American Society of Hematology
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2015 American Society of Hematology / American Society of Clinical Oncology

Hematology and Oncology Carrier Advisory Committee (CAC) Network Meeting

July 9 – 10, 2015

American Society of Clinical Oncology Headquarters
2318 Mill Road, Suite 800
Alexandria, Virginia
571-483-1300

8th Floor Conference Center

2015 ASH/ASCO Carrier Advisory Committee (CAC)
Network Meeting Agenda

Friday, July 10, 2015
8:00 AM – 3:00 PM ET

7:30 AM	**Breakfast**
8:00 AM	**Welcome and Introductions** Steven Allen, MD *ASH Co-Chair* Roscoe Morton, MD *ASCO Co-Chair*
8:15 AM	**Molecular Diagnostics – Coverage with Evidence Development/ Data Development, Role of FDA, Panels** Elaine Jeter, MD *Palmetto GBA* Dane Dickson, MD *MED-C*
9:15 AM	**Medicare Oncology Care Model – Practice Implications and Potential Pitfalls** Ronald Kline, MD *Center for Medicare and Medicaid Innovation*
10:15 AM	**Morning break**
10:30 AM	***Breakout session – Ways to Improve the CAC Process in Your Region***
11:20 AM	**ICD-10 Transition Issues** Arthur Lurvey, MD, FACP, FACE *Noridian Healthcare Solutions*
11:50 PM	**Infusions/DME/Orals** Richard (Dick) Whitten, MD, MBA, FACP *Noridian Healthcare Solutions*
12:30 PM	**Networking Lunch**
1:00 PM	**Biosimilars – FDA Interchangeability Coverage** John Warren *McDermott+ Consulting*
2:00 PM	**Open Forum** *Panel: Contractor Medical Directors*
2:45 PM	**Meeting Wrap-up** Steven Allen, MD Roscoe Morton, MD *CAC Meeting Co-Chairs*
3:00 PM	**Adjournment**

Welcome and Introductions

2015 ASH/ASCO CAC Network Meeting
Attendee List

Abbreviations

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COP = ASH Committee on Practice
CPC = ASCO Clinical Practice Committee
RS = ASH Reimbursement Subcommittee

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Molecular Diagnostics

Elaine K Jeter, MD is a Palmetto GBA medical director and director of the Molecular Diagnostic (MolDX) project in J11. She is a graduate of the Medical University of South Carolina (MUSC) and is board certified in Clinical and Anatomic Pathology, and Blood Banking/Transfusion Medicine. She received her undergraduate degree from the State University of New York at Geneseo and her master's from the University of South Carolina. Elaine was an academic physician at MUSC for ten years and in the private practice of pathology in Columbia, SC for a number of years. She has been with Palmetto GBA for more than 10 years.

Dane Dickson, M.D., CEO, MED-C

Dr. Dickson graduated in 1992 from the University of Utah with a BA in chemistry and a minor in Mandarin Chinese. He attended medical school at the University of Utah graduating in 1996 with honors. Subsequently, he completed an internal medicine residency at Washington University in St. Louis in 1999. He specialized at the Huntsman Cancer Institute at the University of Utah.

In 2001, he started a solo practice (Teton Oncology) in Rexburg, Idaho, which eventually encompassed over 8,000 square miles of Idaho and Wyoming. In 2010, his small group practice was acquired by a local hospital, and Dr. Dickson spearheaded the development of the Teton Cancer Institute and served as its Medical Director until 2014.

Also in 2001, he started the Summarius Corporation, a medical informatics company specializing in clinical trial review and development of OIG compliant materials for education and training. Summarius developed revolutionary methods of summarizing and presenting clinical trials and revised the complete training and educational materials for fortune 100 pharmaceutical companies.

In 2012, he started working with Noridian LLC, a Medicare Administrative Contractor, as an oncology subject matter expert, and then in 2013 he accepted, as a contractor, the position of Director of Clinical Science for the Molecular Diagnostic Program (MolDX) with Palmetto GBA (another CMS MAC contractor). In this capacity, he advises Palmetto on policy for implementation of molecular testing and personalize medicine policy from a clinical perspective.

