Reimbursement Reform in Oncology

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Rising costs of drugs – typical monthly cost at introduction

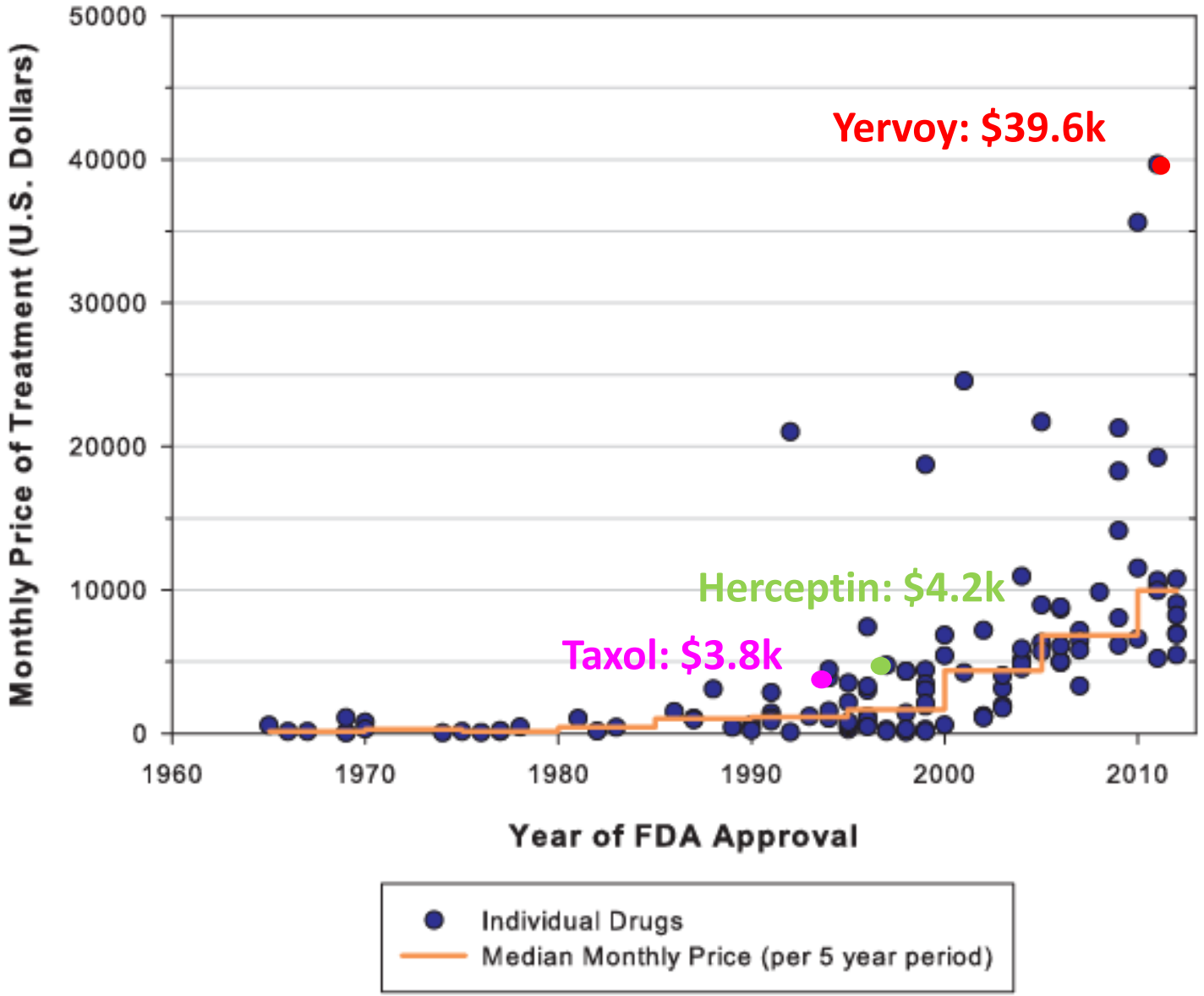
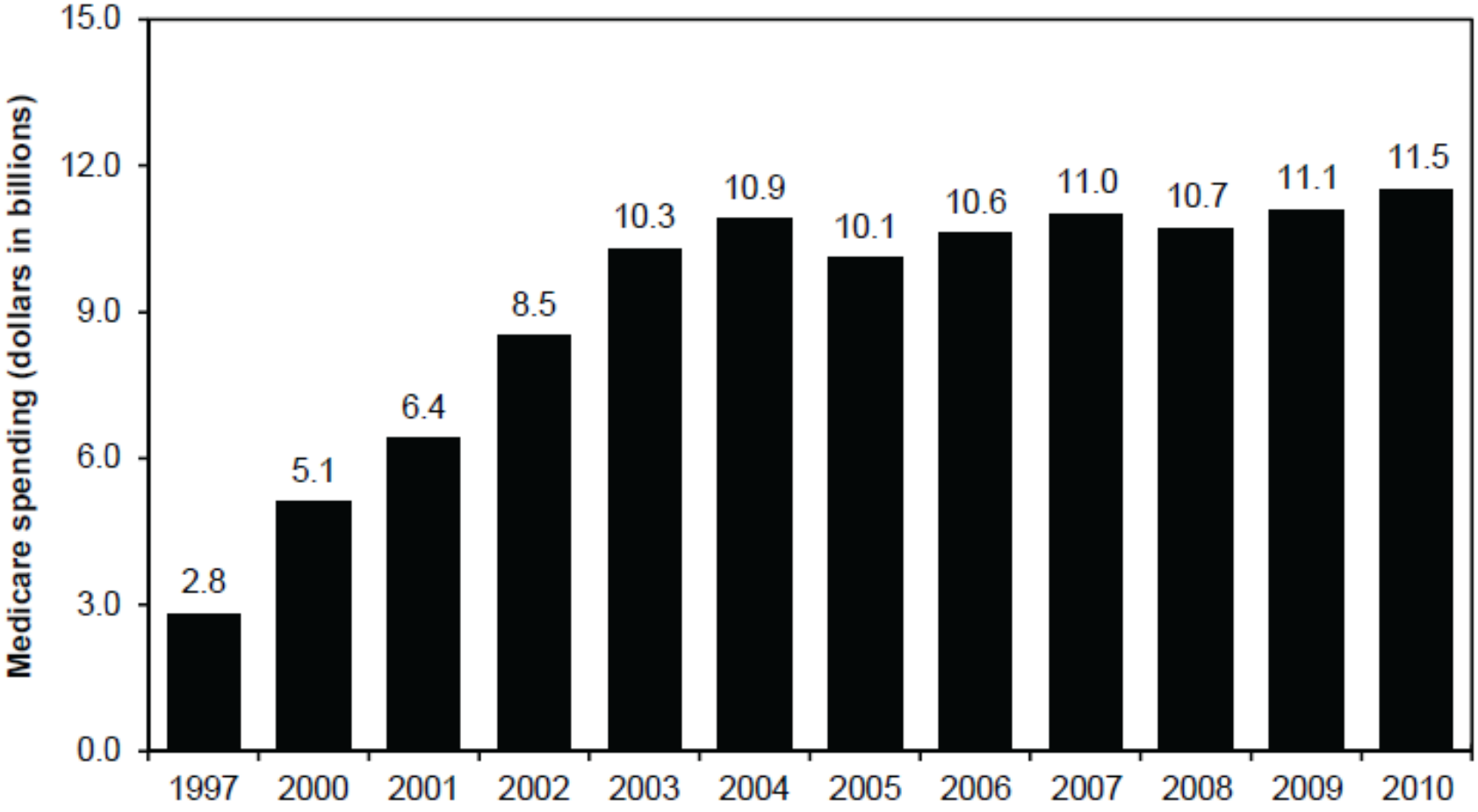


