Assessing the Potential Revenue Impact to Oncology Practices under a Cancer Drug Therapy Bundled Reimbursement Model

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EXECUTIVE SUMMARY

The treatment of cancer is complex, as the intensity of care needed by individual patients varies according to the staging of their condition, among other factors. Over the past few years, advances in diagnostic techniques and treatment options have increased survival durations from diagnosis for patients with cancer. Advances in technology, high dollar treatments, and longer treatment times have improved patient survival and increased (by 27% to 39%) the overall projected cost of cancer care.[1]

As a means to control cost and improve quality, the Centers for Medicare and Medicaid Services (CMS) has proposed the Oncology Care Model (OCM) and Merit-based Incentive Payment System (MIPS) as an alternative to fee-for-service (FFS) reimbursement to pay for services and drugs used to treat cancer.[2] There are also other alternative payment models (APMs) such as shared savings programs which are being implemented with the intent of improving the alignment between quality and reimbursement.

The innovative reimbursement models explicitly move away from volume based reimbursement towards a budget-based approach which is intended to be adequate assuming care is delivered efficiently and appropriately. There has been significant success with reimbursement innovations, particularly for services which have little variation in the provision of care, but which benefit significantly from quality outcomes, such as joint replacement. For more complicated disease areas, or disease areas with significant emerging innovation, the additional inherent variation suggests approaches are needed to help differentiate between risk that can be managed or reduced by the provision of superior care and risk that is inherently uncertain or unmanageable.

Milliman, Inc. (Milliman) was retained by the American Society of Clinical Oncology, Inc. (ASCO) to evaluate the potential impact to provider reimbursement under alternative oncology payment structures and illustrate the inherent variability across patients using a simplified alternative oncology payment bundle for cancer drug treatments (CDTs) and related professional services. Our objective was to create a model using patient vignettes (using a Monte Carlo approach) that would demonstrate the importance of CDT bundle design features to mitigate the illustrated range of financial outcomes.

The clinical variations we included in the patient vignette model are often outside an oncology practice's control. The ideal model should preserve incentives to align quality and reimbursement. Some of the mitigating features are addressed in CMS's Oncology Care Model (OCM) and it's important to note that this illustrative model is not representative of any proposed or adopted oncology related alternative payment model nor is this paper an illustration of OCM.

In performing our work, we did the following:

1. Based on clinical judgment of ASCO volunteers, we chose to model advanced stage III colon cancer (CC) and non-small cell lung cancer (NSCLC).
2. ASCO volunteers identified typical types of patients (vignettes) for both of these cancers.
3. For each vignette, ASCO volunteers identified the standard of care (i.e., the medical procedures and chemotherapeutic agents (chemo) provided to these patients) based on the guidelines published by National Comprehensive Cancer Network (NCCN). As described below, our analysis assumes that these standards of care were clinically appropriate for the patients we modeled, and did not permit revision or substitution.

4. Using CMS 1st quarter 2016 Medicare reimbursement rates, Milliman determined the FFS reimbursement for these patients. For purposes of illustration, Milliman set the bundled payment to be the average of these reimbursements under an assumed distribution of vignettes for each cancer scenario. Note that reimbursement in this study was limited to physician Evaluation and Management (E&M) services, chemo administration, and supportive drugs which are used to treat some of the side effects of chemo.
5. Milliman developed simulations for different types of oncology practices for these vignettes to assess the variation of the expected change in reimbursement. We identified four types of oncology practices based on practice area (urban vs rural) and practice setting (office vs hospital outpatient).

This analysis is focused on the practice revenues using the Medicare fee schedule from CDTs and related administration services for two specific cancer types. As mentioned above, this is an illustration and therefore is not representative of any bundled CDT reimbursement model to our knowledge currently implemented by Medicare or commercial payers. However, it highlights the potential for reimbursement variation in bundled CDT reimbursement methods that could be discussed between payers and oncology practices. The study was limited to physician reimbursement for E&M services, chemo administration, chemotherapy, and supportive drugs which are used to treat some of the side effects of chemo. The illustration assumes a fixed fee or bundled payment for these services equal to the average CMS FFS fee schedule rate for the identified cancer vignettes. Specifically, facility reimbursements were excluded from our analysis. Furthermore, we assumed no overall cost or savings compared to Medicare FFS reimbursement rates. That is, we assumed that the reimbursement under the limited bundle approach was set equal to the expected overall cost of the services within the scope of the program.

Our analysis shows that as compared to FFS reimbursement, the financial impact on an oncology practice of a straightforward CDT bundle would be impacted by randomness beyond a practice's control. Specifically, Milliman identified the following key findings:

1. A change from existing FFS reimbursement to the illustrative bundled CDT / related services payment methodology would likely create significant variation in reimbursement to oncology practices. The financial variation is particularly notable for practices that treat a disproportionate volume of highly complex patients.
2. On a percentage basis, the reimbursement variations are greatest for the practices with smaller patient panels than larger sized practices (i.e., based on the number of patients treated by the oncology practice).
3. As compared to FFS, there's an additional risk to the practice as the patient case mix could greatly skew the financial performance for the CDT/related services included in the bundled payment.
4. Risk mitigation strategies can help reduce the financial impact to smaller practices in particular, but may not be sufficient to produce stable revenue streams.

It is important to keep in mind that this analysis is comparing FFS reimbursements to a bundle payment system only for specific CDTs, and it is not an evaluation of an OCM, which itself would account for the inclusions of various other services, pooled participants, winsorization, risk adjustments, CMS discounting, and adjustments for novel therapies among other things. The patient

vignettes used in this model reflect specific cancer staging and their related NCCN treatment guidelines. We have not attempted to model all variation in cancer treatment or reimbursement. For simplicity, we have considered only two types of cancer. In addition, the analysis does not consider how Medicare Part D drugs would be managed between prescription drug plans (PDP) and oncology providers engaged in the bundle, nor does it consider providers' access to 340-B and group purchasing organizations which may be a constraint for smaller practices and/or practices located in more rural areas.

This analysis is intended to quantify the financial impact to oncology practices related to patient mix associated with an illustrative bundled CDT / related services payments (as one type of alternative payment model). Within that context, we also discuss the importance of aligning incentives and mitigating operation issues in order to preserve the current high quality clinical standards in the treatment of cancer patients.

GLOSSARY OF TERMS AND ABBREVIATIONS

Abbreviations

ASCO – American Society of Clinical Oncology, Inc.

APM – Alternative Payment Model

ASP – Average Sales Price

CC – Advanced Stage III Colon Cancer

CDT – Cancer Drug Treatments

CMS – Centers for Medicare and Medicaid Services

CPT – the CPT (Current Procedural Terminology) is a medical code set used to report medical, surgical and diagnostic procedures and services These are also described as HCPCS Level I codes.

CTE – Conditional Tail Expectation

E&M – Evaluation and Management

FFS – Medicare Fee For Service

HCPCS – Healthcare Common Procedures Coding System

HOP – Hospital Outpatient

NCCN – National Comprehensive Cancer Network

NSCLC – Non-Small Cell Lung Cancer

OCM – Oncology Care Model

PBM – Pharmacy Benefit Manager

Terms

Bundled Payment – reimbursement received for an episode of care for a defined period of time, regardless of treatment protocol used. In this paper, this is a payment from Medicare to an oncology practice

Bundled Payment Revenue – the average Medicare FFS reimbursement under an assumed distribution of patient vignettes for each cancer type

FFS Reimbursement – reimbursement under 2016 Q1 Medicare FFS rates, adjusted for area and place of service

Gain/Loss – the change in reimbursement to a practice from the Bundled Payment Revenue and the Medicare FFS reimbursement (e.g., Bundled Payment Revenue > FFS reimbursement represents a gain)

J Codes – HCPCS Level II billing codes mainly used to identify infusions, injections, and supplies

Medicare Part B Drugs – Outpatient prescription drugs covered by Medicare under limited conditions, typically administered in a physician office or hospital outpatient setting

Medicare Part D Drugs – Drugs not covered under Part B offered through either Medicare Advantage Prescription Drug plans (MA-PD) or stand-alone Prescription Drug Plan (PDP)

Monte Carlo Simulation – A simulation method used to model the probability of different outcomes drawing on a large number of random variables

Patient Vignette – the patients as defined in this analysis to have specific treatment protocol based on the NCCN protocols

Practice Area – Rural or Urban

Practice Setting – Hospital Outpatient or Office

Procedure Code – A code used to describe professional and other services for billing purposes. Professional services are billed using CPT codes. Injectable drugs are billed using HCPCS Level II codes

Winsorization – A process which limits the extreme values in the simulations in an attempt to reduce the impact of outliers

BACKGROUND

For some cancers, such as carcinoma *in situ*, treatment is fairly predictable and relatively straight forward, often consisting only of minor surgery. For advanced stage cancer, however, care is much less predictable and often changes course during treatment. The treatment of advanced stage cancers depends on the type of cancer, and often involves multiple treatment options. These options may include surgery, radiation therapy, and chemotherapy (drugs used to fight cancer). As the results of clinical trials identify promising treatment options, the treatment of many cancers has become more nuanced as it depends on the type of cancer, its stage, its molecular profile, the patient's response, and any toxicities from the therapy. The oncologist must manage the treatment process according to the type of cancer, staging, patient's response to treatment, and other factors. These treatment options are increasing survival rates, but are often also accompanied by a corresponding increase in treatment cost.[4,5]

The potential shift away from FFS to bundled payments is one attempt to control the costs of cancer care. CMS has turned to bundled payments for many common episodes of care, attempting to moderate the increase in treatment costs.[2,3] Bundled payments would be an alternative approach for Medicare reimbursement of oncologists through which the oncologist would receive a single payment for all services and products provided for the care of the patient over a specified time period. Among payers that have implemented bundled payments there are different definitions and adjudication processes for bundled payments. In some cases, providers and payers still use the FFS process, but the final payment is adjusted to account for the bundled payment. As another example, the bundled payment agreement might only cover the infusion services for administering the chemo, but not a physical examination (PE) of the patient. In this case the claim for the infusion will be adjusted to the rate in the bundled payment, while the PE services will still be reimbursed under FFS.[2,3]

Under the current Medicare FFS reimbursement system, Medicare is billed by the facility and oncologists for each of the services and chemo-support involved with cancer care. Table 1.0 below shows a comparison of Medicare FFS reimbursement and an alternative bundled payment method.

Table 1.0 Comparison of Fee-For-Service and Generalized Bundled Payment Reimbursement

Reimbursement Category[†]	Medicare FFS Reimbursement	Bundled Payment Revenue
Professional – covers the services performed by healthcare professionals including the physician (i.e., oncologist).	• Reimbursed for each service provided to a patient (i.e., no limitations on volume). • Time and intensity is a factor for individual patients. • Reimbursement for services has regional variances.	• All services associated with patient care are included in one single payment for a predetermined amount (i.e., volume limited to pre-specified services, drugs and/or time). • Considers FFS experience data and trends to establish a global bundled payment prospectively. • May have regional variances.

Table 1.0 Comparison of Fee-For-Service and Generalized Bundled Payment Reimbursement (Cont)

Reimbursement Category†	Medicare FFS Reimbursement	Bundled Payment Revenue
Administration - signifies what is paid to the place where the infusion services are rendered (i.e., hospital or clinic).	• Services provided by the facility or clinic and its staff are paid separately from professional. • Hospital outpatient and professional fees are separate.	• Likely would be covered by bundled payment, similar to professional services above.
Cancer drug treatments (CDT)¤ - represents the various drugs used in treating the patient.	Medicare Part B Drugs: • Reimbursed at the average sales price (ASP) plus a mark-up. The current CMS reimbursement is ASP + 4.3% for non-oral drugs. Medicare Part D Drugs: • Part D is a separate Medicare program. Enrollees purchase coverage from private insurers. Insurers negotiate with pharmacy benefit managers (PBMs) to determine the cost of drugs.	Medicare Part B Drugs: • Likely would be covered by bundled payment, similar to professional and administration services listed above. • Including CDTs in the bundle adds a degree of uncertainty and risk to the provider. Medicare Part D Drugs: • Part D drugs could be included in the bundled payment, but requires the Part D Plan Sponsor to have an agreement with the oncology practice for a reimbursement method. • Oncology practices would want the Part D sponsor to share the drug manufacturer rebates.
Incentives – characterizes those activities physicians would likely be focused on in their practice.	• In cases where CDT products are equal in efficacy and clinically appropriate, there could be a possible incentive to use the product that generates the higher marginal revenue for the practice. • Revenue is not linked to quality measures. Physicians strive to provide high quality services in accordance with practice standards.	• In cases where CDT products are equal in efficacy and clinically appropriate, there is an incentive to use products with the lowest acquisition cost. Financial metrics are likely to be linked to pre-defined quality metrics.
Operations – denotes activities	• Requires no coordination of care between providers.	• Financial and outcome metrics.

†Reimbursement category is a general description, there might be differences in the market that are specific to other reimbursement methods not listed.   ¤For the purpose of this project, we defined cancer drug treatments (CDTs) to include chemotherapy and related drugs used in the administration of chemotherapy (e.g., blood products, anti-nausea, etc.).

METHODOLOGY

Working closely with the ASCO expert oncologist panel, Milliman utilized a vignette approach to illustrate how simplified bundling of oncology-related treatments compares to FFS reimbursement. Specifically, we compared the existing payments made under FFS reimbursement methodology with reimbursement under a general bundling methodology for the CDT/related services within a cancer treatment vignette. We restricted our analysis to Medicare FFS in part because the reimbursement rules are publicly available. While the concepts may also apply to other populations, we have not attempted to analyze them.

For purposes of this analysis, the bundled payment for each cancer type is defined as the average FFS reimbursement under an assumed distribution of patient vignettes for the procedures and drugs defined to be in the treatment protocol for each cancer scenario. Thus, our primary analysis assumes no savings to the Medicare program. For the remainder of the paper, the aggregate revenue associated with the bundled payment is referred to as "bundled payment revenue" to the practice. The FFS compensation is referred to as "FFS reimbursement."

If the bundled payment revenue is greater than the FFS reimbursement, the practice will have a **gain** compared to what they would have in FFS reimbursement. Similarly, if the bundled payment revenue is less than the FFS reimbursement, the practice will have a **loss**, compared to what they would have in FFS reimbursement.

We note that gains and losses are associated exclusively with differences between the actual mix of patient vignettes observed by the simulated oncology practice compared to the assumed distribution of patient vignettes underlying the CDT bundled payment amount. That is, assuming that care is delivered according to NCCN guidelines, the gains and losses are attributable solely to patient mix. We also assumed that there is no change in treatment regimen for the patient types included in the analysis

Bundled Payment Methodology

To illustrate the potential variability in practice revenue associated with a change in reimbursement between existing FFS reimbursement versus under an APM, specifically bundling of CDT/related services, we worked closely with and relied on the ASCO clinician volunteers to define typical treatment regimens. The treatments included in our patient vignettes were based on the NCCN cancer guidelines for advanced stage III colon cancer (CC) and non-small cell lung cancer (NSCLC). The specific procedures and their codes and associated reimbursements for each patient type is provided in Exhibit 1 of Appendix B and D for CC and NSCLC respectively. Due to the complexity of treatment, many potential regimens are possible and could vary based on how each patient reacts to the treatment. To account for this variability, we have modeled three patient vignettes for CC and twelve patient vignettes for NSCLC based on the presence of cancer cell line genetic mutations. It was not practical to attempt to model all possible variations in patients and their treatments, so our patient vignettes are a simplified representation of the range of potential results for CC and NSCLC.

