Value of Next Generation Sequencing (NGS) Using the OncoExTra™ Test in Advanced Cancer Patients

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Background

- In oncology, next generation sequencing (NGS) tests are used to identify biomarkers to inform targeted therapy use as directed by clinical guidelines and/or regulatory approvals, and to inform eligibility for clinical trials.[1]
- Targeted therapies have prompted increased use of comprehensive genomic profiling to identify eligible patients.[2]
- Several testing options are available including single-gene, small-panel (≤ 50 genes), and large-panel tests, which includes the OncoExTra test, a whole exome (WES), whole transcriptome (WTS) NGS test with tumor-normal pairing.[3]
- Given the rapidly evolving landscape, it is important to assess cost and outcomes associated with different types of genomic testing options.

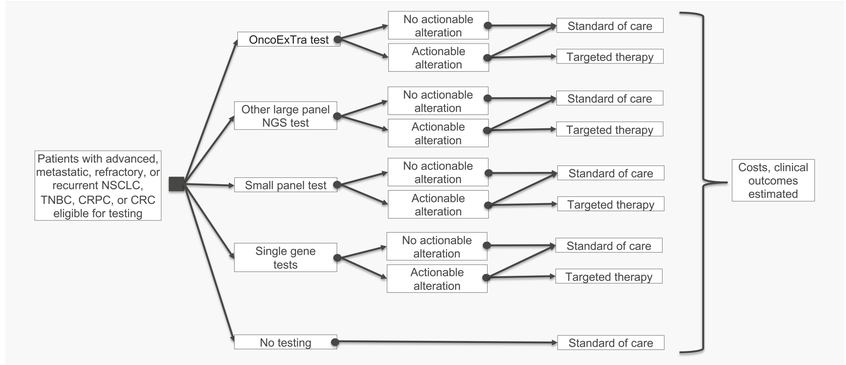
Objective

We assessed the costs and clinical benefits associated with using the OncoExTra test in advanced cancer patients.

Methods

- A Microsoft Excel-based model was developed to evaluate patients with advanced/metastatic Non-small cell lung cancer (NSCLC), triple-negative breast cancer (TNBC), castration-resistant prostate cancer (CRPC), or colorectal cancer (CRC). ISPOR good practices in economic modeling were followed.[4]
- We assessed the first line of therapy where NGS testing would most commonly be performed, therefore in some cases, it was among subgroups (i.e., TNBC and CRPC).
- A pairwise comparison was conducted on a per tested patient basis between the OncoExTra test and single-gene testing.
- Separately, a hypothetical plan of one-million members receiving the current mix of tests was compared with incorporating the OncoExTra test in 5% of members, taking share equally from single-gene testing and no testing.
- Treatment pathways were based on NCCN guidelines. In cases where multiple treatments were recommended, a single alternative was assigned based on expert opinion.[5]
- Clinical inputs, including the proportion of patients with an alteration detected and survival, were based on pivotal trials for each therapy.
- Test costs were based on generic Current Procedural Terminology codes for large panel NGS tests.[6] Pharmacy costs were treatment-specific based on wholesale acquisition prices.[7] Productivity costs were included and differed based on whether treatment regimens included chemotherapy.[8]
- Annual costs were estimated by cancer type and all cancers combined. One-way and probabilistic sensitivity analyses were conducted, and the impact of varying the uptake of the OncoExTra test was explored in scenario analyses.
- A simplified model schematic is shown in **Figure 1**.

Figure 1. Model Schematic



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Results

Pairwise Comparison Between the OncoExTra Test and Single-Gene Testing

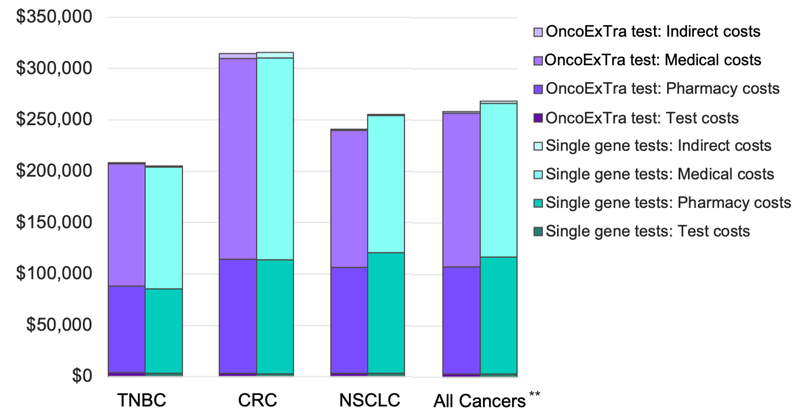
Clinical Outcomes

- When compared directly to single-gene testing, the OncoExTra test detected alterations in an additional 21% of TNBC patients, 24% of CRC patients, and 26% of NSCLC patients.
- Over 80% of TNBC and NSCLC patients were identified as being potentially eligible for a clinical trial.

Economic Outcomes

- Testing with the OncoExTra test compared with single-gene testing reduced costs by $9,951 per patient tested, ranging from a cost savings of $14,602 in NSCLC to an increase of $2,866 per TNBC patient.
- Across tumor types in which single-gene testing is used, costs are driven primarily by pharmacy and medical costs (**Figure 2**).

