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Cancer Genomics

Cost Effectiveness of Tumor Genomic Analysis and Immunotherapy

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Cost Effectiveness of Tumor Genomic Analysis and Immunotherapy

AUTHOR James Timmins, MBA
Breakthrough Development Co.
Society of Actuaries

Caveat and Disclaimer

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Cancer Genomics

Cost Effectiveness of Tumor Genomic Analysis and Immunotherapy

Background

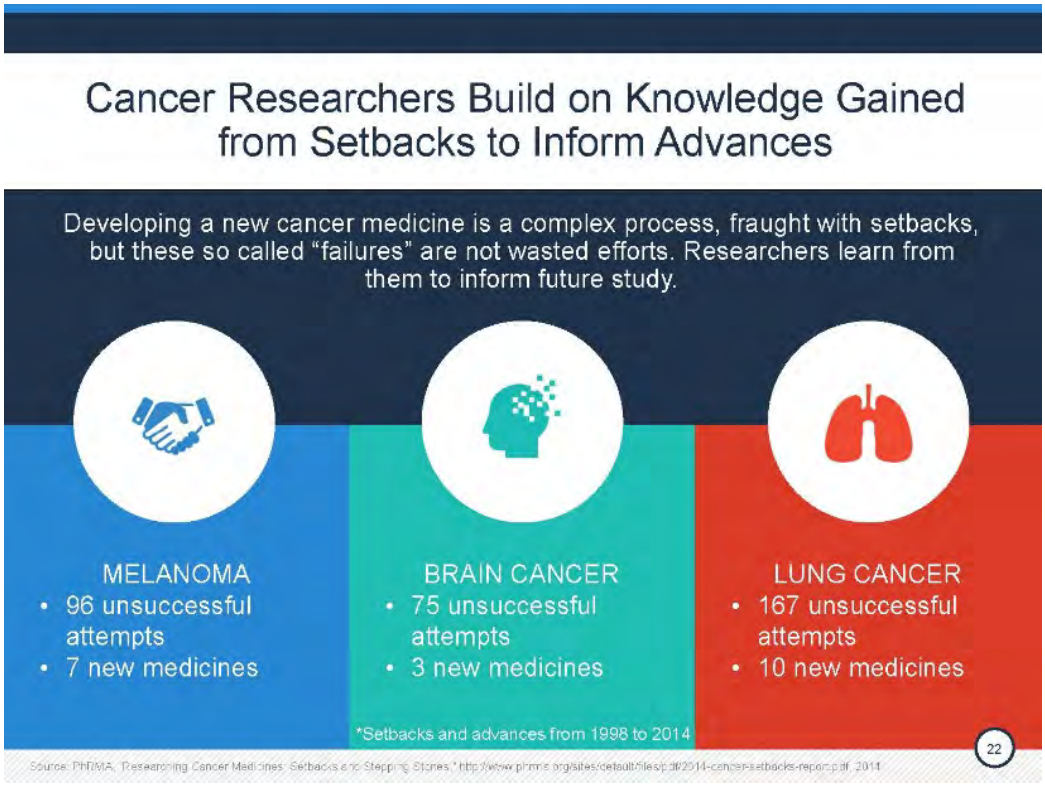
The treatment of advanced cancer is undergoing a major paradigm shift.

Traditional pillars of cancer treatment – surgery, radiation, and chemotherapy – are moving to two new efficacious approaches: tumor genomics and immunotherapy. This analysis report introduces SOA stakeholders to these brand-new areas, examines the growing clinical evidence, and sets initial projections for cost effectiveness.

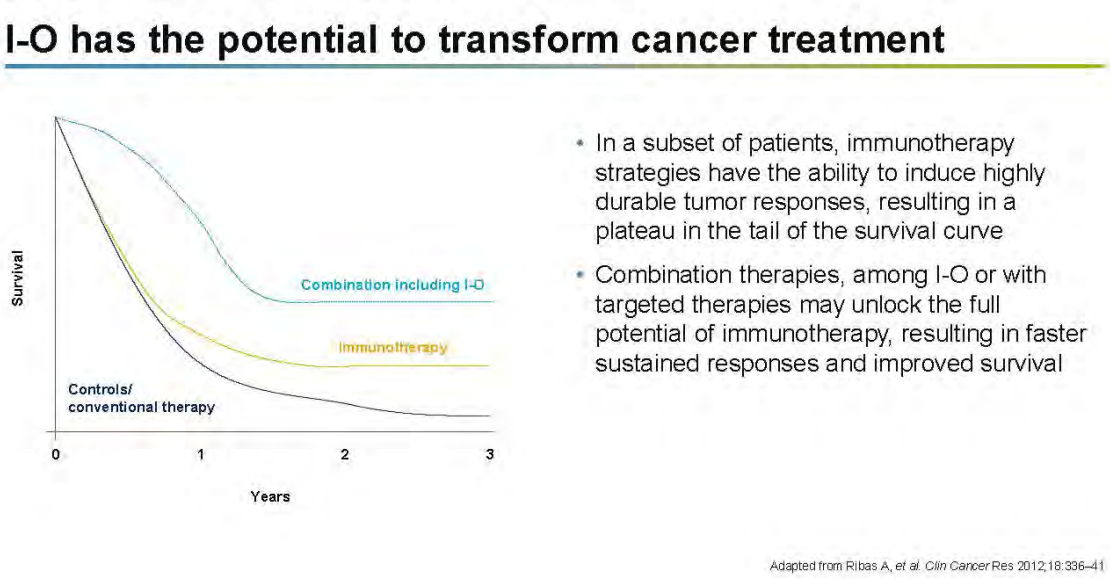
Below are the summarized Project Goals:

(i) Outline costs of a breakthrough (2018) high-efficacy cancer genomics/therapeutic combination: TMB (tumor mutational burden) testing and IO (immuno-oncology drug) therapy,
(ii) Project the costs for efficacy/cure over a five-year survival window,
(iii) Consider other related immunotherapies if more cost effective, and
(iv) Summarize the potential impacts on insurers.

Three cancers were selected as the focus for this report, which in raw numbers are some of the deadliest: lung (non-small cell or NSCLC), melanoma, and head-neck (glioblastoma). Mid-late stage patients face a 20% survival rate at best after five years, and drug development has been challenging, as shown below[1].



