Payer Relations Support and Pricing Analysis for Company X's Technology Y® 5-FU Testing Platform for Colorectal Cancer Patient Treatment

tJun17 Life Sciences Advisors

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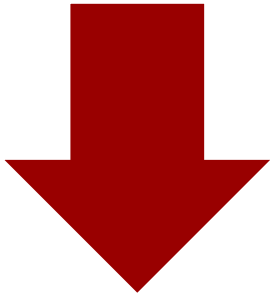
Project Overview

01

Statement of Purpose and Approach

Company X's *Statement of Purpose*

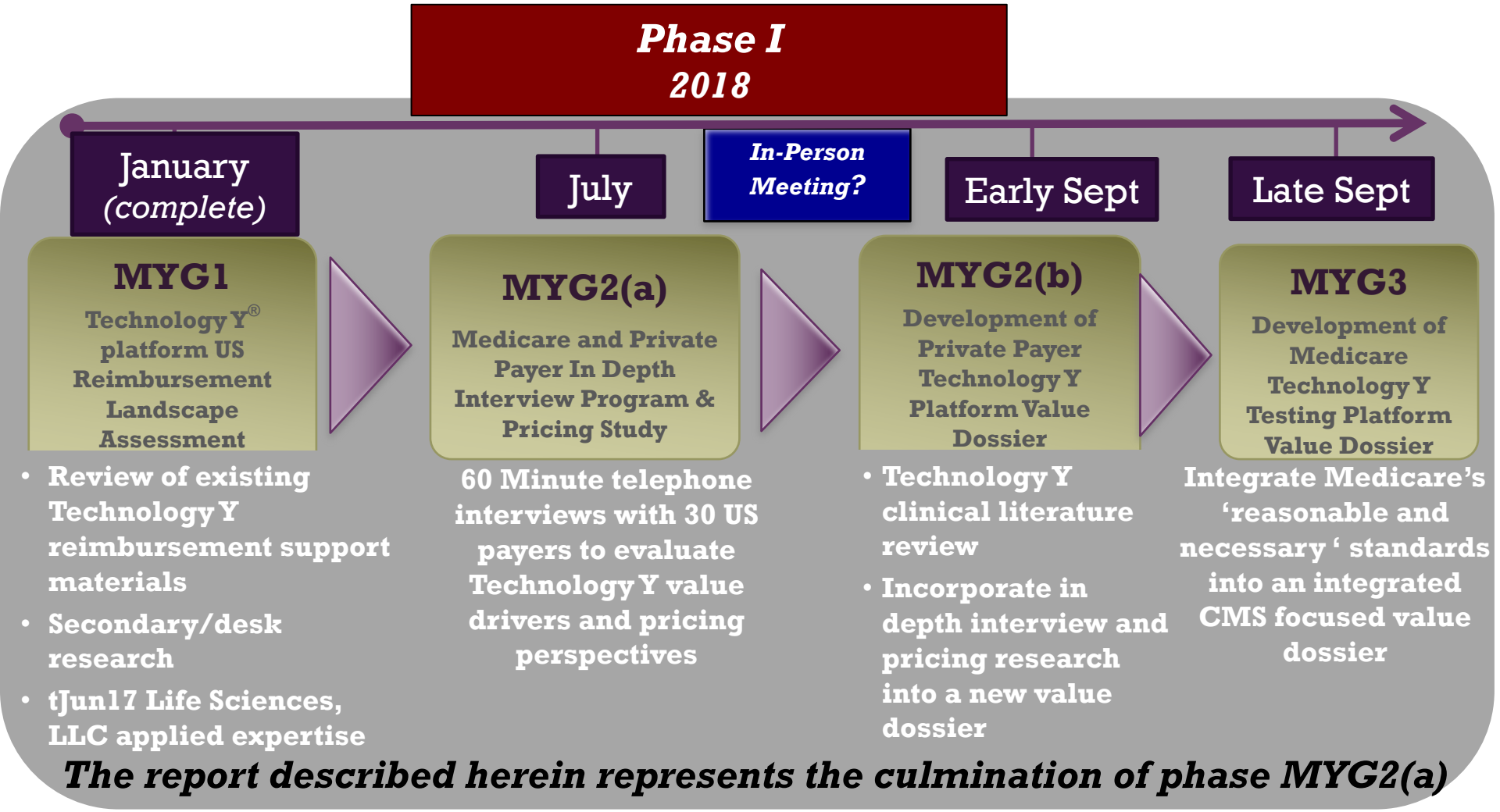
In order to maximize the value of its Technology Y® testing platform, Company X seeks to more fully understand the price sensitivity for its 5-FU dose management products among both Medicare and US private payers



Approach

To support Company X's pricing objectives, tJun17 Life Sciences, LLC conducted a comprehensive pricing analysis based on both secondary and primary research with Medicare and private payers from each major geographic region of the US

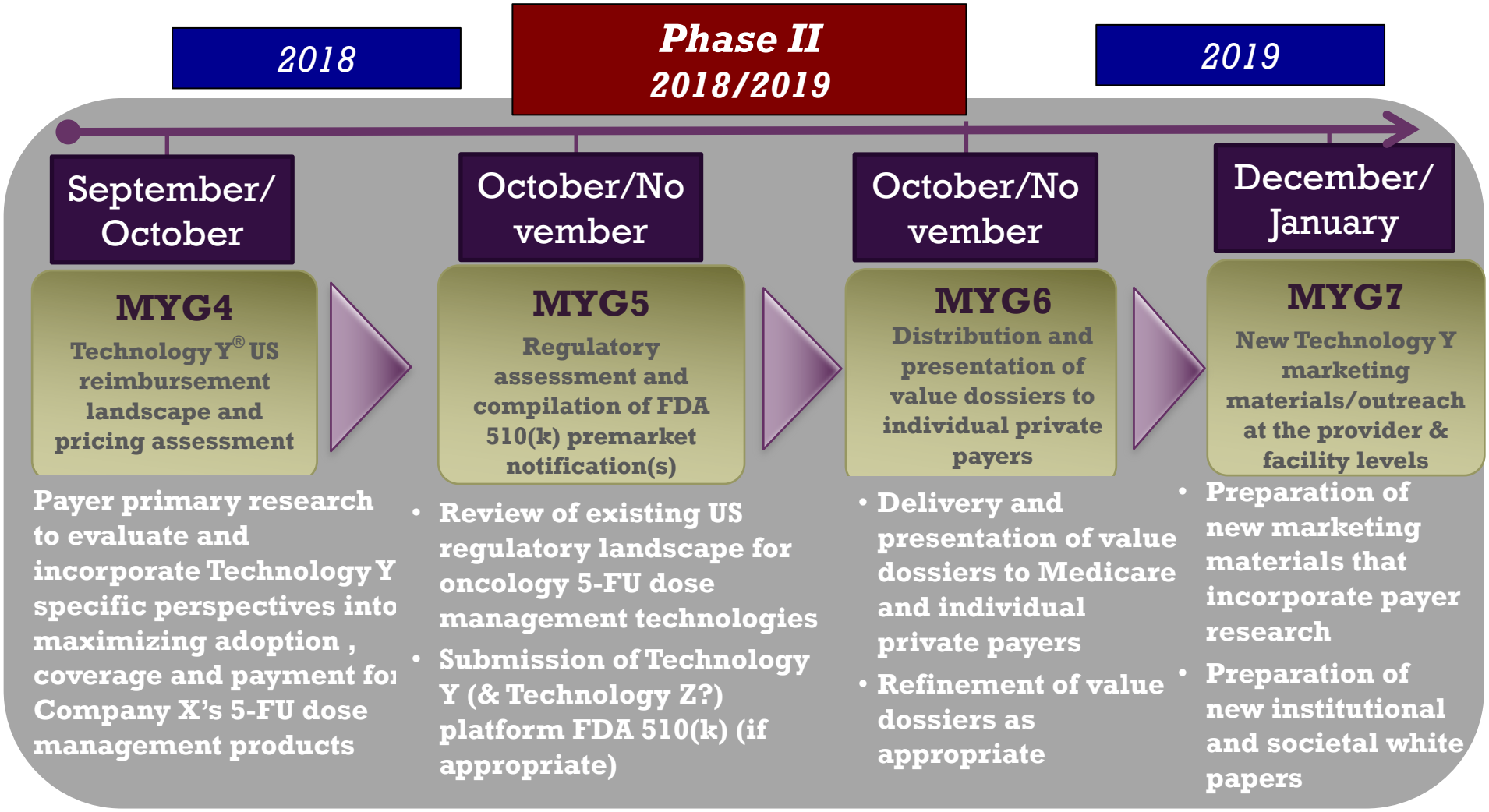
The team's multi-phased project approach has a final goal to maximize US coverage and payment for the Technology Y® testing platform among both Medicare and private payers



The report described herein represents the culmination of phase MYG2(a)

Phase I focused on utilizing secondary and primary research to develop value dossiers to support US Technology Y reimbursement

Phase II of the project could incorporate execution of the Technology Y® testing platform reimbursement landscape optimization strategies described in Project Phase I



Phase II will focus on executing the packaging, bundling, regulatory and value development strategies recommended in Phase I - *timing is flexible!*

Pricing Study Project Component Objectives

1	Conduct a comprehensive US reimbursement payment assessment for personalized 5-FU dose management products in the adjuvant and metastatic colorectal cancer clinical setting
2	Detail US Medicare and private payer price sensitivity to utilization of the Technology Y® test platform in colorectal cancer patients, requirements to maximize Technology Y test platform pricing, and environmental factors that may impact additional payment opportunities
3	Develop and present actionable strategies and tactics to optimize the pricing opportunity for Company X's Technology Y pharmacokinetic testing platform
4	Align the Technology Y testing platform long-term pricing strategy with associated clinical and economic evidence development and regulatory strategies

Project Methodology

02

tJun17 Life Sciences leveraged both secondary and primary research using multiple pricing methodologies to meet the project objectives

To develop a comprehensive understanding of pricing perspectives among Medicare and private payers for personalized 5-FU dose management products in colorectal cancer patients, tJun17 Life Sciences:

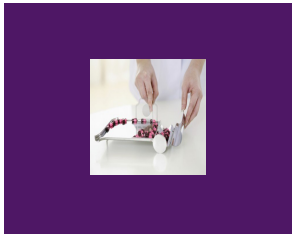
1	Identified comparator technologies to provide insights into potential Medicare and private payer pricing hurdles and to pressure test current list pricing for the Technology Y® testing platform
2	Conducted primary research with US Medicare and private payers utilizing Gabor Granger and Van Westendorp pricing methodologies to better understand their perceived value of the Technology Y testing platform, drivers of market penetration and financial incentives for clinical utilization
3	Integrated primary & secondary observations and data into actionable recommendations to address and optimize the pricing & payment opportunities for the Technology Y testing platform in current clinical oncology practice

tJun17 Life Sciences conducted primary research with US Medicare and commercial payer stakeholders to inform Company X's key pricing questions

30 interviews were conducted with Medicare and private payers in 6 geographic regions of the US

2 Pharmacy Directors

19 Medical Directors



2 Doctors of Pharmacy

7 Chief Medical Officers

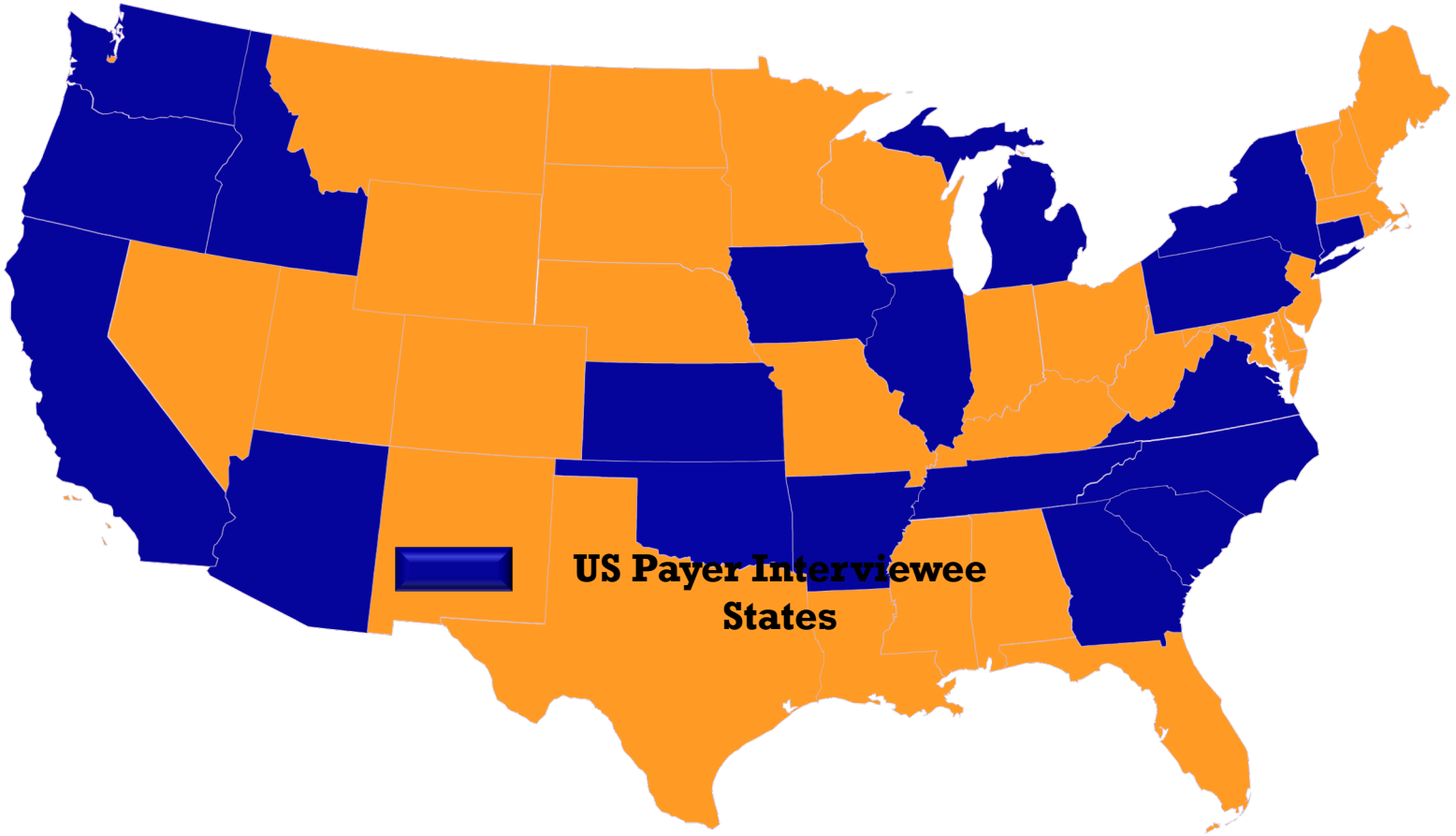
UnitedHealthcare
Healing health care. Together.®