Chart 10-1. Medicare spending for Part B drugs administered in physicians' offices or furnished by suppliers



Note: Data include Part B–covered drugs administered in physicians' offices or furnished by suppliers (e.g., certain oral drugs and drugs used with durable medical equipment). Data do not include Part B–covered drugs furnished in hospital outpatient departments or dialysis facilities.

Source: MedPAC analysis of Medicare claims data.

Themes for payment reform

- Episode based payment/global fees
  - Shift risk: Make decider more prudent
- New payment to substitute for volume
  - Patient centered medical home
  - Value based modifiers/Quality scores
  - Disintermediation
- Eliminate certain services
  - “Choosing wisely”
- Some harder things . . .

PAYMENT

By Peter B. Bach, Joshua N. Mirkin, and Jason J. Luke

Episode-Based Payment For Cancer Care: A Proposed Pilot For Medicare

What occurs in *episode based payment*?

- Provider (e.g. oncologist) given single payment for the care of a patient during an 'episode of care'
- Puts provider at risk for 'performance' – appropriate utilization during episode
- Different from fee-for-service which has no such risk
- Different from 'capitation', which includes an insurance risk
- Works when there are 'competitive' approaches

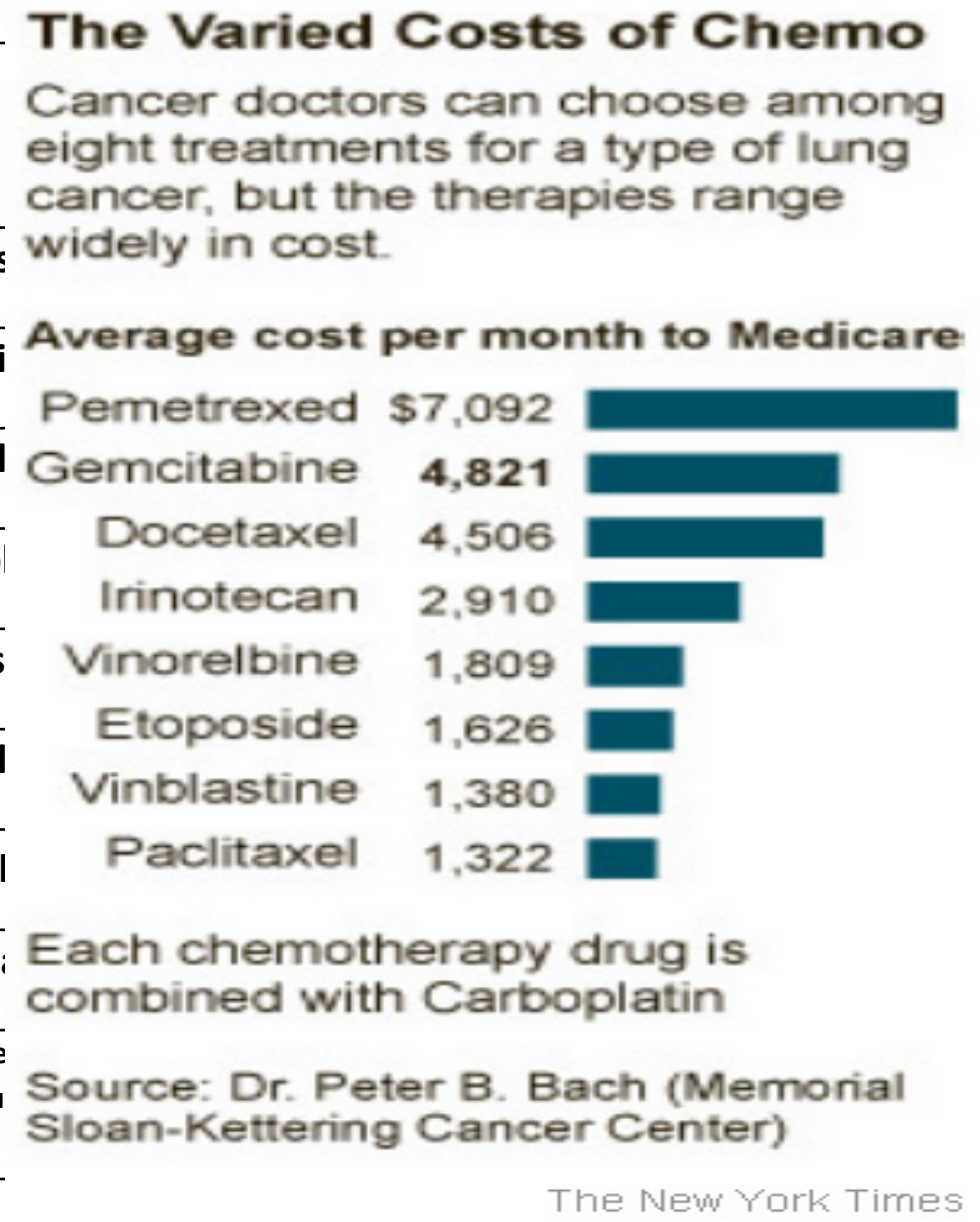
Guidelines for Metastatic Non-Small Cell Lung Cancer