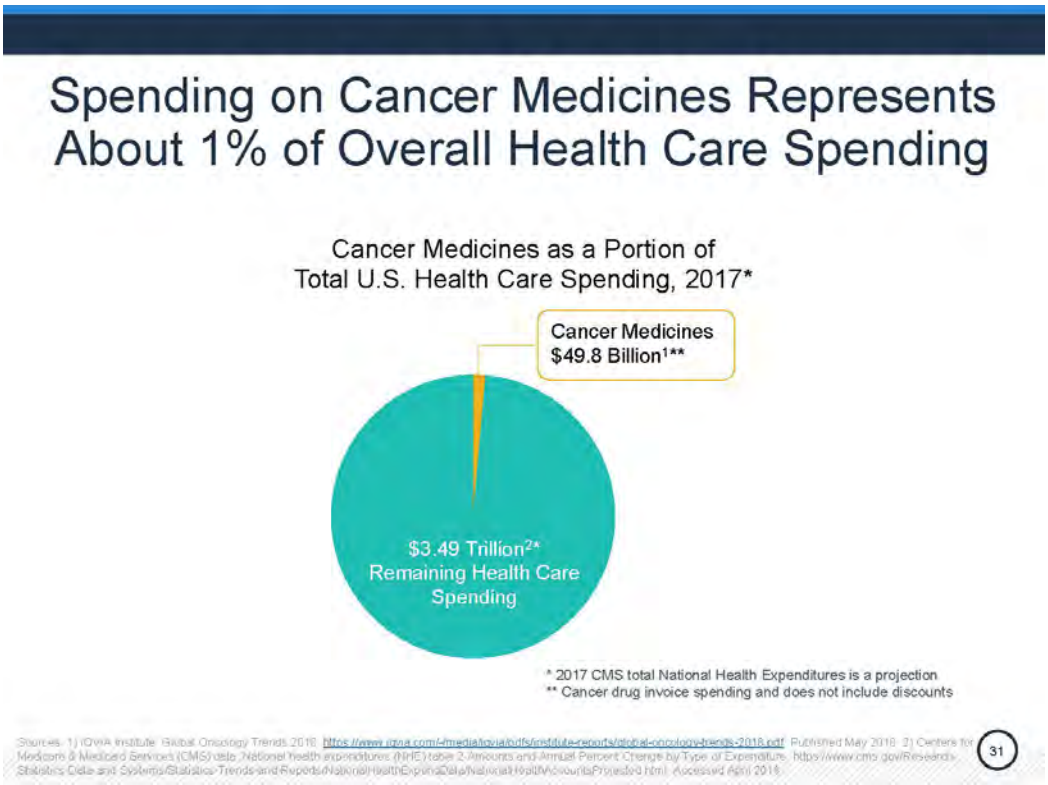
This new combination of 'one-and done' genomic analysis of tumors, plus new immuno-oncology drugs such as Keytruda (together here called TMB/IO), is generating durable survival increases of 20% or more in at least two of these cancers, raising the five-year survival rate to nearly 50% in recent clinical trials.



Survivors receiving this combination are clinically cured, e.g. Jimmy Carter, will likely have reduced cancer-related morbidities following treatment, and will return to normalcy and remain among the insured population.

Traditional treatment standards of care (SOC) for the above-targeted cancers are unacceptable. These patients often incur low quality of life and high morbidity costs, as health care providers try - and insurers pay - for multiple approaches as patients progress and near the End-of-Life stage. Increased survival and decreased morbidity would be embraced by the health care system.

Until recently, the economic burden of cancer drugs has remained relatively muted when compared to the total health care spent, largely because chemotherapy is relatively inexpensive, but ineffective, for most cancers.



Over the past decade, highly-targeted agents, e.g. Sutent and Gleevec, have shown impressive, but isolated, success, and their higher costs are steadily increasing the cancer drugs' share of the health care cost pie. IO drugs will substantially add to these costs as there are over 60 candidate drugs in development according to PhRMA. Thus, it is important to examine IO for cost effectiveness at this time.

IO drugs work by first targeting a silent immune cell receptor (PD/L1) (PD = 'programmed death'), which then re-activates the entire cancer immune system, a new approach that goes beyond narrower targeted therapies to date and, instead, like chemotherapy, triggers a systemic treatment. This discovery was also the subject of the 2018 Nobel Prize – the finding that specifically the PD/L1-receptor target on our thymus-derived, or "T"-immune cells, could be modified by a synthetic antibody drug to unleash a previously-muted attack on cancer cells, which constitutes Immuno-oncology or IO therapy.

What is Immunotherapy - or IO* Therapy?

1. Tumors resist the immune system by causing suppression of our natural Thymus (T) cells.

2. Researchers discovered a cell surface marker – called PD/L1 – that when blocked allows the T cells to avoid suppression, and attack cancer.

3. Immunotherapy is the use of synthesized antibodies that bind to PD/L1, and stop suppression. The most notable drugs are Keytruda, and Opdivo.

4. The result is an 'awakened' immune system against the tumor cells, shrinking or eliminating tumor cells exposed to now-activated T cells.

Initially, testing for PD/L1 itself was the 'qualifying test' for treatment. However, in parallel, researchers at the University of California-San Diego[2] made the discovery that you can rapidly sequence hundreds of cancer-related genes using modern-day genomics, then simply count the mutations in those genes to predict efficacy of IO drugs above a threshold. This has surpassed the PD/L1 test in popularity and has rapidly become a major discovery in cancer diagnostics. The more mutations, the more 'different' a tumor looks, e.g. like a mismatched organ, leading to a much more effective immune attack on cancer cells using IO drugs. This new multi-gene genomics test gained increasing interest, which became the TMB, or tumor mutational burden test.

What is Tumor Mutational Burden Testing, or TMB?

1. Tumors start from an internal genetic flaw that leads to uncontrolled growth. As the tumor grows, generally the number of genetic mutations grow as well.

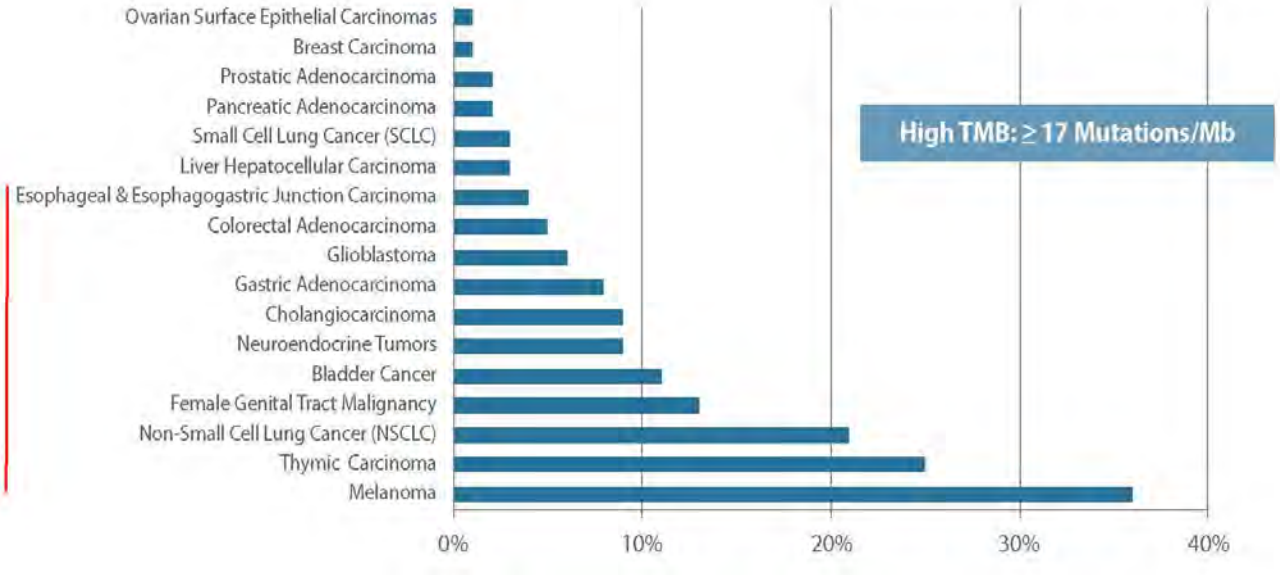
2. Unlike the traditional 'gene-by-gene' testing approach, with each test costing $500+, researchers are finding that using Genomics – sequencing of hundreds of cancer genes at once – is more cost-effective and faster for actionable diagnosis.