CIGNA®

BlueCross BlueShield

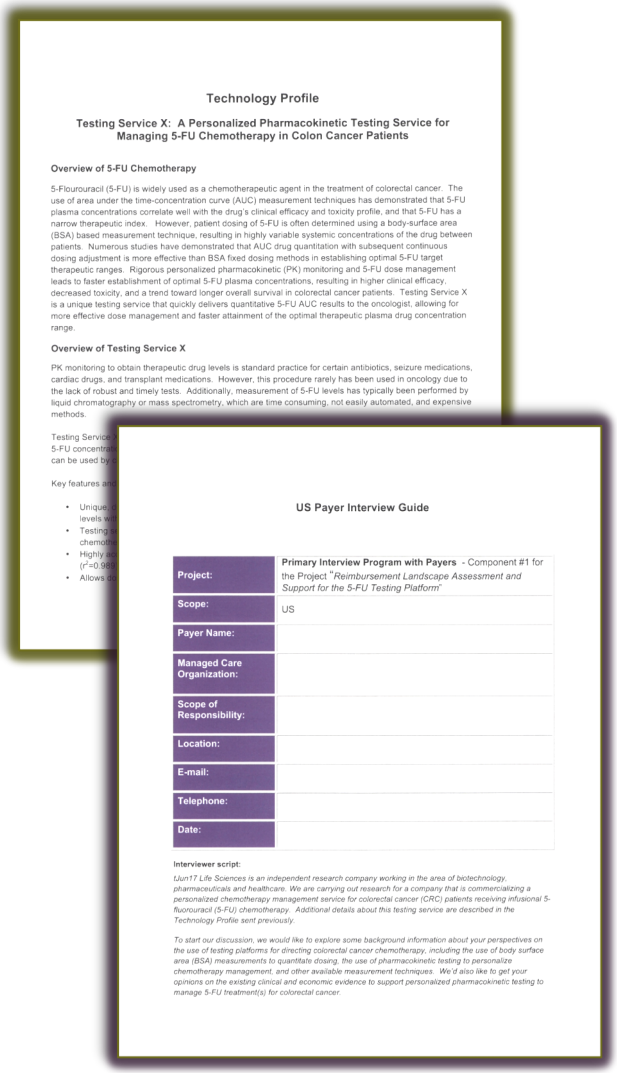
aetna℠

tJun17 Life Sciences conducted interviews with Medicare and private payers representing over 93.5 million covered lives and patient populations in 21 different states, including Alaska and Hawaii (not shown)



A Technology Profile and a specialized pricing Discussion Guide were developed to standardize the payment research interview program

- A Technology Profile was developed to inform payer interviewees about the Technology Y® platform's targeted indications, value proposition, and existing clinical data to support utilization of personalized pharmacokinetic 5-FU dose management – this was distributed at least 48 hours prior to the scheduled interview time
- A Discussion Guide was developed to provide a framework for assessment of payer attitudes toward clinical utilization of personalized 5-FU dose management technologies in colorectal cancer and to incorporate Gabor Granger and Van Westendorp survey methodologies into the evaluation of payer sensitivities around pricing of these technologies



Technology Profile

Testing Service X: A Personalized Pharmacokinetic Testing Service for Managing 5-FU Chemotherapy in Colon Cancer Patients

Overview of 5-FU Chemotherapy

5-Flourouracil (5-FU) is widely used as a chemotherapeutic agent in the treatment of colorectal cancer. The use of area under the time-concentration curve (AUC) measurement techniques has demonstrated that 5-FU plasma concentrations correlate well with the drug's clinical efficacy and toxicity profile, and that 5-FU has a narrow therapeutic index. However, patient dosing of 5-FU is often determined using a body-surface area (BSA) based measurement technique, resulting in highly variable systemic concentrations of the drug between patients. Numerous studies have demonstrated that AUC drug quantitation with subsequent continuous dosing adjustment is more effective than BSA fixed dosing methods in establishing optimal 5-FU target therapeutic ranges. Rigorous personalized pharmacokinetic (PK) monitoring and 5-FU dose management leads to faster establishment of optimal 5-FU plasma concentrations, resulting in higher clinical efficacy, decreased toxicity, and a trend toward longer overall survival in colorectal cancer patients. Testing Service X is a unique testing service that quickly delivers quantitative 5-FU AUC results to the oncologist, allowing for more effective dose management and faster attainment of the optimal therapeutic plasma drug concentration range.

Overview of Testing Service X

PK monitoring to obtain therapeutic drug levels is standard practice for certain antibiotics, seizure medications, cardiac drugs, and transplant medications. However, this procedure rarely has been used in oncology due to the lack of robust and timely tests. Additionally, measurement of 5-FU levels has typically been performed by liquid chromatography or mass spectrometry, which are time consuming, not easily automated, and expensive methods.

US Payer Interview Guide

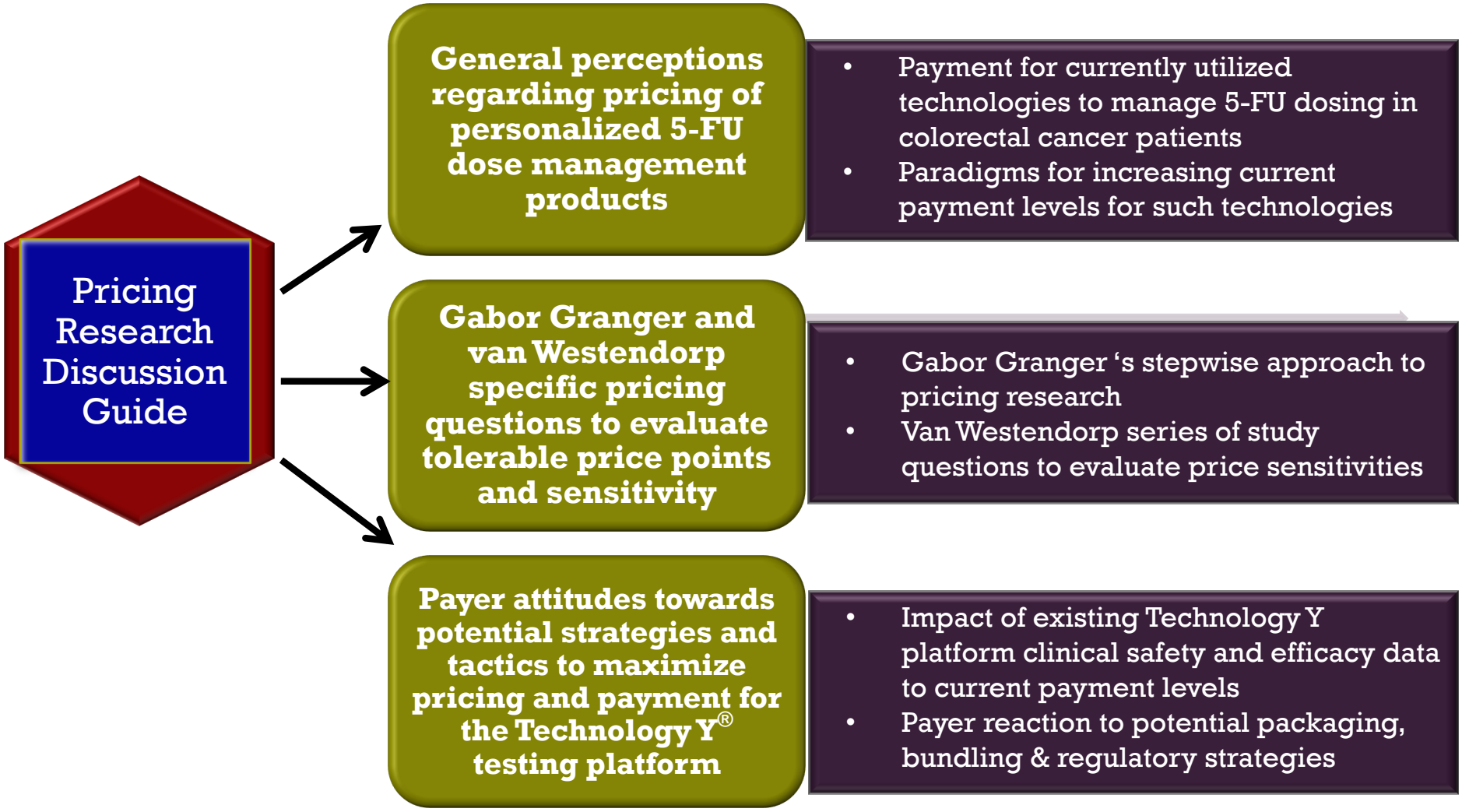
Project:	Primary Interview Program with Payers - Component #1 for the Project "*Reimbursement Landscape Assessment and Support for the 5-FU Testing Platform*"
Scope:	US
Payer Name:	
Managed Care Organization:	
Scope of Responsibility:	
Location:	
E-mail:	
Telephone:	
Date:	

Interviewer script:

tJun17 Life Sciences is an independent research company working in the area of biotechnology, pharmaceuticals and healthcare. We are carrying out research for a company that is commercializing a personalized chemotherapy management service for colorectal cancer (CRC) patients receiving infusional 5-fluorouracil (5-FU) chemotherapy. Additional details about this testing service are described in the Technology Profile sent previously.

To start our discussion, we would like to explore some background information about your perspectives on the use of testing platforms for directing colorectal cancer chemotherapy, including the use of body surface area (BSA) measurements to quantitate dosing, the use of pharmacokinetic testing to personalize chemotherapy management, and other available measurement techniques. We'd also like to get your opinions on the existing clinical and economic evidence to support personalized pharmacokinetic testing to manage 5-FU treatment(s) for colorectal cancer.

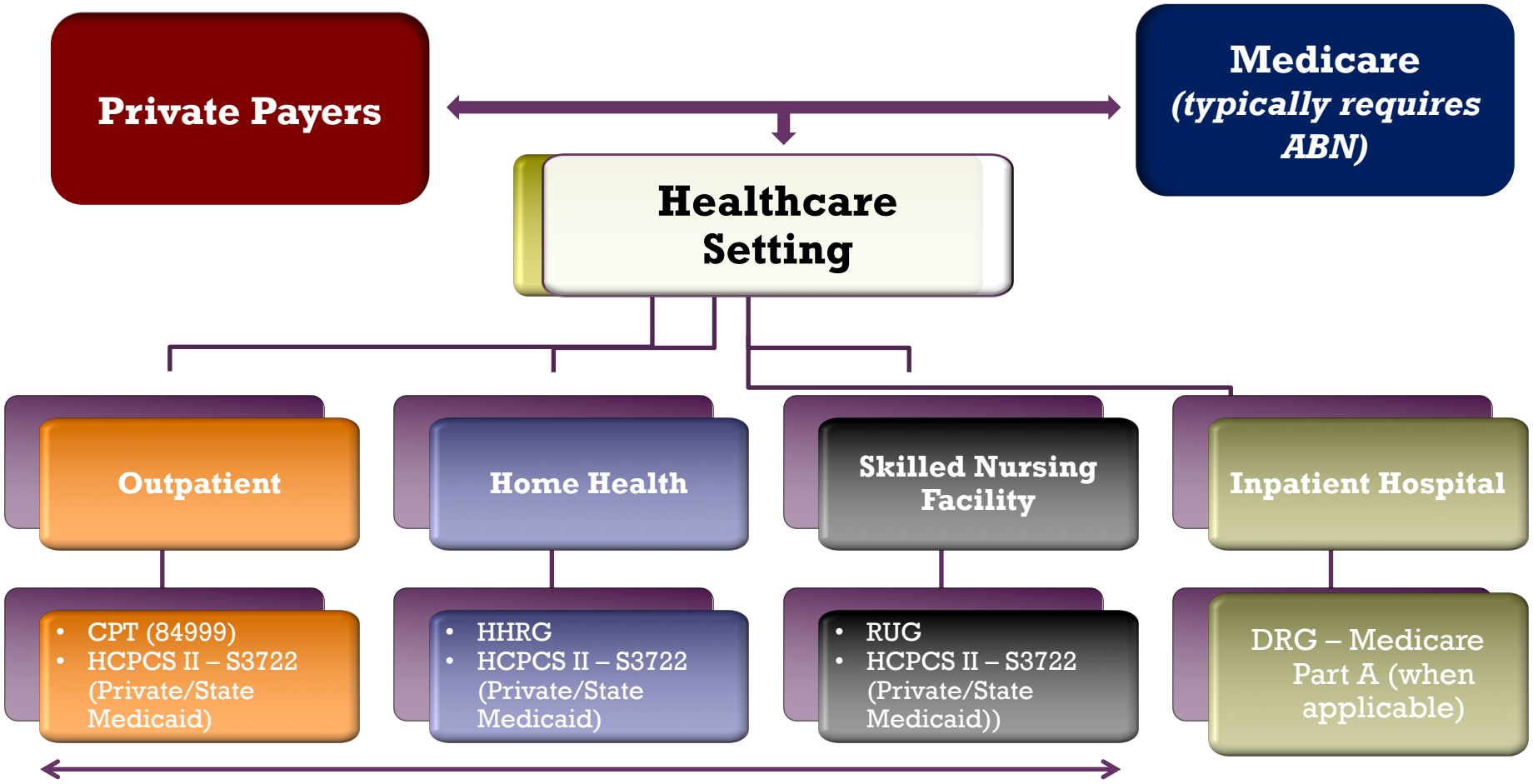
The research program was designed to evaluate payer perspectives on pricing of pharmacokinetic 5-FU dose management in colorectal cancer patient treatment



General Payment Parameters for Personalized 5-FU Pharmacokinetic Dose Management in Colorectal Cancer Patients