Figure 2. Costs Per Tested Patient Using the OncoExTra Test or Single-Gene Testing*



*Comparison not performed within CRPC patients as single-gene testing not commonly conducted in that tumor type, per expert opinion.
**Combination of the cancer types included in the study.

Impact to a Health Plan of Using the OncoExTra Test in 5% of Patients

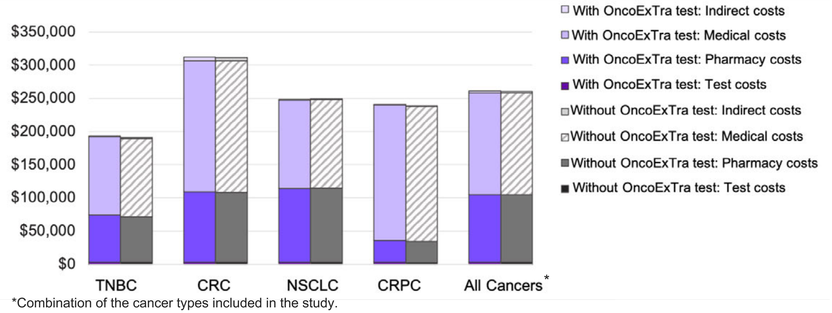
Clinical Outcomes

- In the scenario without the OncoExTra test, actionable alterations were detected in 30% of CRPC patients and between 50-56% of patients with CRC, TNBC, and NSCLC.
- When using the OncoExTra test in 5% of the population, additional patients across all tumor types had alterations identified, ranging from an additional 3.5% of TNBC patients to an additional 4.1% of TNBC patients.

Economic Outcomes

- Costs to a health plan without use of the OncoExTra test were $260,897 per cancer patient, ranging from $190,686 for TNBC patients to $311,340 for CRC patients (**Figure 3**).
- When using the OncoExTra test in 5% of the population, per patient costs were $260,989, an increase of $71 per cancer patient. The difference in costs ranged from a savings of $527 per testing-eligible NSCLC patient to an increase of $2,646 per TNBC patient.
- Increased use of the OncoExTra test led to a savings of $163,080 to the plan associated with patients enrolling in clinical trials, of which 88% was attributable to NSCLC patients.
- On a per-member per-month (PMPM) basis, the use of the OncoExTra test in 5% of patients led to an increased cost of $0.0051 per member per month, ranging from a savings of $0.024 for NSCLC patients to an increase of $0.010 for CRC patients.
- When using the OncoExTra test in 2% of patients, the budget impact decreased from $0.005 to $0.002 PMPM, and using the OncoExTra test in 10% of patients the budget impact increased to $0.011 PMPM.

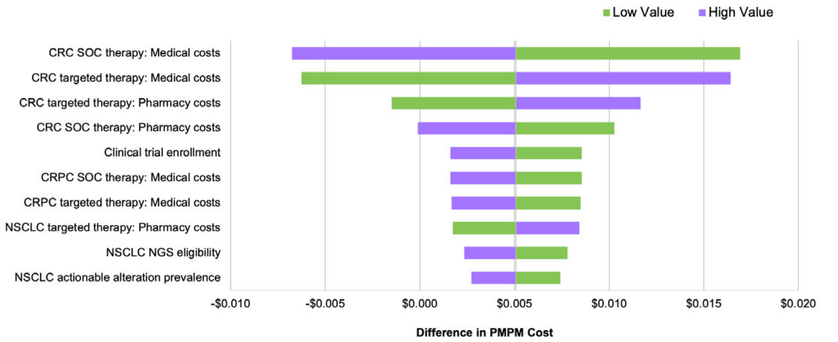
Figure 3. Health Plan Costs With and Without the OncoExTra Test Use in 5% of Patients



*Combination of the cancer types included in the study.

- In sensitivity analyses, each parameter was varied ± 20% of the base case value. Model-predicted PMPM cost difference was most impacted by changes in costs of treating CRC and CRPC patients and clinical trials eligibility assumptions. Characteristics of the OncoExTra test including the cost and test sensitivity were less influential (**Figure 4**).
- In probabilistic sensitivity analyses, the use of the OncoExTra test was cost-saving in 49% of model simulations when considering all cancer sites combined, and cost-saving within NSCLC in 74% of model iterations.
- **Figure 4** depicts the impact of parameter uncertainty combining all tumor types, however it would be important to also explore the impact within individual cancers.

Figure 4. Sensitivity Analysis: Tornado Diagram



Limitations of this study include the use of list prices for treatment acquisition costs, simplifications around the treatment pathways in cases where there were multiple guideline recommended options, and a high degree of uncertainty in certain inputs (e.g., rate of clinical trial enrollment, underlying rates of genetic alterations).

Conclusions

- Among patients with advanced/metastatic NSCLC, TNBC, CRPC, and CRC using a WES/WTS NGS test such as the OncoExTra test increases alterations identified with minimal budget impact.
- Findings should be considered when developing guidelines, determining coverage, and treating patients.

Poster presented at ISPOR 2023 on May 9, 2023.

This study was funded by Exact Sciences. Contact Gebra Cuyún Carter, gcuyuncarter@exactsciences.com, for questions regarding content.