	NCCN (2009)	ACCP (2007)	CCO (2009)	Alberta (2009)	Australian (2004)	NICE (2009)
Pemetrexed/Cisplatin	X	X	X	X	-	X
Gemcitabine/Cisplatin	X	X	X	X	X	X
Docetaxel/Cisplatin	X	X	X	X	X	X
Irinotecan/Cisplatin	X	X	X	X	X	-
Vinorelbine/Cisplatin	X	X	X	X	X	X
Etoposide/Cisplatin	X	X	X	X	X	-
Vinblastine/Cisplatin	X	X	X	X	X	-
Paclitaxel/Cisplatin	X	X	X	X	X	X

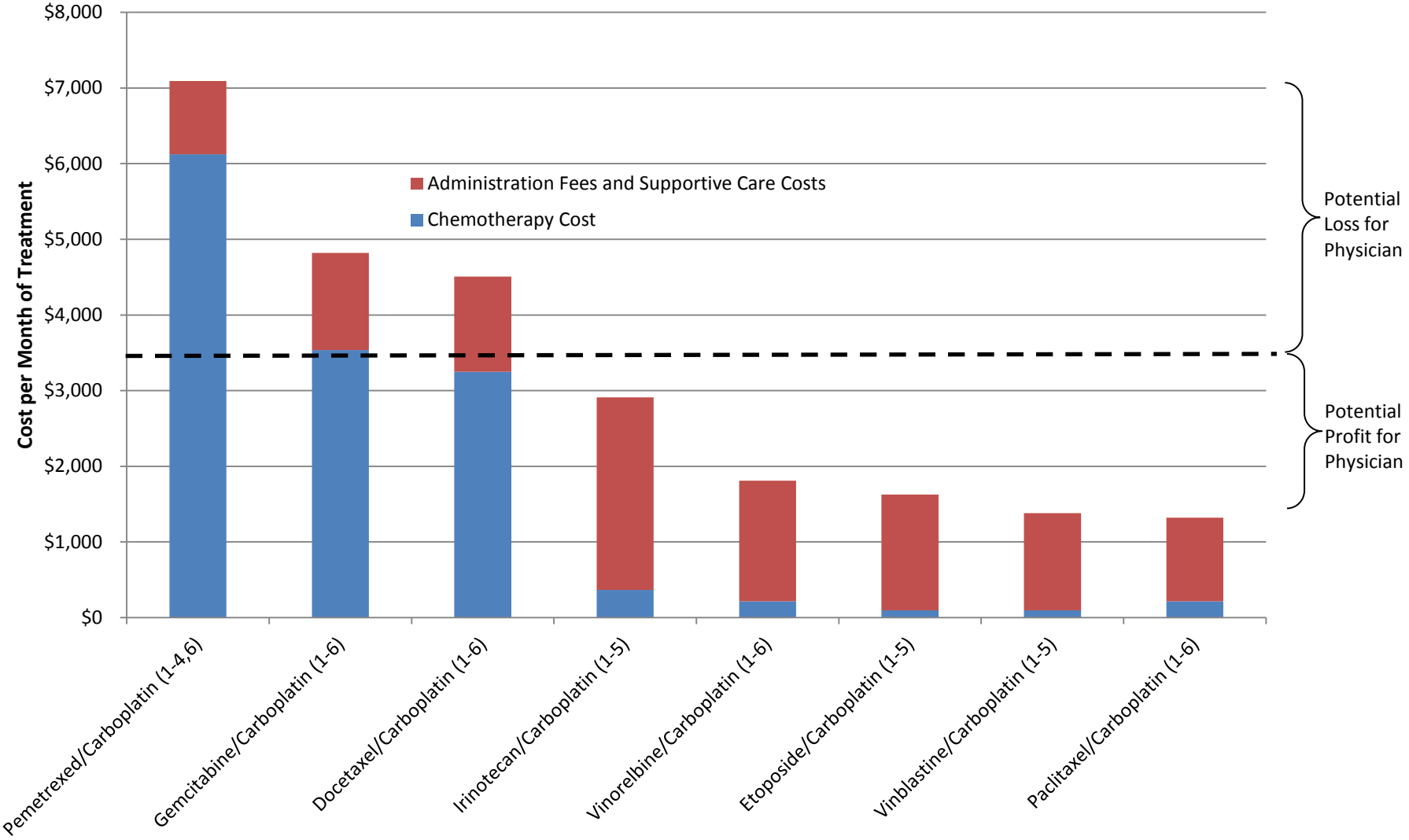
Metastatic Non-Small Cell Lung Cancer

Name		Total Cost (12 Weeks)	Monthly Cost
Pemetrexed/Cis	91	$19,594.13	$7,073.69
Gemcitabine/Ci	35	$13,303.24	$4,802.61
Docetaxel/Cispl	00	$11,647.20	$4,204.77
Irinotecan/Cispl	40	$7,984.63	$2,882.54
Vinorelbine/Cis	53	$4,929.03	$1,779.43
Etoposide/Cispl	36	$4,453.86	$1,607.89
Vinblastine/Cisp	41	$3,741.38	$1,350.68
Paclitaxel/Cispl	17	$3,578.70	$1,291.95