03

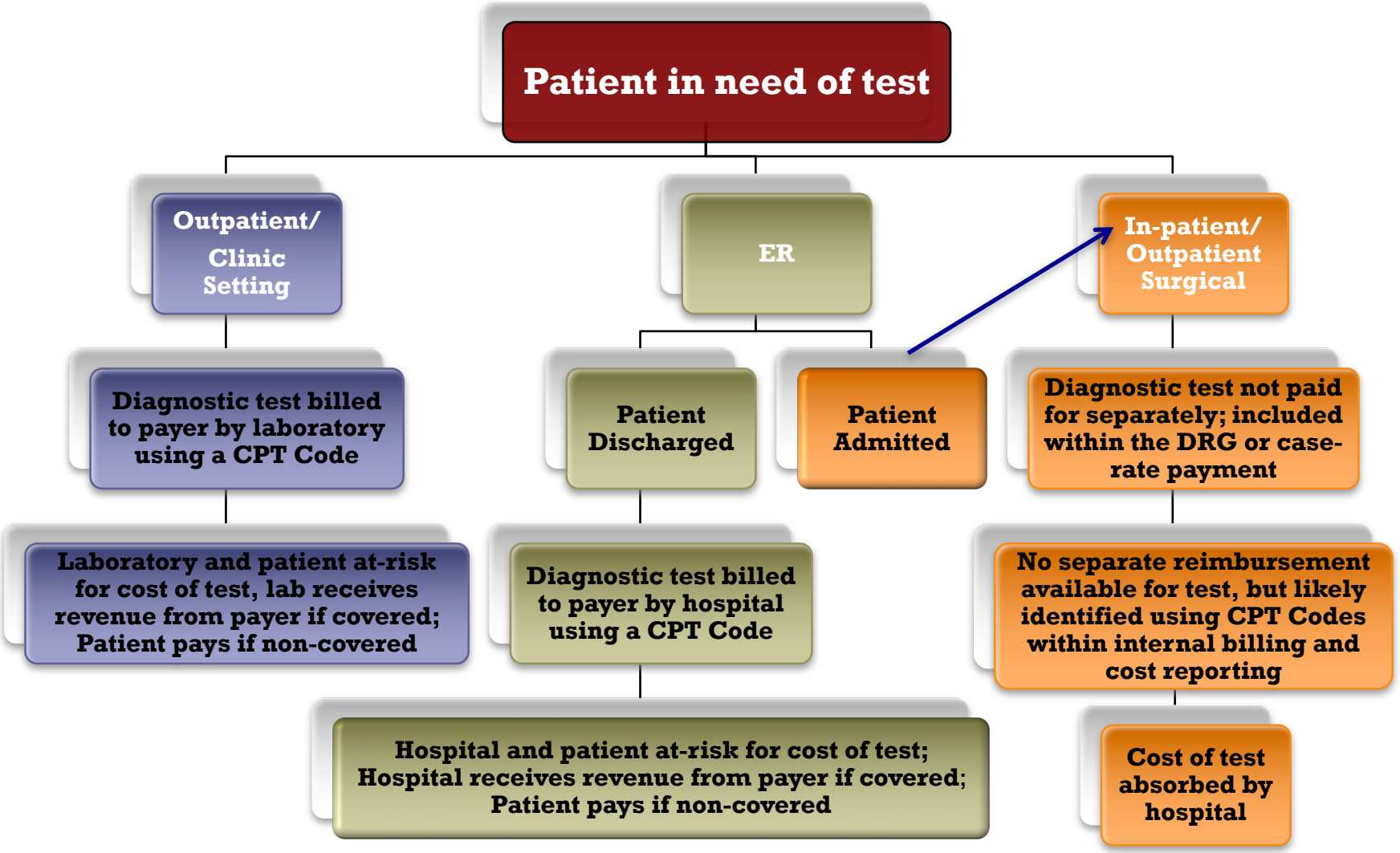
tJun17 Life Sciences reviewed the potential US Healthcare coding and payment systems that may be applicable to Technology Y® testing in colorectal cancer cases



Most 5-FU therapy occurs outside the inpatient setting[1] unless toxicity is an issue

1. Society for Translational Oncology, Guidelines for Hospitalization for Chemotherapy, 2017

CPT codes are sponsored by the American Medical Association (AMA) and are used to describe testing services, payment processes and financial risk by site of care



Medicare and private payer reimbursement mechanisms and payment for *in vitro* laboratory services, including Technology Y® testing are dependent upon site of care

- Diagnostics and *in vitro* tests are typically reimbursed in the US either on a fee for service basis, or included in a global prospective payment fee, in which case, their utilization does not warrant incremental payment and must be absorbed by the provider into the global payment fee

- Global prospective payment fees include:
  - ***Outpatient:*** APC or Case Rate
  - ***Home Health:*** Global rate/daily rate
  - ***Skilled Nursing Facility:*** Global rate or Case Rate
  - ***Inpatient:*** DRG

- Utilization controls may be put into place by either the insurer or the provider and patients may be responsible for co-pays, deductibles, or co-insurances associated with care depending upon payment levels

- Non-covered diagnostic or *in vitro* testing costs are billed directly to patients

Multiple payer payment options are potentially available for Technology Y® testing in colorectal cancer patients

Depending on the type of insurance, the payment options differ:

	Name	Description
Applicable for Medicare & some private insurance plans	**DRG payments**	DRGs for inpatient services; hospital receives a single DRG payment for all services and products used; if the patient has more than one diagnosis, hospital is reimbursed for most expensive DRG
	Transitional inpatient pass-through payments	Applied when new technology costs are inadequately covered by current DRG payments. Must be viewed as a significant advance in medical technology. Takes 2 years for approval. Pass-through status is only applicable for 2-3 years.
Applicable for Medicare only	**APC payments**	Separate payment generally made for each outpatient service provided. New technology APCs are reserved for novel procedures with a distinct beginning, middle and end
	Transitional outpatient pass through payments	Allows new device to be paid in addition to the APC rate for the associated procedure. Devices must represent substantial clinical improvement and significantly increase costs. Pass-through status is only applicable for 2-3 years.
Applicable for private insurance only	**Per diem payments**	Hospital receives a daily payment for specific cases. These rates can be renegotiated, usually on an annual basis
	Case rate payments	Hospital receives a specific case. These rates can be renegotiated, usually on an annual basis
	Percentage of charge payments	Hospital receives a payment based on their charges for services used. Insurer usually does not reimburse for full charges, but rather sets a percent of the charges

Private payer coverage and payment policies for diagnostic and *in vitro* tests, including Technology Y® testing are initially benchmarked with Medicare's CLFS

- Diagnostic and *in vitro* testing reimbursement payment rates are routinely benchmarked from Medicare's Clinical Lab Fee Schedule (CLFS)
- Medicare's CLFS represents outpatient clinical laboratory services that are paid based on a fee schedule developed in accordance with Section 1833(h) of the Social Security Act[1]
- Coverage policies are usually linked to payment through coverage algorithms associated with specific CPT codes
  - The level of restrictions, unit limits, and need for prior authorization depends on how strictly the payer is managing utilization of the technology and associated CPT code
  - Most private payers will pay roughly 10 to 15% above the CLFS rates, though significant variation exists across plans and products
  - Explicit coverage policies do not exist for all laboratory tests - some are paid because they use covered CPT codes that are not product specific
  - Technology Y coverage and payment is typically associated with CPT code 84999

1. *www.cms.gov*

Medicare and Private Payer Pricing Landscape for Personalized 5-FU Pharmacokinetic Dose Management in Colorectal Cancer Patients

04

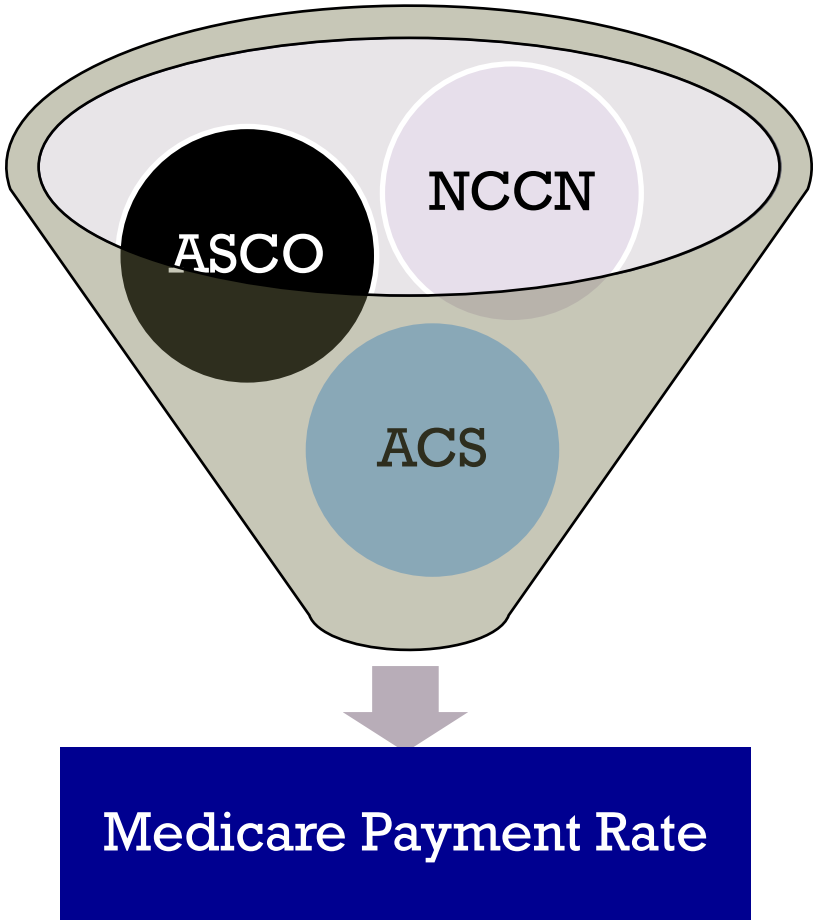
Medicare uses a method called cross-walking to establish payment levels for new laboratory codes

- Cross-walking is used to map new diagnostic or *in vitro* tests to existing tests on Medicare's Clinical Lab Fee Schedule (CLFS)
- The process is based largely on technological similarities between the novel test and its predecessor
- The process is *in lieu* of the RUC (RBRVS Updated Committee) process which establishes relative value units (RVUs) to procedure codes
- The methodology attempts to provide reimbursement based on expected work units associated with running a given test

  Cross-walking largely does not take clinical impact into account when used to set rates
- Another methodology, gap-filling, is largely being phased out

  For example, CMS decided to gap-fill CPT Code 83037 – Hemoglobin, glycosylated (A1c) in 2006 but revised this decision in 2007 to crosswalk this code to 82985 – Glycosylated protein, ruling that the gap-fill process was flawed in this situation; no laboratory tests were gap-filled from 2007 to 2009

Industry and oncology specialty societies provide input into the cross-walking process and generally agree on payment levels



- When new codes are approved, CMS provides industry the opportunity to give recommendations on what current code (and associated payment) is most analogous to the new code (usually through clinical specialty societies)
- CMS reviews society/industry recommendations but makes the final determination
- A recent analysis of the previous three years of recommended CPT crosswalks (21 instances) shows that industry and CMS generally agree on appropriate reimbursement codes:
  - **15 out of 21 decisions** – Industry & CMS agreed on payment
  - **4 out of 21 decisions** – CMS decided on a lower rate than industry recommendation
    - *The difference in recommendation and final payment decision ranged from $11.81 to $28.51 less*
  - **2 out of 21 decisions** – CMS decided on a higher rate than industry recommendation
    - *The difference in recommendation and final payment decision was < $3.00 for both decisions*

Not all *in vitro* testing payment rates are based on cross-walking - some novel diagnostics achieve coverage and payment through direct negotiation with payers

- There are many critics of the CLFS and cross-walking system who believe that it does not accurately capture the value of innovative diagnostics
- Some newer diagnostics manufacturers (i.e. Genomic Health) have gone directly to payers to negotiate coverage and value-based pricing for their test or testing service
- This strategy attempts to align reimbursement for the diagnostic with the economic benefits, including direct cost-savings versus standard of care. In addition, the potential clinical benefits the technology provides are highlighted during the payer outreach campaign. This type of strategy could conceivably be applied to maximize the market adoption and clinical utilization of the Technology Y® testing platform
- A novel bundle that incorporates an initial Technology Y® test with an Technology Z® test for 5-FU dose management could represent a substantial increase in value versus body surface area (BSA) based dosing with the clinical evidence that currently exists[1]

1. *Reference MYG2(a) In Depth Interview Report*

Payers reported that an ideal study to support coverage and maximize payment should demonstrate clinical efficacy, include statistically significant patient numbers and multiple centers

- Prospective, randomized multi-center comparative trials are preferred by payers
- Clinical endpoints should be gathered at key intervals like 3, 6, 12 and 18 month
- Follow-up data should be published after 12 and 24 months

"Pick the patients for the trial carefully. Maybe this isn't a product for every patient, but you can demonstrate improved outcomes for a targeted sub-population, for example older patients." - Payer

"Maybe the likelihood of developing toxicity decreases, but the root cause of the problem may still be present if the patient is DPYD deficient – these must be addressed or else toxicity is a constant threat. I want to see the whole picture." - Payer