For the purposes of our analysis, we categorized chemo and supportive drugs (such as drugs intended to minimize the nausea often caused by chemotherapeutic agents) into one group called CDT. The facility (physician office or hospital outpatient) purchases the CDT directly from a drug

wholesaler and then it is administered at the facility. The chemotherapy and supportive care drugs are typically administered intravenously. Oncologists provide CDT to patients in a variety of settings, including office, hospital outpatient (HOP) facility, or hospital inpatient. The physician office or HOP is the setting where the administration of the CDT is most often provided to patients, and the trend is expected to continue shifting from the physician office to the HOP setting.[5-7]

The patient vignette definitions and thus FFS reimbursement amounts are categorized by E&M, drug administration, and drug therapy. The amounts vary by setting and geographic area; therefore, the results of our model illustrate expected reimbursement by setting (HOP vs office) and by area (Rural vs Urban). Drug reimbursement is fixed as a percentage of average sales price (ASP) and is not influenced by geography. In addition, the FFS reimbursement is provided per patient vignette. Milliman's 2016 Reimbursement Benchmarking Model was used to calculate the reimbursement amount based on the 2016 Q1 Medicare Fee Schedule. This model uses a mixture of the outpatient prospective payment system (OPPS), physician resource-based relative value scale (RBRVS), and ASP to adjudicate and develop a Medicare reimbursement amount. In order to illustrate variability by area we have shown the results for "urban" versus "rural". We used the Chicago, Illinois metropolitan statistical area (MSA) for Urban and Non-MSA, Illinois for Rural.

Modeling Methodology

To demonstrate the effect on revenue that a bundled payment could have on specific practices, Milliman created a model that randomly assigned the type of patient seen by a given practice, based on the underlying assumed distribution of patient types within each cancer type, and ran these simulations 1,000 times. The steps are as follows:

1. The model assumed an underlying distribution of patients for each cancer type and scenario provided by ASCO and are shown in the table below:

Table 1.1: Patient Distributions			
Stage III Colon Cancer			
Patient Descriptions			
Patient 1 - "Simple Patient"	45.0%		
Patient 2 - "Simple Patient" with Grade III Nausea	35.0%		
Patient 3 - "Simple Patient" with Grade III Neutropenia	20.0%		
Non-small Cell Lung Cancer			
Patient Descriptions	Scenario 1	Scenario 2	Scenario 3
Patient 1 - Carbo/Taxol	5.0%	6.2%	12.5%
Patient 2 - Carbo/Taxol + Neutropenia	1.0%	1.3%	2.6%
Patient 3 - Carbo/Taxol + Bevacizumab	4.5%	5.6%	11.3%
Patient 4 - Carbo/Taxol + Bevacizumab + Neutropenia	1.5%	1.9%	3.8%
Patient 5 - Carbo/Pemetrexed	5.4%	6.8%	13.5%
Patient 6 - Carbo/Pemetrexed + Neutropenia	0.6%	0.8%	1.5%
Patient 7 - Carbo/Pemetrexed + Bevacizumab	4.5%	5.6%	11.1%
Patient 8 - Carbo/Pemetrexed + Bevacizumab + Neutropenia	1.5%	1.9%	3.9%
Patient 9 - EGFR	15.0%	15.0%	30.0%
Patient 10 - Crizotinib	5.0%	5.0%	10.0%
Patient 11 - Pembrolizumab	50.0%	50.0%	0.0%
Patient 12 - Pembrolizumab + "Chemo"	6.0%	0.0%	0.0%

    a. For more detailed information regarding the clinical assumptions for the distributions above that were provided by ASCO, see Appendix A.

2. The bundled payment revenue was calculated based on the assumed underlying distribution of patients (i.e., a weighted average of FFS reimbursements) for each cancer type and scenario.

3. For each simulation, the practice's patient types were randomly selected from the underlying distribution for each of the assumed number of patients treated. Each simulation represents an outcome for a single practice.

4. Each of the 1,000 simulations produced a patient cohort that reflects a patient mix that may be different from the underlying assumed distribution of patient types. The FFS reimbursement the practice would have received for its patient cohort was calculated as a result of the simulated distribution (i.e., the reimbursement the practice would have received if no bundled payment existed).

5. The FFS reimbursement calculated was compared to the bundled payment revenue based on the assumed underlying distribution (i.e., the bundled payment the practice is expected to receive for each patient, regardless of patient type).

The simulations were developed separately for each practice size. The practice size was defined as small, medium, or large based on the number of CC or NSCLC patients treated in a given year. The practice sizes were provided by ASCO, see the *Key Data Used* section for more specifics.

Probability of Gain/Loss

Based on the results of the simulation, the probability of loss was calculated as well as the magnitude of the loss as a percentage of total FFS reimbursement. The probability of loss was calculated based

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on the number of the 1,000 simulations that produced bundled payment revenue less than the FFS reimbursement, divided 1,000 (number of simulations). Similar metrics were produced to describe the probability of gain. We calculated the probability of percent loss greater than 10%, 20%, and 30% and the probability of gain. See Appendix C and E, for CC and NSCLC respectively, for each of these probabilities.

Percentiles

Percentiles of the revenue impact are ordered by the magnitude of the change between the FFS reimbursement and the bundled payment revenue. For example, the 5th percentile means that 5% of the simulations represent a specific dollar amount in loss or greater.

Conditional Tail Expectations (CTEs)

Milliman also calculated CTEs, which provide a different way to measure the volatility of the change in reimbursement. The CTE can be defined as a probability-weighted loss above a certain probability level (i.e., the CTE (95) represents the average financial outcome of the worst 5% of the simulations for the loss tail and the average of the best 5% of the simulations for the gain tail). While the 5th percentile represents a specific dollar amount in loss or greater, the CTE (95) represents the average of those losses that are the specific dollar amount at the 5th percentile or greater.

The CTE segments the data and only includes a defined portion on each tail end of the curve. The CTE summaries illustrate the large financial impacts that are driven solely due to the random set of patients the simulations generated for the practice.

Stage III Colon Cancer

1. The simulations were run 1,000 times for one bundled payment scenario. This scenario assumed three possible patient types to be included in the bundle. The specific treatment protocols can be found in Appendix B, Exhibit 1.
2. The FFS reimbursement amount was determined and summarized for each patient type, under each location and setting. These results are provided in Appendix B, Exhibit 2.
3. Additional details including the probability of gain/loss can be found in Appendix C. This is provided for each practice size (small, medium, or large).

Non-Small Cell Lung Cancer

1. The simulations were run 1,000 times each for three bundled payment scenarios. Each scenario assumed up to twelve possible patient types to be covered by the bundle. Pembrolizumab was singled out due to its high cost uniqueness as a targeted drug therapy, and potential for combination chemotherapy. The specific treatment patterns can be found in Appendix D, Exhibit 1.
   a. Scenario 1 - Assumes that the bundle includes all patient types, including those using pembrolizumab.
   b. Scenario 2 - Assumes that the bundle methodology will carve out patients on a combination of pembrolizumab and additional chemo treatments, however those only on pembrolizumab were still included in the bundle.

      c. Scenario 3 - Assumes that any patient taking pembrolizumab was carved out of the bundle.

2. The FFS reimbursement amount was determined and summarized for each patient, under each location and setting. These results are provided in Appendix D, Exhibit 2.

3. Additional details including the probability of gain/loss can be found in Appendix E. This is provided for each practice size (small, medium, or large).

Note that we did not attempt to evaluate existing factors affecting provider profitability. In other words, our analysis does not factor the practice expenses nor any other reimbursement arrangements outside of FFS for the cancer types discussed. A practice's financial sensitivity to the variation shown in our model will depend on many factors including the existing profitability and the percentage of revenue shifted to the APM. We also assumed that there is no change in treatment regimen for the patient types included in the analysis.

FINDINGS

Milliman's analysis indicates that a bundled payment method can lead to significant variation in revenue for oncology providers as compared to a FFS reimbursement methodology. That is, practices with a disproportionate share of higher-cost patients (compared to the average patient covered by the bundle) would likely have revenues well below FFS reimbursement, while practices with a disproportionate share of lower-cost patients (compared to the average patient covered by the bundle) would likely have revenues well above FFS reimbursement. The variations illustrated by our analysis are solely the result of differences in patient mix. The illustration does not vary either the quality of care provided or the efficiency in providing care. Note that small practices would be subjected to wider fluctuations than larger practices.

Bundled Payment Results

The estimated payment made under the existing Medicare FFS reimbursement structure as well as the proposed bundled payment revenue are shown in Exhibit 2 of Appendix B and Appendix D for CC and NSCLC respectively. Total Medicare FFS reimbursement per treatment could vary from $9,800 to $37,000 for CC patient vignettes and $2,300 to $106,000 for NSCLC patient vignettes defined in this study and dependent on the clinical needs of the patient. CDTs are the largest contributors of total FFS reimbursement for the vast majority of patient vignettes as defined for this analysis.

Any patient's clinical response to chemo and associated adverse events may vary, and may require adjustments to treatment. These variations suggest that including drugs in a bundled payment is complicated by the unpredictability of a patient's response to treatment regimens (which may require more or fewer drugs, or drugs at different reimbursement levels). Administration service and the E&M reimbursement do not have as large a variance as the related drug reimbursement in these particular patient vignettes and assumed treatment regimens.

Based on the different potential mix of patients who seek care at an individual oncologist setting and area, the drug therapy selected can make quite an impact on reimbursement under the existing FFS reimbursement methodology. For example, as shown in Exhibit 2 of Appendix D, the CDT's reimbursement for Patient Vignette 8 in the Outpatient Urban Setting for NSCLC is over $100,000 under the FFS reimbursement model. Alternatively, the CDTs reimbursement for Patient Vignette 2 is around $19,000 under the FFS reimbursement model. The range between these two is $87,000. However, the bundled payment revenue by scenario is expected to be between $51,000 and $58,000, depending on the setting and area. If there are more Vignette 8 patients versus Vignette 2 patients, and the practice only receives $51,000-$58,000 in reimbursement for treating these patients, this demonstrates that the differential between the reimbursement under the current FFS reimbursement model and the illustrated bundled payment revenue would vary considerably. Smaller practices have fewer patients over which they can spread the shortfall in revenue.

Modeling Results

In order to model the potential impact at a practice level, Milliman performed Monte Carlo simulations for each practice size to simulate revenue risk associated with patient type mix. Our simulations demonstrate the potential variability in reimbursement due to patient mix on small, medium, and large

practice sizes when reimbursed under a bundled payment compared to FFS reimbursement. Specifically, Milliman examined the probability of gain or loss, the percentiles and the CTEs for each practice size, for both tails (i.e., those with gains and losses under the new bundled payment methodology).

Probability of Gain/Loss

Table 1.2 below shows the probability of gain/loss by practice size for the office urban setting.

Table 1.2 Simulation Results: Probability of Gain/Loss by Practice Size (Stage III Colon Cancer, Office-Urban setting)					
Small Sized Practices					
			Cumulative Loss [1]		
Practice Distribution	**Gain**	**Loss**	**-10%**	**-20%**	**-30%**
Practices	559	441	441	147	33
% of Simulations	56%	44%	44%	15%	3%
Averages (Per Practice)					
Bundled Payment Revenue	$107,151	$107,151	$107,151	$107,151	$107,151
Medicare FFS Reimbursement	$90,344	$130,480	$130,480	$149,616	$169,561
Change in Revenue	$16,807	($23,329)	($23,329)	($42,465)	($62,410)
Change in Revenue (%)	18.6%	-17.9%	-17.9%	-28.4%	-36.8%
Medium Sized Practices					
			Cumulative Loss [1]		
Practice Distribution	**Gain**	**Loss**	**-10%**	**-20%**	**-30%**
Practices	507	493	291	49	3
% of Simulations	51%	49%	29%	5%	0%
Averages (Per Practice)					
Bundled Payment Revenue	$275,530	$275,530	$275,530	$275,530	$275,530
Medicare FFS Reimbursement	$243,847	$307,636	$323,561	$361,472	$407,012
Change in Revenue	$31,683	($32,106)	($48,031)	($85,942)	($131,482)
Change in Revenue (%)	13.0%	-10.4%	-14.8%	-23.8%	-32.3%
Large Sized Practices					
			Cumulative Loss [1]		
Practice Distribution	**Gain**	**Loss**	**-10%**	**-20%**	**-30%**
Practices	541	459	132	5	0
% of Simulations	54%	46%	13%	1%	0%
Averages (Per Practice)					
Bundled Payment Revenue	$642,904	$642,904	$642,904	$642,904	n/a
Medicare FFS Reimbursement	$598,747	$695,102	$744,261	$821,767	n/a
Change in Revenue	$44,157	($52,198)	($101,357)	($178,863)	n/a
Change in Revenue (%)	7.4%	-7.5%	-13.6%	-21.8%	n/a

(1) Each column contains practices with a loss of the specified amount or greater (i.e., practices with at least a 10% loss also include those with 20% and 30% losses).

For a small sized practice, the probability of a cumulative loss greater than 10% (44%) is much greater than for the medium (29%) and large sized practices (19%) while the expected size of the revenue losses, given there is a loss worse than 10% is 17.9%, 14.8% and 13.6% respectively. This highlights the potential shortcomings of using averages instead of an individual patient to calculate the bundled payment reimbursement rate. See more details in Appendix C and Appendix E for CC and NSCLC, respectively.

Note that these gain and loss figures are based on the assumption that the bundled payment is calculated specifically for stage III colon cancer. Making the calculation of the bundled payment more precise (e.g., by patient treatment pathway within stage III colon cancer) would serve to reduce the amount of fluctuation. Making the calculation of the bundled payment less precise, on the other hand, would increase the amount of fluctuation.

Percentiles

Table 1.3 below shows the percentiles for Stage III Colon Cancer in an office urban setting by practice size. While this table only shows results for the office urban, results were consistent in the other settings.