In 2014, multiple groups recognized a substantial unmet need in the advancement of personalized medicine, and the Molecular Evidence Development Consortium (MED-C) was conceived. It was vetted in various groups where it was highly acclaimed and warmly received by clinicians, laboratories, payors, industry, pharma, patient groups and regulators. In 2015, after extensive searching by and finding no existing group that could implement this unmet need, the non-profit public charity (MED-C.org) was formed. Its mission is to advance personalized medicine through data collection and education. Its strength is brining all the major stakeholders together to work in a shared and scientific manner. MED-C continues to gain traction as a "transformative effort that will dramatically advance health care in the world." Dr. Dickson has been asked to be its CEO.

Dr. Dickson has been an active member of the American Society of Clinical Oncology (ASCO). He served on ASCO's Clinical Practice Committee from 2002-2005. In 2011, he helped revive the Idaho Society of Clinical Oncology (ISCO) and served as President from 2012-2014. He was elected to the executive sub-committee of the ASCO State Affiliate Council in 2013 and in 2014.

On a personal note, Dr. Dickson is the second oldest in a family of eight boys. He is happily married and has three sons ranging from 14 to 19. He enjoys backpacking/hiking (especially in the Wind River Range of Wyoming), running, biking and snow skiing. He is active in his community serving as an advisor to the President of Brigham Young University Idaho as well as being a faithful member of the Church of Jesus Christ of Latter-day Saints.

https://www.med-c.org/board/

Coverage with Data Development

PALMETTO GBA
A CELERIAN GROUP COMPANY

Elaine K Jeter, MD

Coverage with Data Development (CDD)

SSA 1862(a)(1)(e):

- CMS authority
- NCD; CED is subcomponent of NCD

SSA 1862(a)(1)(a):

- Contractor's authority
- LCDs - "R&N" – standard coverage requires CU
- CDD – Palmetto GBA's approach for limited CU in high frequency diseases that would require 10-20 yrs to accrue prospective utilization data

MolDx: ConfirmMDx Prostate Cancer Genetic Assay - L35368

- Developed by MDxHealth, Irvine, CA
- Epigenetic molecular methylation assay to reduce unnecessary repeat prostate biopsies
- Intended use: High-risk men with elevated/rising PSA or abnormal DRE, with negative for Ca, being considered for repeat bx
- Retrospective data only - ~40% repeat bx rate reduced to 4.5%

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MolDx: ConfirmMDx Prostate Cancer Genetic Assay - L35368

Criteria for coverage:

- Males aged 40 -75 years old, with previous cancer-negative prostate biopsy (transrectal) within 15 months, being considered for a repeat biopsy, and
- Previous negative prostate biopsy, >8 tissue cores, FFPE cores with 20 microns/core minimal volume available for testing, and
- Previous biopsy histology with HGPIN, proliferative inflammatory atrophy, or glandular inflammation acceptable, and
- Patient not under AS for low stage prostate CA, and
- Not previously tested by ConfirmMDx or similar test, and
- Testing ordered by physician certified via ConfirmMDx Certification and Training Registry (CTR) Program

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MolDx: Decipher® Prostate Cancer Classifier Assay – L35650

Coverage with Data Development

- To identify patients traditionally considered high risk after radical prostatectomy who can be closely followed rather than receive post-op XRT
- 22 biomarker expression assay (GenomeDX, San Diego, CA)
  - Developed by GenomeDX
  - Array technology
  - Interrogates 1.4 million RNAs
  - FFPE specimen
  - Core with highest Gleason grade

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MolDx: Decipher® Prostate Cancer Classifier Assay – L35650

Criteria for coverage:

- S/p radical prostatectomy (RP) in 60 mos; considering secondary therapy for >1 risk factor, and
- Patient achieved PSA nadir in 30 da after RP, and
- No evidence of distant mets, or neo-adjuvant tx prior to surgery, and
- Decipher performed on RP specimen, and
- Surgical path report with pT2 with a positive margin, or pT3, or rising PSA after initial nadir, and
- Testing ordered by CTR certified physician

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MolDx: Decipher® Prostate Cancer Classifier Assay – L35650

Certification and Training Registry (CTR) Program

- Ensure physicians understand limitation of test re: retrospective and heterogeneous patient populations
- Inform physicians on safe use
- Avoid missing clinically relevant development of mets or cancer related deaths in low risk patients
- to maintain secure registry database,
- Immediately report any distant mets or prostate cancer - related deaths
- Publish findings regardless of outcomes