Desired Endpoints

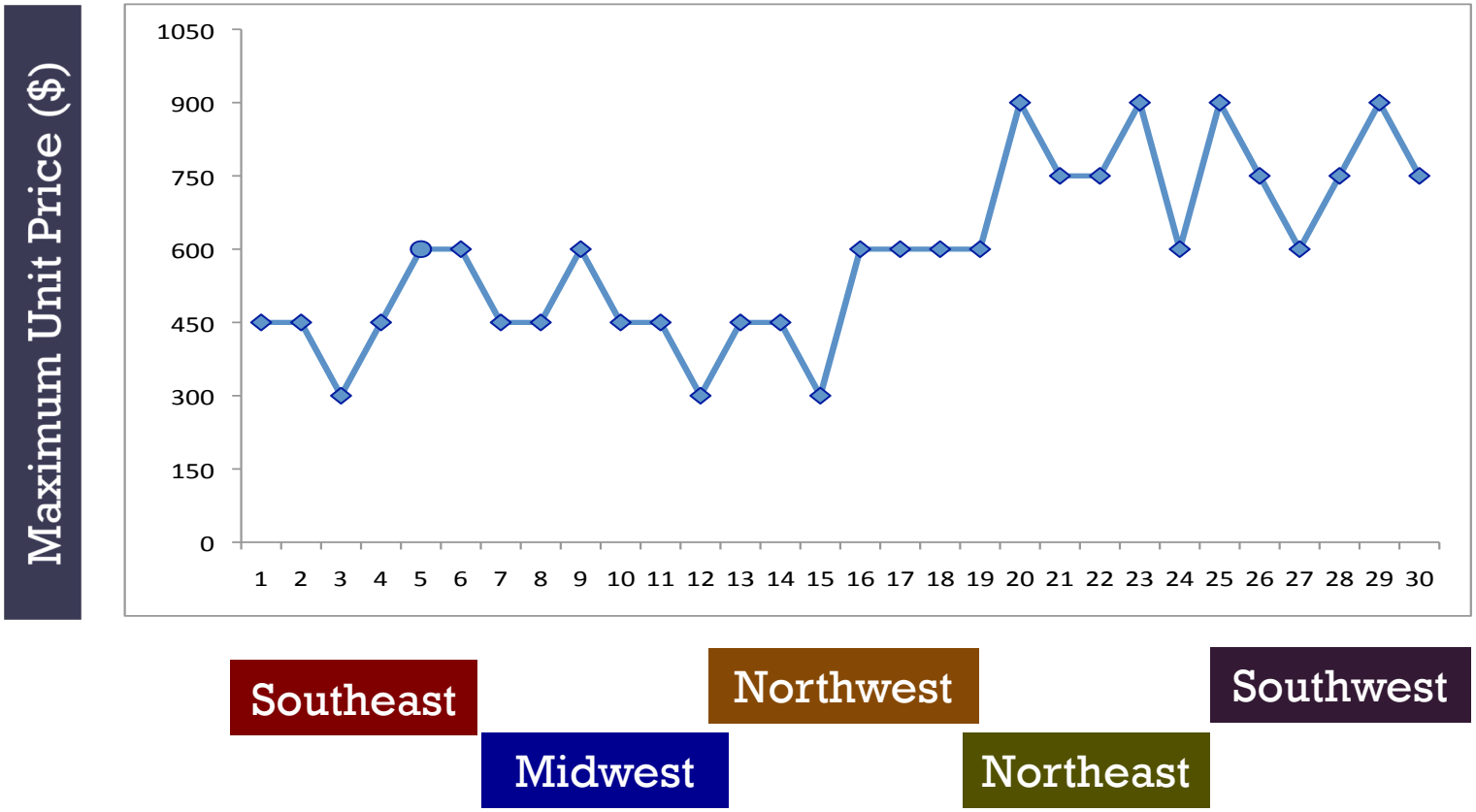
- Progression free survival and QoL
- Readmission rates
- Durability/Recurrence
- Resource utilization
- Ease of testing
- Total cost of care
- Bed Days
- Impact on disease progression

Quantitative Payer Primary Research Results on Technology Y® Platform Pricing Tolerance and Sensitivity in Colorectal Cancer Patient Treatment

05

Gabor Granger payer surveys suggest that there are regional differences in payer tolerance to Technology Y® unit pricing

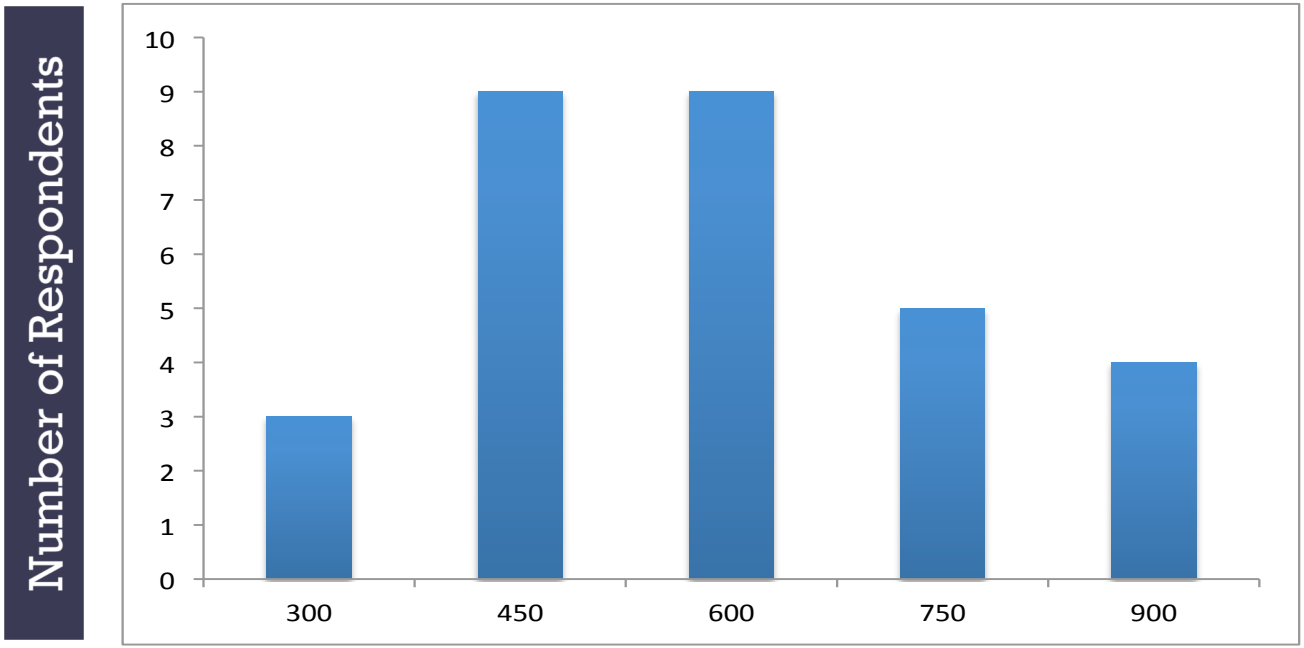
Q. What is the maximum price you would be willing to pay for a single personalized pharmacokinetic test for 5-FU dose management given the clinical evidence presented in the Technology Profile?



Region	Avg ($)
SE	475
MW	450
NW	500
NE	750
SW	775

Payer surveys conducted using the Gabor Granger methodology suggest that tolerance to Technology Y® unit pricing is approximately twice its current list price

Q. What is the maximum price you would be willing to pay for a single personalized pharmacokinetic test for 5-FU dose management given the clinical evidence presented in the Technology Profile?



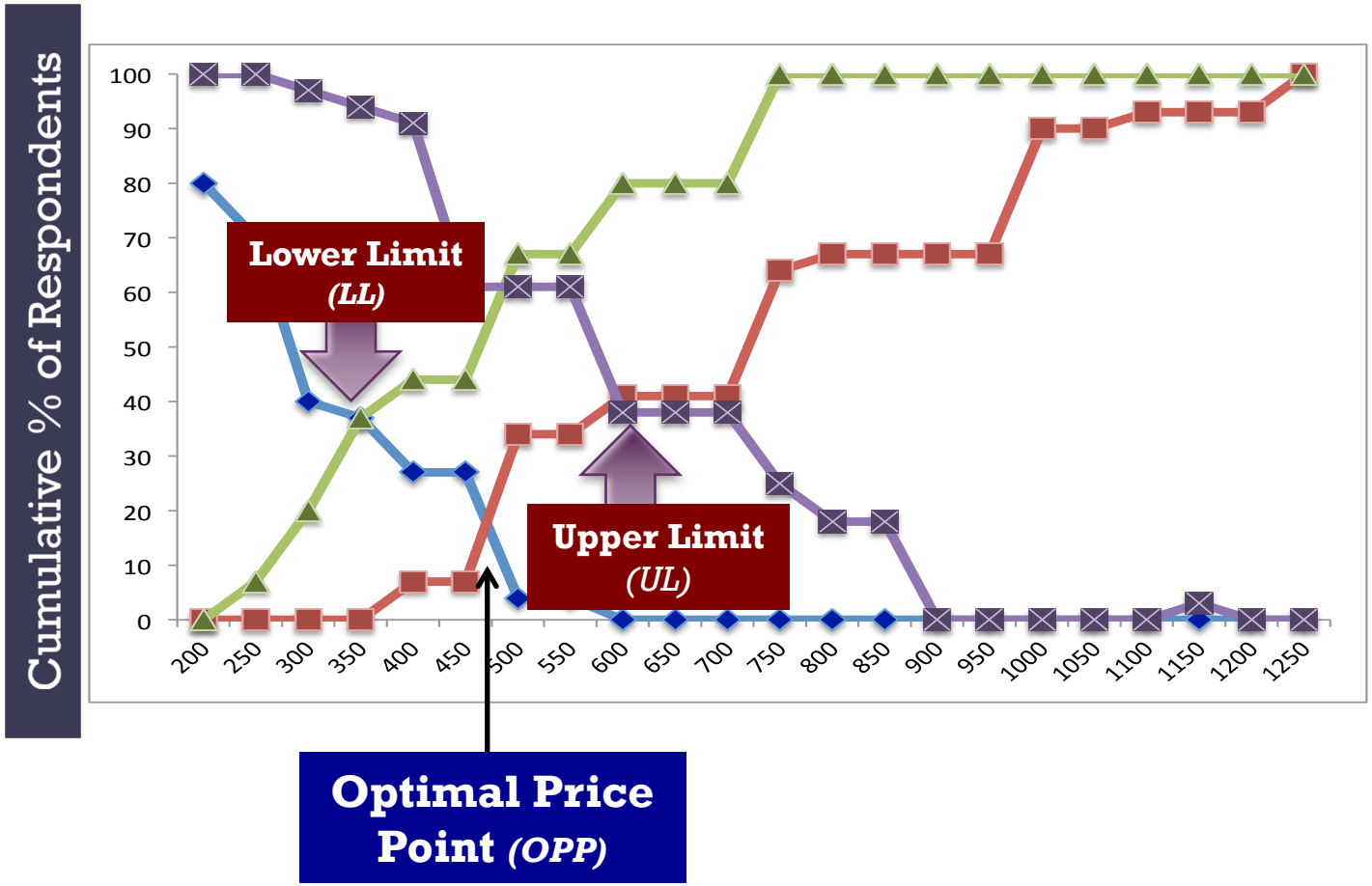
	($)
Mean	***590***
Std Dev	180
Median	600
Mode	450

"I would have no problem recommending coverage at triple the existing payment levels with the existing clinical evidence you've described to me"

Northeast Payer

Van Westendorp price sensitivity analysis suggests an optimal Technology Y® price point of $475 +/- ~150 per test

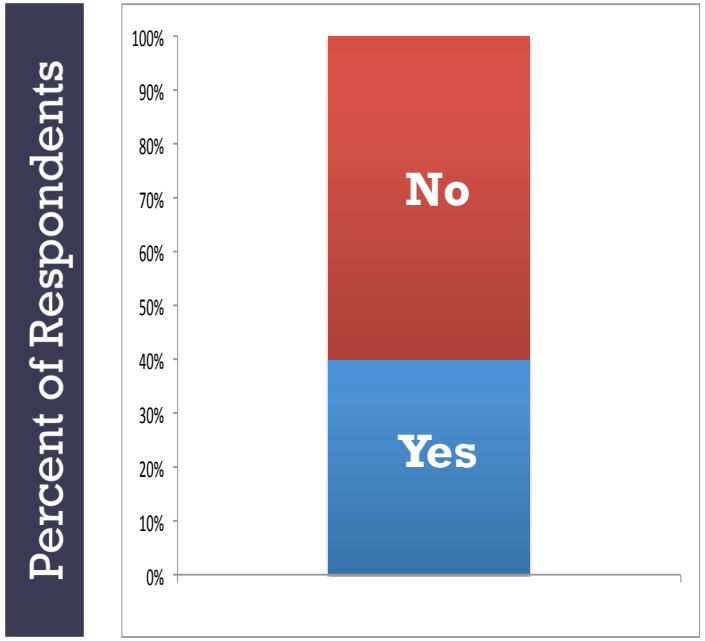
Q. What are the prices you would be willing to pay for a single personalized pharmacokinetic test for 5-FU dose management given the clinical evidence presented in the Technology Profile?



	($)
LL	325
OPP	475
UL	600

Payer surveys suggest slight differences in maximum price tolerance for Technology Y® when used in the adjuvant versus the metastatic colorectal cancer patient

Q. Is the maximum price you would be willing to pay for a single personalized pharmacokinetic test for 5-FU dose management given the clinical evidence presented in the Technology Profile different in the adjuvant versus the metastatic setting?



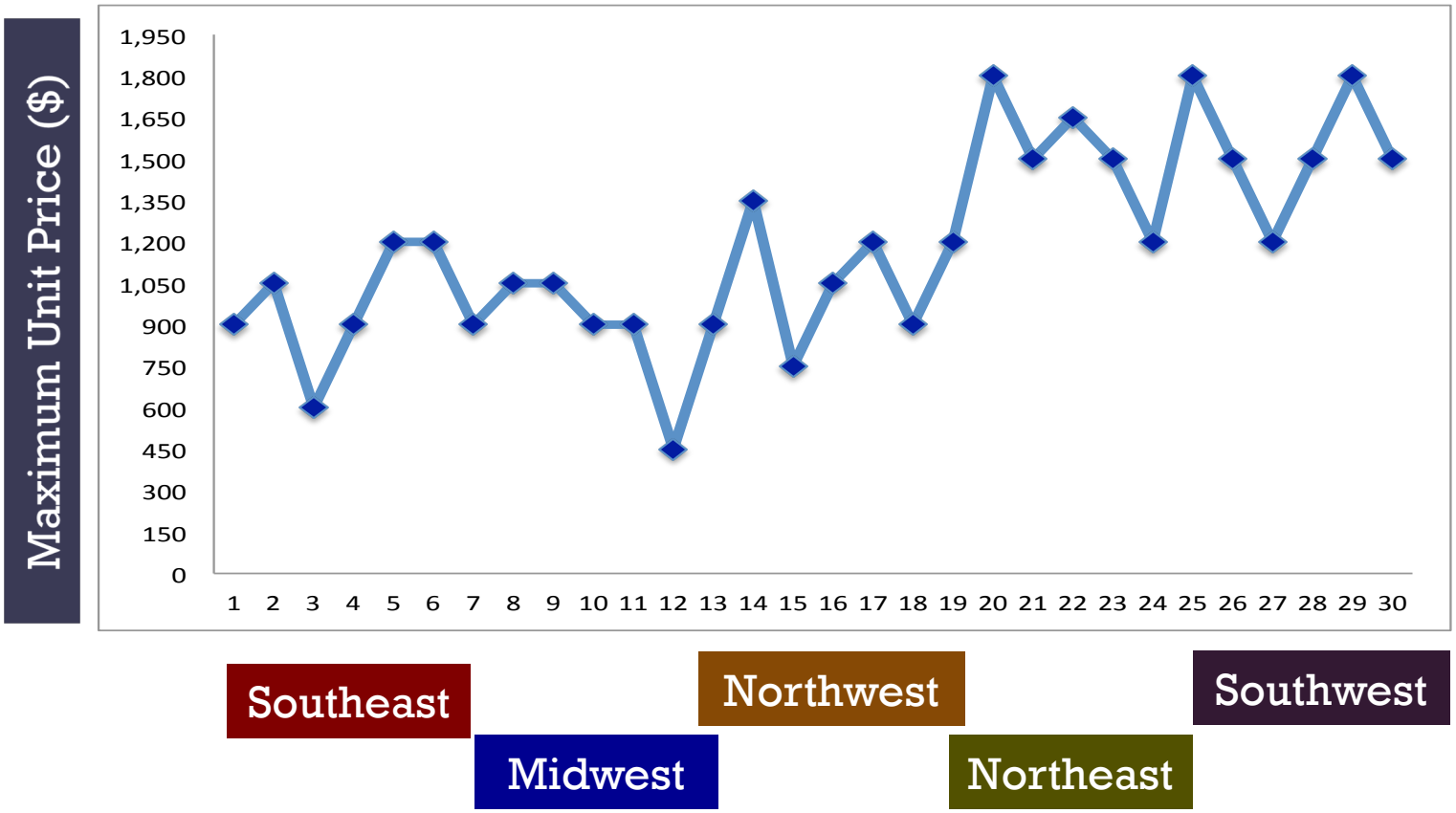
Region	Avg ($)	# Payers w/ Higher Tolerance Adjuvant	# Payers w/ Higher Tolerance Metastatic
SE	475	2 (+10%)	0
MW	450	1 (+8%)	0
NW	500	0	2 (+15%)
NE	750	4 (+10%)	0
SW	775	1 (+7%)	1 (+10%)