Table 1.3 Simulation Results: Percentiles by Practice Size (Stage III Colon Cancer, Office-Urban setting)							
Small Sized Practices							
	Min	**5th**	**10th**	**15th**	**85th**	**90th**	**95th**	**Max**
Bundled Payment Revenue	$107,151	$107,151	$107,151	$107,151	$107,151	$107,151	$107,151	$107,151
Medicare FFS Reimbursement	$189,747	$143,935	$143,810	$121,090	$75,091	$75,029	$74,967	$74,842
Change in Revenue	-$82,597	-$36,784	-$36,660	-$13,940	$32,060	$32,122	$32,184	$32,308
Change in Revenue Percentage	-43.5%	-25.6%	-25.5%	-11.5%	42.7%	42.8%	42.9%	43.2%

Medium Sized Practices							
	Min	**5th**	**10th**	**15th**	**85th**	**90th**	**95th**	**Max**
Bundled Payment Revenue	$275,530	$275,530	$275,530	$275,530	$275,530	$275,530	$275,530	$275,530
Medicare FFS Reimbursement	$422,138	$330,823	$330,574	$307,792	$238,762	$216,042	$215,855	$192,762
Change in Revenue	-$146,607	-$55,292	-$55,044	-$32,262	$36,768	$59,488	$59,675	$82,768
Change in Revenue Percentage	-34.7%	-16.7%	-16.7%	-10.5%	15.4%	27.5%	27.6%	42.9%

Large Sized Practices							
	Min	**5th**	**10th**	**15th**	**85th**	**90th**	**95th**	**Max**
Bundled Payment Revenue	$642,904	$642,904	$642,904	$642,904	$642,904	$642,904	$642,904	$642,904
Medicare FFS Reimbursement	$839,955	$748,392	$725,485	$702,641	$587,674	$564,954	$542,234	$473,204
Change in Revenue	-$197,051	-$105,488	-$82,581	-$59,737	$55,230	$77,950	$100,670	$169,700
Change in Revenue Percentage	-23.5%	-14.1%	-11.4%	-8.5%	9.4%	13.8%	18.6%	35.9%

The percentiles provide the cutoff points as the simulations are ranked by their gain/loss. For example, the small sized practices in Table 1.3 show the practice with the largest loss (labeled "Min" in the table) had a loss of 43.5% in revenue under the bundled payment system, compared to the existing FFS reimbursement methodology. Similarly, at the 5th percentile, the loss is 25.6%. This indicates that 5% of practices experienced a decrease in revenue between 25.6% and 43.5%. Alternatively, 5% of practices had a gain between 42.9% and 43.2% (i.e., between the 95th percentile and "Max" in the table above).

The range of the potential change in revenue varies much more for the smaller practices than the medium and large practices.

Conditional Tail Expectations (CTEs)

While the percentiles demonstrate the cutoff points and what the change in revenue would be when ranked (i.e., the 5th percentile for the small practice is -25.6%), it does not provide insight into how those practices performed on average. The CTE (95) of the loss tail represents the average of the 5% of practices with the largest losses (i.e., the average of those practices that had a loss between 25.6% and 43.5% in Table 1.3 above).

As described in the methodology section, the CTE can be defined as a probability-weighted loss above a certain probability level (i.e., the CTE (95) represents the average financial outcome of the worst 5% of the simulations (the loss tail) and the average of the best 5% of the simulations (the gain tail)). The CTE (95) for the loss tail likely represents practices with a disproportionate share of highly complex patients, whose treatment regimen is more complex than the average patient. The CTE (95) values (i.e., the revenue gain/loss of the 5% most extreme results) are consistently higher for smaller practices as a percentage of FFS reimbursement, as larger practices tend to have patient mix that is more consistent with the underlying population on which the bundled payment revenue was set.

The table below summarizes the dollar and percentage differences in revenue for the CTE (95) for practices within the urban office setting as defined in this analysis.

Table 1.4 Simulation Results: Conditional Tail Expectations (CTE 95)						
Stage III Colon Cancer, Office-Urban Setting						
	Practices with Loss			**Practices with Gain**		
	CTE(95)			**CTE(95)**		
	Small	**Medium**	**Large**	**Small**	**Medium**	**Large**
Bundled Payment Revenue	$107,151	$275,530	$642,904	$107,151	$275,530	$642,904
Medicare FFS Reimbursement	$160,853	$360,859	$770,038	$74,947	$207,707	$528,885
Change in Revenue	($53,702)	($85,329)	($127,134)	$32,204	$67,823	$114,018
Change in Revenue (%)	-33.4%	-23.6%	-16.5%	43.0%	32.7%	21.6%
Non-small Cell Lung Cancer, Office-Urban Setting						
	Practices with Loss			**Practices with Gain**		
	Scenario 1: CTE(95)			**Scenario 1: CTE(95)**		
	Small	**Medium**	**Large**	**Small**	**Medium**	**Large**
Bundled Payment Revenue	$677,731	$1,807,283	$4,631,164	$677,731	$1,807,283	$4,631,164
Medicare FFS Reimbursement	$840,760	$2,055,120	$5,056,826	$523,491	$1,575,285	$4,245,104
Change in Revenue	($163,029)	($247,836)	($425,662)	$154,241	$231,998	$386,060
Change in Revenue (%)	-19.4%	-12.1%	-8.4%	29.5%	14.7%	9.1%
	Scenario 2: CTE(95)			**Scenario 2: CTE(95)**		
	Small	**Medium**	**Large**	**Small**	**Medium**	**Large**
Bundled Payment Revenue	$637,628	$1,700,343	$4,357,128	$637,628	$1,700,343	$4,357,128
Medicare FFS Reimbursement	$770,864	$1,936,238	$4,741,130	$489,276	$1,449,882	$3,992,238
Change in Revenue	($133,235)	($235,895)	($384,002)	$148,353	$250,461	$364,889
Change in Revenue (%)	-17.3%	-12.2%	-8.1%	30.3%	17.3%	9.1%
	Scenario 3: CTE(95)			**Scenario 3: CTE(95)**		
	Small	**Medium**	**Large**	**Small**	**Medium**	**Large**
Bundled Payment Revenue	$605,364	$1,614,304	$4,136,653	$605,364	$1,614,304	$4,136,653
FFS Reimbursement	$798,131	$1,941,291	$4,649,006	$419,831	$1,313,133	$3,618,581
Medicare FFS Reimbursement	($192,767)	($326,988)	($512,353)	$185,533	$301,171	$518,072
Change in Revenue (%)	-24.2%	-16.8%	-11.0%	44.2%	22.9%	14.3%

For a small size practice treating CC patients in an urban office setting, the average of the 5% worst losses (i.e., CTE (95) for loss) is -33.4% (i.e., a 33.4% reduction from FFS revenue) as shown in the table directly above. As shown in table 1.3 above, the maximum loss for these practices observed in the 1,000 simulations is -43.5% and the 5th percentile is -25.6% under the simulation. The CTE (95) represents the average of those practices that had between -25.6% and -43.5% loss. As the number of patients increases for a practice, the risk exposure decreases, but still exists. For example, a large size practice has a CTE (95) of -16.5% compared to -33.4% for the small size practice.

Winsorization

Winsorization is a technique that limits the impact of outliers by setting values outside the 5th and 95th percentiles to those values at the 5th and 95th percentiles, for example. The table below shows that winsorization, or removing outliers, has an impact on the change in reimbursement and thus the probabilities of larger loses. However, after applying winsorization, there is still a significant amount of uncertainty that remains. For example, in the table below, the probability of a cumulative loss greater than 20% is 28.4% without winsorization but still 25.5% with winsorization. Please note the left side of Table 1.5 matches the results from Table 1.2

Table 1.5 Simulation Results: Probability of Gain/Loss by Practice Size (Stage III Colon Cancer, Office-Urban setting)												
Without Winsorization							**With Winsorization** [(1)]					
Small Sized Practices							**Small Sized Practices**					
				Cumulative Loss [(2)]							**Cumulative Loss** [(2)]	
Practice Distribution	**Gain**	**Loss**	**-10%**	**-20%**	**-30%**		**Practice Distribution**	**Gain**	**Loss**	**-10%**	**-20%**	**-30%**
Practices	559	441	441	147	33		Practices	559	441	441	147	0
% of Simulations	56%	44%	44%	15%	3%		% of Simulations	56%	44%	44%	15%	0%
Averages (Per Practice)							**Averages (Per Practice)**					
Bundled Payment Revenue	$107,151	$107,151	$107,151	$107,151	$107,151		Bundled Payment Revenue	$107,151	$107,151	$107,151	$107,151	n/a
Medicare FFS Reimbursement	$90,344	$130,480	$130,480	$149,616	$169,561		Medicare FFS Reimbursement	$90,346	$128,562	$128,562	$143,861	n/a
Change in Revenue	$16,807	($23,329)	($23,329)	($42,465)	($62,410)		Change in Revenue	$16,805	($21,411)	($21,411)	($36,710)	n/a
Change in Revenue (%)	18.6%	-17.9%	-17.9%	-28.4%	-36.8%		Change in Revenue (%)	18.6%	-16.7%	-16.7%	-25.5%	n/a
Medium Sized Practices							**Medium Sized Practices**					
				Cumulative Loss [(2)]							**Cumulative Loss** [(2)]	
Practice Distribution	**Gain**	**Loss**	**-10%**	**-20%**	**-30%**		**Practice Distribution**	**Gain**	**Loss**	**-10%**	**-20%**	**-30%**
Practices	507	493	291	49	3		Practices	507	493	291	0	0
% of Simulations	51%	49%	29%	5%	0%		% of Simulations	51%	49%	29%	0%	0%
Averages (Per Practice)							**Averages (Per Practice)**					
Bundled Payment Revenue	$275,530	$275,530	$275,530	$275,530	$275,530		Bundled Payment Revenue	$275,530	$275,530	$275,530	n/a	n/a
Medicare FFS Reimbursement	$243,847	$307,636	$323,561	$361,472	$407,012		Medicare FFS Reimbursement	$244,666	$304,590	$318,400	n/a	n/a
Change in Revenue	$31,683	($32,106)	($48,031)	($85,942)	($131,482)		Change in Revenue	$30,864	($29,059)	($42,870)	n/a	n/a
Change in Revenue (%)	13.0%	-10.4%	-14.8%	-23.8%	-32.3%		Change in Revenue (%)	12.6%	-9.5%	-13.5%	n/a	n/a
Large Sized Practices							**Large Sized Practices**					
				Cumulative Loss [(2)]							**Cumulative Loss** [(2)]	
Practice Distribution	**Gain**	**Loss**	**-10%**	**-20%**	**-30%**		**Practice Distribution**	**Gain**	**Loss**	**-10%**	**-20%**	**-30%**
Practices	541	459	132	5	0		Practices	541	459	132	0	0
% of Simulations	54%	46%	13%	1%	0%		% of Simulations	54%	46%	13%	0%	0%
Averages (Per Practice)							**Averages (Per Practice)**					
Bundled Payment Revenue	$642,904	$642,904	$642,904	$642,904	n/a		Bundled Payment Revenue	$642,904	$642,904	$642,904	n/a	n/a
Medicare FFS Reimbursement	$598,747	$695,102	$744,261	$821,767	n/a		Medicare FFS Reimbursement	$600,005	$692,744	$736,062	n/a	n/a
Change in Revenue	$44,157	($52,198)	($101,357)	($178,863)	n/a		Change in Revenue	$42,899	($49,840)	($93,158)	n/a	n/a
Change in Revenue (%)	7.4%	-7.5%	-13.6%	-21.8%	n/a		Change in Revenue (%)	7.1%	-7.2%	-12.7%	n/a	n/a

(1) Winsorization is applied at the 5th and 95th percentiles
(2) Each column contains practices with a loss of the specified amount or greater (i.e., practices with at least a 10% loss also include those with 20% and 30% losses).

The results of the probabilities of gain/loss in appendix C and E are provided both with and without the application of winsorization for all practice sizes and both cancer types.

For reference, the table below shows what content can be found in which appendix.

Table 1.6 Appendix Contents		
Item	**CC**	**NSCLC**
Key Data Used	A	A
Patient Vignettes	B	D
Probability of Gain/Loss	C	E
Updated Patient Distribution		F

Updated Non-Small Cell Lung Cancer Simulation Results

After this analysis had been initially completed, but prior to its publication, new information emerged regarding the treatment for NSCLC.[16,17] See the table below for the original and updated assumed patient distributions for NSCLC Scenario 2. Pembrolizumab was assumed to decrease from 50% to 30% of the patient distribution. The 20% were then distributed to the non-targeted chemo groups.

Table 1.7 Patient Distributions - Non-small Cell Lung Cancer, Scenario 2		
Patient Descriptions	**Original**	**Updated**
Patient 1 - Carbo/Taxol	6.2%	10.4%
Patient 2 - Carbo/Taxol + Neutropenia	1.3%	2.1%
Patient 3 - Carbo/Taxol + Bevacizumab	5.6%	9.4%
Patient 4 - Carbo/Taxol + Bevacizumab + Neutropenia	1.9%	3.1%
Patient 5 - Carbo/Pemetrexed	6.8%	11.3%
Patient 6 - Carbo/Pemetrexed + Neutropenia	0.8%	1.3%
Patient 7 - Carbo/Pemetrexed + Bevacizumab	5.6%	9.3%
Patient 8 - Carbo/Pemetrexed + Bevacizumab + Neutropenia	1.9%	3.2%
Patient 9 - EGFR	15.0%	15.0%
Patient 10 - Crizotinib	5.0%	5.0%
Patient 11 - Pembrolizumab	50.0%	30.0%
Patient 12 - Pembrolizumab + "Chemo"	0.0%	0.0%

See Appendix F for the simulation results based on this updated patient distribution including the probability of gain/loss, percentiles and CTEs. The results of the updated scenario are slightly more volatile than the original Scenario 2 as the bundled payment revenue has slightly decreased and the distribution has become more dispersed. This is one example that demonstrates how payments may vary over time due to further innovation in drug therapies and changes in NCCN guidelines and compendiums.

CONSIDERATIONS

Comparison to CMS's Oncology Care Model

The potential revenue impact quantified in this report is based on a comparison between the reimbursement associated with the FFS reimbursement methodology and a simplified bundled payment revenue that is based on the average FFS reimbursement of the services and CDTs included in the bundle.

CMS's Oncology Care Model (OCM) defines bundles differently and addresses the following, which our simplified, bundle does not:[4]

1. Inclusion of services – the OCM includes all Medicare Part A and Part B FFS and certain Part D expenditures.
2. Pooled participants – practices may be able to partner with other practices to pool episodes.
3. Winsorization – limits the impact of outliers by setting values outside the 5th and 95th percentiles to those values at the 5th and 95th percentiles.
4. Risk adjustment – the OCM methodology risk adjusts the baseline price for each episode.
5. CMS discounting – CMS assumes a 4% reduction to the expected bundle price for one-sided risk and 2.75% for two-sided risk.
6. Adjustment for novel therapies – possible adjustments for practices that have a higher proportion of spend for newly FDA approved oncology drugs within a given timeframe.

While we did not specifically design the reimbursement modeling to be consistent with the OCM, adjusting our analysis for some of the items above would help mitigate the risks of the potential variation shown in our bundle illustration. Of note, the OCM pooled participants and winsorization particularly could mitigate the impact on small practices. Robust risk adjustments specific for oncology providers may lessen the impact on oncology providers with a high case mix of patient vignettes requiring advanced chemo. Note that we are partially reflecting the potential impact of risk-adjusted reimbursement by assuming that the bundled CDT payment reimbursement amounts are calculated by type of cancer and stage.