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MolDx: Prolaris™ Prostate Cancer Genomic Assay – L35629

- RNA based, 31 cell cycle gene assay; FFPE prostate cancer blocks; numerical score
- Intended use - early stage, needle biopsy proven prostate cancer who can be managed conservatively, rather than definitive surgery or XRT
- Based on retrospective data

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MolDx: Prolaris™ Prostate Cancer Genomic Assay – L35629

- NCCN & AUA guidelines recommend normograms to determine patients at risk for mets
  - Has led to high cure rates BUT many men are still over treated for early stage prostate cancer
  - Physicians struggle to know who can safely be observed vs subgroup that needs more aggressive tx
- Prospective data takes decades to develop & patient accrual hard in US in conservatively managed arm
- CU extrapolated from retrospective data

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MolDx: Prolaris™ Prostate Cancer Genomic Assay – DL35629

Coverage criteria:

- Needle bx with adenoCa of prostate, and FFPE specimen with >0.5 mm of cancer
- Stage defined as:
  - Very-low risk disease- T1c, Gleason Score ≤6, PSA ≤10 ng/mL ,<3 prostate cores with tumor, ≤50% CA in any core & PSA density of <0.15 ng/mL/g), **or**
  - Low risk Disease - (T1-T2a, Gleason Score ≤ 6 & PSA ≤10 ng/mL), **and**
- Life expectancy of >10 yrs
- Patient would be eligible for RP or XRT

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MolDx: Prolaris™ Prostate Cancer Genomic Assay – L35629

Coverage criteria:

- Test results used to determine conservative mgmt vs definitive therapy
- Physician certified by CTR
- Patient monitored for disease progression according to established standard of care, and
- Physician must report development of mets or prostate Ca deaths in patients not treated definitively who were deemed low risk by this assay

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MolDX: Genomic Health™ Oncotype DX® Prostate Cancer Assay - DL36153

Coverage with Data Development:

- 17 gene RT-PCR assay
- Indicated for men considered candidates for AS:
  - Needle bx with no mets or LN involvement
  - Very low-, or low-risk prostate cancer with 10-20 yr life expectancy
  - Physician CTR certified
  - Patient treated according to test result
  - Patient registry

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What Have We Learned

- Many assays are NOT ready for prime time
  - Technology is way ahead of clinical utility
- Labs have to adapt to evidence standard
  - Evidence standard hasn't changed but expectation of evidence has
- Every detail regarding prospective data collection must be addressed in LCD, and consistent from assay to assay
- Palmetto GBA looks to professional associations to assess evidence and add to guidelines when evidence for standard of care

13

Questions?
Elaine.jeter@palmettogba.com

14

MED-C

Molecular Evidence Development Consortium

ASCO/ASH Carrier Advisory Meeting

July, 2015

ASCO HeadQuarters

Overview

MED-C

Objectives

- A frank review of the scientific status of molecular medicine
- Level of evidences behind NGS (and much of personalized medicine)
- Lack of standards in testing,
  - LDTs
  - False Positives
- FDA Role

The Science Behind Molecular Medicine

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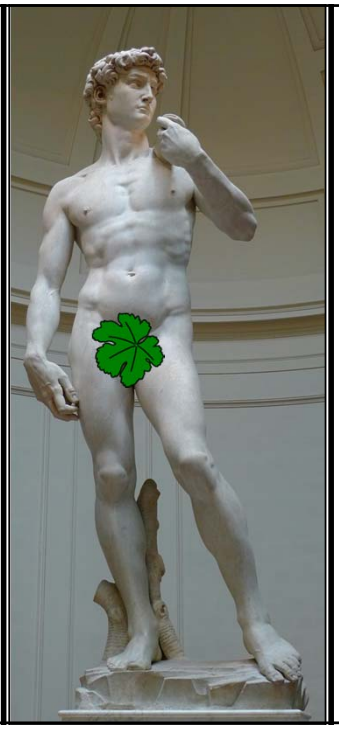
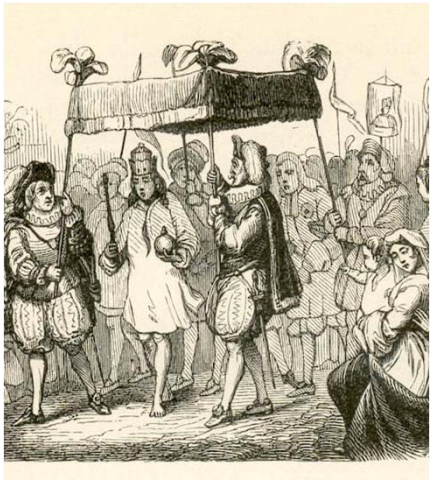


