years, while low risk patients exceeded it in 15 years, respectively. Coexisting risk results in a shared hazard function, the incidence of CRC exceeding the benchmark risk in less than 3 years. **CONCLUSIONS:** Intervals based on incidence of CRC diverge from adenoma only surveillance recommendations and suggest a longer interval of follow-up except for those with coexisting risk.

**MEDICAL DEVICE/DiAGNOSTICS – Cost Studies**

**PMD13**  
**BUDGET IMPACT MODEL OF A BLOOD BASED PROTEOMIC CLASSIFIER FOR INDETERMINATE PULMONARY NODULES**  
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The incidence of atypical nodules in chest CT refers to a conundrum that is being encountered increasingly in clinical practice. While atypical nodules are usually resolved with serial imaging, the risk that an indeterminate (IA) nodule may be malignant is a source of concern. This is especially true among patients with a history of smoking, who are at increased risk of developing lung cancer. In this setting, the potential for early identification of malignancy is of great importance. Several diagnostic modalities are available to evaluate lung nodules, including bronchoscopy, computed tomography-guided biopsy, and positron emission tomography. However, the high cost of these procedures and the associated complications have limited their widespread use. Given the high prevalence of lung cancer and the significant healthcare burden it poses, the development of more economical and efficient diagnostic tools is essential.

In this study, we aimed to develop a cost-impact model to analyze the budget impact of a blood-based proteomic classifier for the diagnosis of indeterminate pulmonary nodules (IPNs). The model was developed using available data on diagnostic accuracy, cost-effectiveness, and patient outcomes. The results of the model showed that the blood-based proteomic classifier has the potential to reduce the cost of managing IPNs while maintaining a high level of diagnostic accuracy.

**PMD14**  
**AN ECONOMIC MODEL OF THE IMPACT OF DIGITAL MEDICINES WITH A MOBILE APPLICATION IN PATIENTS WITH COMBINED HYPERTENSION, DIABETES, AND HYPERCHOLESTEROLEMIA**  
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**OBJECTIVES:** There is a strong correlation between cardiovascular disease and diabetes with management of blood pressure (BP), blood glucose (BG), and lipids being essential to preventing disease progression and complications. The FDA-cleared Proteus device captures and shares information about medication-taking, rest and activity patterns through a mobile device and app, a patch with a wearable sensor and reaction monitoring mass spectroscopy allows for an objective and quantitative assessment of FN negativity. This budget impact analysis was performed to quantify the molecular test cost impact on a US commercial health plan’s direct medical costs. **METHODS:** The budget impact model was developed from a commercial health plan perspective, with direct medical costs estimated from the MarketScan reimbursement benchmark data. Total PNG diagnostic evaluation costs were estimated for a 3-year time horizon and were calculated for the costs of care and care with the rapid molecular test. Diagnostic procedure resource utilization was obtained from a retrospective chart review analysis of a geographically representative sample of indeterminate FNPs (n=350) managed by outpatient cardiologists. **RESULTS:** Currently, 52% of FNPs are evaluated with an invasive procedure (biopsy/surgery) and 48% with surveillance alone, with significant cost differences observed between these two groups. The base case analysis using a health plan of one million members and a rate of 0.25% PNs within the health plan, estimated a 27% reduction in avoidable invasive procedures with the introduction of the molecular test. This amounted to a total potential cost savings of 20% from procedure and complication avoidance. **CONCLUSIONS:** Adoption of this molecular test may help reduce the number of unnecessary invasive procedures being performed for individuals presenting with indeterminate pulmonary nodules. The reduced resource utilization can result in cost savings for the health plan.

**PMD15**  
**MEDICARE BENEFICIARY OUT-OF-POCKET SPENDING FOR STROKE PREVENTION IN NON-VALVULAR ATRIAL FIBRILLATION: A BUDGET ANALYSIS**  
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**OBJECTIVES:** Healthcare costs today are increasingly being shifted from payers to patients due to high out-of-pocket (OOP) costs, factors patient costs into treatment decisions. Recent advancements in stroke prevention in atrial fibrillation (AF) have resulted in new treatment options where previously there were few. While the clinical benefit and cost effectiveness of these treatments are supported by a growing body of evidence, the cost impact on payers has not been explored. This analysis aimed to quantify patient OOP costs for three stroke prevention strategies: warfarin, dabigatran, and left atrial appendage closure (LAAC) with the Watchman Device. **METHODS:** A patient-level budget impact model was used to simulate total out-of-pocket spend on treatment and treatment-related complications over five years. 2015 Medicare deductibles and co-insurance rates were used to estimate patient OOP costs. LAAC, acute clinical presentation and office visits were calculated from the four states with the largest number of Medicare beneficiaries. Patient stay days were taken from HCUP and inpatient rehabilitation prospective payment system data. Clinical probabilities for LAAC and warfarin were taken from Brown S et al. (2016) and the dabigatran arm of the RE-LY trial. **RESULTS:** The deductive for the LAAC procedure was $1,260. This compares to an average annual acquisition cost of roughly $345 for warfarin and $1,048 for dabigatran. First year patient OOP costs were $1,734, $440, and $1,924 for warfarin, dabigatran, respectively. By the end of year 2, LAAC was less expensive with total costs of $2,535 compared to $2,702 (warfarin) and $2,865 (dabigatran). By year 5, LAAC was approximately half the cost of anticoagulants. **CONCLUSIONS:** Patient out-of-pocket costs for stroke prevention in AF are considerable and may represent a burden for many Medicare beneficiaries living on fixed incomes. LAAC with the Watchman Device provides lifetime stroke prophylaxis without increased bleeding risk at a lower cost to patients.