Our analysis only compared the FFS reimbursement to a bundled payment, without addressing any discounting like that used in the OCM (i.e., reducing the parity reimbursement level by a specific percentage to determine a target price). The proposed discounting in the OCM can be as high as 4%.[2] It is likely that discounting would have the potential to generate reimbursement savings to the Medicare program, while the bundled payment revenue in our analysis assumes parity to the status quo (i.e., no change in reimbursement level, on average).

While patient mix risk can be substantially reduced using mechanisms such as those mentioned above, most bundling approaches will continue to pass some of the patient mix risk to providers.

Any proposed bundling reimbursement mechanism should consider the risk shifted to providers, their ability to manage the risk, and their financial exposure for assuming the risk. A CDT bundle is highly dependent on what CDT is needed and which services are delivered by the oncology providers and facilities. Oncologist practices will need specific details about the payments for drugs (i.e., chemotherapy, supportive), oncologist services, facility related fees, diagnostics, technology

advances, and actuarial risk in order to evaluate whether a CDT bundled payment approach is appropriate for their practice.

The patient vignettes defined for this analysis are dependent on the cancer staging and related NCCN treatment guidelines. Should there be newer CDT regimens and related alterations in reimbursement, the bundled payment revenue would need to be readdressed, to stay current with best clinical practice. Since newer treatment options tend to be more expensive than the existing treatment options, delays in updating the bundled payment rates would tend to result in higher losses and more frequent losses than our results show. Under the OCM, for example, CMS has suggested a possible adjustment for novel therapies. This becomes important when one considers the investment by pharmaceutical companies in this therapeutic area. It is estimated that there are over 700 cancer treatments in Phase I – III trials (i.e., in clinical trial or waiting for review).[8,9] The manner in which these new technologies are factored into the bundle will require cost and utilization projections between providers and payers. The OCM mentions possible adjustments for novel therapies, but the exact reimbursement adjustment and payment mechanism will need further assessment and are beyond the scope of this analysis. If these novel technologies, which could be service or product related, achieve actual cost off-sets in other areas (e.g., lowering chemo side effects, achieving higher accuracy in diagnosis, lowering work-up coordination time), consideration should be given as to how reimbursement will account for any potential resource offsets. One potential way to manage the newer technology is to allow a carve-out for a set time period until the market has assessed the newer technology.

Adherence and Quality

The vignettes assume complete adherence to the NCCN care guidelines and as such follow a six-month treatment regimen. The patient vignettes do not attempt to measure the nuances of clinical practice in cancer treatment. In many cases, the timelines and treatment courses might change due to a patient having an adverse event (e.g., low platelet counts). This might result in a complete change from the original course of chemo to one that is less toxic, but takes longer to complete or involves a separate course of radiation or surgery.

Oncologist-patient collaborative decisions to pursue a selected course of therapy are made consistent with patient preferences for treatment, such as surgery or pursuing hospice. A bundled CDT/related services payment system would likely take into account the following: (1) the experience data of recent patients, (2) adjustments that reflect the adherence factors (e.g., complications or patients not making infusions in a timely manner), (3) the payer decision to incorporate surgical cost or therapeutic radiology in to the bundle, or (4) a decision to exclude cases involving hospice care or advanced technologies. Please note our modeling did not adjust for these factors.

With any changes in payment methods, it is important to consider the impact that it might have on the following: (1) patient quality of care, (2) clinical and service outcomes, and (3) access to care. If not coordinated in an appropriate manner, a bundled payment approach has the potential to impact the accountability of delivering high quality cancer care.[10-13] To counter any issues with care delivery, a bundled CDT payment should include a mechanism to ensure the patient is receiving the appropriate treatment at the appropriate time. Oncology practices will need to evaluate historical data and patient case mix to assess the ability to shift practice patterns to achieve cost savings while adhering with the NCCN guidelines.

Medicare Part D

In our conversations with oncologists from ASCO, they expressed an interest in having us consider the Medicare Part D and 340-B drug acquisition program. While these topics do not specifically influence the introduction of a CDT bundle payment, they are two issues of consideration to oncologists.

In our patient vignettes, oral oncology drugs play a role in the NCCN treatments, but we did not consider how Part D drugs would be effectively managed between Prescription Drug Plans (PDPs) and oncology providers engaged in a CDT bundled payment. The reimbursement of oral oncology drugs is further complicated under Medicare Part D as many patients in Medicare FFS would have access to these drugs covered under Part D, rather than Part B. Oral oncology drugs are considered a protected class in Part D and should be covered by the Part D sponsors with limited formulary restrictions that could be influenced by drug rebating contracts. Patient cost sharing in Part D drug benefit designs is likely to be a higher percentage than the standard 20% seen under FFS and this could limit access to oral oncology drugs. Oncology practices would need to ensure patients can access the prescribed regimens. Providers and payers would need to consider the extensive CMS guidance concerning risk sharing programs that include both Medicare Part C and Medicare Part D.

340-B Drug Acquisition Program

The ability to purchase CDT at an acquisition cost below that of the cost in the CDT bundled payment will have an influence on the financial success of the oncology practice and patient access. The community oncology practices, which are associated with a 340-B covered entity, have access to a lower actual acquisition cost than those practices which are not participating in 340-B. Likewise, a rural community oncology provider might not have access to volume discounts that are more likely with the use of a group purchasing organization (GPO) serving a large academic teaching facility. The access to 340-B and GPO best pricing could be a factor in the decision of smaller oncology providers to consolidate into a larger community hospital. Market consolidation might have a negative influence on patient access to oncology care as fewer oncology providers are available in limited number of communities, if these oncologists relocate to larger cities.

Closing

In this report, we highlight the reimbursement modeling challenges with a bundled CDT payment using two fairly prevalent cancers. We did not account for any other types of cancer that are seen with the various oncology practices. These other cancer types could produce significant revenues beyond the patient vignettes listed in our bundled CDT reimbursement and could offset any losses from our vignettes. Our modeling highlights a challenge with bundling CDT/related service payments that do not include some type of ability to mitigate the financial risks associated with high cost patients.

Our analysis indicates that migrating the reimbursement of cancer patients to a bundled CDT/related services payment approach, even if all practice and logistical issues are addressed, may still expose providers to significant potential financial losses/gains, due solely to the characteristics of patients who enter their office. As payers develop payment mechanisms that are more comprehensive than what we illustrated, practices will need to consider whether the reimbursement will provide the incentives for the practice to deliver high quality care. The addition of cost considerations beyond the

expenses associated with CDT may help align the financial and clinical incentives to successfully manage adverse events resulting in improved rates of hospital visits, relative to the benchmark underlying the reimbursement, for example - patient volume, case mix, drug outcomes, risk adjustment, and life expectency.[11-15]

CAVEATS AND LIMITATIONS

This report was completed under the terms of the executed consulting services agreement between Milliman and the American Society of Clinical Oncology, Inc. (ASCO).

The information contained in this report has been prepared solely for the use of ASCO to illustrate alternative oncology-related reimbursement. This information should not be used for any other purpose. However, as agreed to with ASCO, this complete report is expected to be available through ASCO via a direct link to a Milliman hosting website. Any user of the data must possess a certain level of expertise in actuarial science and healthcare modeling, or be advised by someone with the appropriate expertise, so as not to misinterpret the data presented.

Although Milliman consents to this report being available, Milliman makes no representations or warranties regarding the contents of this report to third parties. Likewise, third parties are instructed that they are to place no reliance upon this report prepared for ASCO by Milliman that would result in the creation of any duty or liability under any theory of law by Milliman or its employees to third parties. Other third parties receiving this report must rely upon their own experts in drawing conclusions about the results that have been presented in this report.

The information contained in this report and the enclosures are based upon data provided by ASCO, CMS, and other internal Milliman data. We have relied upon ASCO for the accuracy of the information provided. Milliman did not perform an independent audit or review of the data and information. To the extent that the information provided by ASCO is incomplete or otherwise inaccurate, the results of this analysis will be impacted.

Specifically, the information presented in this report is based on the 2016 Q1 Medicare Reimbursement rates, applied to the selected procedure codes provided by ASCO. The reimbursement amounts used in this model reflect prospective amounts and do not reflect any settlements with CMS. In addition, it applies no adjustment for sequestration or incentive programs with regards to the physician's payment. It was assumed that all of the oncology practice Medicare patients would adhere to the vignettes as established by the NCCN treatment guidelines. The hypothetical bundle assumed no savings to the Medicare program. It also did not include additional costs associated with care (e.g., hospitalizations, emergency room visits, radiology) because the purpose of the analysis was to isolate practice revenues from insurance payments associated with CDT.

The provided results are intended to illustrate differences given a set of parameters and it is certain that actual experience will not conform exactly to the assumptions used in this analysis. No adjustments were made for risk scores, case mix changes, clinical severity of patients in the vignettes, clinical outcomes influencing treatment modifications or the influence that clinical practice patterns might have on cost.

Guidelines issued by the American Academy of Actuaries require actuaries to include their professional qualifications in all actuarial communications. Stuart Rachlin is a member of the American Academy of Actuaries and he meets its qualification standards for performing the analyses in this report.

APPENDIX A: KEY DATA USED

The underlying data used in this analysis includes the following:

- Treatment Regimens for each patient type – The associated procedure codes, number of units and cycles were discussed with and agreed upon by ASCO. The regimens are provided in the Exhibit 1 in Appendix B and D.

- Medicare FFS Fee Schedule – The 2016 Q1 rates can be found on the CMS website (*https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/FeeScheduleGenInfo/index.html*) and provide the supporting data utilized in the Milliman 2016 Reimbursement Benchmark Model.

- Estimated number of patients receiving treatment for CC and NSCLC based on the size of the practice.
    - o The CMS Alliance to Modernize Healthcare report received from ASCO was used to develop this assumption for CC, which results in 7 patients for a small practice, 18 patients for a medium sized practice, and 42 patients for a large practice (Specialty Payment Model Opportunities and Assessment. Oncology Model Design Report 2014).

- Assumed distribution of patients by each patient type to be used in the simulation.
    - o The patient mix used in the simulation results were provided by ASCO; specific clinical assumptions and references provided by the ASCO Bundled Payment Working Group – Clinical Practice Committee per email communication on March 2, 2017 and are stated below.

Clinical Assumptions Text

"This evaluation makes multiple clinical assumptions. For both the colon cancer (CC) and the nonsmall cell lung cancer (NSLC) scenarios, the treatments are in accordance with the National Comprehensive Cancer Network oncology guidelines[1,2] and the dosing was based on a BSA of 1.9. In addition, the evaluation assumed that all patients completed the course of therapy.

In the CC vignettes, patients were treated with FOLFOX every two weeks for 12 cycles. Patients also received the supportive drugs, dexamethasone sodium phosphate and palonestron hcl (ALOXI®). The model assumed that 45% of patients were "simple patients" and were treated only with FOLFOX and the supportive drugs, 35% of patients developed grade II and above nausea and vomiting and required 6-cycles of treatment with fosprepitant dimeglumine (EMEND®), and 20% of patients developed grade III neutropenia and required 6-cyles of treatment with pegfilgrastim (NEULASTA®) (See Table 1.1 Patient Distributions).[3,4]

The NSLC analysis included 12 patients vignettes (see Table 1.1 Patient Distributions), including patients treated with both nontargeted chemotherapy regimens and targeted drugs. For patients treated with nontargeted regimens, the model included two distinct chemotherapy regimens provided every 3 weeks for 6 cycles with and without bevacizumab (AVASTIN®): carboplatin/paclitaxel (TAXOL®) and carboplatin/pemetrexed (ALIMTA®). These patients also received Ondansetron (ZOFRAN®). In addition,

the model assumed the following percentage of patients with each treatment regimen would develop grade III neutropenia and require treatment with pegfilgrastim (Neulasta®) over the final 4 cycles of treatment: 17% carboplatin/taxol, 25% carboplatin/taxol/bevacizumab, 10% carboplatin/pemetrexed, and 26% carboplatin/pemetrexed/bevacizumab.[5-7]

The distribution of the NSLC patients treated with targeted agents was based on data from My Cancer Genome. In the model, 15% of patients were EGFR+ and treated with erlotinib (TARCEVA®) and 5% of patients were ALK-1/ROS-1+ and treated with crizotinib (XALKORI®).[8] The cost of these oral agents was modeled for 6-months of treatment.

In addition, the NSLC model examined the impact on bundled payments of the Food and Drug Administration's (FDA's) approval of pembrolizumab (KEYTRUDA®) for first line treatment of PDL1-positive patients. The model evaluated three clinical scenarios: (1) 50% of patients treated with pembrolizumab alone and 6% of patients treated with pembrolizumab plus a standard chemotherapy regimen, (2) 50% of patients treated with pembrolizumab alone (and no patients treated with Pembrolizumab plus chemotherapy), and (3) no patients treated with pembrolizumab.

The number of patients seen by small, medium, and large practices was based on the RAND analysis of oncology payment model opportunities, with the CC scenario assuming 7, 18, and 42 patients per practice respectively and the NSCL scenario assuming 12, 32, and 82 patients per practice respectively.[9]

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APPENDIX B: STAGE III COLON CANCER PATIENT VIGNETTES

Exhibit 1

Patient Vignette Definition

Patient 1 - "Simple Patient"

HCPCS Level II Codes and Dosage							
HCPCS Level II Codes	Drug	Regimen details	Dosage (mg)	Size Factor	Calc Dose (mg)	Billing units	Cycles
J0640	Leucovorin calcium injection	400 mg/m2	50	1.9	760	16	12
J9190	Fluorouracil injection	2800 mg/m2	500	1.9	5320	11	12
J9263	Oxaliplatin	85 mg/m2	0.5	1.9	161.5	323	12
J1100	Dexamethasone sodium phos	1 mg x 8	1	1.0	8.0	8	12
J2469	Palonosetron hcl	25 mcg x 1	0.025	1.0	0.025	1	12

Administration			
Proc Code	Description	Units	Cycles
96360	Hydration iv infusion init	1	12
96361	Hydrate iv infusion add-on	1	12
96367	Tx/proph/dg addl seq iv inf	1	12
96368	Ther/diag concurrent inf	1	12
96375	Tx/pro/dx inj new drug addon	1	12
96411	Chemo iv push addl drug	1	12
96413	Chemo iv infusion 1 hr	1	12
96415	Chemo iv infusion addl hr	1	12
96416	Chemo prolong infuse w/pump	1	12
99601	Home infusion/visit 2 hrs	1	12

DME			
Proc Code	Description	Units	Cycles
E0779	Amb infusion pump mechanical	1	12

Note: Procedure Codes 99211 and 99213 were added to account for the office visits and G0463 was used for each Outpatient Hospital visits.

