

**Udugama A1, Jindal A2, Murugundas P3**

**OBJECTIVES:** To identify and assess the different options which the Centers for Medicare & Medicaid Services (CMS) has to review new drugs and biologics under its National Coverage Determination (NCD) process, and conduct such review in the wake of its recent NCD for sipuleucel-T. This analysis seeks to better understand if CMS will employ NCD’s to centralize its control over drug coverage. **METHODS:** The net benefit approach was applied to drugs and biologics that have been approved previously which could result in product misuse. Such misuse may lead to unwanted use, use that increases costs without commensurate outcomes, us that may impact patient safety or use outside of indication that is not deemed reasonable and necessary. **RESULTS:** The review of the most recent CMS NCD covering sipuleucel-T provides some indication as to how CMS may use its NCD authority to control product coverage. **CONCLUSIONS:** Using CMS’s sipuleucel-T NCD as a potential predictor of future NCD actions, CMS may continue to make overall coverage decisions regarding labeled indications, but defer offer label coverage determinations to individual contractors.