Emperor's New Clothes

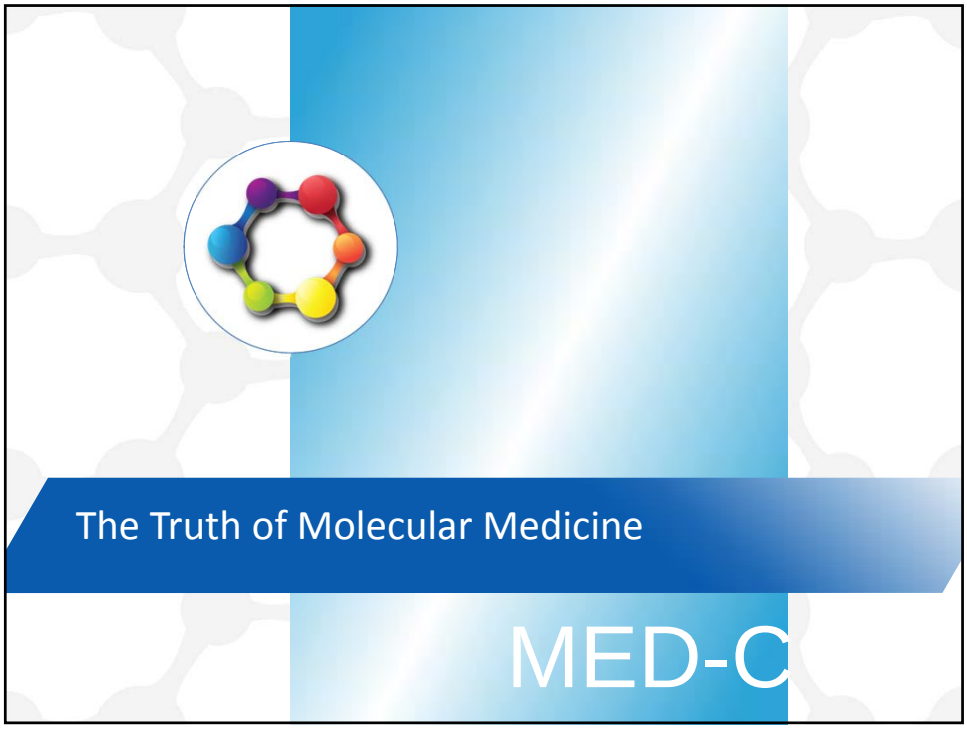
- Hans Christian Anderson
- Emperor – liked new clothes
- Weavers said would make him an outfit
- Cloth so fine that could not be seen by those who were
  - Unworthy of their office
  - Incredibly stupid