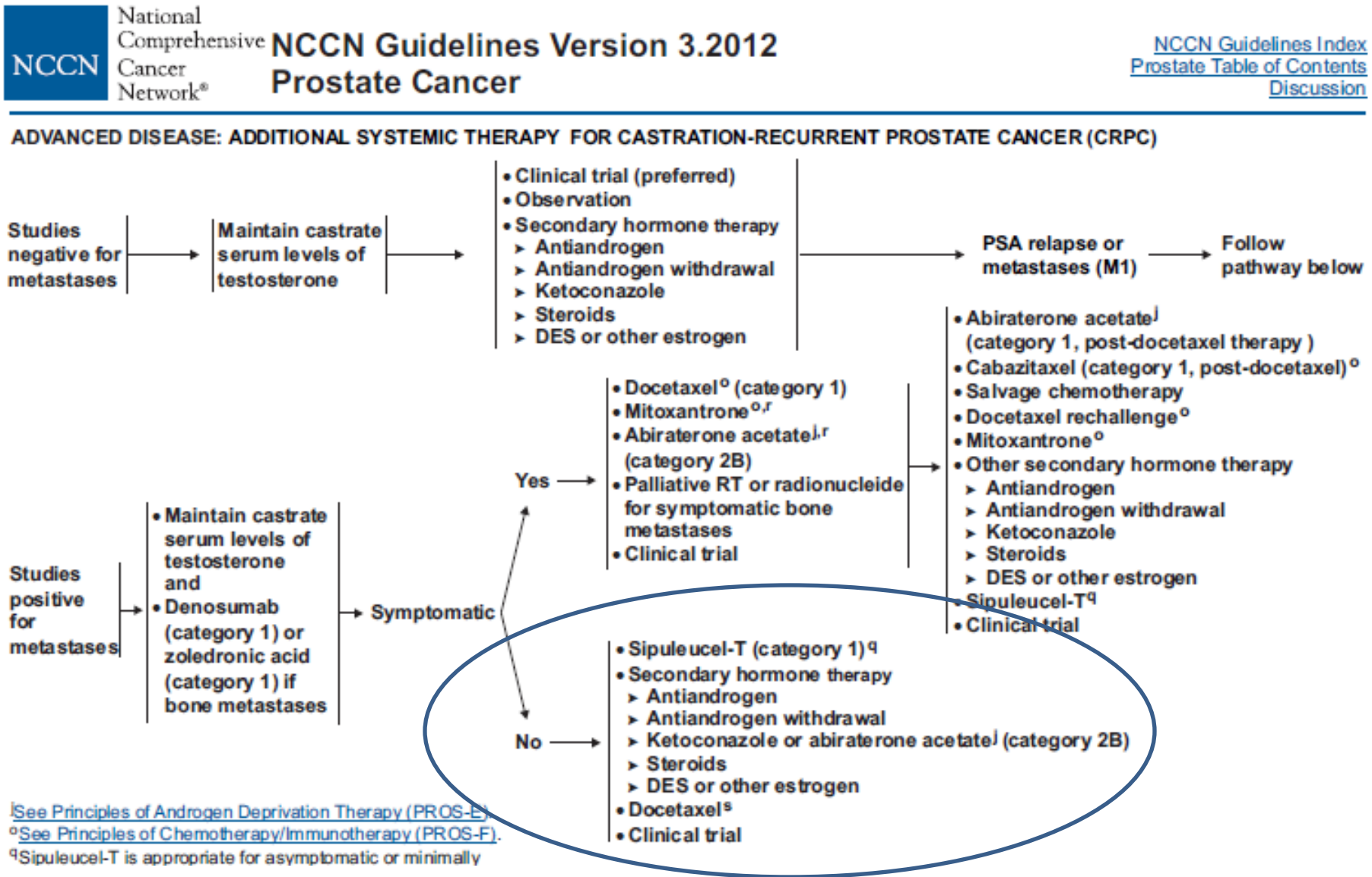
[1] National Comprehe... cer Care Ontario (CCO), [4] Alberta Health Services, [5] Au... e for Health and Clinical Excellence (NICE)



What incentive does oncologist face? (lung example)

