Background

Identification and workup of pulmonary nodules (PNs) can be essential to early diagnosis and management of non-small cell lung cancer (NSCLC). 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.

Unnecessary invasive interventions are often performed in PNs that are low to moderate risk. In fact, 35% of surgeries are performed on benign nodules.

A blood-based integrated classifier (IC) test, the Nodify XL2®, may be utilized to help reclassify PNs into a lower risk category and avoid unnecessary invasive interventions.

This economic analysis aimed to estimate the budget impact of a blood-based IC test from a US Medicare payer perspective.

Methods

An Excel-based budget impact model was developed to evaluate the use of a blood-based IC test within a hypothetical 1 million-member US Medicare health plan over a 2-year time horizon.

Blood-based IC test use within a payer system was compared to standard of care without the test.

Model inputs included procedures associated with PNs and NSCLC, workup costs, and downstream costs associated with NSCLC.

A decision-tree was developed to model pathways for scenarios with and without the IC 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 SPN Calculator) that is ≤65%, and no previous invasive procedure.
- No discounting on 2022 test list price

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

In a 1 million-member US Medicare health plan, it is estimated that 4,170 patients would utilize the IC test (Figure 2).

- For standard of care (SOC) without the IC test, an estimated 1,701 patients would undergo invasive procedures to characterize their PN with approximately 1,102 identified as benign (Table 2).
- With the IC test, it is anticipated that there would be a 35.2% reduction in invasive procedures amongst all nodules, with a 55.6% reduction amongst benign nodules (Table 2).
- By introducing the blood-based IC test, a Medicare plan is expected to save $3,506,824 over 2 years, largely attributed to reduction in costs associated with benign nodules (Table 3).
- As a sub-category of overall benign nodule cost, avoidance of biopsy and surgeries in benign nodules equates to a cost-savings of $7,556,633 (Table 3).

Overall budget impact equates to $32.51 per-member-per-year (PMPY) or -$0.292 per-member-per-month (PMPM) (Table 3).

Limitations

- 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.

Conclusions

- Introduction of a blood-based immune classifier test to reclassify 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 XL2® test within a Medicare health plan’s coverage may reduce unnecessary invasive procedures leading to improved health outcomes, avoidance of procedural complications, and overall healthcare expenditure savings.