3. With the advent of IO, it also was found that simply counting all the mutations – instead of just testing for PD/L1 – was more consistently predictive of IO therapy benefit. This 'counting of mutations' and correlation to IO drug administration is the TMB Test.

The cost of genomics – sequencing for ALL your genes either from normal cells or cancer cells – is now in a price range ($3,000 including analysis) where it makes economic sense to do it once, then mine that data for individual genetic profiling for your diagnosis. This capability goes beyond cancer and can eventually be applied throughout medicine. McKinsey's recent review of genomics technologies names TMB and individual-gene tests as the most clinically-relevant applications within oncology, and Medicare agrees with reimbursement of $2,000 and more per genetic test used for cancer, e.g., BRCA for breast cancer[3].

Nearly every biopsied tumor is eligible for TMB analysis. If the patient fails TMB with a low mutational count, all is not lost, as the tumor DNA readout can be salvaged for further analysis for individual gene-targeting therapeutics. High on the list is the older PD/L1 test itself, which can also qualify failed TMB patients for IO drugs.

Summary statistics are rapidly evolving, where the definition of 'high TMB' is different for each cancer. Below is an early chart showing, from one survey, the percentage of each cancer that exceeds a then-arbitrary 'high TMB' reading of 17 mutations per million DNA bases.



A report from January 2019[4] at Sloan Kettering (NY) defined the mutation-count thresholds in far greater detail using data from over 1,600 patients, where now lung cancer, melanoma, and glioblastoma have cutoffs of 10, 31, and 14 mutations per million DNA bases read by genomic analysis. A full assessment of the percentage of high TMB scores at each cancer's stage is not yet available and will likely take several years to mature as seen in the past decade for prostate PSA and breast ER/Her2 tests.

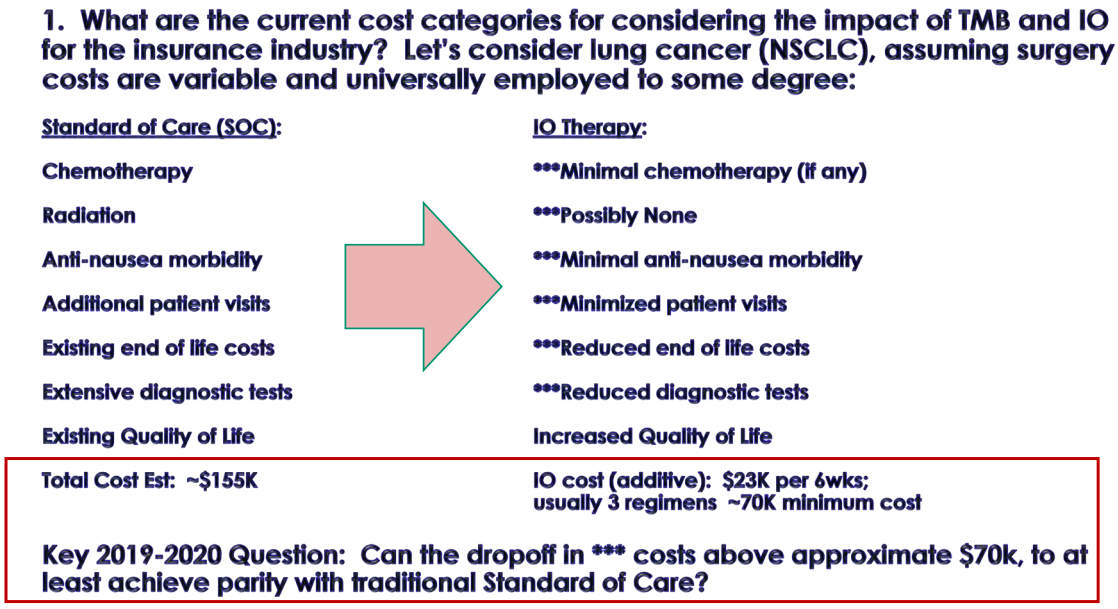
An interesting conclusion one can draw here, for the medical and insurance professions and for public policy, is that early-detected cancer cases may not immediately qualify for the new TMB/IO therapies since they likely hold fewer mutations at that stage. In any event, Merck and others obtained their first FDA approvals of IO drugs without a companion TMB test. With the latter, now efficacy and survival should be improving as clinical researchers find and establish correlation metrics between TMB scores and IO efficacy.

Will the observation of a higher percentage of patients who plateau into survival – potentially up to 40% - result in reduced overall payouts in lung cancer, melanoma, and head-neck cancer?

Section 1: Cost Categories for Treatment

The existing cost categories that could show a reduction from TMB/IO therapy are chemotherapy, radiation, associated morbidity, and associated office visits. Surgery, which is a variable cost unique to each patient depending on the size and location of their tumor, is not considered in this assessment.

The following chart first shows the cost categories for both Standard of Care (SOC; left), and TMB/IO (right) for lung cancer. Categories that have a high potential for reduction are asterisked. While these reductions are not yet firm or documented, what is clear is that TMB/IO will add roughly $70,000 to treatment costs: a minimum of three rounds at six weeks each, at $23,000 per round – plus the cost of TMB screening, $3,000.

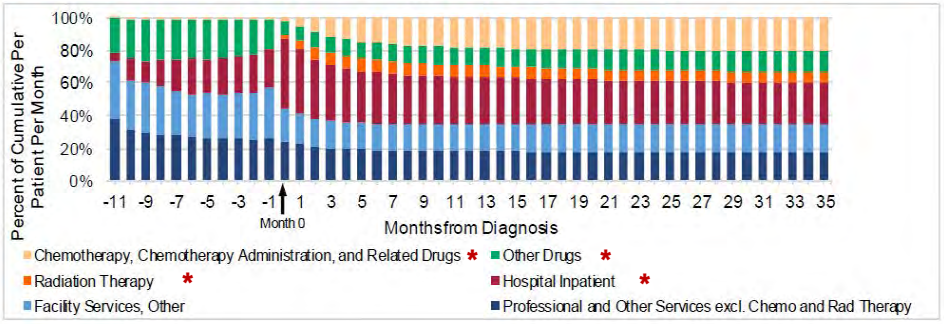


In the actuarial sciences, Milliman additionally conducted a recent analysis outlining the cumulative health expenditures in lung cancer[5]. Their cost estimate was significantly higher, up to $282,000 after four years (see below chart). Chemotherapy, and other drugs assumed for morbidity treatment, consume roughly 40% of total costs. As SOC cost estimates are higher, TMB/IO may have an even greater cost-effectiveness impact.