APPENDIX B: STAGE III COLON CANCER PATIENT VIGNETTES

Exhibit 1

Patient Vignette Definition

Patient 2 - "Simple Patient" with Grade II Nausea and Above

HCPCS Level II Codes and Dosage							
HCPCS Level II Codes	Drug	Regimen details	Dosage (mg)	Size Factor	Calc Dose (mg)	Billing units	Cycles
J0640	Leucovorin calcium injection	400 mg/m2	50	1.9	760	16	12
J9190	Fluorouracil injection	2800 mg/m2	500	1.9	5320	11	12
J9263	Oxaliplatin	85 mg/m2	0.5	1.9	161.5	323	12
J1100	Dexamethasone sodium phos	1 mg x 8	1	1.0	8.0	8	12
J2469	Palonosetron hcl	25 mcg x 1	0.025	1.0	0.025	1	12
J1453	Fosaprepitant	1 mg x 6	1	1.0	6.0	6	6

Administration			
Proc Code	Description	Units	Cycles
96360	Hydration iv infusion init	1	12
96361	Hydrate iv infusion add-on	1	12
96367	Tx/proph/dg addl seq iv inf	1	12
96368	Ther/diag concurrent inf	1	12
96375	Tx/pro/dx inj new drug addon	1	12
96411	Chemo iv push addl drug	1	12
96413	Chemo iv infusion 1 hr	1	12
96415	Chemo iv infusion addl hr	1	12
96416	Chemo prolong infuse w/pump	1	12
99601	Home infusion/visit 2 hrs	1	12

DME			
Proc Code	Description	Units	Cycles
E0779	Amb infusion pump mechanical	1	12

Note: Procedure Codes 99211 and 99213 were added to account for the office visits and G0463 was used for each Outpatient Hospital visits.

APPENDIX B: STAGE III COLON CANCER PATIENT VIGNETTES
Exhibit 1
Patient Vignette Definition

Patient 3 - "Simple Patient" with Grade III Neutropenia

HCPCS Level II Codes	Drug	Regimen details	Dosage (mg)	Size Factor	Calc Dose (mg)	Billing units	Cycles
J0640	Leucovorin calcium injection	400 mg/m2	50	1.9	760	16	12
J9190	Fluorouracil injection	2800 mg/m2	500	1.9	5320	11	12
J9263	Oxaliplatin	85 mg/m2	0.5	1.9	161.5	323	12
J1100	Dexamethasone sodium phos	1 mg x 8	1	1.0	8.0	8	12
J2469	Palonosetron hcl	25 mcg x 1	0.025	1.0	0.025	1	12
J2505	Pegfilgrastim	6 mg x 1	6	1.0	6.0	6	6

HCPCS Level II Codes and Dosage

Proc Code	Description	Units	Cycles
96360	Hydration iv infusion init	1	12
96361	Hydrate iv infusion add-on	1	12
96367	Tx/proph/dg addl seq iv inf	1	12
96368	Ther/diag concurrent inf	1	12
96375	Tx/pro/dx inj new drug addon	1	12
96411	Chemo iv push addl drug	1	12
96413	Chemo iv infusion 1 hr	1	12
96415	Chemo iv infusion addl hr	1	12
96416	Chemo prolong infuse w/pump	1	12
99601	Home infusion/visit 2 hrs	1	12

Administration

Proc Code	Description	Units	Cycles
E0779	Amb infusion pump mechanical	1	12

DME

Note: Procedure Codes 99211 and 99213 were added to account for the office visits and G0463 was used for each Outpatient Hospital visits.

APPENDIX B: STAGE III COLON CANCER PATIENT VIGNETTES
Exhibit 2
Patient Vignette FFS Reimbursement

	Setting: Office - Rural				
	Drug	Admin	E&M	DME	Total
Patient 1 - "Simple Patient"	$2,746	$5,742	$1,076	$218	**$9,783**
Patient 2 - "Simple Patient" with Grade II Nausea and Above	$2,808	$5,742	$1,076	$218	**$9,845**
Patient 3 - "Simple Patient" with Grade III Neutropenia	$25,715	$5,742	$1,076	$218	**$32,751**

Bundled Payment $14,398

	Setting: Outpatient - Rural				
	Drug	Admin	E&M	DME	Total
Patient 1 - "Simple Patient"	$1,758	$10,195	$1,153	$218	**$13,323**
Patient 2 - "Simple Patient" with Grade II Nausea and Above	$1,820	$10,195	$1,153	$218	**$13,385**
Patient 3 - "Simple Patient" with Grade III Neutropenia	$24,726	$10,195	$1,153	$218	**$36,292**

Bundled Payment $17,939

	Setting: Office - Urban				
	Drug	Admin	E&M	DME	Total
Patient 1 - "Simple Patient"	$2,746	$6,541	$1,186	$218	**$10,692**
Patient 2 - "Simple Patient" with Grade II Nausea and Above	$2,808	$6,541	$1,186	$218	**$10,754**
Patient 3 - "Simple Patient" with Grade III Neutropenia	$25,715	$6,541	$1,186	$218	**$33,660**

Bundled Payment $15,307

	Setting: Outpatient - Urban				
	Drug	Admin	E&M	DME	Total
Patient 1 - "Simple Patient"	$1,758	$11,048	$1,249	$218	**$14,274**
Patient 2 - "Simple Patient" with Grade II Nausea and Above	$1,820	$11,048	$1,249	$218	**$14,336**
Patient 3 - "Simple Patient" with Grade III Neutropenia	$24,726	$11,048	$1,249	$218	**$37,242**

Bundled Payment $18,889

APPENDIX C: STAGE III COLON CANCER SIMULATION RESULTS – PROBABILITY OF GAIN/LOSS

Exhibit 1

Simulation Results – Small Sized Practice, Probability of Gain/Loss

I. Change in Revenue (without Winsorization)

Small Sized Practices					
EXAMPLE: Office-Urban Setting					
			Cumulative Loss [1]		
Practice Distribution	**Gain**	**Loss**	**-10%**	**-20%**	**-30%**
Practices	559	441	441	147	33
% of Simulations	56%	44%	44%	15%	3%
Averages (Per Practice)					
Bundled Payment Revenue	$107,151	$107,151	$107,151	$107,151	$107,151
Medicare FFS Reimbursement	$90,344	$130,480	$130,480	$149,616	$169,561
Change in Revenue	$16,807	($23,329)	($23,329)	($42,465)	($62,410)
Averages (Per Patient)					
Bundled Payment Revenue	$15,307	$15,307	$15,307	$15,307	$15,307
Medicare FFS Reimbursement	$12,906	$18,640	$18,640	$21,374	$24,223
Change in Revenue	$2,401	($3,333)	($3,333)	($6,066)	($8,916)
Change in Revenue (%)	18.6%	-17.9%	-17.9%	-28.4%	-36.8%

(1) Each column contains practices with a loss of the specified amount or greater.

(i.e., practices with at least a 10% loss also include those with 20% and 30% losses)

II. Change in Revenue (with Winsorization)

Small Sized Practices					
EXAMPLE: Office-Urban Setting					
			Cumulative Loss [1]		
Practice Distribution	**Gain**	**Loss**	**-10%**	**-20%**	**-30%**
Practices	559	441	441	147	0
% of Simulations	56%	44%	44%	15%	0%
Averages (Per Practice)					
Bundled Payment Revenue	$107,151	$107,151	$107,151	$107,151	n/a
Medicare FFS Reimbursement	$90,346	$128,562	$128,562	$143,861	n/a
Change in Revenue	$16,805	($21,411)	($21,411)	($36,710)	n/a
Averages (Per Patient)					
Bundled Payment Revenue	$15,307	$15,307	$15,307	$15,307	n/a
Medicare FFS Reimbursement	$12,907	$18,366	$18,366	$20,552	n/a
Change in Revenue	$2,401	($3,059)	($3,059)	($5,244)	n/a
Change in Revenue (%)	18.6%	-16.7%	-16.7%	-25.5%	n/a

(1) Each column contains practices with a loss of the specified amount or greater.

(i.e., practices with at least a 10% loss also include those with 20% and 30% losses)

APPENDIX C: STAGE III COLON CANCER SIMULATION RESULTS – PROBABILITY OF GAIN/LOSS
Exhibit 2
Simulation Results – Medium Sized Practice, Probability of Gain/Loss

I. Change in Revenue (without Winsorization)

Medium Sized Practices					
EXAMPLE: Office-Urban Setting					
				Cumulative Loss [1]	
Practice Distribution	**Gain**	**Loss**	**-10%**	**-20%**	**-30%**
Practices	507	493	291	49	3
% of Simulations	51%	49%	29%	5%	0%
Averages (Per Practice)					
Bundled Payment Revenue	$275,530	$275,530	$275,530	$275,530	$275,530
Medicare FFS Reimbursement	$243,847	$307,636	$323,561	$361,472	$407,012
Change in Revenue	$31,683	($32,106)	($48,031)	($85,942)	($131,482)
Averages (Per Patient)					
Bundled Payment Revenue	$15,307	$15,307	$15,307	$15,307	$15,307
Medicare FFS Reimbursement	$13,547	$17,091	$17,976	$20,082	$22,612
Change in Revenue	$1,760	($1,784)	($2,668)	($4,775)	($7,305)
Change in Revenue (%)	13.0%	-10.4%	-14.8%	-23.8%	-32.3%

(1) Each column contains practices with a loss of the specified amount or greater.
(i.e., practices with at least a 10% loss also include those with 20% and 30% losses)

II. Change in Revenue (with Winsorization)

Medium Sized Practices					
EXAMPLE: Office-Urban Setting					
				Cumulative Loss [1]	
Practice Distribution	**Gain**	**Loss**	**-10%**	**-20%**	**-30%**
Practices	507	493	291	0	0
% of Simulations	51%	49%	29%	0%	0%
Averages (Per Practice)					
Bundled Payment Revenue	$275,530	$275,530	$275,530	n/a	n/a
Medicare FFS Reimbursement	$244,666	$304,590	$318,400	n/a	n/a
Change in Revenue	$30,864	($29,059)	($42,870)	n/a	n/a
Averages (Per Patient)					
Bundled Payment Revenue	$15,307	$15,307	$15,307	n/a	n/a
Medicare FFS Reimbursement	$13,593	$16,922	$17,689	n/a	n/a
Change in Revenue	$1,715	($1,614)	($2,382)	n/a	n/a
Change in Revenue (%)	12.6%	-9.5%	-13.5%	n/a	n/a

(1) Each column contains practices with a loss of the specified amount or greater.
(i.e., practices with at least a 10% loss also include those with 20% and 30% losses)

APPENDIX C: STAGE III COLON CANCER SIMULATION RESULTS – PROBABILITY OF GAIN/LOSS

Exhibit 3

Simulation Results – Large Sized Practice, Probability of Gain/Loss

I. Change in Revenue (without Winsorization)

Large Sized Practices					
EXAMPLE: Office-Urban Setting					
			Cumulative Loss [1]		
Practice Distribution	**Gain**	**Loss**	**-10%**	**-20%**	**-30%**
Practices	541	459	132	5	0
% of Simulations	54%	46%	13%	1%	0%
Averages (Per Practice)					
Bundled Payment Revenue	$642,904	$642,904	$642,904	$642,904	n/a
Medicare FFS Reimbursement	$598,747	$695,102	$744,261	$821,767	n/a
Change in Revenue	$44,157	($52,198)	($101,357)	($178,863)	n/a
Averages (Per Patient)					
Bundled Payment Revenue	$15,307	$15,307	$15,307	$15,307	n/a
Medicare FFS Reimbursement	$14,256	$16,550	$17,721	$19,566	n/a
Change in Revenue	$1,051	($1,243)	($2,413)	($4,259)	n/a
Change in Revenue (%)	7.4%	-7.5%	-13.6%	-21.8%	n/a

(1) Each column contains practices with a loss of the specified amount or greater.

(i.e., practices with at least a 10% loss also include those with 20% and 30% losses)

II. Change in Revenue (with Winsorization)

Large Sized Practices					
EXAMPLE: Office-Urban Setting					
			Cumulative Loss [1]		
Practice Distribution	**Gain**	**Loss**	**-10%**	**-20%**	**-30%**
Practices	541	459	132	0	0
% of Simulations	54%	46%	13%	0%	0%
Averages (Per Practice)					
Bundled Payment Revenue	$642,904	$642,904	$642,904	n/a	n/a
Medicare FFS Reimbursement	$600,005	$692,744	$736,062	n/a	n/a
Change in Revenue	$42,899	($49,840)	($93,158)	n/a	n/a
Averages (Per Patient)					
Bundled Payment Revenue	$15,307	$15,307	$15,307	n/a	n/a
Medicare FFS Reimbursement	$14,286	$16,494	$17,525	n/a	n/a
Change in Revenue	$1,021	($1,187)	($2,218)	n/a	n/a
Change in Revenue (%)	7.1%	-7.2%	-12.7%	n/a	n/a

(1) Each column contains practices with a loss of the specified amount or greater.

(i.e., practices with at least a 10% loss also include those with 20% and 30% losses)

APPENDIX D: NON-SMALL CELL LUNG CANCER PATIENT VIGNETTES

Exhibit 1

Patient Vignette Definition

Patient 1 - Carbo/Taxol

		HCPCS Level II Codes and Dosage						
HCPCS Level II Codes	Drug	Regimen details	Cycle Days	Dosage (mg)	Size Factor	Calc Dose (mg)	Billing units	Cycles
J9267	Paclitaxel	200 mg/m2 over 3 hours	21	1	1.9	380	380	6
J9045	Carboplatin	900 mg over __ hours	21	50	1	900	18	6
J2405	Ondansetron	8 mg, IV push	21	1	1	8	8	6

	Administration		
Proc Code	Description	Units	Cycles
96413	Chemo iv infusion 1 hr	1	6
96415	Chemo iv infusion addl hr	2	6
96417	Chemo iv infus each addl seq	1	6
96374	Ther/proph/diag inj iv push	1	6

Patient 2 - Carbo/Taxol + Neutropenia

		HCPCS Level II Codes and Dosage						
HCPCS Level II Codes	Drug	Regimen details	Cycle Days	Dosage (mg)	Size Factor	Calc Dose (mg)	Billing units	Cycles
J9267	Paclitaxel	200 mg/m2 over 3 hours	21	1	1.9	380	380	6
J9045	Carboplatin	900 mg over __ hours	21	50	1	900	18	6
J2405	Ondansetron	8 mg, IV push	21	1	1	8	8	6
J2505	Pegfilgrastim	6 mg x 1	21	6	1	6	1	4

	Administration		
Proc Code	Description	Units	Cycles
96413	Chemo iv infusion 1 hr	1	6
96415	Chemo iv infusion addl hr	2	6
96417	Chemo iv infus each addl seq	1	6
96374	Ther/proph/diag inj iv push	1	6
96372	Ther/proph/diag inj sc/im	1	4

Patient 3 - Carbo/Taxol + Bevacizumab

		HCPCS Level II Codes and Dosage						
HCPCS Level II Codes	Drug	Regimen details	Cycle Days	Dosage (mg)	Size Factor	Calc Dose (mg)	Billing units	Cycles
J9267	Paclitaxel	200 mg/m2 over 3 hours	21	1	1.9	380	380	6
J9045	Carboplatin	900 mg over __ hours	21	50	1	900	18	6
J2405	Ondansetron	8 mg, IV push	21	1	1	8	8	6
J9035	Bevacizumab	15 mg/kg over __ hours	21	10	80	1200	120	6