"In the adjuvant setting we want to make sure we maximize the chance that surgery plus chemo gets it all and that the patient will not have to come back for further treatment or will not be re-hospitalized"

Midwest Payer

Gabor Granger methodology suggests that FDA clearance or approval for Technology Y could substantially increase US payer tolerance to Technology Y® unit pricing

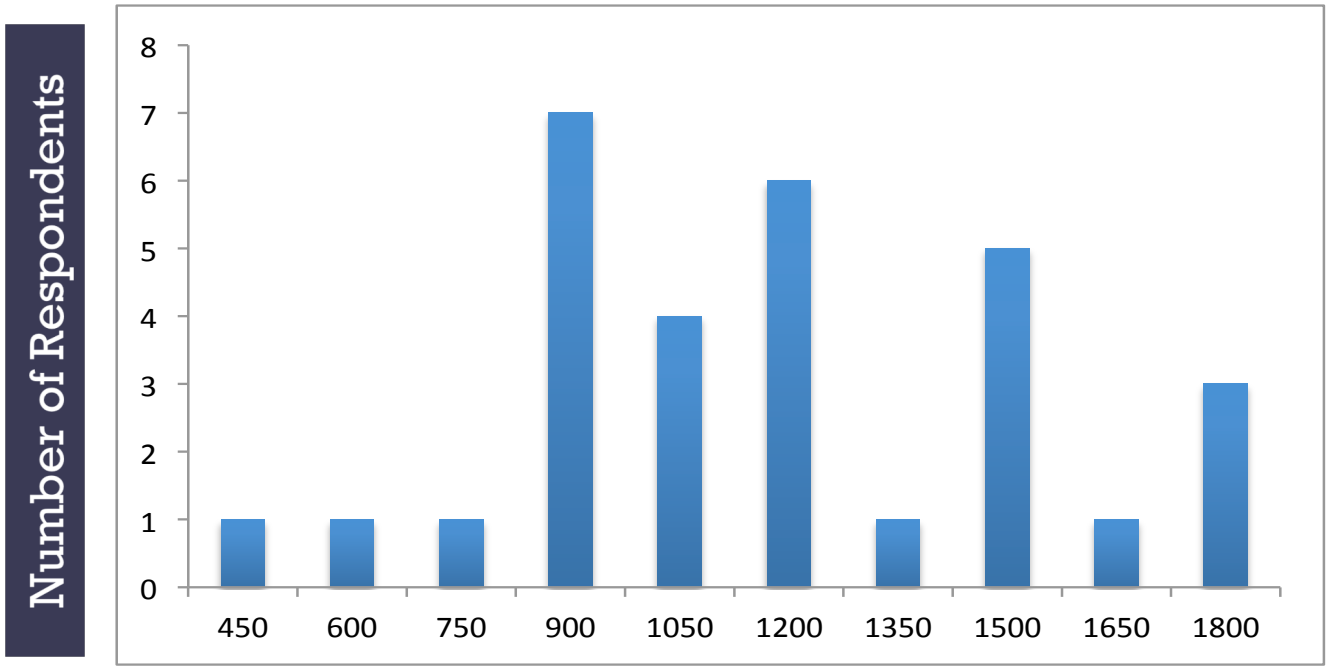
Q. What is the maximum price you would be willing to pay for a single personalized pharmacokinetic test for 5-FU dose management if the test were cleared or approved by FDA?



Region	Avgas ($)
SE	975
MW	875
NW	1,025
NE	1,475
SW	1,550

Payer surveys conducted using the Gabor Granger methodology suggest that FDA clearance or approval of the Technology Y® platform could at least double its payer value

Q. What is the maximum price you would be willing to pay for a single personalized pharmacokinetic test for 5-FU dose management if the test were cleared or approved by FDA?



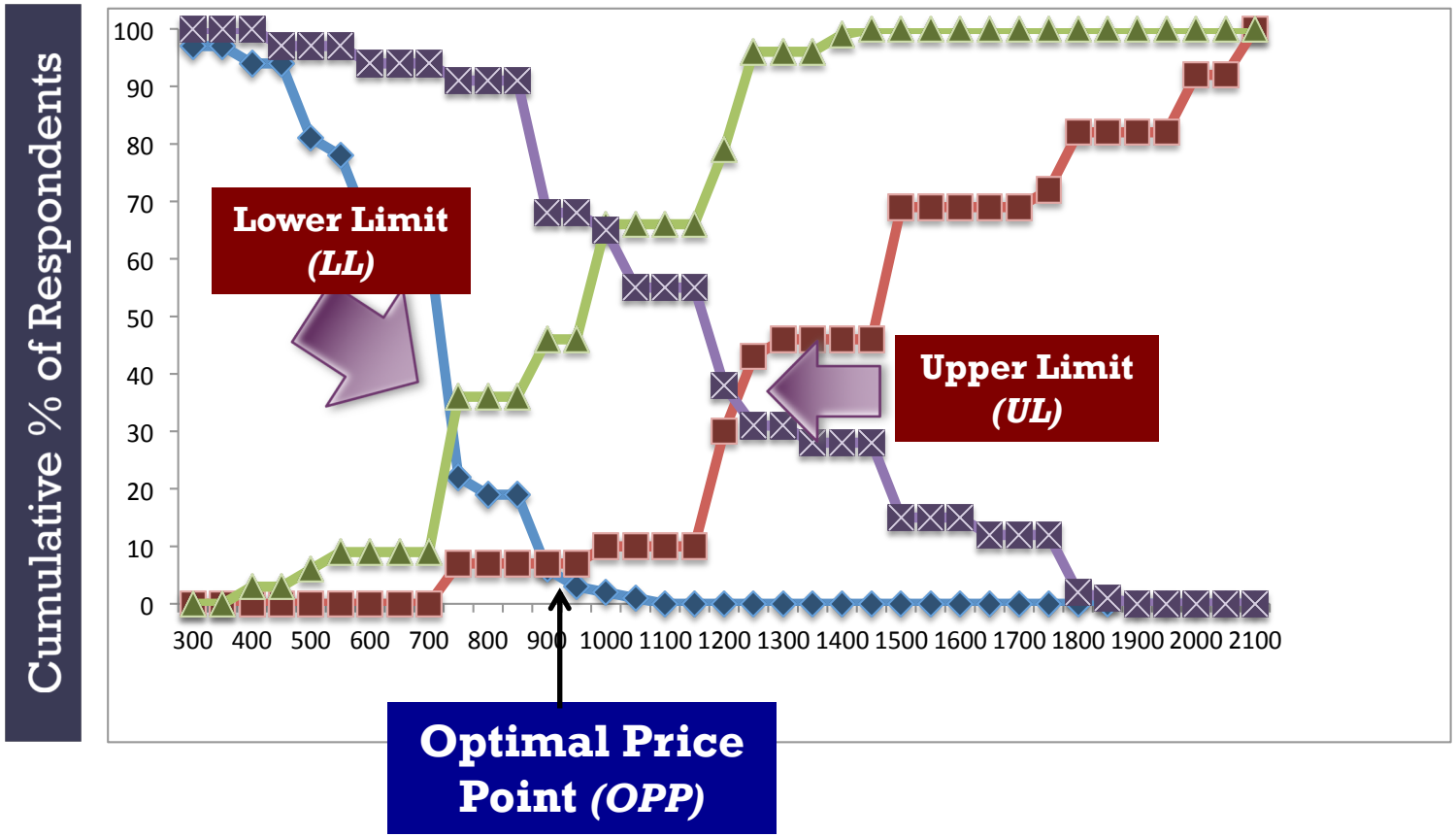
	($)
Mean	***1,180***
Std Dev.	352
Median	1,200
Mode	900

"If the test passed the FDA's safety and efficacy hurdle(s) for use in colorectal cancer applications it would add substantial value for us"

Southwest Payer

Van Westendorp price sensitivity analysis suggests an optimal Technology Y® price point of $925 +/- ~300 per test if it is cleared or approved by FDA

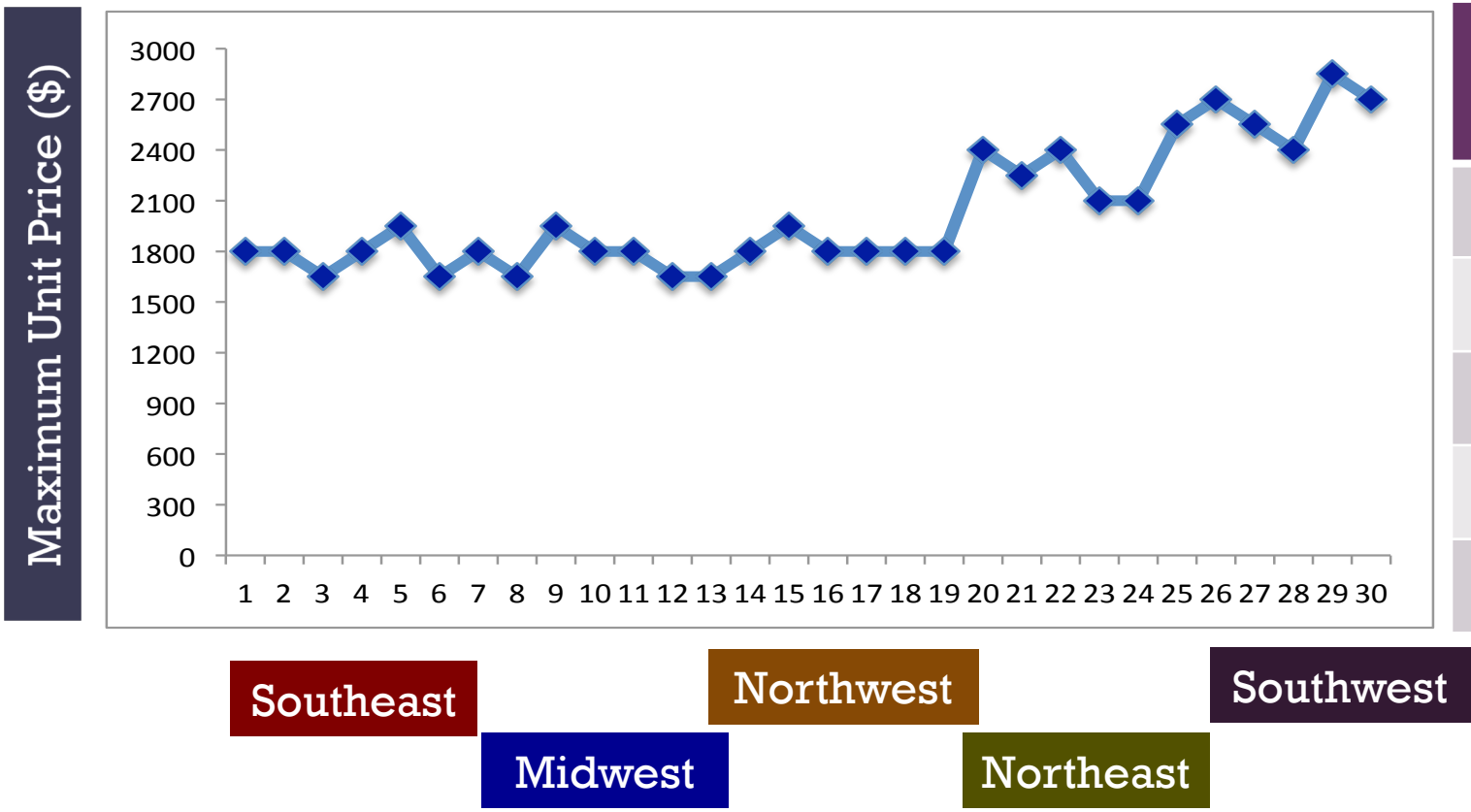
Q. What are the prices you would be willing to pay for a single personalized pharmacokinetic test for 5-FU dose management if the test were cleared or approved by FDA?