Lung Cancer Costs (Milliman) – Can IO Avoid Costs* after 1y?

MONTHS FROM DIAGNOSIS	0	5	11	17	23	29	35	41	47
CUMULATIVE TOTAL HEALTH SPENDING									
LUNG CANCER	$37,621	$99,062	$139,958	$172,213	$200,580	$225,270	$248,163	$265,725	$282,147 *
CUMULATIVE PATIENT OUT-OF-POCKET COST									
LUNG CANCER	$2,918	$4,299	$5,489	$6,648	$7,747	$8,848	$9,794	$10,588	$11,180

FIGURE 4A: DISTRIBUTION OF CUMULATIVE TOTAL HEALTHCARE SPENDING BY SERVICE CATEGORY BEFORE AND AFTER DIAGNOSIS, – PATIENTS DIAGNOSED WITH LUNG CANCER (2011-2014)



Source: Milliman, 2017

TMB/IO therapy has the potential to impact nearly all these Milliman cost categories.

Similar cost-category analyses for melanoma and glioblastoma were conducted, and they remain the same. The comparator SOC cost is $102,000 for mid-stage melanoma and, for glioblastoma, a treatment-intensive cancer, $355,000. Therefore, TMB/IO has a higher economic barrier to achieve cost effectiveness (C-E) in melanoma, and a lower economic barrier to reach cost effectiveness in glioblastoma. Ironically, all studies to date show that C-E is clearly evident in melanoma, raising hopes that more expensive cancers may easily show C-E as well. Note: In this analysis, since increased survival is a common outcome, "cost effective" is being used in this report to mean "cost neutral" or "cost saving."

Section 2: Preliminary Models

While the current incremental approach in the emerging clinical trial literature includes at least one round of chemotherapy followed by IO administration[6], the complete avoidance of chemotherapy is projected to be the ultimate therapeutic approach. With that assumption, preliminary Markov models were constructed for each cancer, and are discussed in the next section.

These models also assume that every presenting cancer patient has an available biopsy that will undergo TMB testing. The TMB score will then determine the treatment plan, either IO for those with a high TMB score, or SOC for those with a low TMB score. Once TMB is known, probabilities of further transitions are estimated.

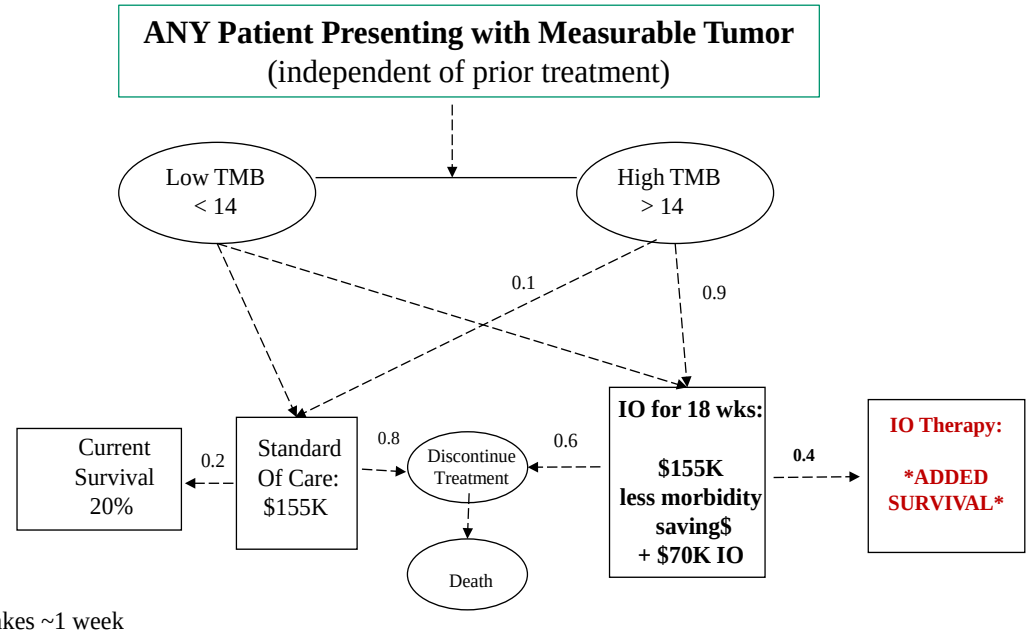
It is important to note that, without benefit of TMB screening, a major literature review[7] concluded that Keytruda was cost effective in lung cancer and melanoma. The authors stressed that "it cannot be overstated that careful patient selection is critical for C-E." This is a role that TMB is rapidly filling in 2019-2020.

While these Markov models must result in two outcomes – death or survival – they do not consider the economic benefit of increased survival and lower morbidities for the health care system and insurers. In a later summary section, these benefits will be estimated and factored into cost effectiveness.

For the patients who qualify as high TMB in the models below, 90% are considered for IO therapy for lung cancer and melanoma. This is based on the recent (January 2019) Sloan Kettering data showing better overall survival for all patients with high TMB and following IO therapy. Because of less-mature data availability for head-neck cancer, a more conservative 60% of high TMB patients are considered for IO therapy.

2.1 Lung Cancer (NSCLC)

Tentative (Hidden) Markov Model for TMB Testing* and **NSCLC**



*TMB testing takes ~1 week

Lung Cancer (NSCLC) Narrative/Assumptions:

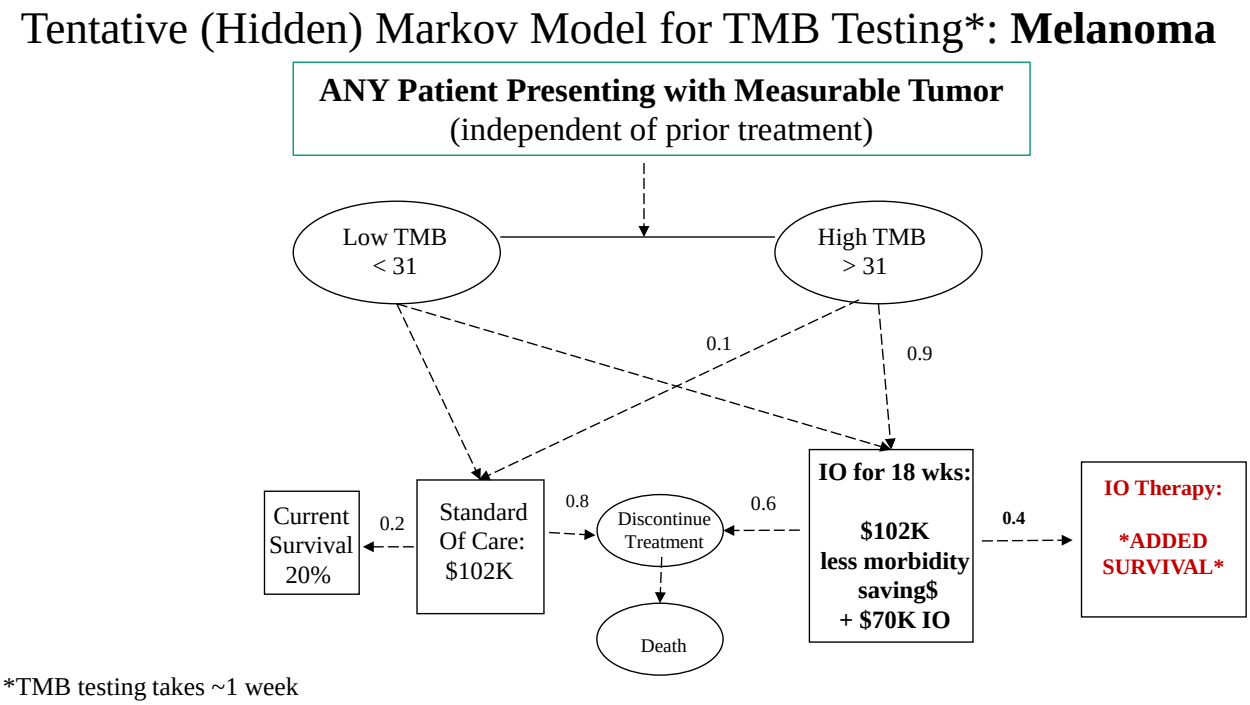
1) All patients with measurable tumors are eligible for TMB testing, e.g. a memory-less requirement for Markov treatment.

2) For high TMB patients (over 14 mutations), 90% receive IO therapy. Ten percent will go to SOC due to an adverse event or other reason.

3) Low TMB patients (under 14 mutations) remain in the current SOC, resulting in a 20% or lower survival rate**.

**Since IO was approved for treatment without a TMB score, low TMB patients are eligible for IO therapy (e.g. PD/L1 test) and a minority of them will pursue this approach. However, there is a risk of a 'cytokine storm' immune overload in the patient, thus oncologists are cautious unless the patient has a high PD/L1.

2.2 Malignant Melanoma



*TMB testing takes ~1 week

Melanoma Narrative/Assumptions:

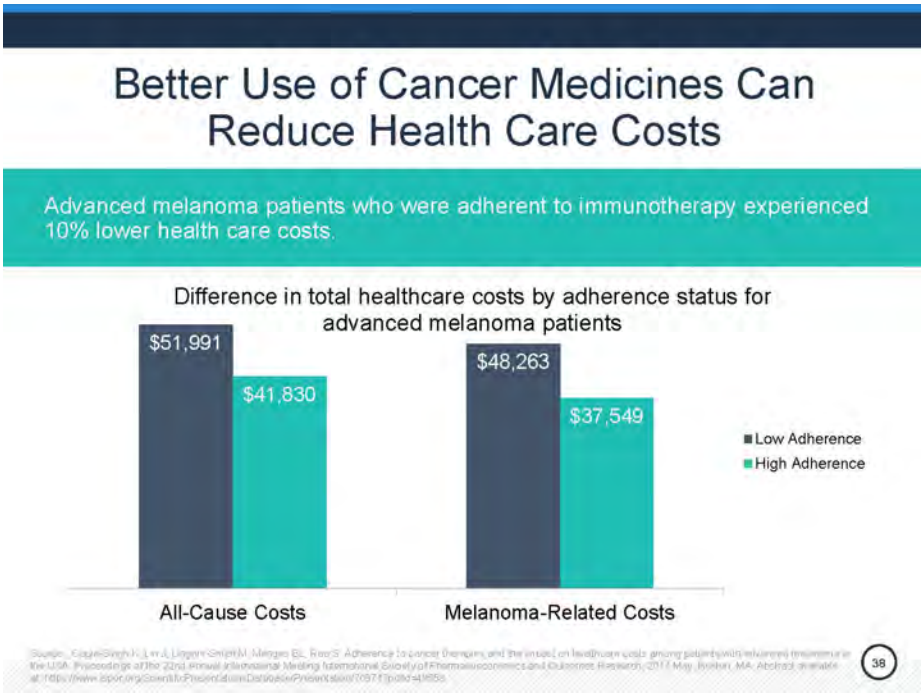
1) All patients with measurable tumors are eligible for TMB testing, e.g. a memory-less requirement for Markov treatment.

2) For high TMB patients (over 31 mutations), 90% receive IO therapy. Ten percent will go to SOC due to an adverse event or other reason.

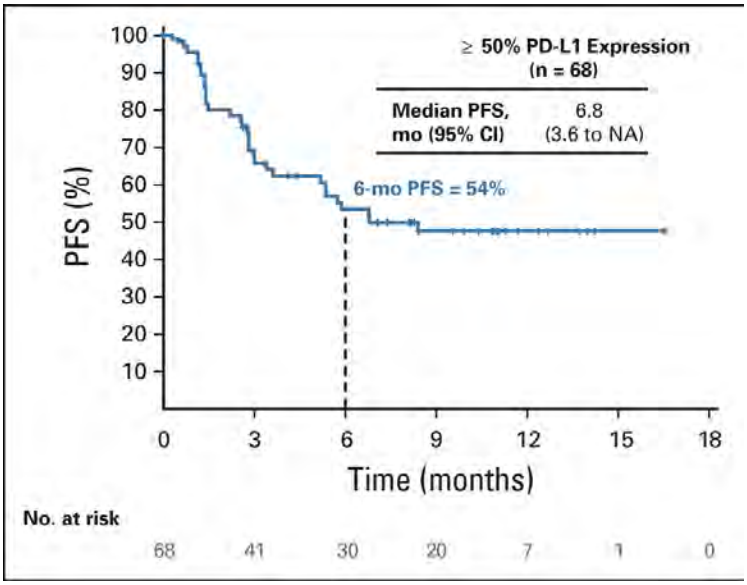
3) Low TMB patients (under 31 mutations) remain in a current SOC, resulting in a 20% or lower survival rate**.

**Again here, low TMB patients are eligible for IO therapy and a large minority of them will switch over.

As mentioned earlier, the SOC for early-stage melanoma is relatively less costly. Even without benefit of TMB screening, PhRMA estimated 10-20% lower costs for IO in melanoma treatment as shown in the figure below.