	Administration		
Proc Code	Description	Units	Cycles
96413	Chemo iv infusion 1 hr	1	6
96415	Chemo iv infusion addl hr	2	6
96417	Chemo iv infus each addl seq	1	6
96374	Ther/proph/diag inj iv push	1	6
96417	Chemo iv infus each addl seq	1	6
96415	Chemo iv infusion addl hr	1	1

Patient 4 - Carbo/Taxol + Bevacizumab + Neutropenia

		HCPCS Level II Codes and Dosage						
HCPCS Level II Codes	Drug	Regimen details	Cycle Days	Dosage (mg)	Size Factor	Calc Dose (mg)	Billing units	Cycles
J9267	Paclitaxel	200 mg/m2 over 3 hours	21	1	1.9	380	380	6
J9045	Carboplatin	900 mg over __ hours	21	50	1	900	18	6
J2405	Ondansetron	8 mg, IV push	21	1	1	8	8	6
J9035	Bevacizumab	15 mg/kg over __ hours	21	10	80	1200	120	6
J2505	Pegfilgrastim	6 mg x 1	21	6	1	6	1	4

	Administration		
Proc Code	Description	Units	Cycles
96413	Chemo iv infusion 1 hr	1	6
96415	Chemo iv infusion addl hr	2	6
96417	Chemo iv infus each addl seq	1	6
96374	Ther/proph/diag inj iv push	1	6
96417	Chemo iv infus each addl seq	1	6
96415	Chemo iv infusion addl hr	1	1
96372	Ther/proph/diag inj sc/im	1	4

APPENDIX D: NON-SMALL CELL LUNG CANCER PATIENT VIGNETTES
Exhibit 1
Patient Vignette Definition

Patient 5 - Carbo/Pemetrexed

HCPCS Level II Codes	Drug	Regimen details	Cycle Days	Dosage (mg)	Size Factor	Calc Dose (mg)	Billing units	Cycles
J9305	Pemetrexed injection	500 mg/m2 over 15 minutes	21	10	1.9	950	95	6
J9045	Carboplatin	900 mg over __ hours	21	50	1	900	18	6
J2405	Ondansetron	8 mg, IV push	21	1	1	8	8	6

Proc Code	Description	Units	Cycles
96409	Chemo iv push sngl drug	1	6
96413	Chemo iv infusion 1 hr	1	6
96374	Ther/proph/diag inj iv push	1	6

Patient 6 - Carbo/Pemetrexed + Neutropenia

HCPCS Level II Codes	Drug	Regimen details	Cycle Days	Dosage (mg)	Size Factor	Calc Dose (mg)	Billing units	Cycles
J9305	Pemetrexed injection	500 mg/m2 over 15 minutes	21	10	1.9	950	95	6
J9045	Carboplatin	900 mg over __ hours	21	50	1	900	18	6
J2405	Ondansetron	8 mg, IV push	21	1	1	8	8	6
J2505	Pegfilgrastim	6 mg x 1	21	6	1	6	1	4

Proc Code	Description	Units	Cycles
96409	Chemo iv push sngl drug	1	6
96413	Chemo iv infusion 1 hr	1	6
96374	Ther/proph/diag inj iv push	1	6
96372	Ther/proph/diag inj sc/im	1	4

Patient 7 - Carbo/Pemetrexed + Bevacizumab

HCPCS Level II Codes	Drug	Regimen details	Cycle Days	Dosage (mg)	Size Factor	Calc Dose (mg)	Billing units	Cycles
J9305	Pemetrexed injection	500 mg/m2 over 15 minutes	21	10	1.9	950	95	6
J9045	Carboplatin	900 mg over __ hours	21	50	1	900	18	6
J2405	Ondansetron	8 mg, IV push	21	1	1	8	8	6
J9035	Bevacizumab	15 mg/kg over __ hours	21	10	80	1200	120	6

Proc Code	Description	Units	Cycles
96409	Chemo iv push sngl drug	1	6
96413	Chemo iv infusion 1 hr	1	6
96374	Ther/proph/diag inj iv push	1	6
96417	Chemo iv infus each addl seq	1	6
96415	Chemo iv infusion addl hr	1	1

Patient 8 - Carbo/Pemetrexed + Bevacizumab + Neutropenia

HCPCS Level II Codes	Drug	Regimen details	Cycle Days	Dosage (mg)	Size Factor	Calc Dose (mg)	Billing units	Cycles
J9305	Pemetrexed injection	500 mg/m2 over 15 minutes	21	10	1.9	950	95	6
J9045	Carboplatin	900 mg over __ hours	21	50	1	900	18	6
J2405	Ondansetron	8 mg, IV push	21	1	1	8	8	6
J9035	Bevacizumab	15 mg/kg over __ hours	21	10	80	1200	120	6
J2505	Pegfilgrastim	6 mg x 1	21	6	1	6	1	4

Proc Code	Description	Units	Cycles
96409	Chemo iv push sngl drug	1	6
96413	Chemo iv infusion 1 hr	1	6
96374	Ther/proph/diag inj iv push	1	6
96417	Chemo iv infus each addl seq	1	6
96415	Chemo iv infusion addl hr	1	1
96372	Ther/proph/diag inj sc/im	1	4

Assessing the Potential Revenue Impact to Oncology Practices Under a Cancer Drug Therapy Bundled Reimbursement Model
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APPENDIX D: NON-SMALL CELL LUNG CANCER PATIENT VIGNETTES
Exhibit 1
Patient Vignette Definition

Patient 9 - EGFR

HCPCS Level II Codes	Drug	Regimen details	Cycle Days	Dosage (mg)	Size Factor	Calc Dose (mg)	Billing units	Cycles
Rx	Erolotinib	150 mg po qd	1	30	1		1	6

Patient 10 - Crizotinib

HCPCS Level II Codes	Drug	Regimen details	Cycle Days	Dosage (mg)	Size Factor	Calc Dose (mg)	Billing units	Cycles
Rx	Crizotinib	250 mg po bid	1	60	1		1	6

Patient 11 - Pembrolizumab

HCPCS Level II Codes	Drug	Regimen details	Cycle Days	Dosage (mg)	Size Factor	Calc Dose (mg)	Billing units	Cycles
J9271	Pembrolizumab	200 mg q 3 weeks	21	1	1	200	200	6

Administration			
Proc Code	Description	Units	Cycles
96413	Chemo iv infusion 1 hr	1	6

Patient 12 - Pembrolizumab + "Chemo"

HCPCS Level II Codes	Drug	Regimen details	Cycle Days	Dosage (mg)	Size Factor	Calc Dose (mg)	Billing units	Cycles
J9271	Pembrolizumab	200 mg q 3 weeks	21	1	1	200	200	6

Administration			
Proc Code	Description	Units	Cycles
96417	Chemo iv infus each addl seq	1	6

Notes:
- Patient 12 will use the weighted average of the non-squamous patient charges as the cost for "Chemo"
- All patients (except 9 and 10) will also be charged an E&M code (G0463 for Outpatient Setting and 99211 for Office Visit)
- Patients 9 and 10 will only be charged for 3 visits over the 6 months

APPENDIX D: NON-SMALL CELL LUNG CANCER PATIENT VIGNETTES

Exhibit 2

Patient Vignette FFS Reimbursement

	Setting: Office - Rural			
	Drug	**Admin**	**E&M**	**Total**
Patient 1 - Carbo/Taxol	$746	$1,425	$114	**$2,284**
Patient 2 - Carbo/Taxol + Neutropenia	$16,058	$1,520	$114	**$17,692**
Patient 3 - Carbo/Taxol + Bevacizumab	$51,752	$1,776	$114	**$53,641**
Patient 4 - Carbo/Taxol + Bevacizumab + Neutropenia	$67,064	$1,871	$114	**$69,049**
Patient 5 - Carbo/Pemetrexed	$35,600	$1,693	$114	**$37,407**
Patient 6 - Carbo/Pemetrexed + Neutropenia	$50,912	$1,789	$114	**$52,815**
Patient 7 - Carbo/Pemetrexed + Bevacizumab	$86,606	$2,071	$114	**$88,791**
Patient 8 - Carbo/Pemetrexed + Bevacizumab + Neutropenia	$101,919	$2,166	$114	**$104,199**
Patient 9 - EGFR	$42,710	$0	$57	**$42,767**
Patient 10 - Crizotinib	$83,342	$0	$57	**$83,399**
Patient 11 - Pembrolizumab	$54,834	$755	$114	**$55,703**
Patient 12 - Pembrolizumab + "Chemo"	$101,488	$2,866	$114	**$104,468**

	Bundled Payment		
	Scenario 1	**Scenario 2**	**Scenario 3**
Bundled Payment	$56,351	$52,995	$50,287

	Setting: Outpatient - Rural			
	Drug	**Admin**	**E&M**	**Total**
Patient 1 - Carbo/Taxol	$0	$2,342	$576	**$2,919**
Patient 2 - Carbo/Taxol + Neutropenia	$15,312	$2,501	$576	**$18,390**
Patient 3 - Carbo/Taxol + Bevacizumab	$51,006	$2,581	$576	**$54,164**
Patient 4 - Carbo/Taxol + Bevacizumab + Neutropenia	$66,319	$2,740	$576	**$69,635**
Patient 5 - Carbo/Pemetrexed	$35,203	$3,081	$576	**$38,860**
Patient 6 - Carbo/Pemetrexed + Neutropenia	$50,516	$3,240	$576	**$54,332**
Patient 7 - Carbo/Pemetrexed + Bevacizumab	$86,209	$3,359	$576	**$90,145**
Patient 8 - Carbo/Pemetrexed + Bevacizumab + Neutropenia	$101,522	$3,519	$576	**$105,617**
Patient 9 - EGFR	$42,710	$0	$288	**$42,998**
Patient 10 - Crizotinib	$83,342	$0	$288	**$83,630**
Patient 11 - Pembrolizumab	$54,834	$1,582	$576	**$56,992**
Patient 12 - Pembrolizumab + "Chemo"	$100,917	$4,454	$576	**$105,947**

	Bundled Payment		
	Simulation 1	**Simulation 2**	**Simulation 3**
Bundled Payment	$57,372	$53,987	$50,981

APPENDIX D: NON-SMALL CELL LUNG CANCER PATIENT VIGNETTES

Exhibit 2

Patient Vignette FFS Reimbursement

	Setting: Office - Urban			
	Drug	**Admin**	**E&M**	**Total**
Patient 1 - Carbo/Taxol	$746	$1,628	$126	**$2,500**
Patient 2 - Carbo/Taxol + Neutropenia	$16,058	$1,734	$126	**$17,919**
Patient 3 - Carbo/Taxol + Bevacizumab	$51,752	$2,028	$126	**$53,906**
Patient 4 - Carbo/Taxol + Bevacizumab + Neutropenia	$67,064	$2,134	$126	**$69,324**
Patient 5 - Carbo/Pemetrexed	$35,600	$1,937	$126	**$37,663**
Patient 6 - Carbo/Pemetrexed + Neutropenia	$50,912	$2,044	$126	**$53,082**
Patient 7 - Carbo/Pemetrexed + Bevacizumab	$86,606	$2,367	$126	**$89,099**
Patient 8 - Carbo/Pemetrexed + Bevacizumab + Neutropenia	$101,919	$2,473	$126	**$104,518**
Patient 9 - EGFR	$42,710	$0	$63	**$42,773**
Patient 10 - Crizotinib	$83,342	$0	$63	**$83,405**
Patient 11 - Pembrolizumab	$54,834	$864	$126	**$55,824**
Patient 12 - Pembrolizumab + "Chemo"	$101,488	$2,875	$126	**$104,489**

	Bundled Payment		
	Scenario 1	**Scenario 2**	**Scenario 3**
Bundled Payment	$56,478	$53,136	$50,447

	Setting: Outpatient - Urban			
	Drug	**Admin**	**E&M**	**Total**
Patient 1 - Carbo/Taxol	$0	$2,538	$625	**$3,163**
Patient 2 - Carbo/Taxol + Neutropenia	$15,312	$2,711	$625	**$18,648**
Patient 3 - Carbo/Taxol + Bevacizumab	$51,006	$2,797	$625	**$54,428**
Patient 4 - Carbo/Taxol + Bevacizumab + Neutropenia	$66,319	$2,970	$625	**$69,913**
Patient 5 - Carbo/Pemetrexed	$35,203	$3,339	$625	**$39,167**
Patient 6 - Carbo/Pemetrexed + Neutropenia	$50,516	$3,511	$625	**$54,652**
Patient 7 - Carbo/Pemetrexed + Bevacizumab	$86,209	$3,641	$625	**$90,475**
Patient 8 - Carbo/Pemetrexed + Bevacizumab + Neutropenia	$101,522	$3,813	$625	**$105,960**
Patient 9 - EGFR	$42,710	$0	$312	**$43,022**
Patient 10 - Crizotinib	$83,342	$0	$312	**$83,655**
Patient 11 - Pembrolizumab	$54,834	$1,714	$625	**$57,173**
Patient 12 - Pembrolizumab + "Chemo"	$100,917	$4,827	$625	**$106,368**

	Bundled Payment		
	Scenario 1	**Scenario 2**	**Scenario 3**
Bundled Payment	$57,561	$54,169	$51,164

APPENDIX E: NON-SMALL CELL LUNG CANCER SIMULATION RESULTS - PROBABILITY OF GAIN/LOSS

Exhibit 1a

Simulation Results – Scenario 1, Small Sized Practice, Probability of Gain/Loss

Bundled Payment Scenario 1 – Pembrolizumab and additional chemo, included in bundle.