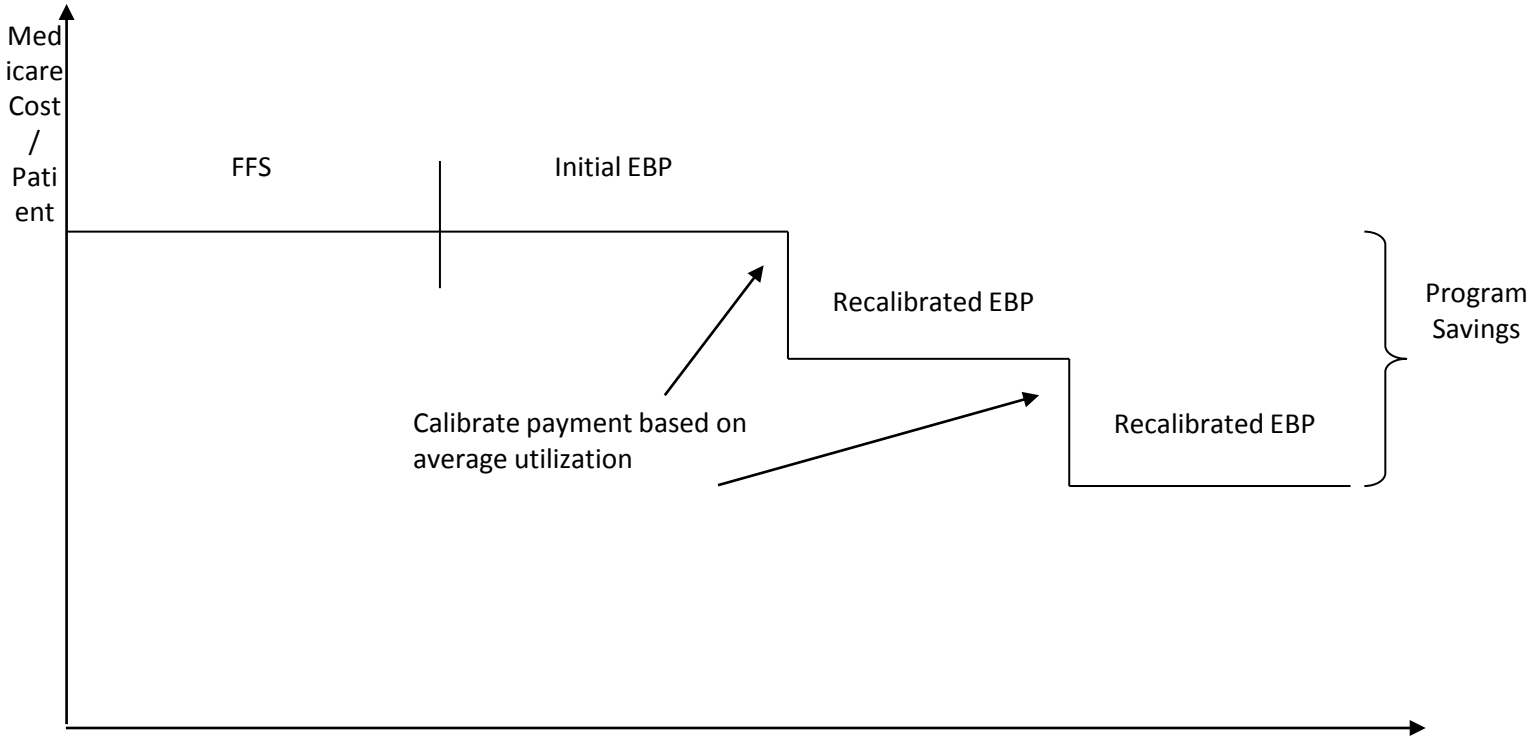


Metastatic Hormone Refractory Prostate Cancer



Drug (does not include support or adminstration)	Monthly Cost
Sipuleucel-T (Provenge)	$ 37,668
Docetaxel (Generic)	$ 772
Anti-Androgens: Flutamide (Generic)	$ 237
Anti-Androgens: Bicalutamide (Casodex)	$ 552
Anti-Androgens: Bicalutamide (Generic)	$ 43
Anti-Androgens: Nilutamide (Nilandron)	$ 749
Antiandrogen withdrawal	$ -
Ketoconazole	$ 201
Arbiraterone acetate (Zytiga)	$ 5,778
Steroids	*negligible*
Diethylstilbestrol (or other estrogen)	*negligible*

Why bundling saves money



What are the challenges to this

- Accounting – how big should the payment be?
  - Easier if you stay narrow: focus on drugs alone
  - Staying narrow leaves behind opportunities in areas like reduced hospitalization
- When are treatments substitutes?
  - The lung cancer regimens have been largely compared
  - Others have not (e.g. XRT vs RP for early prostate ca)
- Keeping people from thinking this is least costly alternative payment

New and different payments

- Patient Centered Medical Home
  - Add-on payments for coordination
  - Eventually ‘gain share’ back to primary doctor for preventing adverse events (e.g. ER visits)
- Quality and other modifiers
  - Quality measures from ASCO (QOPI), first draft out for PPS exempt hospitals
- Disintermediation
  - UHC demonstration, brown-bagging, CAP

Disintermediation (take out the profit)

- United Healthcare Demonstration
  - Pay (essentially) 'invoice' prices for cancer drugs
    - Doctors get management fee, no profits from drugs themselves
  - Brownbag: some private payers having drugs shipped to patients rather than doctors
  - CAP – the competitive acquisition program
    - Part of the 2003 Medicare Modernization Act
    - Failed for administrative reasons
    - Seen a resurgence in interest in a pared down form

COMPETITIVE ACQUISITION OF OUTPATIENT DRUGS AND BIOLOGICALS[307]

SEC. 1847B. [42 U.S.C. 1395w–3b] (a) IMPLEMENTATION OF COMPETITIVE ACQUISITION.—

(1) IMPLEMENTATION OF PROGRAM.—

(A) IN GENERAL.—The Secretary shall establish and implement a competitive acquisition program under which—

(i) competitive acquisition areas are established for contract award purposes for acquisition of and payment for categories of competitively biddable drugs and biologicals (as defined in paragraph (2)) under this part;

(ii) each physician is given the opportunity annually to elect to obtain drugs and biologicals under the program, rather than under section 1847A; and

(iii) each physician who elects to obtain drugs and biologicals under the program makes an annual selection under paragraph (5) of the contractor through which drugs and biologicals within a category of drugs and biologicals will be acquired and delivered to the physician under this part. This section shall not apply in the case of a physician who elects section 1847A to apply.

Chart 10-2. Top 10 Part B drugs administered in physicians' offices or furnished by suppliers, by share of expenditures, 2010

Drug name	Clinical indications	Allowed Charges (in millions)	Competition	Percent of spending	Rank in 2009
Ranibizumab	Age-related macular degeneration	$1,119	Sole source	9.7%	2
Rituximab	Lymphoma, leukemia, rheumatoid arthritis	$849	Sole source	7.4	1
Bevacizumab	Cancer, age-related macular degeneration	$766	Sole source	6.6	3
Infliximab	Rheumatoid arthritis, Crohn's disease	$647	Sole source	5.6	4
Pegfilgrastim	Cancer	$553	Sole source	4.8	5
Darbepoetin alfa	Anemia	$374	Sole source	3.2	6
Epoetin alfa	Anemia	$327	Multisource biologic	2.8	7
Pemetrexed	Lung cancer	$276	Sole source	2.4	not listed
Docetaxel	Cancer	$269	Sole source*	2.3	9
Tacrolimus	Prevent organ transplant rejection	$259	Multisource	2.2	10

Note: Data do not include Part B drugs furnished in hospital outpatient departments or dialysis facilities. Allowed charges include Medicare program payments and beneficiary cost-sharing. Clinical indications may include on- and off-label use. *Docetaxel was sole source in 2009, but generic versions have since become available.

Source: MedPAC analysis of Medicare claims data from CMS and information on drug and biologic approval information from the Food and Drug Administration website (http://www.fda.gov).

Choosing Wisely®
An initiative of the ABIM Foundation

Eliminate certain services

Don't use cancer-directed therapy for patients with solid tumors with the following characteristics: low performance status (3 or 4), no benefit from prior evidence-based interventions, not eligible for a clinical trial, and no strong evidence supporting the clinical value of further anticancer treatment.

Don't perform PET, CT, and radionuclide bone scans in the staging of early prostate cancer at low risk for metastasis.

Don't perform PET, CT, and radionuclide bone scans in the staging of early breast cancer at low risk for metastasis.

Don't perform surveillance testing (biomarkers) or imaging (PET, CT, and radionuclide bone scans) for asymptomatic individuals who have been treated for breast cancer with curative intent.

Don't use white cell stimulating factors for primary prevention of febrile neutropenia for patients with less than 20% risk for this complication.

ASCO
American Society of Clinical Oncology

Five Things Physicians and Patients Should Question

Can it be this easy?