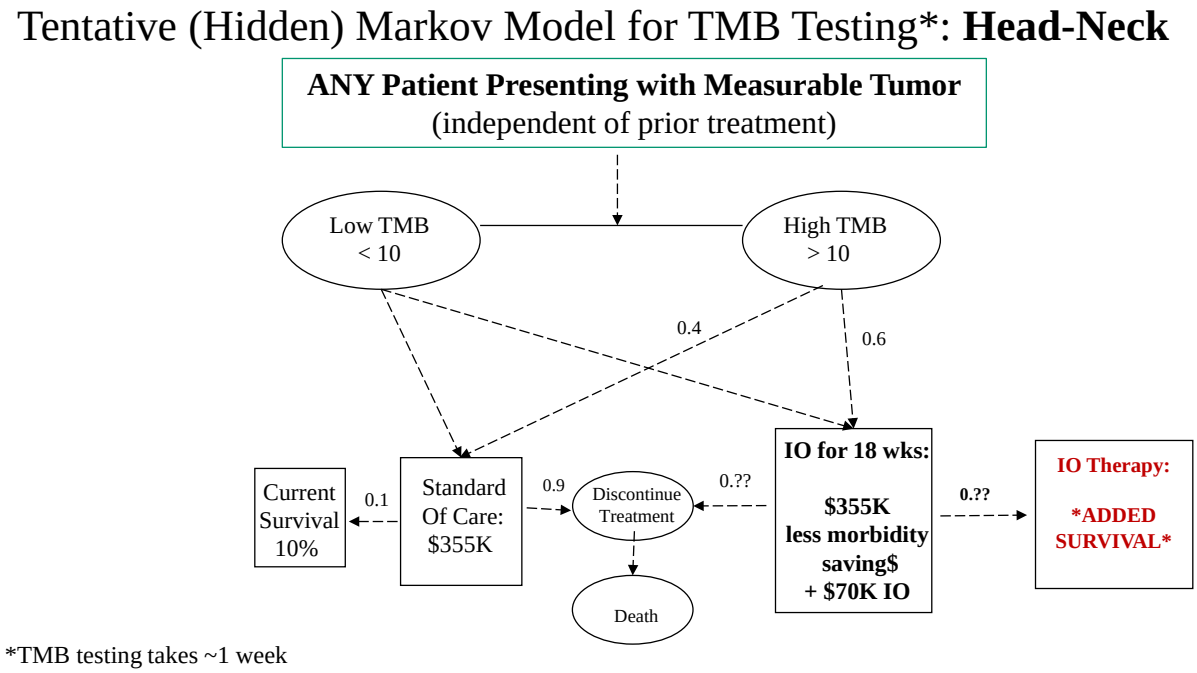


For mid-late stages, new data is showing an unprecedented 50% long-term survival by prior screening, versus less than a 20% survival rate via the older SOC. The below chart displays the benefit of the earlier PD/L1 test method, which is now being eclipsed by the higher-confidence TMB test.



Progression-free survival (PFS) in patients with 50% or greater tumor programmed death ligand 1 (PD-L1) expression. NA, not available.

2.3 Head-Neck (Glioblastoma)



*TMB testing takes ~1 week

Head-Neck (Glioblastoma) Narrative/Assumptions:

1) All patients with measurable tumors are eligible for TMB testing, e.g. a memory-less requirement for Markov treatment.

2) For high TMB patients (over 10 mutations), 60% receive IO therapy. Forty percent will go to SOC due to an adverse event or other reason. Note: Fewer patients are estimated for eligibility due to the multi-modal therapies that occur for glioblastoma.

3) Low TMB patients (under 10 mutations) remain in a current SOC, resulting in a 10% or lower survival rate**.

**As seen with Jimmy Carter and John McCain, IO is being applied regardless of TMB at this time on an 'off-label' treatment basis, thus the IO therapy percentages for low TMB patients may rise significantly.

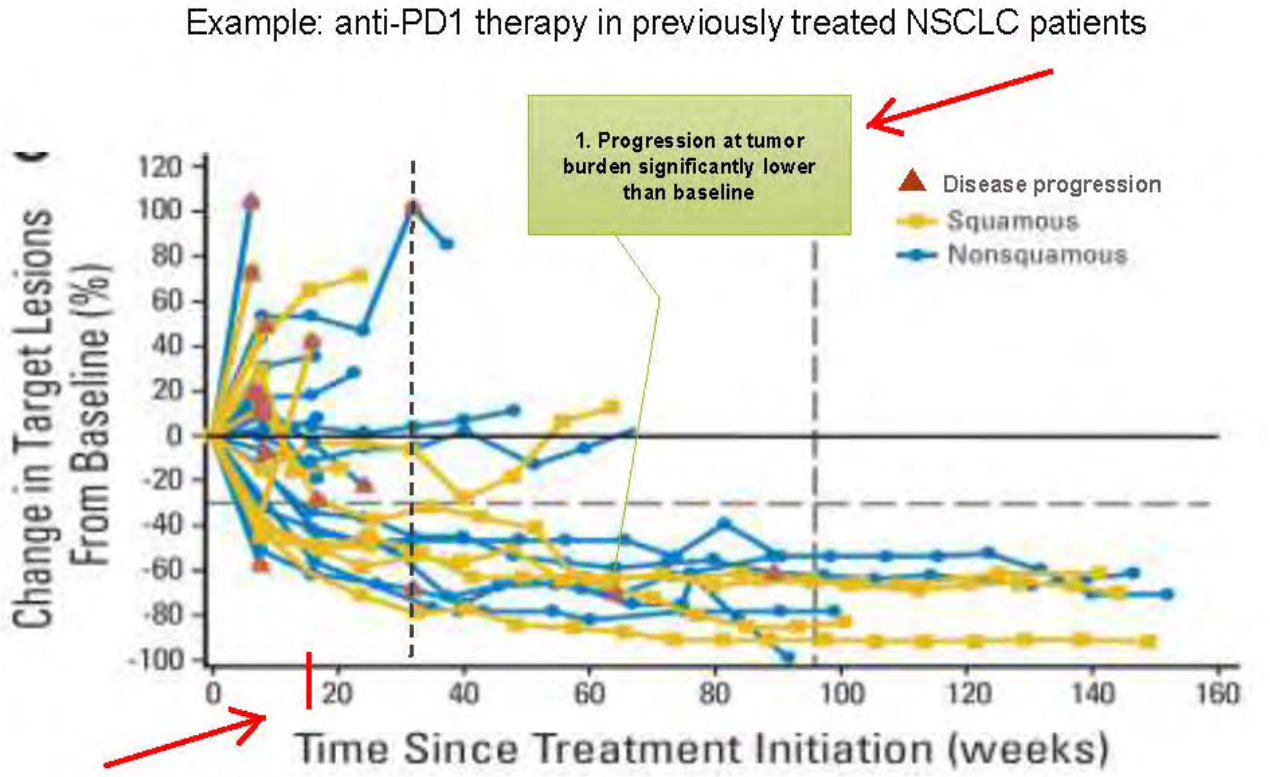
Overall, patient numbers are too small currently for detailed IO cost effectiveness in head-neck cancer. However, guidance is beginning to emerge. A just-released March 2019 article by Foundation Medicine / Roche that studied nearly 10,000 cancer patients retrospectively showed that TMB ranking for glioblastoma may require more data versus already-high IO eligible cancers like melanoma and lung cancer[8].