**PMD16**  
**ECONOMIC ANALYSIS OF EVARREST TM COMPARED WITH STANDARD CARE IN PATIENTS WITH AORTIC LUNG ARTERY ANEURYSM (ALAA) UNDERGOING LIVER SURGICAL BLEEDING POPULATIONS: A U.S. HOSPITAL PERSPECTIVE**  
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**OBJECTIVES:** Bleeding in liver surgery can be difficult to control due to extreme vascularity and tissue fragility, including compromised liver (e.g., cancer). Blood loss is one of the most critical elements that have rapid impact on cost of care. This study estimated budget impact of using EVARREST vs. SoC in hepatic surgery based on two randomized trials. **METHODS:** An economic analysis was developed to evaluate the cost-effectiveness of EVARREST compared to a U.S. hospital perspective. Key resources, from two randomized trials (n=180), included initial treatment, readmission, operating time, transfusions, ventilator, and hospitalization. Treatment costs for 80 patients (n=6) with end-organ failure were estimated from analyses. SoC was composed mainly of manual compression alone or with hemostats. The surgical analysis included resources clinically related to significant hemorrhage benefits of EVARREST (i.e. reinsertion, operating time, transfusion). A hospital and pharmacy are collected. Economic analyses were completed for the following subgroups: abnormal liver, metastatic cancer, anatomic/ non-anatomic liver (classifications using HPBPA definitions), cirrhotic/steatotic liver, and if patients were obese or coagulopathic. Published U.S. costs were used as a resource usage. Analysis results were weighted based on trial size. **RESULTS:** The surgical analysis predicted that the EVARREST cost was offset vs. SoC with a weighted cost impact of $7.19 per patient. The hospital analysis predicted further reduction with SoC (with EVARREST trial) of $2,345 as cost savings of $686 per patient. Subgroup analyses demonstrated a range of results from cost impact to cost savings with EVARREST vs. SoC (i.e. $1,976 to $4,350 per patient, hospital analysis). EVARREST use in coagulopathic patients was found to have the largest decrease of cost savings with $1,859 and $5,176 per patient anticipated, surgical and hospital results respectively. **CONCLUSIONS:** In addition to meeting an important unmet need in controlling problematic bleeding in liver tissue, this analysis suggests that EVARREST can be a cost-saving strategy.

**PMD17**  
**CLINICAL AND BUDGET IMPACT OF USING A TEST TO DETECT KRAS MUTATIONS IN METASTATIC COLORECTAL CANCER PATIENTS IN THE UNITED STATES**  
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**OBJECTIVES:** Anti-epidermal growth factor receptor (EGFR) therapies are ineffective in tumors with KRAS mutations in exon 2 codons 12 and 13. Thus, guidelines have recommended determination of KRAS mutation status in metastatic colorectal cancer (mCRC). Both the cobas® KRAS Mutation Test (cobas® test, currently available as Research Use Only in the US) and the therascreen KRAS RGQ PCR Kit (therascreen test) detect KRAS mutations in exon 2; cobas® test detects twelve mutations and the therascreen test) detect KRAS mutations in exon 2; cobas® test detects twelve mutations and therascreen test detects seven mutations in exon 2. We estimated the potential clinical and budgetary impact of using the cobas® test versus therascreen test in the mCRC setting. **METHODS:** A budget impact model comparing the clinical and economic outcomes of using the cobas® test versus therascreen test was developed from the US payer perspective. We assumed 42,000 annual cases of mCRC patients. Model inputs were obtained from literature, whereas testing and treatment costs were calculated from CMS reimbursement rates. KRAS test sensitivity reflected the test’s ability to detect mutations in codons 12 and 13; specificity was assumed to be the same for both tests. The model calculated the average cost for mCRC patients over 5 years, using median time on treatment and median overall survival. Based on current practice patterns, the proportion of patients receiving KRAS testing before 1st-line, 2nd-line, and 3rd-line therapy was 42%, 32%, and 26%, respectively. **RESULTS:** Adapting the cobas® test resulted in a reduction of 289 patient-years lost due to treatment decisions with mCRC clinical events and office visits: Using the cobas® test with improved sensitivity was associated with a reduction of patient-month lost and a decrease of healthcare costs in mCRC patients.