- A waste would be 'zero effect'
  - Here are the data for prostate ca staging 'low risk'

TABLE 2. *Bone scan results in newly diagnosed PC by stage*

References	No. Pts	No. Pos Scans	No./Total No. Pts With Pos Scans (%)	
			Localized	Locally Advanced
Chybowski et al[12]	521	71	26/405 (6.4)	45/116 (38.7)
Vijayakumar et al[15]	90	17	2/47 (4.2)	1/12 (8.3)
Gleave et al[19]	490	28	5/369 (1.3)	23/121 (19)
Ataus et al[27]	160	51	13/95 (13.6)	59/65 (90.7)
Bruwer et al[28]	404	206	17/148 (11.4)	188/352 (53.4)
Wymenga et al[33]	363	111	13/143 (9)	92/208 (44.2)
All studies (%, 95% CI)	2,028	484	76/1,207 (6.2, 5.0–7.8)	408/874 (46.6, 43.3–50.1)

TABLE 3. *Bone scan results in newly diagnosed PC by Gleason score*

References	No. Pts	No. Pos Scans	No./Total Pts With Pos Bone Scans (%)	
			Gleason 7 or Less	Gleason 8 or Greater
Lin et al[29]	270	24	12/243 (4.9)	12/51 (23.5)
Lee et al[31]	631	88	24/411 (5.8)	46/155 (29.6)
Total No. (%, 95% CI)	901	112	36/654 (5.5, 3.9–7.5)	58/206 (28.1, 22.1–34.8)

American Society of Clinical Oncology

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Five Things Physicians and Patients Should Question

- Bone Scans
  - Skeletal metastases were detected in 0.5% of women with Stage I disease and 2.4% of women with stage II disease, across 9 studies conducted from 1985-1995.
- FDG-PET
  - PET scan alone identified metastatic disease in 2/189 (1%) of women in one 2006 study.
- PET/CT
  - 2/83 (2.4%) women with stage I-III disease in a 2006 study were confirmed to have metastatic disease.

Baseline Staging Tests in Primary Breast Cancer: Practice Guideline Report # 1-14: Members of the Breast Cancer Disease Site Group. 2003. Available at: http://www.cancercare.on.ca/common/pages/UserFile.aspx?serverId=6&path=/File%20Database/CCO%20 Files/PEBC/pebc1-14f.pdf. Accessed December 20, 2010.

Carr CE, Conant EF, Rosen MA, et al. The impact of FDG PET in the staging of breast cancer [abstract]. J Clin Oncol 2006;24(Suppl 18):Abstract 530.

Khan QJ, O'Dea AP, Dusing R, et al. Integrated FDG-PET/ CT for initial staging of breast cancer [abstract]. J Clin Oncol 2007;25(Suppl 18):Abstract 558.

Now for the hard questions . . .

- Why can't we all get along?
  - All payment modifications depend on some consensus on quality or standard of care
- How large could shifts be from payment changes, and should we worry?
- Can we go from eliminating 'waste' to reducing 'marginally beneficial'?

News & Events

FDA NEWS RELEASE

For Immediate Release: Nov. 18, 2011
Media Inquiries: Karen Riley, 301-796-4674, karen.riley@fda.hhs.gov
Consumer Inquiries: 888-INFO-FDA

FDA Commissioner announces Avastin decision

Drug not shown to be safe and effective in breast cancer patients

After the accelerated approval of Avastin for breast cancer, the drug's sponsor, Genentech, completed two additional clinical trials and submitted the data from those studies to the FDA. These data showed only a small effect on tumor growth without evidence that patients lived any longer or had a better quality of life compared to taking standard chemotherapy alone – not enough to outweigh the risk of taking the drug.

FDA's Center for Drug Evaluation and Research, which is responsible for the approval of this drug, ultimately concluded that the results of these additional studies did not justify continued approval and notified Genentech it was proposing to withdraw approval of the indication.

http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm280536.htm

CHEMOTHERAPY REGIMENS FOR RECURRENT OR METASTATIC BREAST CANCER[1]

Preferred Single Agents

Anthracyclines
- Doxorubicin
- Epirubicin
- Pegylated liposomal doxorubicin

Taxanes
- Paclitaxel
- Docetaxel
- Albumin-bound paclitaxel

Anti-metabolites
- Capecitabine
- Gemcitabine

Other microtubule inhibitors
- Vinorelbine
- Eribulin

Other Single Agents
- Cyclophosphamide
- Mitoxantrone
- Cisplatin
- Etoposide (po) (category 2B)
- Vinblastine
- Fluorouracil CI
- Ixabepilone

Preferred Agents With Bevacizumab[2]
- Paclitaxel

Preferred Chemotherapy Combinations
- CAF/FAC (cyclophosphamide/doxorubicin/fluorouracil)
- FEC (fluorouracil/epirubicin/cyclophosphamide)
- AC (doxorubicin/cyclophosphamide)
- EC (epirubicin/cyclophosphamide)
- AT (doxorubicin/docetaxel; doxorubicin/paclitaxel)
- CMF (cyclophosphamide/methotrexate/fluorouracil)
- Docetaxel/capecitabine
- GT (gemcitabine/paclitaxel)

Other Combinations
- Ixabepilone + capecitabine (category 2B)

Preferred First-line Agents For HER2-positive Disease
- Pertuzumab + trastuzumab + docetaxel (category 1)
- Pertuzumab + trastuzumab + paclitaxel

Other First-line Agents For HER2-positive Disease

Trastuzumab with:
- Paclitaxel ± carboplatin
- Docetaxel
- Vinorelbine
- Capecitabine

Agents For Trastuzumab-exposed HER2-positive Disease
- Lapatinib + capecitabine
- Trastuzumab + capecitabine
- Trastuzumab + lapatinib (without cytotoxic therapy)
- Trastuzumab + other agents

A Government that doesn't know whom to believe

(B) In subparagraph (A), the term "medically accepted indication", with respect to the use of a drug, includes any use which has been approved by the Food and Drug Administration for the drug, and includes another use of the drug if—

(i) the drug has been approved by the Food and Drug Administration; and

(ii)(I) such use is supported by one or more citations which are included (or approved for inclusion) in one or more of the following compendia: the American Hospital Formulary Service-Drug Information, the American Medical Association Drug Evaluations, the United States Pharmacopoeia-Drug Information, and other authoritative compendia as identified by the Secretary, unless the Secretary has determined that the use is not medically appropriate or the use is identified as not indicated in one or more such compendia, or