Noninflamed			Inflamed	Hypermutated
<7% Staining positive for PD-L1; TMB < 10	7%–13% Staining positive for PD-L1; TMB < 10	13%–33% Staining positive for PD-L1; TMB < 10	≥33% Staining positive for PD-L1; TMB < 10	Any PD-L1 TMB ≥ 10
Adenoid cystic, adrenocortical, appendix, cholangiocarcinoma, colorectal, neuroendocrine, pancreatic, papillary thyroid, prostate, small bowel	Breast, endometrial, gastric, glioblastoma, ovarian, sarcomas, skin (nonsquamous), small cell lung	Anal, cervical, esophageal, HCC, HNSCC, mesothelioma, NSCLC (squamous), renal cell carcinoma, urothelial, uveal	Merkel cell, nasopharyngeal, NSCLC (nonsquamous), thymic	DLBCL, melanoma, mismatch repair–deficient cancers, skin (squamous)

Section 3: Initial Forecast of Cost Impact for Insurers of TMB/IO

As shown above, TMB genomic testing of tumors is accelerating rapidly and will simplify IO therapy decisions in the target cancers. Avoidance of late-stage treatment and morbidity and End-of-Life costs may be substantial by the early 2020s.

The key issue in the months ahead is whether TMB and IO can be optimized for each cancer to minimize cost, chemotherapy, radiation, and morbidity. At present, Merck's Keytruda is indicated for three-week interval administrations until cancer advances, or for 24 months. However, early data on tumor shrinkage shows that completing just the first 18 weeks of IO treatment alone might be efficacious, at least in tumor shrinkage, and – by extension - immunity.



Expansion of this data into optimal dosing recommendations is not yet in place but should be available within the coming months, along with survival data and morbidity and chemotherapy reduction studies, all of which should be of keen interest to insurers and health care systems. Efficacy at 18 weeks of IO treatment is critical for C-E, as shown below.

Tentative Analysis of Cost Effectiveness

The estimates for total cost of the pre-existing SOC for the target cancers are backed up by available references, which have their basis in generic chemotherapy drugs. Similarly, the estimate of three regimens at $23,000, or roughly $70,000 additive cost, is also confirmed by Merck.

Below is the current five-year SOC cost summary (before IO therapeutics were approved) for the three target cancers studied in this analysis.

Pre-IO Standard of Care (SOC) Cost Estimates

(likely IO therapy costs: $70,000**)

Lung Cancer/NSCLC		
Utah/Harvard (2016)		$137,000
AJMC (Pre-IO) (2018)		$165,000
NCI (2020 estimate)		$164,000
	Average SOC	**$155,333**
Melanoma		
Hilner (2001)		$101,000
Davis (2009)		$152,000
Yabroff (2008)		$85,000
NCI (2020 estimate)		$70,000
	Average SOC	**$102,000**
Head-Neck (GlioB)		
Brain Tumor Foundation		$450,000
NCI (2020 estimate)		$259,000
	Average SOC	**$354,500**

At present, the new IO SOC is not yet settled by the clinical community. However, the following summarizes the situation in each target cancer, leading to conclusions that IO will be cost-neutral, at best, for lung and head-neck cancers, and cost effective for melanoma.

a. IO therapy will reduce overall treatment and morbidity costs in *progressing* patients by 50% of the anticipated $73,000 TMB/IO cost (e.g. $37,000). Chemotherapy and cancer-associated morbidity and End-of-Life costs comprise roughly 40% of the existing SOC cost, which appears to be $75,000 or more for lung cancer according to Milliman.

The use of chemotherapy may be expected to drop to only one or two rounds (if any), just to 'disrupt the tumor' for better immunotherapy results. This is a far different purposing of chemotherapy, where currently a maximum-tolerated dose is applied to extinguish all cancer cells and, at the same time, normal immune/regenerative cells, that often results in lifetime morbidities such as chronic neuropathy.

b. IO therapy will reduce SOC costs in *survivors* by the same percentage as the increased survival rate.

c. Survivors will be healthy and, thus, will remain as insureds.

Tentative Payers' 5-Year Cost Savings Analysis

Lung Cancer/NSCLC		
Standard of Care	$155,000	
TMB/IO, assuming $37K net increase	$192,000	
less discount @20% incr survival	($31,000)	
Net payout, new SOC	**$161,000**	**roughly equal cost**
Melanoma		
Standard of Care	$102,000	
TMB/IO, assuming $37K net increase	$139,000	
less discount @50% incr survival	($51,000)	
Net payout, new SOC	**$88,000**	**TMB/IO superior**
Head-Neck		
Standard of Care	$355,000	
TMB/IO, assuming $37K net increase	$392,000	
less discount @10% incr survival	($35,500)	
Net payout, new SOC	**$356,500**	**roughly equal cost**

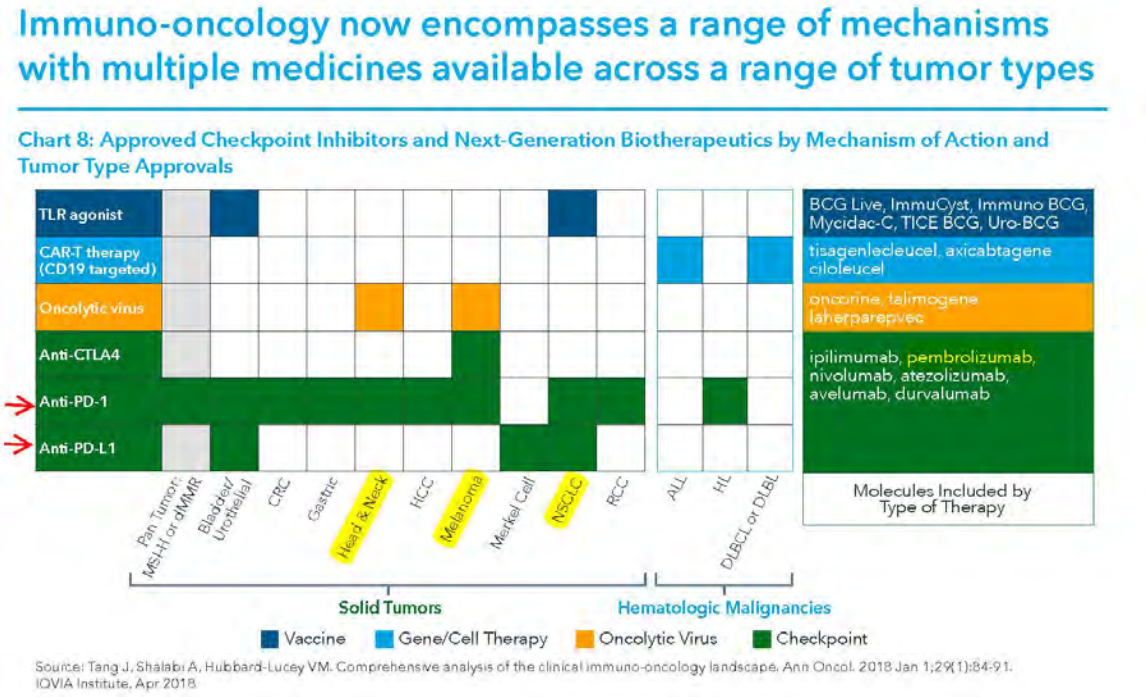
Thus, assuming 18 weeks of IO therapy will ultimately be sufficient for TMB-qualifying patients, both lung and head-neck cancers appear cost-neutral at present. For melanoma, TMB/IO therapy is cost-saving, largely due to the vastly increased number of survivors. Increased survivor percentages should rise from current clinical trials and reported statistics, influencing a new SOC that would increase the C-E for all cancers in coming years.