I. Change in Revenue (without Winsorization)

Small Sized Practices					
EXAMPLE: Office-Urban Setting					
			Cumulative Loss [1]		
Practice Distribution	**Gain**	**Loss**	**-10%**	**-20%**	**-30%**
Practices	522	478	163	16	1
% of Simulations	52%	48%	16%	2%	0%
Averages (Per Practice)					
Bundled Payment Revenue	$677,731	$677,731	$677,731	$677,731	$677,731
Medicare FFS Reimbursement	$618,889	$739,053	$794,792	$876,251	$975,583
Change in Revenue	$58,842	($61,321)	($117,060)	($198,520)	($297,852)
Averages (Per Patient)					
Bundled Payment Revenue	$56,478	$56,478	$56,478	$56,478	$56,478
Medicare FFS Reimbursement	$51,574	$61,588	$66,233	$73,021	$81,299
Change in Revenue	$4,904	($5,110)	($9,755)	($16,543)	($24,821)
Change in Revenue (%)	9.5%	-8.3%	-14.7%	-22.7%	-30.5%

(1) Each column contains practices with a loss of the specified amount or greater.
(i.e., practices with at least a 10% loss also include those with 20% and 30% losses)

II. Change in Revenue (with Winsorization)

Small Sized Practices					
EXAMPLE: Office-Urban Setting					
			Cumulative Loss [1]		
Practice Distribution	**Gain**	**Loss**	**-10%**	**-20%**	**-30%**
Practices	522	478	163	0	0
% of Simulations	52%	48%	16%	0%	0%
Averages (Per Practice)					
Bundled Payment Revenue	$677,731	$677,731	$677,731	n/a	n/a
Medicare FFS Reimbursement	$621,729	$735,304	$783,800	n/a	n/a
Change in Revenue	$56,002	($57,573)	($106,069)	n/a	n/a
Averages (Per Patient)					
Bundled Payment Revenue	$56,478	$56,478	$56,478	n/a	n/a
Medicare FFS Reimbursement	$51,811	$61,275	$65,317	n/a	n/a
Change in Revenue	$4,667	($4,798)	($8,839)	n/a	n/a
Change in Revenue (%)	9.0%	-7.8%	-13.5%	n/a	n/a

(1) Each column contains practices with a loss of the specified amount or greater.
(i.e., practices with at least a 10% loss also include those with 20% and 30% losses)

APPENDIX E: NON-SMALL CELL LUNG CANCER SIMULATION RESULTS - PROBABILITY OF GAIN/LOSS

Exhibit 1b

Simulation Results – Scenario 1, Medium Sized Practice, Probability of Gain/Loss

Bundled Payment Scenario 1 – Pembrolizumab and additional chemo, included in bundle.

I. Change in Revenue (without Winsorization)

Medium Sized Practices					
EXAMPLE: Office-Urban Setting					
			Cumulative Loss[1]		
Practice Distribution	**Gain**	**Loss**	**-10%**	**-20%**	**-30%**
Practices	494	506	45	0	0
% of Simulations	49%	51%	5%	0%	0%
Averages (Per Practice)					
Bundled Payment Revenue	$1,807,283	$1,807,283	$1,807,283	n/a	n/a
Medicare FFS Reimbursement	$1,719,138	$1,898,307	$2,060,947	n/a	n/a
Change in Revenue	$88,145	($91,024)	($253,663)	n/a	n/a
Averages (Per Patient)					
Bundled Payment Revenue	$56,478	$56,478	$56,478	n/a	n/a
Medicare FFS Reimbursement	$53,723	$59,322	$64,405	n/a	n/a
Change in Revenue	$2,755	($2,844)	($7,927)	n/a	n/a
Change in Revenue (%)	5.1%	-4.8%	-12.3%	n/a	n/a

(1) Each column contains practices with a loss of the specified amount or greater.
(i.e., practices with at least a 10% loss also include those with 20% and 30% losses)

II. Change in Revenue (with Winsorization)

Medium Sized Practices					
EXAMPLE: Office-Urban Setting					
			Cumulative Loss[1]		
Practice Distribution	**Gain**	**Loss**	**-10%**	**-20%**	**-30%**
Practices	494	506	0	0	0
% of Simulations	49%	51%	0%	0%	0%
Averages (Per Practice)					
Bundled Payment Revenue	$1,807,283	$1,807,283	n/a	n/a	n/a
Medicare FFS Reimbursement	$1,724,065	$1,892,902	n/a	n/a	n/a
Change in Revenue	$83,219	($85,619)	n/a	n/a	n/a
Averages (Per Patient)					
Bundled Payment Revenue	$56,478	$56,478	n/a	n/a	n/a
Medicare FFS Reimbursement	$53,877	$59,153	n/a	n/a	n/a
Change in Revenue	$2,601	($2,676)	n/a	n/a	n/a
Change in Revenue (%)	4.8%	-4.5%	n/a	n/a	n/a

(1) Each column contains practices with a loss of the specified amount or greater.
(i.e., practices with at least a 10% loss also include those with 20% and 30% losses)

APPENDIX E: NON-SMALL CELL LUNG CANCER SIMULATION RESULTS - PROBABILITY OF GAIN/LOSS

Exhibit 1c

Simulation Results – Scenario 1, Large Sized Practice, Probability of Gain/Loss

Bundled Payment Scenario 1 – Pembrolizumab and additional chemo, included in bundle.

I. Change in Revenue (without Winsorization)

Large Sized Practices					
EXAMPLE: Office-Urban Setting					
			Cumulative Loss[1]		
Practice Distribution	**Gain**	**Loss**	**-10%**	**-20%**	**-30%**
Practices	484	516	4	0	0
% of Simulations	48%	52%	0%	0%	0%
Averages (Per Practice)					
Bundled Payment Revenue	$4,631,164	$4,631,164	$4,631,164	n/a	n/a
Medicare FFS Reimbursement	$4,477,566	$4,798,841	$5,180,762	n/a	n/a
Change in Revenue	$153,598	($167,677)	($549,598)	n/a	n/a
Averages (Per Patient)					
Bundled Payment Revenue	$56,478	$56,478	$56,478	n/a	n/a
Medicare FFS Reimbursement	$54,604	$58,522	$63,180	n/a	n/a
Change in Revenue	$1,873	($2,045)	($6,702)	n/a	n/a
Change in Revenue (%)	3.4%	-3.5%	-10.6%	n/a	n/a

(1) Each column contains practices with a loss of the specified amount or greater.
(i.e., practices with at least a 10% loss also include those with 20% and 30% losses)

II. Change in Revenue (with Winsorization)

Large Sized Practices					
EXAMPLE: Office-Urban Setting					
			Cumulative Loss[1]		
Practice Distribution	**Gain**	**Loss**	**-10%**	**-20%**	**-30%**
Practices	484	516	0	0	0
% of Simulations	48%	52%	0%	0%	0%
Averages (Per Practice)					
Bundled Payment Revenue	$4,631,164	$4,631,164	n/a	n/a	n/a
Medicare FFS Reimbursement	$4,485,504	$4,791,330	n/a	n/a	n/a
Change in Revenue	$145,660	($160,167)	n/a	n/a	n/a
Averages (Per Patient)					
Bundled Payment Revenue	$56,478	$56,478	n/a	n/a	n/a
Medicare FFS Reimbursement	$54,701	$58,431	n/a	n/a	n/a
Change in Revenue	$1,776	($1,953)	n/a	n/a	n/a
Change in Revenue (%)	3.2%	-3.3%	n/a	n/a	n/a

(1) Each column contains practices with a loss of the specified amount or greater.
(i.e., practices with at least a 10% loss also include those with 20% and 30% losses)

APPENDIX E: NON-SMALL CELL LUNG CANCER SIMULATION RESULTS - PROBABILITY OF GAIN/LOSS

Exhibit 2a

Simulation Results – Scenario 2, Small Sized Practice, Probability of Gain/Loss

Bundled Payment Scenario 2 – Pembrolizumab included in bundle, but additional chemo carved out.

I. Change in Revenue (without Winsorization)

Small Sized Practices					
EXAMPLE: Office-Urban Setting					
			Cumulative Loss [1]		
Practice Distribution	**Gain**	**Loss**	**-10%**	**-20%**	**-30%**
Practices	500	500	148	5	0
% of Simulations	50%	50%	15%	1%	0%
Averages (Per Practice)					
Bundled Payment Revenue	$637,628	$637,628	$637,628	$637,628	n/a
Medicare FFS Reimbursement	$582,781	$690,146	$741,614	$826,467	n/a
Change in Revenue	$54,847	($52,517)	($103,986)	($188,838)	n/a
Averages (Per Patient)					
Bundled Payment Revenue	$53,136	$53,136	$53,136	$53,136	n/a
Medicare FFS Reimbursement	$48,565	$57,512	$61,801	$68,872	n/a
Change in Revenue	$4,571	($4,376)	($8,665)	($15,737)	n/a
Change in Revenue (%)	9.4%	-7.6%	-14.0%	-22.8%	n/a

(1) Each column contains practices with a loss of the specified amount or greater.
(i.e., practices with at least a 10% loss also include those with 20% and 30% losses)

II. Change in Revenue (with Winsorization)

Small Sized Practices					
EXAMPLE: Office-Urban Setting					
			Cumulative Loss [1]		
Practice Distribution	**Gain**	**Loss**	**-10%**	**-20%**	**-30%**
Practices	500	500	148	0	0
% of Simulations	50%	50%	15%	0%	0%
Averages (Per Practice)					
Bundled Payment Revenue	$637,628	$637,628	$637,628	n/a	n/a
Medicare FFS Reimbursement	$586,035	$688,072	$734,608	n/a	n/a
Change in Revenue	$51,593	($50,443)	($96,979)	n/a	n/a
Averages (Per Patient)					
Bundled Payment Revenue	$53,136	$53,136	$53,136	n/a	n/a
Medicare FFS Reimbursement	$48,836	$57,339	$61,217	n/a	n/a
Change in Revenue	$4,299	($4,204)	($8,082)	n/a	n/a
Change in Revenue (%)	8.8%	-7.3%	-13.2%	n/a	n/a

(1) Each column contains practices with a loss of the specified amount or greater.
(i.e., practices with at least a 10% loss also include those with 20% and 30% losses)

APPENDIX E: NON-SMALL CELL LUNG CANCER SIMULATION RESULTS - PROBABILITY OF GAIN/LOSS

Exhibit 2b

Simulation Results – Scenario 2, Medium Sized Practice, Probability of Gain/Loss

Bundled Payment Scenario 2 – Pembrolizumab included in bundle, but additional chemo carved out

I. Change in Revenue (without Winsorization)

Medium Sized Practices					
EXAMPLE: Office-Urban Setting					
			Cumulative Loss[1]		
Practice Distribution	**Gain**	**Loss**	**-10%**	**-20%**	**-30%**
Practices	502	498	54	0	0
% of Simulations	50%	50%	5%	0%	0%
Averages (Per Practice)					
Bundled Payment Revenue	$1,700,343	$1,700,343	$1,700,343	n/a	n/a
Medicare FFS Reimbursement	$1,604,436	$1,794,999	$1,932,864	n/a	n/a
Change in Revenue	$95,906	($94,656)	($232,521)	n/a	n/a
Averages (Per Patient)					
Bundled Payment Revenue	$53,136	$53,136	$53,136	n/a	n/a
Medicare FFS Reimbursement	$50,139	$56,094	$60,402	n/a	n/a
Change in Revenue	$2,997	($2,958)	($7,266)	n/a	n/a
Change in Revenue (%)	6.0%	-5.3%	-12.0%	n/a	n/a

(1) Each column contains practices with a loss of the specified amount or greater.
(i.e., practices with at least a 10% loss also include those with 20% and 30% losses)

II. Change in Revenue (with Winsorization)

Medium Sized Practices					
EXAMPLE: Office-Urban Setting					
			Cumulative Loss[1]		
Practice Distribution	**Gain**	**Loss**	**-10%**	**-20%**	**-30%**
Practices	502	498	54	0	0
% of Simulations	50%	50%	5%	0%	0%
Averages (Per Practice)					
Bundled Payment Revenue	$1,700,343	$1,700,343	$1,700,343	n/a	n/a
Medicare FFS Reimbursement	$1,608,505	$1,790,647	$1,892,728	n/a	n/a
Change in Revenue	$91,838	($90,304)	($192,386)	n/a	n/a
Averages (Per Patient)					
Bundled Payment Revenue	$53,136	$53,136	$53,136	n/a	n/a
Medicare FFS Reimbursement	$50,266	$55,958	$59,148	n/a	n/a
Change in Revenue	$2,870	($2,822)	($6,012)	n/a	n/a
Change in Revenue (%)	5.7%	-5.0%	-10.2%	n/a	n/a

(1) Each column contains practices with a loss of the specified amount or greater.
(i.e., practices with at least a 10% loss also include those with 20% and 30% losses)

APPENDIX E: NON-SMALL CELL LUNG CANCER SIMULATION RESULTS - PROBABILITY OF GAIN/LOSS

Exhibit 2c

Simulation Results – Scenario 2, Large Sized Practice, Probability of Gain/Loss

Bundled Payment Scenario 2 – Pembrolizumab included in bundle, but additional chemo carved out

I. Change in Revenue (without Winsorization)

Large Sized Practices					
EXAMPLE: Office-Urban Setting					
			Cumulative Loss[1]		
Practice Distribution	**Gain**	**Loss**	**-10%**	**-20%**	**-30%**
Practices	486	514	4	0	0
% of Simulations	49%	51%	0%	0%	0%
Averages (Per Practice)					
Bundled Payment Revenue	$4,357,128	$4,357,128	$4,357,128	n/a	n/a
Medicare FFS Reimbursement	$4,213,053	$4,504,347	$4,928,940	n/a	n/a
Change in Revenue	$144,075	($147,219)	($571,812)	n/a	n/a
Averages (Per Patient)					
Bundled Payment Revenue	$53,136	$53,136	$53,136	n/a	n/a
Medicare FFS Reimbursement	$51,379	$54,931	$60,109	n/a	n/a
Change in Revenue	$1,757	($1,795)	($6,973)	n/a	n/a
Change in Revenue (%)	3.4%	-3.3%	-11.6%	n/a	n/a

(1) Each column contains practices with a loss of the specified amount or greater.
(i.e., practices with at least a 10% loss also include those with 20% and 30% losses)

II. Change in Revenue (with Winsorization)

Large Sized Practices					
EXAMPLE: Office-Urban Setting					
			Cumulative Loss[1]		
Practice Distribution	**Gain**	**Loss**	**-10%**	**-20%**	**-30%**
Practices	486	514	0	0	0
% of Simulations	49%	51%	0%	0%	0%
Averages (Per Practice)					
Bundled Payment Revenue	$4,357,128	$4,357,128	n/a	n/a	n/a
Medicare FFS Reimbursement	$4,220,792	$4,496,294	n/a	n/a	n/a
Change in Revenue	$136,336	($139,166)	n/a	n/a	n/a
Averages (Per Patient)					
Bundled Payment Revenue	$53,136	$53,136	n/a	n/a	n/a
Medicare FFS Reimbursement	$51,473	$54,833	n/a	n/a	n/a
Change in Revenue	$1,663	($1,697)	n/a	n/a	n/a
Change in Revenue (%)	3.2%	-3.1%	n/a	n/a	n/a

(1) Each column contains practices with a loss of the specified amount or greater.
(i.e., practices with at least a 10% loss also include those with 20% and 30% losses)

APPENDIX E: NON-SMALL CELL LUNG CANCER SIMULATION RESULTS - PROBABILITY OF GAIN/LOSS

Exhibit 3a

Simulation Results – Scenario 3, Small Sized Practice, Probability of Gain/Loss

Bundled Payment Scenario 3 – Pembrolizumab and additional chemo carved out.