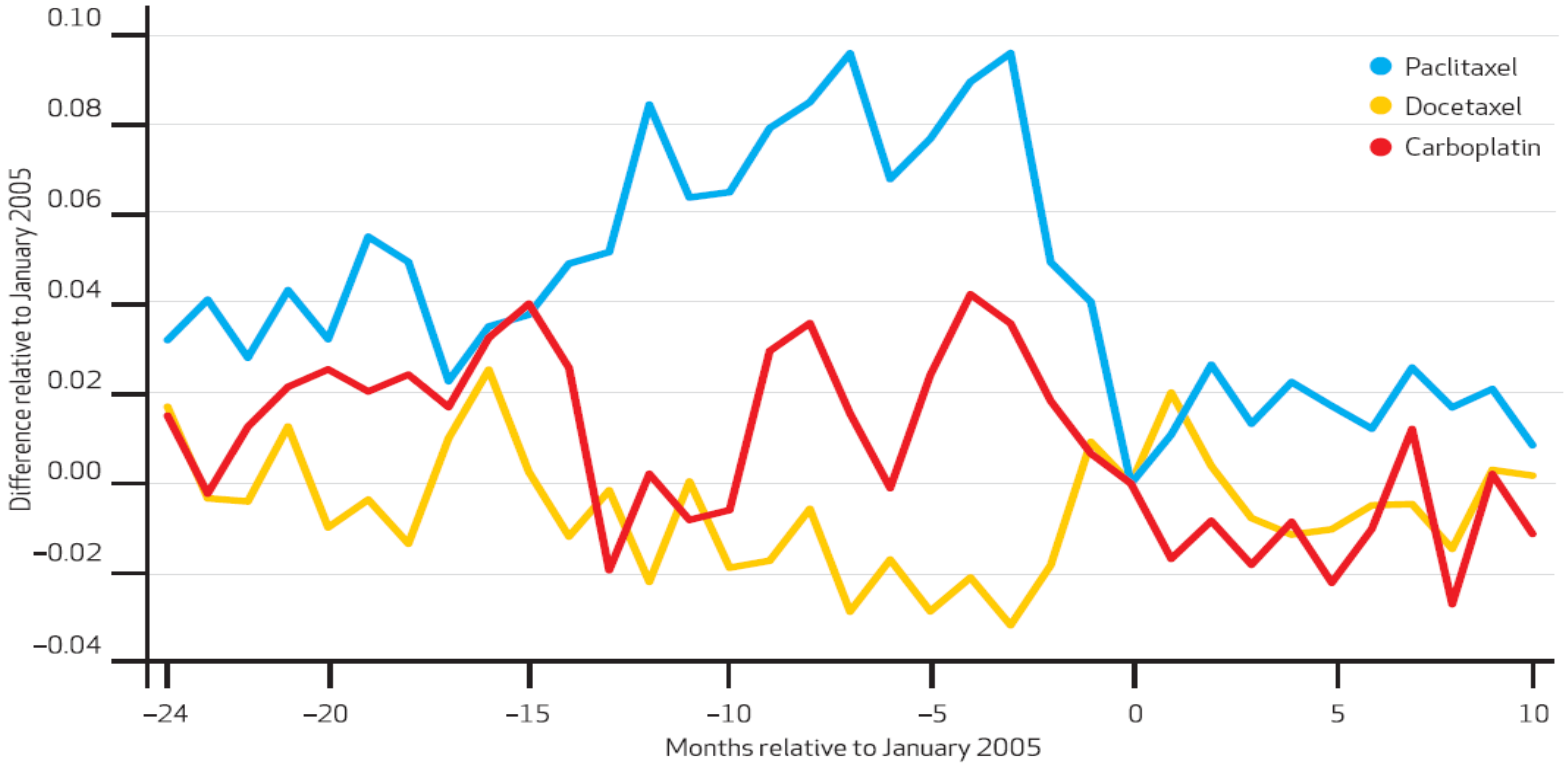
Dispute over what is best – Breast cancer

		USPSTF 2009 Update	American Cancer Society 2003 and others	Current BCS HEDIS Measure
Age to Begin Routine Screening		50 years	40 years	40 years
Age to Stop Routine Screening		74 years	Not specified	69 years
Screening Method and Frequency	**Mammography**	Yes (B Rec) Biennial	Yes Annual	Yes At least once in past 2 years
	Breast Self-Exam	No (D Rec)	Optional for age ≥20	No
	Clinical Breast Exam	Insufficient Evidence	Yes About every 3 years age 20s-30s and every year for age ≥40	No
	MRI	Insufficient Evidence	Yes for certain high-risk women	No

Payment change = Practice change

EXHIBIT 4

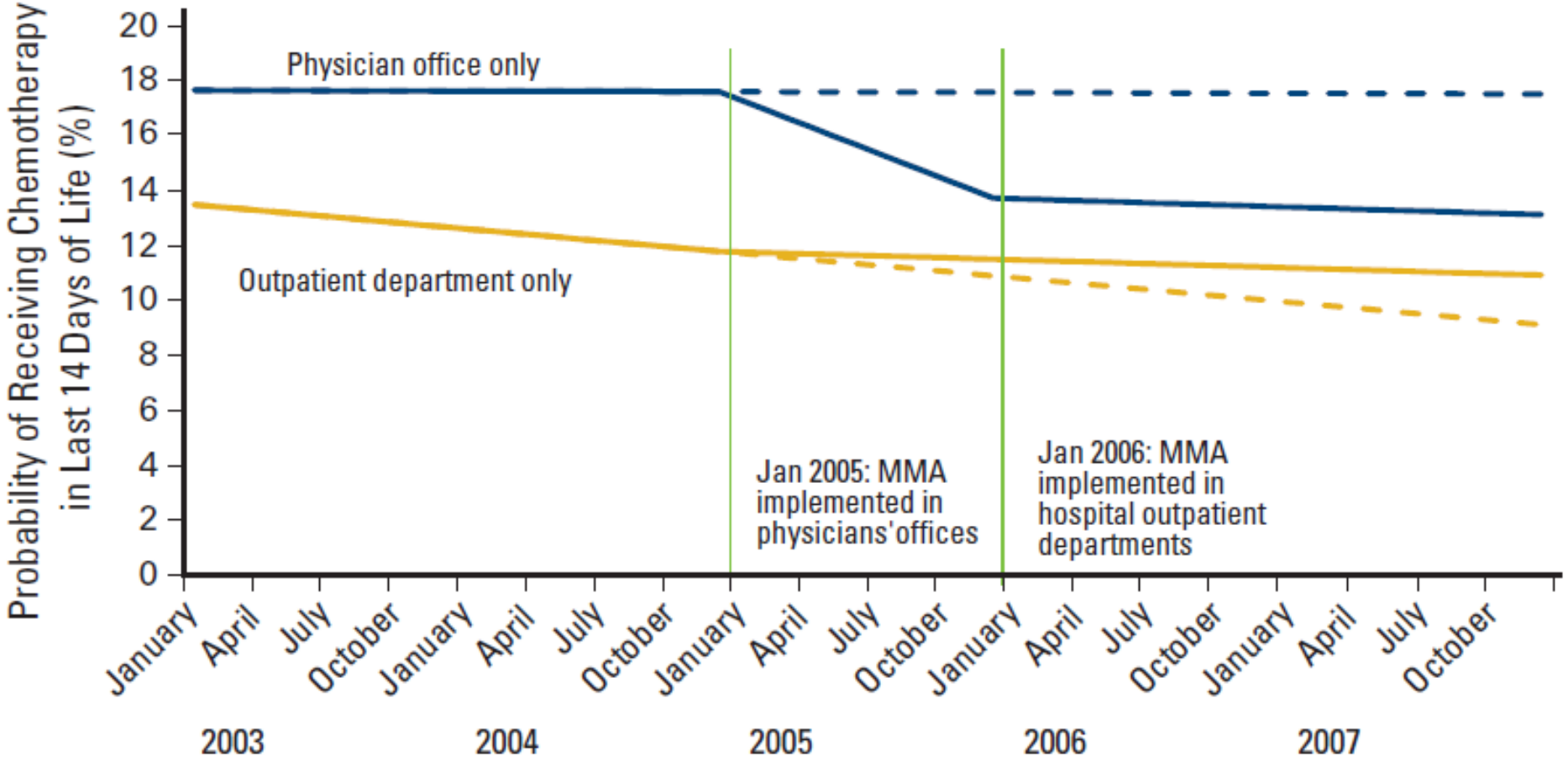
Change In The Use Of Paclitaxel, Docetaxel, And Carboplatin, By Month Of Diagnosis Relative To The January 2005 Payment Change