	($)
LL	700
OPP	925
UL	1225

Gabor Granger methodology suggests that regional tolerances to Technology Y® unit pricing are amplified if bundled with a preliminary Technology Z® test

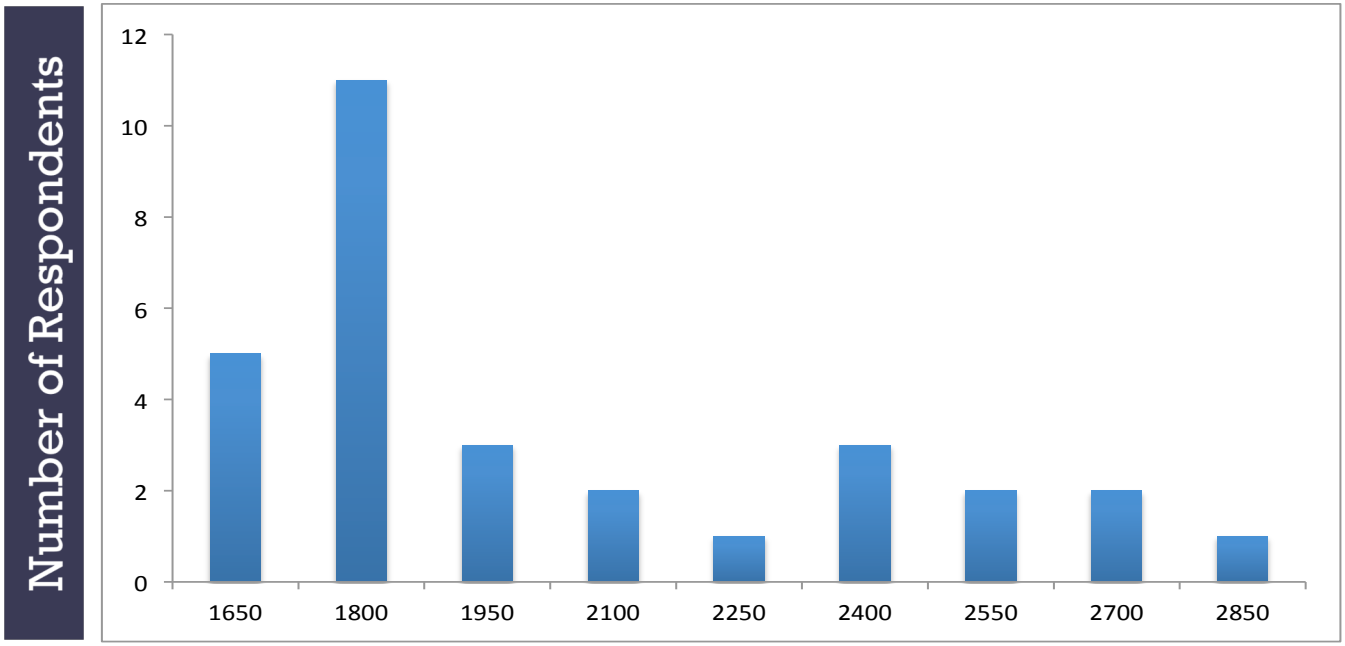
Q. What is the maximum price you would be willing to pay for a single personalized pharmacokinetic test if the test were bundled with a preliminary pharmacogenetic test for DPD deficiency?



Region	Avg ($)
SE	1,775
MW	1,775
NW	1,800
NE	2,175
SW	2,625

Gabor Granger price assessments suggest that bundling of a Technology Y® test with an initial Technology Z® test could command a premium price point

Q. What is the maximum price you would be willing to pay for a single personalized pharmacokinetic test if the test were bundled with a preliminary pharmacogenetic test for DPD deficiency?



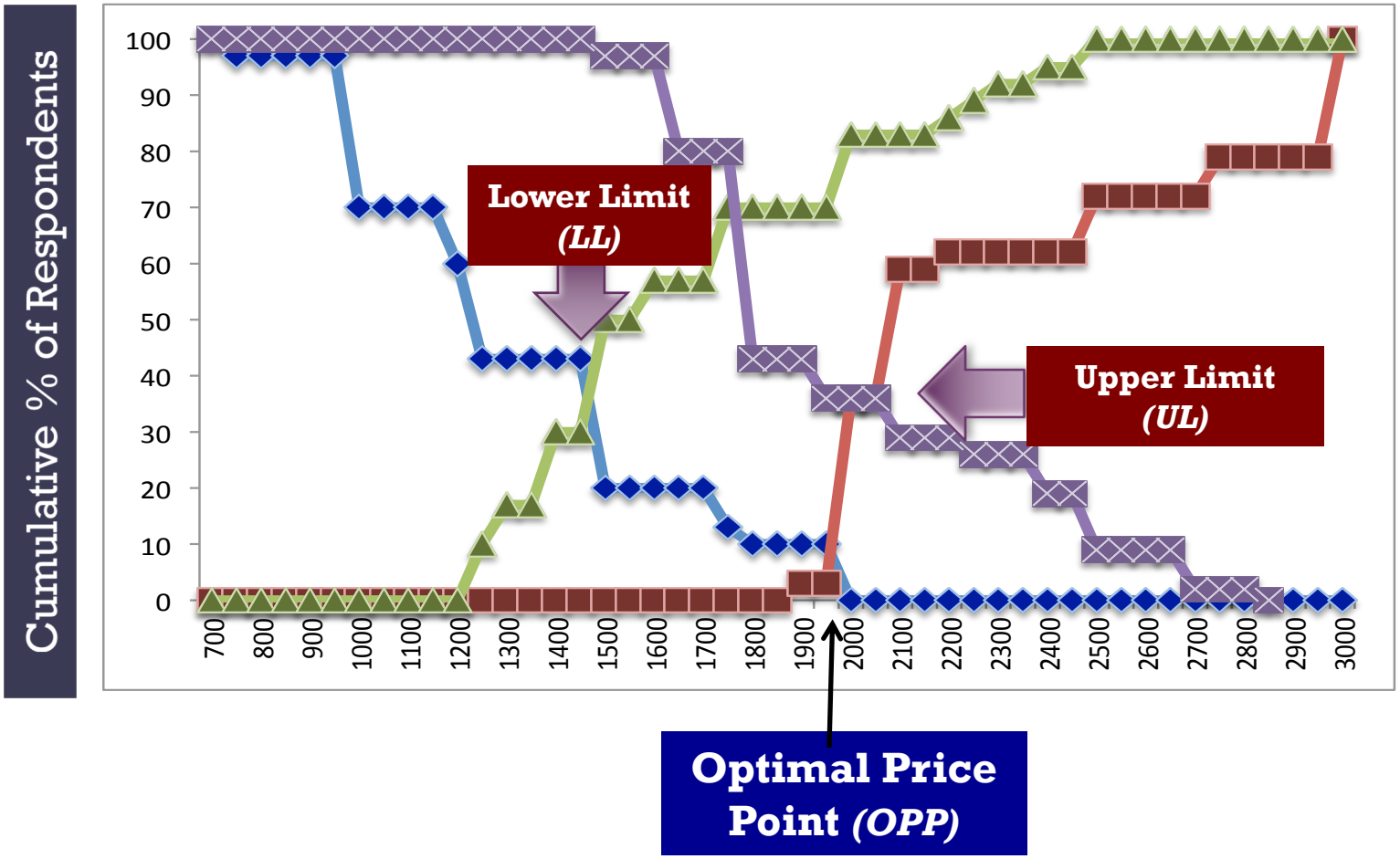
	($)
Mean	***2,030***
Std Dev	367
Median	1,800
Mode	1,800

"There is no question that a preliminary pharmacogenetic test would add substantial value….. might save us from paying for a $10,000 chemotherapy regimen that is destined to fail and could actually kill the patient"

Midwest Payer

Van Westendorp price sensitivity analysis suggests an optimal price point of $1,975 for an initial Technology Y® test packaged with the first Technology Z® test

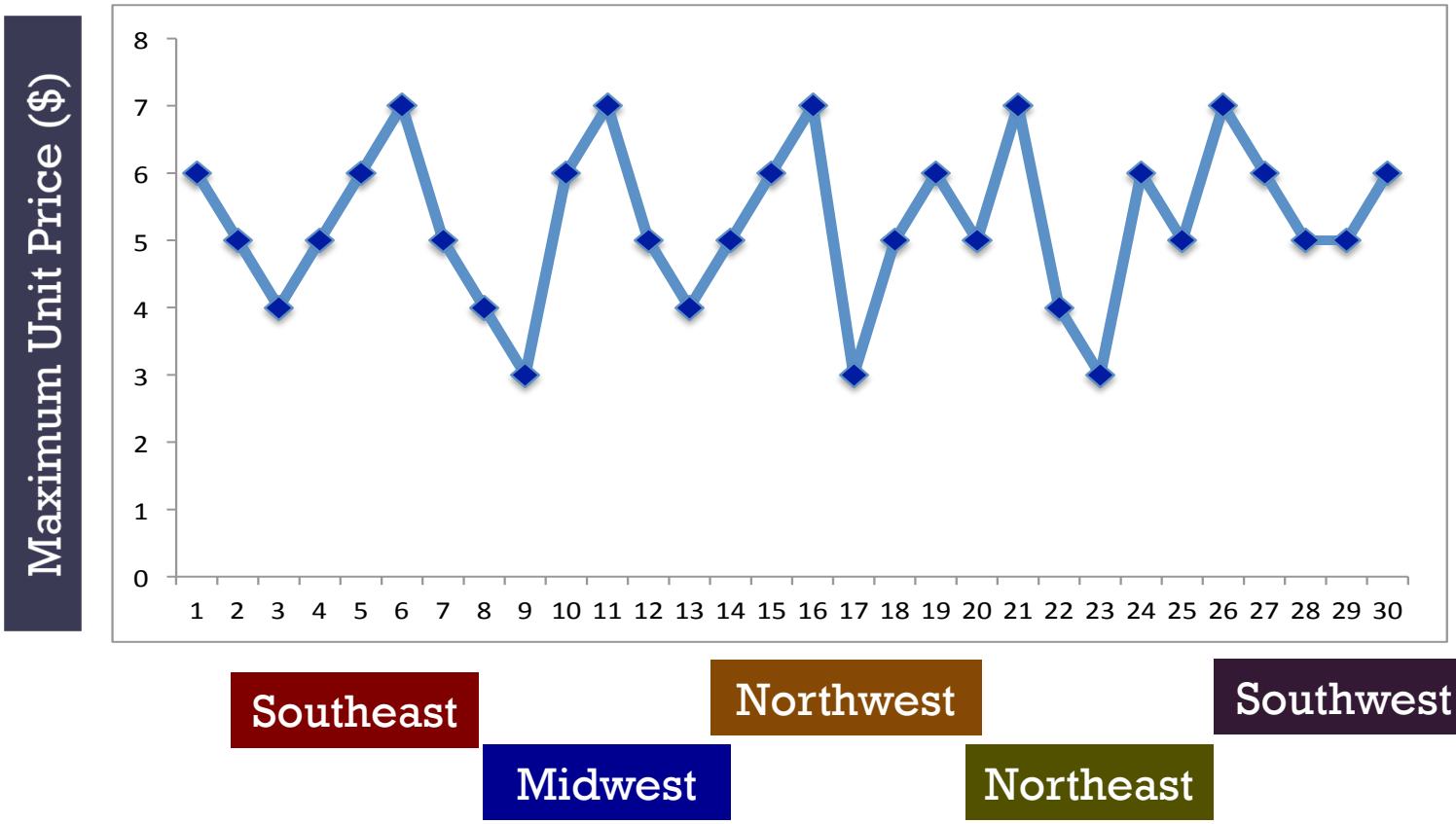
Q. What is the maximum price you would be willing to pay for a single personalized pharmacokinetic test if the test were bundled with a preliminary pharmacogenetic test for DPD deficiency?



	($)
LL	1,450
OPP	1,975
UL	2,100

Survey data suggests that payers would commit to reimbursement for a bundled package of 5-6 Technology Y® tests for metastatic colorectal cancer patients

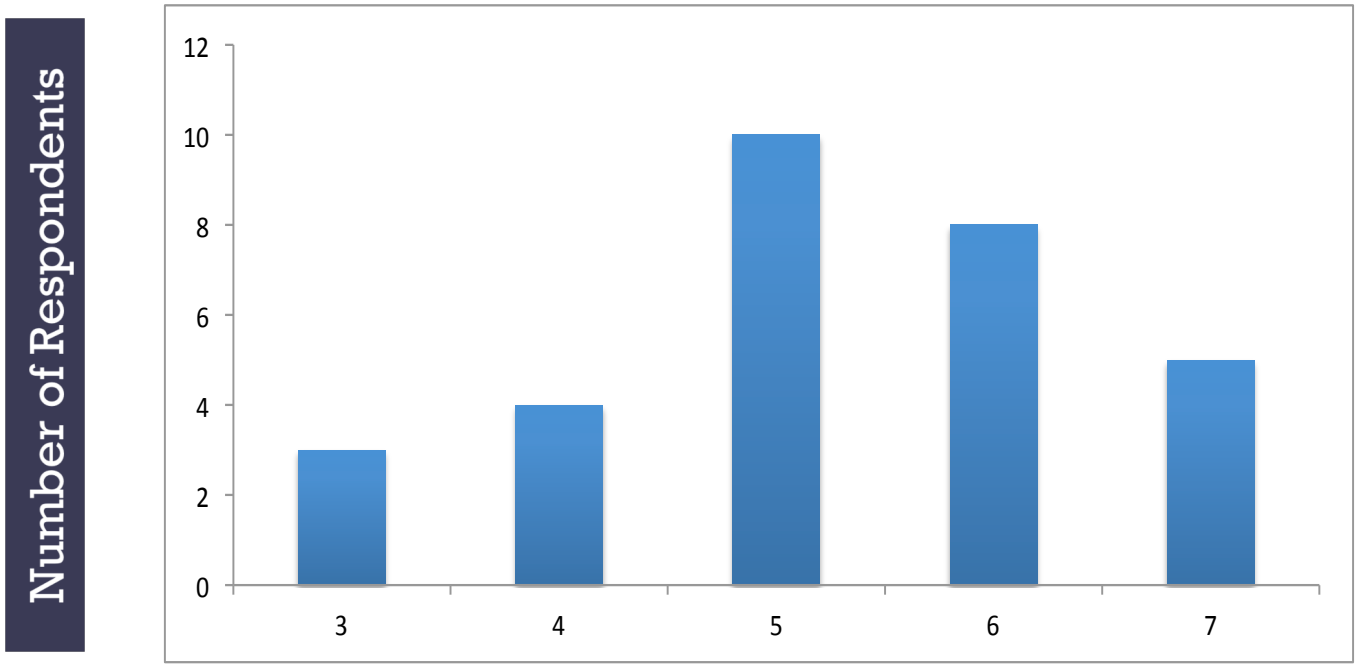
Q. What is the maximum number of personalized pharmacokinetic tests that you would be willing to commit to paying for as a bundled package for 5-FU dose management in the metastatic setting given the clinical evidence presented in the Technology Profile?