I. Change in Revenue (without Winsorization)

Small Sized Practices					
EXAMPLE: Office-Urban Setting					
			Cumulative Loss[1]		
Practice Distribution	**Gain**	**Loss**	**-10%**	**-20%**	**-30%**
Practices	507	493	219	50	2
% of Simulations	51%	49%	22%	5%	0%
Averages (Per Practice)					
Bundled Payment Revenue	$605,364	$605,364	$605,364	$605,364	$605,364
Medicare FFS Reimbursement	$530,322	$675,273	$725,041	$798,131	$897,016
Change in Revenue	$75,042	($69,909)	($119,677)	($192,767)	($291,652)
Averages (Per Patient)					
Bundled Payment Revenue	$50,447	$50,447	$50,447	$50,447	$50,447
Medicare FFS Reimbursement	$44,194	$56,273	$60,420	$66,511	$74,751
Change in Revenue	$6,253	($5,826)	($9,973)	($16,064)	($24,304)
Change in Revenue (%)	14.2%	-10.4%	-16.5%	-24.2%	-32.5%

(1) Each column contains practices with a loss of the specified amount or greater.
(i.e., practices with at least a 10% loss also include those with 20% and 30% losses)

II. Change in Revenue (with Winsorization)

Small Sized Practices					
EXAMPLE: Office-Urban Setting					
			Cumulative Loss[1]		
Practice Distribution	**Gain**	**Loss**	**-10%**	**-20%**	**-30%**
Practices	507	493	219	50	0
% of Simulations	51%	49%	22%	5%	0%
Averages (Per Practice)					
Bundled Payment Revenue	$605,364	$605,364	$605,364	$605,364	n/a
Medicare FFS Reimbursement	$533,208	$671,074	$715,588	$756,728	n/a
Change in Revenue	$72,156	($65,710)	($110,224)	($151,364)	n/a
Averages (Per Patient)					
Bundled Payment Revenue	$50,447	$50,447	$50,447	$50,447	n/a
Medicare FFS Reimbursement	$44,434	$55,923	$59,632	$63,061	n/a
Change in Revenue	$6,013	($5,476)	($9,185)	($12,614)	n/a
Change in Revenue (%)	13.5%	-9.8%	-15.4%	-20.0%	n/a

(1) Each column contains practices with a loss of the specified amount or greater.
(i.e., practices with at least a 10% loss also include those with 20% and 30% losses)

APPENDIX E: NON-SMALL CELL LUNG CANCER SIMULATION RESULTS - PROBABILITY OF GAIN/LOSS

Exhibit 3b

Simulation Results – Scenario 3, Medium Sized Practice, Probability of Gain/Loss

Bundled Payment Scenario 3 – Pembrolizumab and additional chemo carved out.

I. Change in Revenue (without Winsorization)

Medium Sized Practices					
EXAMPLE: Office-Urban Setting					
				Cumulative Loss[1]	
Practice Distribution	**Gain**	**Loss**	**-10%**	**-20%**	**-30%**
Practices	499	501	125	5	0
% of Simulations	50%	50%	13%	1%	0%
Averages (Per Practice)					
Bundled Payment Revenue	$1,614,304	$1,614,304	$1,614,304	$1,614,304	n/a
Medicare FFS Reimbursement	$1,497,427	$1,739,328	$1,873,403	$2,087,812	n/a
Change in Revenue	$116,876	($125,025)	($259,099)	($473,508)	n/a
Averages (Per Patient)					
Bundled Payment Revenue	$50,447	$50,447	$50,447	$50,447	n/a
Medicare FFS Reimbursement	$46,795	$54,354	$58,544	$65,244	n/a
Change in Revenue	$3,652	($3,907)	($8,097)	($14,797)	n/a
Change in Revenue (%)	7.8%	-7.2%	-13.8%	-22.7%	n/a

(1) Each column contains practices with a loss of the specified amount or greater.
(i.e., practices with at least a 10% loss also include those with 20% and 30% losses)

II. Change in Revenue (with Winsorization)

Medium Sized Practices					
EXAMPLE: Office-Urban Setting					
				Cumulative Loss[1]	
Practice Distribution	**Gain**	**Loss**	**-10%**	**-20%**	**-30%**
Practices	499	501	125	0	0
% of Simulations	50%	50%	13%	0%	0%
Averages (Per Practice)					
Bundled Payment Revenue	$1,614,304	$1,614,304	$1,614,304	n/a	n/a
Medicare FFS Reimbursement	$1,503,238	$1,732,054	$1,844,248	n/a	n/a
Change in Revenue	$111,066	($117,750)	($229,944)	n/a	n/a
Averages (Per Patient)					
Bundled Payment Revenue	$50,447	$50,447	$50,447	n/a	n/a
Medicare FFS Reimbursement	$46,976	$54,127	$57,633	n/a	n/a
Change in Revenue	$3,471	($3,680)	($7,186)	n/a	n/a
Change in Revenue (%)	7.4%	-6.8%	-12.5%	n/a	n/a

(1) Each column contains practices with a loss of the specified amount or greater.
(i.e., practices with at least a 10% loss also include those with 20% and 30% losses)

APPENDIX E: NON-SMALL CELL LUNG CANCER SIMULATION RESULTS - PROBABILITY OF GAIN/LOSS

Exhibit 3c

Simulation Results – Scenario 3, Large Sized Practice, Probability of Gain/Loss

Bundled Payment Scenario 3 – Pembrolizumab and additional chemo carved out.

I. Change in Revenue (without Winsorization)

Large Sized Practices					
EXAMPLE: Office-Urban Setting					
			Cumulative Loss [1]		
Practice Distribution	**Gain**	**Loss**	**-10%**	**-20%**	**-30%**
Practices	506	494	32	0	0
% of Simulations	51%	49%	3%	0%	0%
Averages (Per Practice)					
Bundled Payment Revenue	$4,136,653	$4,136,653	$4,136,653	n/a	n/a
Medicare FFS Reimbursement	$3,934,872	$4,333,979	$4,695,612	n/a	n/a
Change in Revenue	$201,781	($197,326)	($558,959)	n/a	n/a
Averages (Per Patient)					
Bundled Payment Revenue	$50,447	$50,447	$50,447	n/a	n/a
Medicare FFS Reimbursement	$47,986	$52,853	$57,264	n/a	n/a
Change in Revenue	$2,461	($2,406)	($6,817)	n/a	n/a
Change in Revenue (%)	5.1%	-4.6%	-11.9%	n/a	n/a

(1) Each column contains practices with a loss of the specified amount or greater.
(i.e., practices with at least a 10% loss also include those with 20% and 30% losses)

II. Change in Revenue (with Winsorization)

Large Sized Practices					
EXAMPLE: Office-Urban Setting					
			Cumulative Loss [1]		
Practice Distribution	**Gain**	**Loss**	**-10%**	**-20%**	**-30%**
Practices	506	494	0	0	0
% of Simulations	51%	49%	0%	0%	0%
Averages (Per Practice)					
Bundled Payment Revenue	$4,136,653	$4,136,653	n/a	n/a	n/a
Medicare FFS Reimbursement	$3,943,904	$4,324,020	n/a	n/a	n/a
Change in Revenue	$192,750	($187,367)	n/a	n/a	n/a
Averages (Per Patient)					
Bundled Payment Revenue	$50,447	$50,447	n/a	n/a	n/a
Medicare FFS Reimbursement	$48,096	$52,732	n/a	n/a	n/a
Change in Revenue	$2,351	($2,285)	n/a	n/a	n/a
Change in Revenue (%)	4.9%	-4.3%	n/a	n/a	n/a

(1) Each column contains practices with a loss of the specified amount or greater.
(i.e., practices with at least a 10% loss also include those with 20% and 30% losses)

APPENDIX F: UPDATED NON-SMALL CELL LUNG CANCER SIMULATION RESULTS - PROBABILITY OF GAIN/LOSS

Exhibit 1a

Simulation Results – Small Sized Practice, Probability of Gain/Loss

Bundled Payment Scenario – Same as Scenario 2 in prior Appendices , but patient percentage of Pembrolizumab lowered to 30%.

I. Change in Reimbursement (without Winsorization)

Small Sized Practices						
EXAMPLE: Office-Urban Setting						
Practice Distribution	**Gain**	**Loss**		**-10%**	**-20%**	**-30%**
Practices	484	516		208	30	0
% of Simulations	48%	52%		21%	3%	0%
Averages (Per Practice)						
Bundled Payment Revenue	$620,748	$620,748		$620,748	$620,748	n/a
Medicare FFS Reimbursement	$552,219	$687,342		$735,632	$808,417	n/a
Change in Reimbursement	$68,529	($66,594)		($114,884)	($187,669)	n/a
Averages (Per Patient)						
Bundled Payment Revenue	$51,729	$51,729		$51,729	$51,729	n/a
Medicare FFS Reimbursement	$46,018	$57,278		$61,303	$67,368	n/a
Change in Reimbursement	$5,711	($5,549)		($9,574)	($15,639)	n/a
% Change	12.4%	-9.7%		-15.6%	-23.2%	n/a

(1) Each column contains practices with a loss of the specified amount or greater.
(i.e., practices with at least a 10% loss also include those with 20% and 30% losses)

II. Change in Reimbursement (with Winsorization)

Small Sized Practices						
EXAMPLE: Office-Urban Setting						
Practice Distribution	**Gain**	**Loss**		**-10%**	**-20%**	**-30%**
Practices	484	516		208	0	0
% of Simulations	48%	52%		21%	0%	0%
Averages (Per Practice)						
Bundled Payment Revenue	$620,748	$620,748		$620,748	n/a	n/a
Medicare FFS Reimbursement	$555,934	$684,352		$728,215	n/a	n/a
Change in Reimbursement	$64,814	($63,604)		($107,467)	n/a	n/a
Averages (Per Patient)						
Bundled Payment Revenue	$51,729	$51,729		$51,729	n/a	n/a
Medicare FFS Reimbursement	$46,328	$57,029		$60,685	n/a	n/a
Change in Reimbursement	$5,401	($5,300)		($8,956)	n/a	n/a
% Change	11.7%	-9.3%		-14.8%	n/a	n/a

(1) Each column contains practices with a loss of the specified amount or greater.
(i.e., practices with at least a 10% loss also include those with 20% and 30% losses)

APPENDIX F: UPDATED NON-SMALL CELL LUNG CANCER SIMULATION RESULTS - PROBABILITY OF GAIN/LOSS
Exhibit 1b

Simulation Results – Medium Sized Practice, Probability of Gain/Loss

Bundled Payment Scenario – Same as Scenario 2 in prior Appendices I, but patient percentage of Pembrolizumab lowered to 30%.

I. Change in Reimbursement (without Winsorization)

Medium Sized Practices					
EXAMPLE: Office-Urban Setting					
Practice Distribution	**Gain**	**Loss**	**-10%**	**-20%**	**-30%**
Practices	505	495	82	1	0
% of Simulations	51%	50%	8%	0%	0%
Averages (Per Practice)					
Bundled Payment Revenue	$1,655,328	$1,655,328	$1,655,328	$1,655,328	n/a
Medicare FFS Reimbursement	$1,546,769	$1,764,880	$1,897,291	$2,130,748	n/a
Change in Reimbursement	$108,559	($109,552)	($241,963)	($475,420)	n/a
Averages (Per Practice)					
Bundled Payment Revenue	$51,729	$51,729	$51,729	$51,729	n/a
Medicare FFS Reimbursement	$48,337	$55,153	$59,290	$66,586	n/a
Change in Reimbursement	$3,392	($3,423)	($7,561)	($14,857)	n/a
% Change	7.0%	-6.2%	-12.8%	-22.3%	n/a

(1) Each column contains practices with a loss of the specified amount or greater.

(i.e., practices with at least a 10% loss also include those with 20% and 30% losses)

II. Change in Reimbursement (with Winsorization)

Medium Sized Practices					
EXAMPLE: Office-Urban Setting					
Practice Distribution	**Gain**	**Loss**	**-10%**	**-20%**	**-30%**
Practices	505	495	82	0	0
% of Simulations	51%	50%	8%	0%	0%
Averages (Per Practice)					
Bundled Payment Revenue	$1,655,328	$1,655,328	$1,655,328	n/a	n/a
Medicare FFS Reimbursement	$1,552,304	$1,758,836	$1,860,807	n/a	n/a
Change in Reimbursement	$103,025	($103,508)	($205,478)	n/a	n/a
Averages (Per Practice)					
Bundled Payment Revenue	$51,729	$51,729	$51,729	n/a	n/a
Medicare FFS Reimbursement	$48,509	$54,964	$58,150	n/a	n/a
Change in Reimbursement	$3,220	($3,235)	($6,421)	n/a	n/a
% Change	6.6%	-5.9%	-11.0%	n/a	n/a

(1) Each column contains practices with a loss of the specified amount or greater.

(i.e., practices with at least a 10% loss also include those with 20% and 30% losses)

APPENDIX F: UPDATED NON-SMALL CELL LUNG CANCER SIMULATION RESULTS - PROBABILITY OF GAIN/LOSS

Exhibit 1c

Simulation Results – Large Sized Practice, Probability of Gain/Loss

Bundled Payment Scenario – Same as Scenario 2 in prior Appendices, but patient percentage of Pembrolizumab lowered to 30%.

I. Change in Reimbursement (without Winsorization)

Large Sized Practices					
EXAMPLE: Office-Urban Setting					
Practice Distribution	**Gain**	**Loss**	**-10%**	**-20%**	**-30%**
Practices	502	498	20	0	0
% of Simulations	50%	50%	2%	0%	0%
Averages (Per Practice)					
Bundled Payment Revenue	$4,241,779	$4,241,779	$4,241,779	n/a	n/a
Medicare FFS Reimbursement	$4,071,751	$4,420,985	$4,809,190	n/a	n/a
Change in Reimbursement	$170,028	($179,206)	($567,411)	n/a	n/a
Averages (Per Practice)					
Bundled Payment Revenue	$51,729	$51,729	$51,729	n/a	n/a
Medicare FFS Reimbursement	$49,655	$53,914	$58,649	n/a	n/a
Change in Reimbursement	$2,074	($2,185)	($6,920)	n/a	n/a
% Change	4.2%	-4.1%	-11.8%	n/a	n/a

(1) Each column contains practices with a loss of the specified amount or greater.
(i.e., practices with at least a 10% loss also include those with 20% and 30% losses)

II. Change in Reimbursement (with Winsorization)

Large Sized Practices					
EXAMPLE: Office-Urban Setting					
Practice Distribution	**Gain**	**Loss**	**-10%**	**-20%**	**-30%**
Practices	502	498	0	0	0
% of Simulations	50%	50%	0%	0%	0%
Averages (Per Practice)					
Bundled Payment Revenue	$4,241,779	$4,241,779	n/a	n/a	n/a
Medicare FFS Reimbursement	$4,080,865	$4,411,586	n/a	n/a	n/a
Change in Reimbursement	$160,914	($169,808)	n/a	n/a	n/a
Averages (Per Practice)					
Bundled Payment Revenue	$51,729	$51,729	n/a	n/a	n/a
Medicare FFS Reimbursement	$49,767	$53,800	n/a	n/a	n/a
Change in Reimbursement	$1,962	($2,071)	n/a	n/a	n/a
% Change	3.9%	-3.8%	n/a	n/a	n/a

(1) Each column contains practices with a loss of the specified amount or greater.
(i.e., practices with at least a 10% loss also include those with 20% and 30% losses)

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