BACKGROUND

- Identification and workup of pulmonary nodules (PNs) can be essential to early diagnosis and management of non-small cell lung cancer (NSCLC).
- If identified at early stage (Stage I), patients with NSCLC have more favorable prognosis with 5-year survival rates of up to 90%.
- Clinical management of PNs is often guided by physician judgement or a quantitative risk model coupled with threshold-based decision making.
- Most often, the patient's nodule risk category is low to moderate where further evaluation is required, and guidelines are unclear. In these scenarios, a blood-based auto-antibody (AAb) test, Nodify CDT®, may be utilized to help up-classify the risk of malignancy to better inform management and treatment decisions.
- This economic analysis aimed to estimate the budget impact of a blood-based AAb test from a US Medicare payer perspective.

METHODS

- An excel-based budget impact model was developed to evaluate the use of a blood-based AAb test within a hypothetical 1 million-member US Medicare health plan over a 2-year time horizon.
- Blood-based AAb test use within a payer system was compared to standard of care without the test.
- Model inputs included stage shifts in NSCLC, procedures associated with PNs and NSCLC, and downstream treatment costs associated with NSCLC (Table 1).
- A decision-tree was developed to model pathways for scenarios with and without the AAb test (Figure 1).
- Assumptions included:
  - Eligible population included adults aged 40 years or older, who have a PN that is ≤30 mm in diameter, with a pre-test risk of malignancy (by the Solitary Pulmonary Nodule (SPN) Calculator) that is ≤65%, and no previous diagnosis of NSCLC.
  - The model estimates costs impact from earlier classification of lung nodules as high risk (stage shift).
  - The proportion of patients with stage shift is calculated from AAb test sensitivity and specificity as those identified as benign (Table 2).
  - Although an increase in procedures amongst malignant nodules is expected in invasive procedures amongst benign nodules (Table 2).
  - Economic modeling entails a variety of assumptions regarding disease states, treatment patterns and costs. This model represents a simplified approach to a more complex integration of factors to estimate budget impact by a health plan.

RESULTS AND LIMITATIONS

- In a 1 million-member US Medicare health plan, it is estimated that 4,170 patients would utilize the AAb test (Figure 2).
- For standard of care (SOC) without the AAb test, an estimated 1,701 patients would undergo invasive procedure to characterize their PN with approximately 1,102 identified as benign (Table 2).
- Although an increase in procedures amongst malignant nodules is expected (Table 2), costs are offset in overall costs of malignant nodules and cancer treatment (Table 3).
- By introducing the blood-based AAb test, a Medicare plan is expected to save $1,909,603 over 2 years, largely attributed to reduction in costs of cancer treatment by a shift in patient diagnosis stages to earlier stages that are less costly (Table 3).
- Overall budget impact equates to -$3.91 per-member-per-year (PMPY) or -$0.326 per-member-per-month (PMMP) (Table 3).

CONCLUSIONS

- Introduction of a blood-based auto-antibody test to up-classify risk of PNs in a US Medicare payer setting has a negative budget impact effect and therefore is cost saving to the health plan.
- Inclusion of the Nodify CDT® test within a Medicare health plan’s coverage will result in cost-savings for the health plan through earlier diagnosis of lung cancer and may improve patient health outcomes.