Region	Avg # of PK tests
SE	6
MW	5
NW	5
NE	5
SW	6

Survey data suggests that payers would commit to reimbursement for a bundled package of 5-6 Technology Y® tests

Q. What is the maximum number of personalized pharmacokinetic tests that you would be willing to commit to paying for as a bundled package for 5-FU dose management given the clinical evidence presented in the Technology Profile?



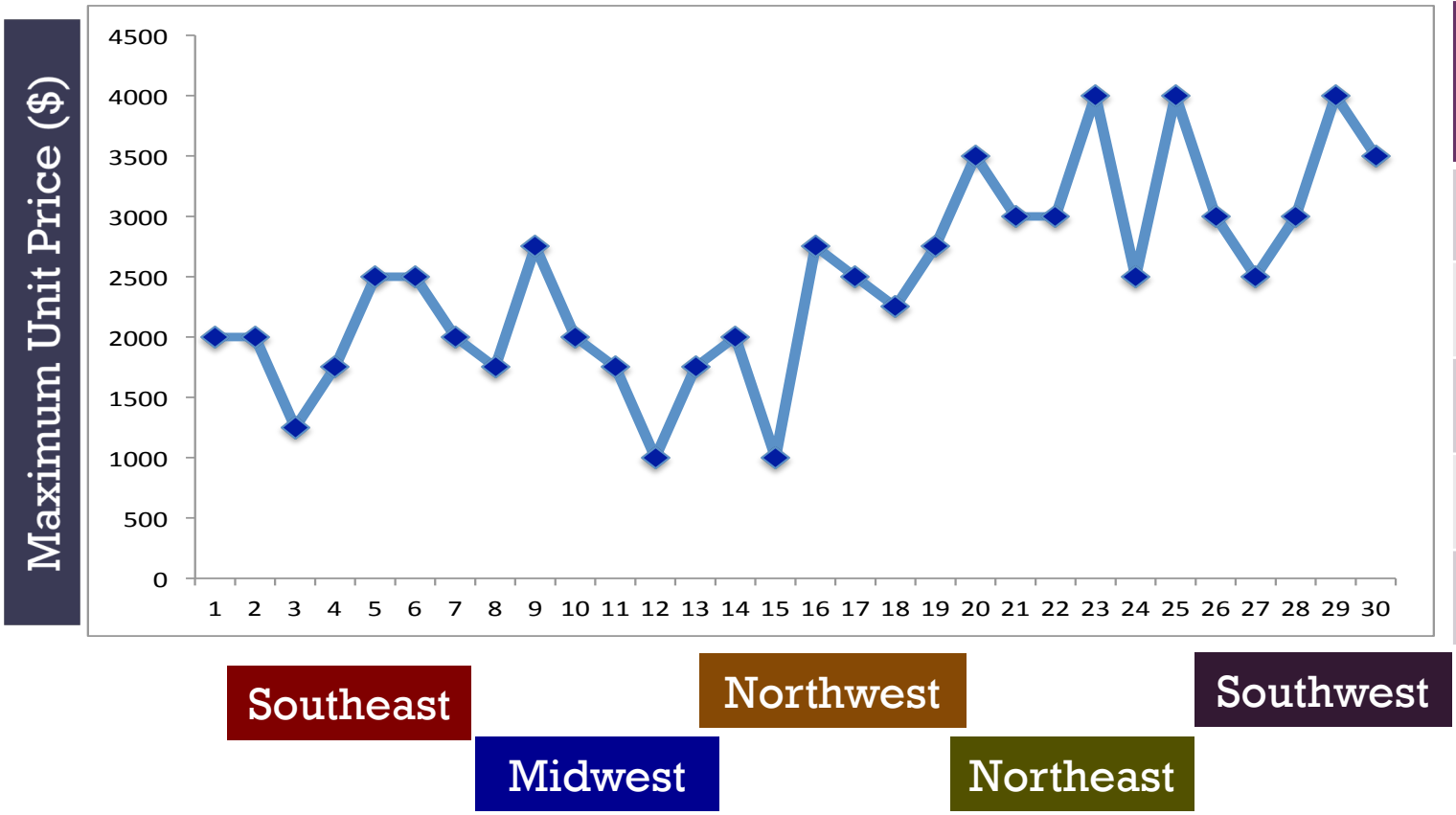
	Number of PK Tests
Mean	***5***
Std Dev	1
Median	5
Mode	5

"We might be more likely to commit to supporting more tests….maybe 6 or 7 in the metastatic setting……..versus supporting 3 or 4 in the adjuvant setting"

Northwest Payer

Gabor Granger surveys suggest that payers would commit to reimbursement for a package of 5 Technology Y® tests but would expect a volume based discounted price

Q. What is the maximum price you would be willing to pay for a bundled package of 5 personalized pharmacokinetic tests for 5-FU dose management given the clinical evidence presented in the Technology Profile?



Region	Avg ($)
SE	2,000
MW	1,875
NW	2,042
NE	3,125
SW	3,333

Southeast

Midwest

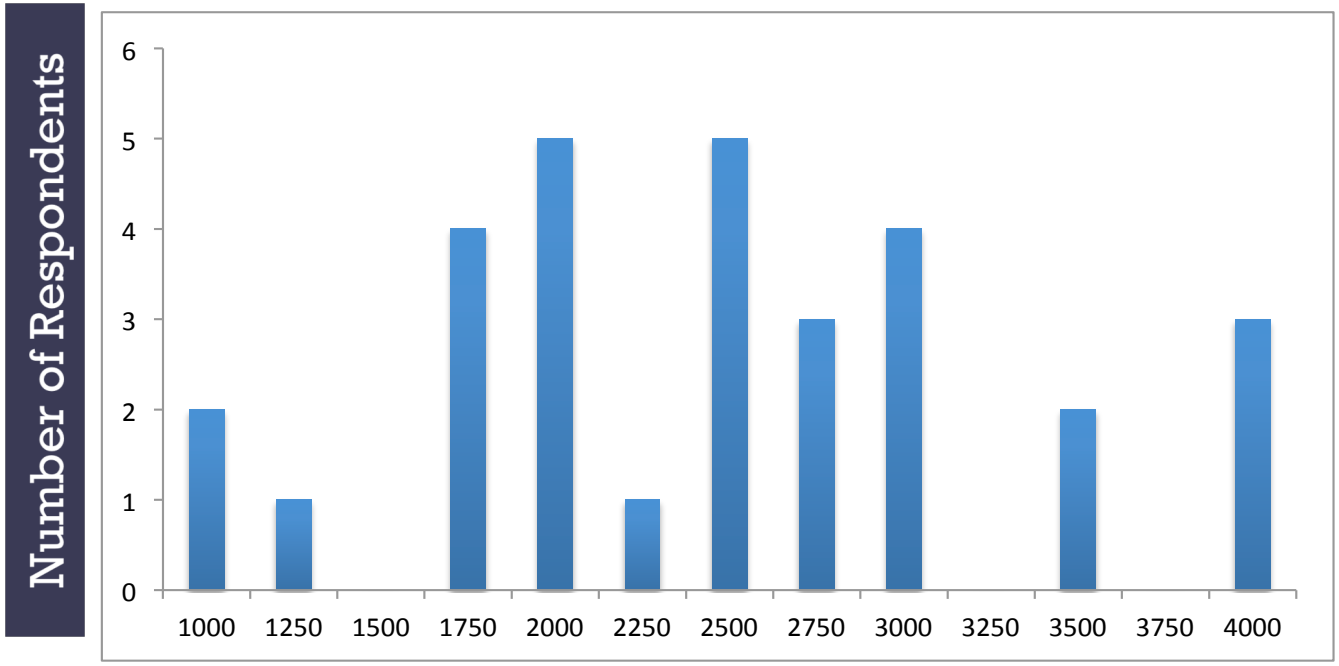
Northwest

Northeast

Southwest

Gabor Granger surveys suggest that payers would commit to reimbursement for a package of 5 Technology Y® tests but there would be wide variation in discounted price tolerance

Q. What is the maximum price you would be willing to pay for a bundled package of 5 personalized pharmacokinetic tests for 5-FU dose management given the clinical evidence presented in the Technology Profile?



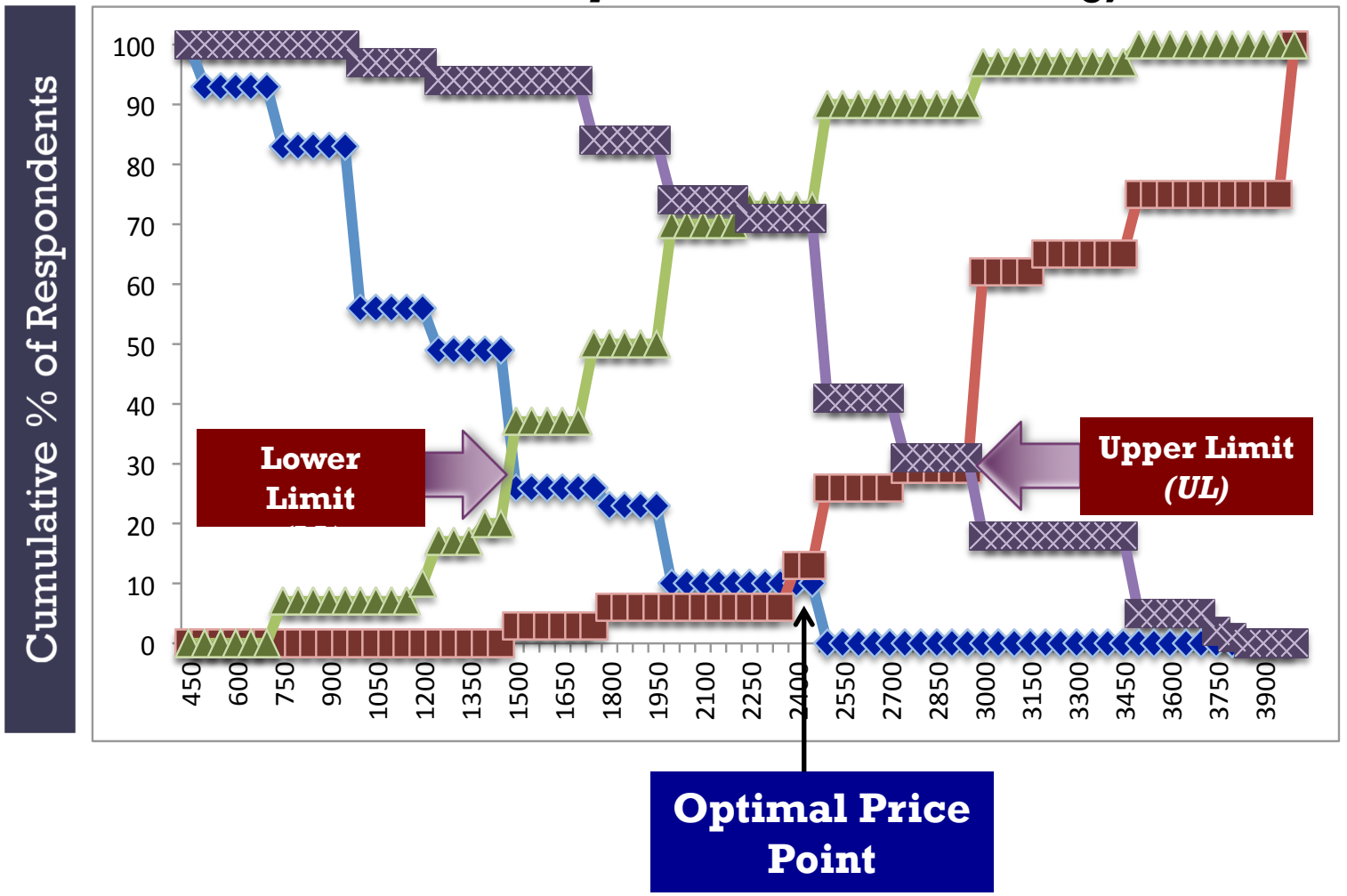
	($)
Mean	***2,475***
Std Dev	821
Median	2,500
Mode	2,000

"It would actually make more sense to me to offer these PK tests in bundles since the only way they would add clinical value to patient care would be through multiple tests administered at regular time points"

Northwest Payer

Van Westendorp price sensitivity analysis suggests an optimal price point of $2,400 for a bundled set of 5 Technology Y tests

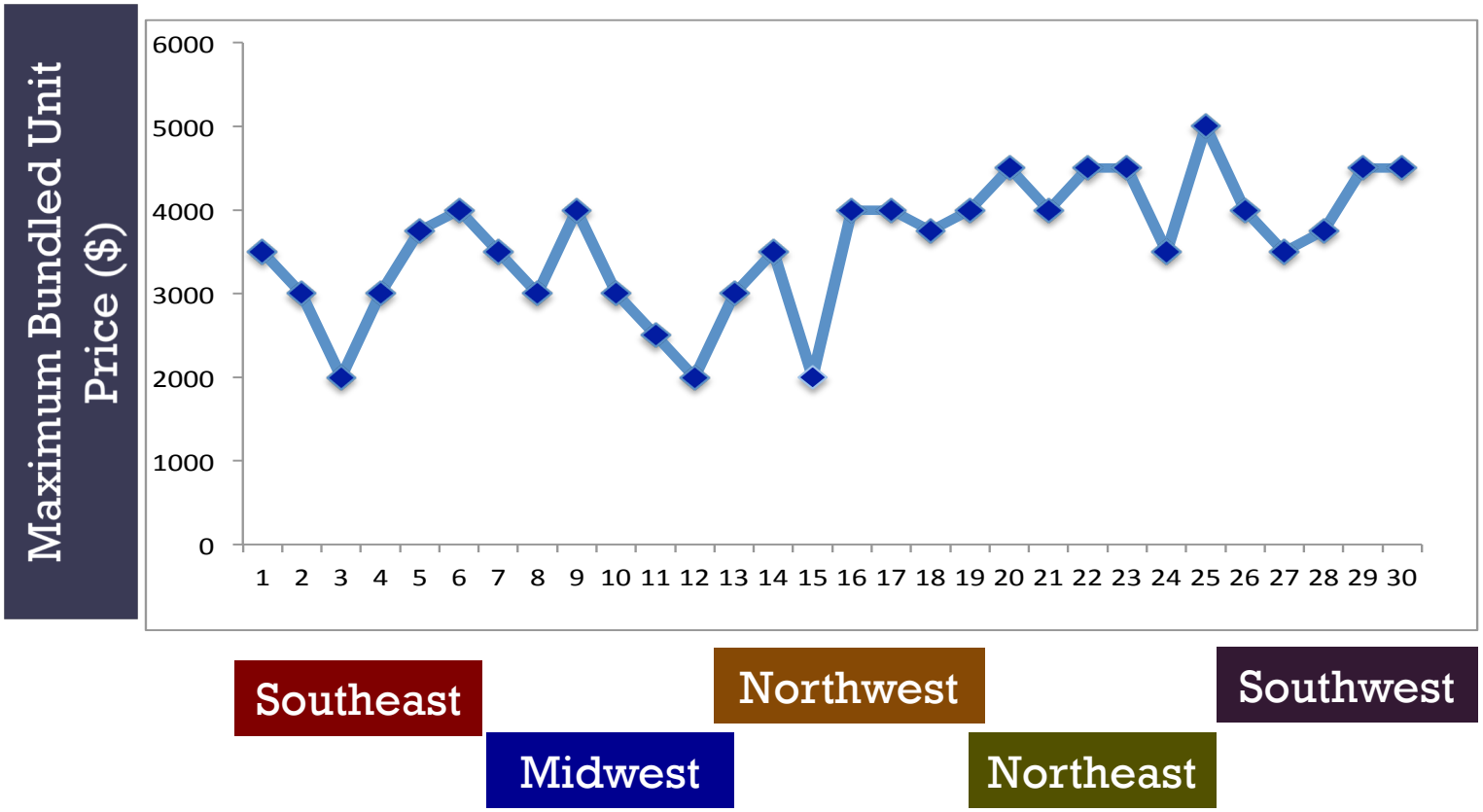
Q. What is the maximum price you would be willing to pay for a bundled package of 5 personalized pharmacokinetic tests for 5-FU dose management given the clinical evidence presented in the Technology Profile?