Impact of Payment Reform on Chemotherapy at the End of Life

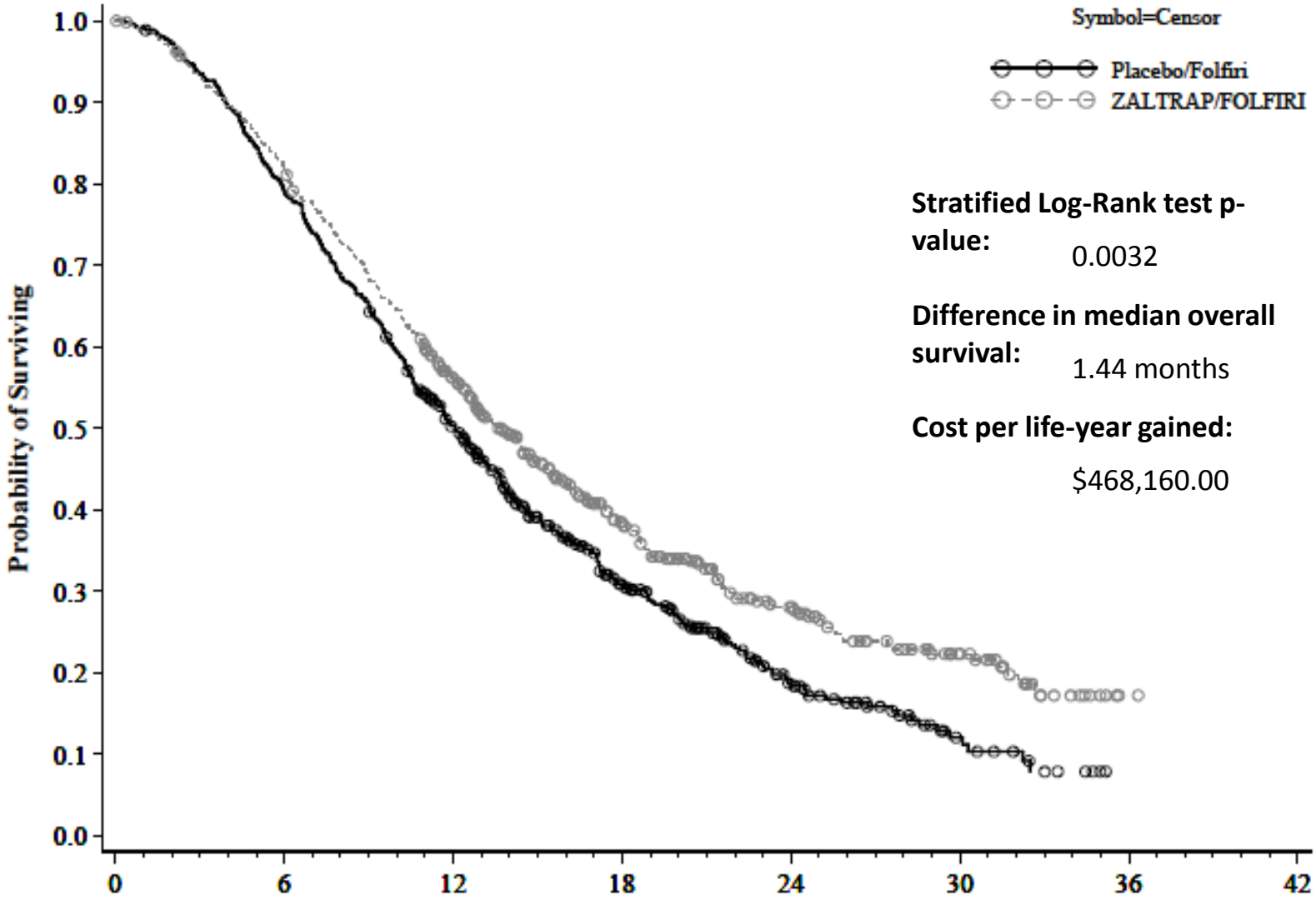
A

By Carrie H. Colla, PhD, Nancy E. Morden, MD, MPH, Jonathan S. Skinner, PhD, J. Russell Hoverman, MD, PhD, and Ellen Meara, PhD



Colla CH, Morden NE, Skinner JS, Hoverman JR, Meara E. Impact of payment reform on chemotherapy at the end of life. Journal of oncology practice / American Society of Clinical Oncology. 2012;8(3 Suppl):e6s-e13s.

Costly, small benefit



Stratified Log-Rank test p-value: 0.0032

Difference in median overall survival: 1.44 months

Cost per life-year gained: $468,160.00

Number at Risk

Placebo	614	485	286	131	51	14
ZALTRAP	612	498	311	148	75	33

Thank you