It is important to note that, all things remaining equal, a requirement for additional IO drug administration could move lung and head-neck cancers negatively (away from cost effectiveness). For melanoma, an additional round of IO therapy should still allow cost effectiveness, in all likelihood.

Section 4: Competitive Therapies Are Not Cost Effective

Of all the new cancer therapeutics, immunological approaches are the most powerful weapons for maximizing efficacy potential. IO drugs are not alone in this field, however, as there are cell-based 'CAR-T' (Chimeric Antigen Receptor-T Cell) and viral infection (oncolytic) approaches that are in the clinic and are also showing efficacy.

These therapies are at an earlier stage than the approved IO drugs (see McKinsey chart below) and are at least five to six times higher in cost. IO therapies have far more numerous cancer applications, while the competitors also have made a broad clinical impact.



Since our current estimate is that IO treatment is not cost effective in over roughly $100,000 in additive costs, assuming concurrent decreases in chemotherapy and morbidity, the selection of an alternative therapy above $400,000 is clearly non-competitive at this time.

Below are descriptions and citations for the top-approved alternatives in these areas:

CAR-T cell therapy. This approach removes T cells from the patient, modifies them genetically, and reinfuses them, compared to the simple infusion of IO drugs. Additional skilled labor and complex procedures are involved as well. "The mean total expected cost of Tisagenlecleucel was $510,963. Costs ranged from $478,777 for patients who did not develop cytokine-release syndrome to $531,813 for those who did"[9].

Oncolytic virus therapy. Here, a genetically modified virus is infused into the patient that targets the tumor and multiplies in tumor cells, raising immunity to both the virus and the tumor cells. Modified viruses have had a checkered past, however, the benefit for terminal cancer patients outweighs the risk. Cost of production is surprisingly high compared to common virus vaccines. "In progression-free survival (PFS) analyses, the cost of Talimogene laherparepvec plus Ipilimumab ($494,983) was almost quadruple that of immunotherapy ($132,950), according to Ivo Abraham, PhD, of the University of Arizona in Tucson"[10].

Section 5: Summary and Conclusions

The combination of TMB qualification tests and IO drugs (e.g. Keytruda) is the most revolutionary approach to cancer treatment in a decade or more and is resulting in durable increases in survival of 20% or more in hundreds of clinical-trial subjects.

It appears that a minimum therapy cost of roughly $70,000 is required to see efficacy. At this level and with assumptions of lower chemotherapy, increased survival, and reduction in morbidity and associated visits, this combination is cost effective for melanoma, and cost-neutral for lung and head-neck cancers.

Conversely, IO costs that would normally exceed $100,000 may not be cost effective pending further clinical data.

Cost categories for the treatment of lung cancer, melanoma, and head-neck cancers also remain intact for now, but TMB/IO therapy should reduce or eliminate chemotherapy and radiation costs within most categories.

The below chart displays the cost-effectiveness profile for TMB/IO therapy, which relies heavily on the avoidance of chemotherapy and related morbidities, where green/light boxes suggest cost effectiveness, orange boxes remain uncertain, and the red/dark box appears to be not cost effective at this time.

Chemotherapy Avoidance* ↓	**1 Round IO** ($26K)**	**2 Rounds IO ($49K)**	**3 Rounds IO ($72K)**	**4 Rounds IO ($95K)**
40% Reduction in Total Cost (no chemo)				Melanoma Only is C-E
30% Reduction in Total Cost				
20% Reduction in Total Cost				
10% Reduction in Total Cost				

*Includes morbidity-associated visits and drugs (Milliman).
**TMB test at $3,000 is included

Competitive approaches, such as CAR-T and oncolytic therapies, are not cost effective for the foreseeable future, as they are at least five-fold higher than the TMB/IO combination.

Final note: Verbal and email correspondence with clinical and research experts at the following institutions was influential in the preparation of this report:

Memorial Sloan Kettering (NY), MD Anderson (Houston), Mass General (Boston), Univ. of Utah, and Univ. of California-San Diego (Moore Cancer Center).

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About The Society of Actuaries

The Society of Actuaries (SOA), formed in 1949, is one of the largest actuarial professional organizations in the world dedicated to serving more than 30,000 actuarial members and the public in the United States, Canada and worldwide. In line with the SOA Vision Statement, actuaries act as business leaders who develop and use mathematical models to measure and manage risk in support of financial security for individuals, organizations and the public.

The SOA supports actuaries and advances knowledge through research and education. As part of its work, the SOA seeks to inform public policy development and public understanding through research. The SOA aspires to be a trusted source of objective, data-driven research and analysis with an actuarial perspective for its members, industry, policymakers and the public. This distinct perspective comes from the SOA as an association of actuaries, who have a rigorous formal education and direct experience as practitioners as they perform applied research. The SOA also welcomes the opportunity to partner with other organizations in our work where appropriate.

The SOA has a history of working with public policymakers and regulators in developing historical experience studies and projection techniques as well as individual reports on health care, retirement and other topics. The SOA's research is intended to aid the work of policymakers and regulators and follow certain core principles:

Objectivity: The SOA's research informs and provides analysis that can be relied upon by other individuals or organizations involved in public policy discussions. The SOA does not take advocacy positions or lobby specific policy proposals.

Quality: The SOA aspires to the highest ethical and quality standards in all of its research and analysis. Our research process is overseen by experienced actuaries and nonactuaries from a range of industry sectors and organizations. A rigorous peer-review process ensures the quality and integrity of our work.

Relevance: The SOA provides timely research on public policy issues. Our research advances actuarial knowledge while providing critical insights on key policy issues, and thereby provides value to stakeholders and decision makers.

Quantification: The SOA leverages the diverse skill sets of actuaries to provide research and findings that are driven by the best available data and methods. Actuaries use detailed modeling to analyze financial risk and provide distinct insight and quantification. Further, actuarial standards require transparency and the disclosure of the assumptions and analytic approach underlying the work.

Society of Actuaries
475 N. Martingale Road, Suite 600
Schaumburg, Illinois 60173
www.SOA.org