	($)
LL	1,500 ($300/test)
OPP	2,400 ($480/test)
UL	3,000 ($600/test)

Gabor Granger surveys suggest that payers would commit to reimbursement for a package of 5 Technology Y® tests but would implement utilization controls at a given price threshold

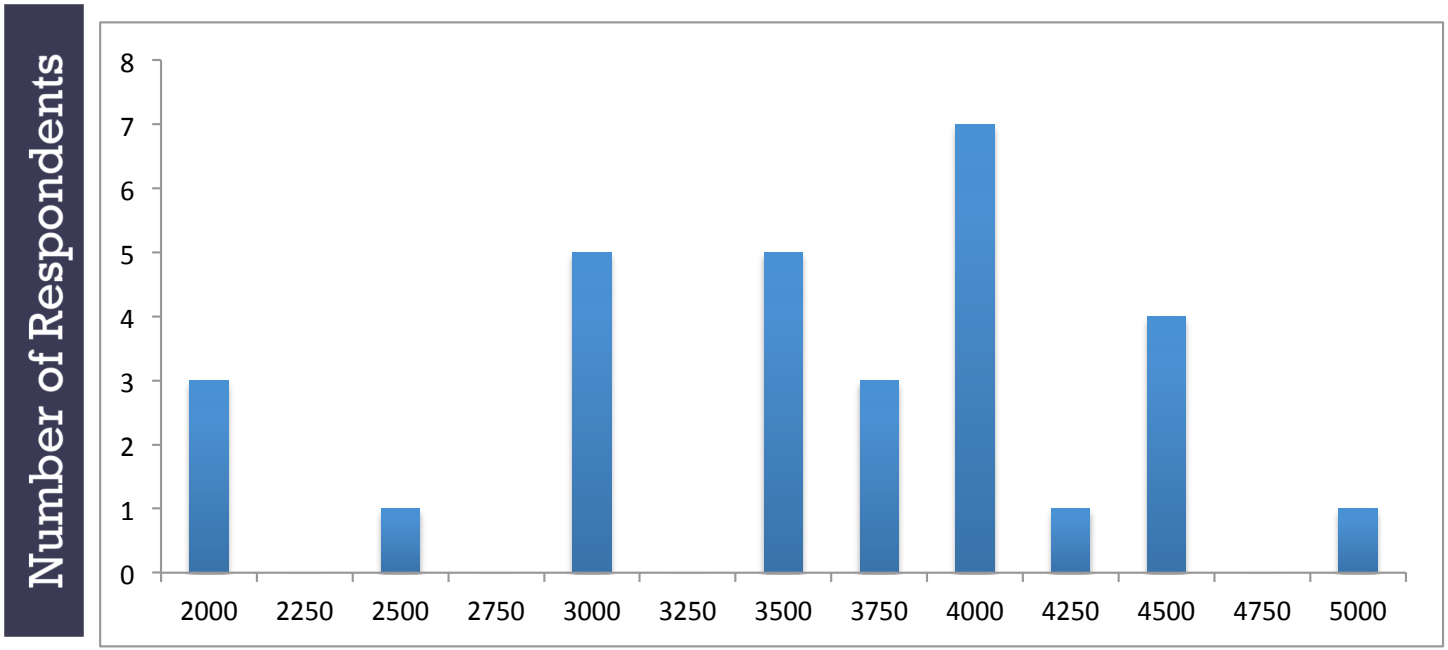
Q. At what price would your organization be likely to implement utilization controls for a personalized pharmacokinetic test for 5-FU dose management given the clinical evidence presented in the Technology Profile?



Region	Avg ($)
SE	3,208
MW	3,000
NW	3,375
NE	4,167
SW	4,208

Survey data suggests that payers would commit to reimbursement for a package of 5 Technology Y® tests but would implement utilization controls at a certain price

Q. At what price would your organization be likely to implement utilization controls for a personalized pharmacokinetic test for 5-FU dose management given the clinical evidence presented in the Technology Profile?



	($)
Mean	***3,592***
Std Dev	786
Median	3,750
Mode	4,000

Southeast

Midwest

Northwest

Northeast

Southwest

Summary of payer pricing feedback utilizing Gabor Granger methodology for Technology Y® based on various environmental, packaging and bundling strategies

($)	Current List Price	Single Test	FDA Clearance	Technology Z®[1]	# of PK Tests	Bundled Price (for 5 tests)[1]	Utilization Controls (for 5 tests)[1]
SE	300	475	975	1,775	6	2,000 ($400/test)	3,280 ($641/test)
MW	300	450	875	1,775	5	1,875 ($375/test)	3,000 ($600/test)
NW	300	500	1,025	1,800	5	2,042 ($408/test)	3,375 ($563/test)
NE	300	750	1,425	2,175	5	3.125 ($625/test)	4,167 ($833/test)
SW	300	775	1,550	2,625	6	3,333 ($666/test)	4,208 ($842/test)

1. Pricing for these tests is based on the assumption that Technology Y does not have FDA regulatory clearance or approval

Summary of payer pricing feedback utilizing Gabor Granger methodology for Technology Y® based on various environmental, packaging and bundling strategies

($)	Current list price	Single test	FDA Clearance	Tecnology Z®	# of PK tests	Bundled Price (for 5 tests)	Utilization Controls (for 5 tests)
Mean	300	590	1,180	2,030	5	2,475 ($495/test)	3,592 ($718/test)
Std Dev	0	180	352	367	1	821 ($164/test)	786 ($157/test)
Median	300	600	1,200	1,800	5	2,500 ($500/test)	3,750 ($750/test)
Mode	300	450	900	1,800	5	2,000 ($400/test)	4,000 ($800/test)

Summary of payer pricing feedback utilizing Van Westendorp methodology for Technology Y® based on various environmental, packaging and bundling strategies

($)	Current list price	Single test	FDA Clearance	Technology Z®	Bundled Price (for 5)
LL	300	325	700	1,450	1,500 ($300/test)
OPP	300	475	925	1,975	2,400 ($480/test)
UL	300	600	1,225	2,100	3,000 ($600/test)

Summary of payer pricing feedback utilizing Van Westendorp (VW) and Gabor Granger (GG) methodology for Technology Y® based on various environmental, packaging and bundling strategies

($)	Current List Price	Single Test	FDA Clearance	Technology Z	Bundled Price (for 5)
GG Mean	300	590	1,180	2,030	2,475 ($495/test)
VW OPP	300	475	925	1,975	2,400 ($480/test)
% difference	0	19	22	3	3

"One thing that we find most frustrating with diagnostic testing services is that the manufacturer never makes it readily transparent how much the test is really costing us – so if you recommend that the patient receives say 5 tests, then you should tell us the price for the 5 tests all together"

Northeast Payer

Recommendations & Next Steps

06

Company X should develop tactical and payment-specific tools to quantify the relative value of clinical and economic benefits of Technology Y® platform utilization versus its up front utilization costs

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

Refine existing and newly developed economic models using pricing inputs from this study, usual and customary costs for chemotherapy regimentation, standard of care tests and provider time/hospital days to measure impact of test adoption

Continue to develop tactics to support the development of economic and clinical evidence to support the requirements of Local Coverage Determinations by local Medicare contractors

Illustrate clinically significant differences in patient care by quantifying increase in efficacy and decrease in toxicity versus up front costs of Technology Y +/- Technology Z® utilization

These tactics are mutually reinforcing

Develop a US provider organizational priority list by site of care, as well as tools specifically targeted towards these sites and use them to drive Technology Y® platform adoption via relative value communication

- Stratify US regional hospitals and other oncology provider institutions by existing number of colorectal cancer patients served, adoption of predicate technologies, and other key metrics, including provider capacity and likelihood of accepting premium pricing for Technology Y testing

  These providers can then be ranked in terms of opportunity and receptivity

- Develop a macroscopic budget model that can be shared with provider administrator contacts and utilized by them at subsequent technology evaluation meetings
  - This tool would include relevant clinical and pricing data points to highlight Technology Y test advantages – the model should be easily manipulated by provider staff for specific colorectal cancer patients
  - Account for provider-specific variables like reagent rentals, discretionary fund availability, and negotiated test pricing

Develop, evaluate and distribute provider specific institutional return on investment (ROI) cost impact models for Technology Y® and/or Technology Z® testing utilization

- Choose existing US and international Technology Y testing platform centers of excellence and gather economic data regarding cost of treatment of new and existing colorectal cancer patients utilizing data obtained from this pricing study and market data obtained by Ipsos Healthcare
- Work with institutional clinical, financial and provider administrators to track differences in treatment costs versus clinical outcomes in patients whose chemotherapy regimens were supported with Technology Y testing to support 5-FU dose management
- Utilize these institution specific cost impact models to support both marketing efforts, as well as Medicare and private payer value dossier development

Develop a return on investment analysis by evaluating the expenses associated with obtaining FDA regulatory clearance or approval versus the resultant benefits of premium pricing for Technology Y® utilization

- Conduct an evaluation of the likely classification of the Technology Y testing platform from FDA's perspective
  - Assess how other predicate *in vitro* testing platforms have been classified by FDA
  - Search for potential predicate devices
  - Determine whether existing clinical study work will support an FDA submission to evaluate safety and efficacy
  - Meet with FDA to better understand their perspectives
- Develop a quantitative excel based return on investment model to determine internal return on investment, based on pricing data presented in this report versus likely clinical development and regulatory filing expenses

Conduct a separate in-depth interview and pricing study on Technology Z® utilization among both Medicare and private payers to better understand drivers of adoption and how the platform could be integrated with Technology Y® testing

- Payers in the present study reported that they would support a 32% (Van Westendorp) or 65% (Gabor Granger) premium in pricing for an initial Technology Y test packaged with a preliminary Technology Z test versus existing list price

- A more in depth Technology Z study could yield additional insights regarding drivers of adoption of pharmacogenetic testing utilization in combination with pharmacokinetic testing in 5-FU dose management in colorectal cancer patients

Determine if the Technology Y® pricing data generated in this study is applicable to other clinical oncology types including head and neck and pancreatic cancer

- The projects designated MYG2(a) and MYG2(b) are focused on evaluating Medicare and private payer perspectives on the use of 5-FU dose management technologies in colorectal cancer
  - Technology Profiles and Discussion Guides were developed to provide a framework for discussions with payer interviewees regarding their perspectives on these issues
  - In addition, the clinical and economic evidence and value development strategies proposed in the associated reports were focused on informing Company X stakeholders of these strategies in colorectal cancer
- Additional clinical and economic studies have been conducted utilizing 5-FU dose management strategies in other oncology patient settings including head and neck cancer and pancreatic cancer
- Additional research should focus on more fully understanding Medicare and private payer attitudes towards coverage and payment scenarios for these alternative oncology disease states

Next Steps

- Continue to develop tactical payment-specific tools to quantify relative potential clinical and economic benefits of Technology Y® platform utilization versus up front costs
- Develop a US provider organizational priority list by site of care as well as tools specifically targeted towards these sites and use them to drive Technology Y® platform adoption via relative value communication
- Develop, evaluate and distribute provider specific institutional return on investment (ROI) cost impact models for Technology Y® and/or Technology Z® testing utilization
- Develop a return on investment analysis for obtaining FDA regulatory clearance or approval for the Technology Y® platform and incorporate the premium pricing data cited by Medicare and private payers in this study
- Conduct a separate in-depth interview and pricing study on Technology Z® utilization among both Medicare and private payers to better understand drivers of adoption and how the platform could be integrated with Technology Y® testing
- Evaluate whether the Technology Y® premium pricing data generated in this study is applicable to other clinical oncology types including head and neck and pancreatic cancer

Appendices

07

The Gabor Granger pricing methodology seeks to estimate levels of demand that could be expected at each price point across the market

- **Gabor-Granger** pricing research is named after the economists who invented it in the 1960s
- Potential customers are asked to say if they would buy a product at a particular price - The price is then increased and respondents again are asked if they would buy or not
- Typically, Gabor Granger is only used when considering one product in isolation, whereas in real life many products, especially in consumer market segments, would face a choice about which product to buy

The Van Westendorp (VW) pricing methodology[1] is utilized to map out price positioning with a range of price levels acceptable to the purchaser

- In the VW technique, respondents are asked 4 key questions related to their price expectations for a product or service:
  - Price at which product/service would be a bargain
  - Price at which it would start to get expensive
  - Price at which it would be so cheap that quality would be doubted
  - Price at which it is too expensive to consider
- These 4 questions are often referred to as: "cheap", "expensive", "too cheap", and "too expensive"
- The optimal price point (OPP)

The "sweet spot" where the number of people who find the price acceptable is maximized, and resistance to price changes is minimized

- Top and bottom "range" numbers:
  - The point of marginal cheapness (MGP)

    Marks the low end of the range of acceptable prices
  - The point of marginal expensiveness (MDP)

    Marks the high end of the range of acceptable prices

1. http://orconsulting.com

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