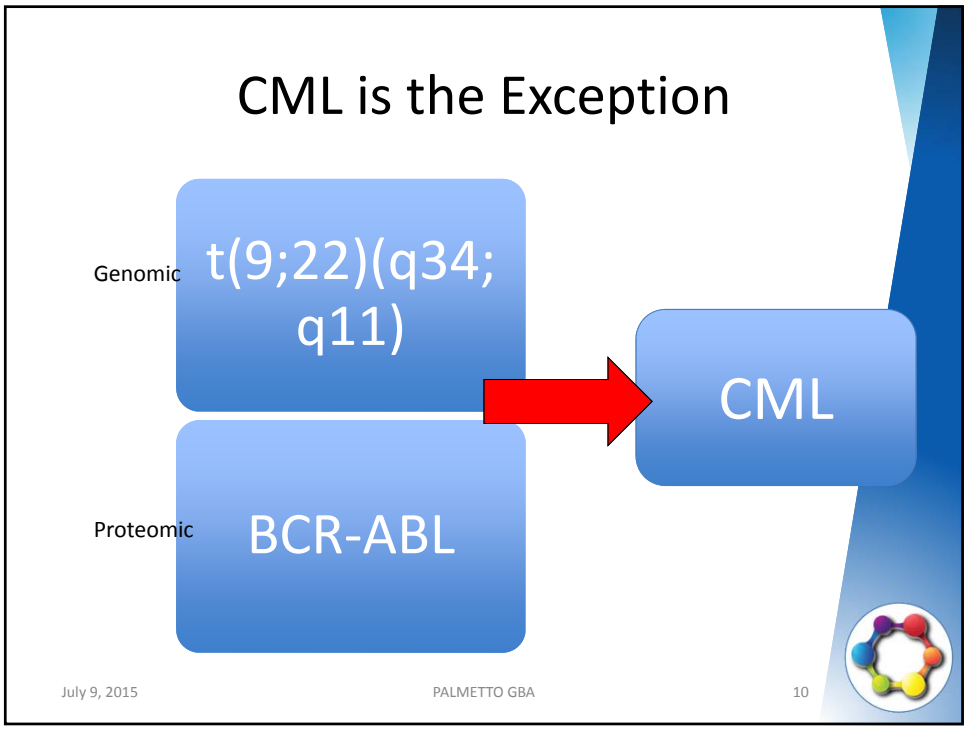
Little Boy, “He’s naked.”



Personalized Medicine

The Full Monty **Monty Python**


The Truth of Molecular Medicine
MED-C


CML is the Exception
Genomic
t(9;22)(q34; q11)
Proteomic
BCR-ABL
CML
July 9, 2015
PALMETTO GBA
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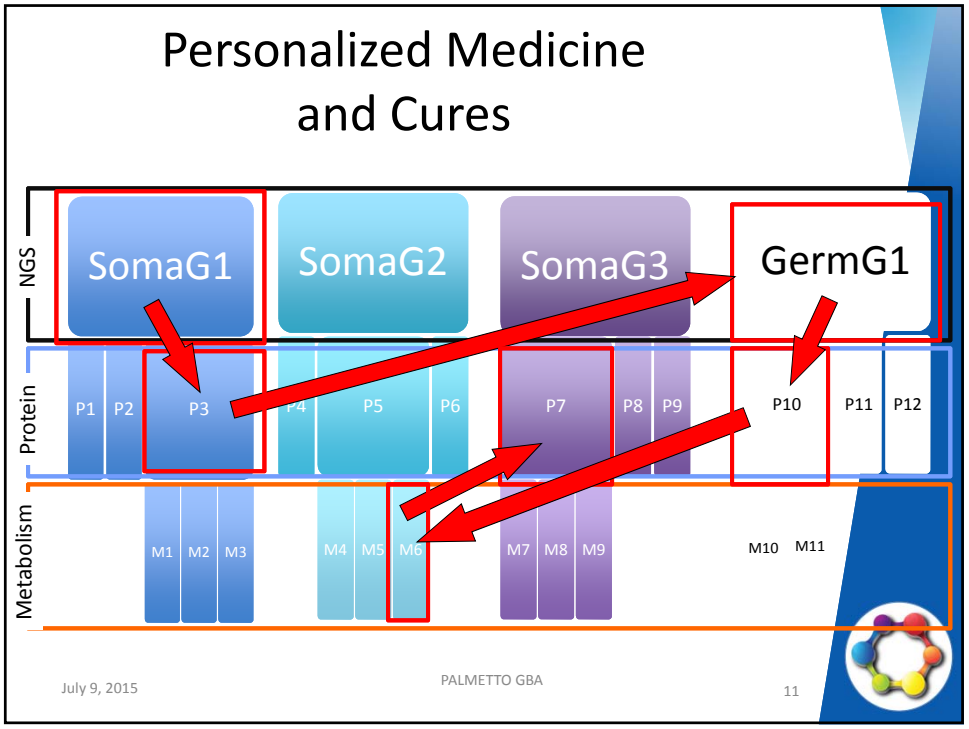
Personalized Medicine and Cures
NGS
SomaG1
SomaG2
SomaG3
GermG1
Protein
P1
P2
P3
P4
P5
P6
P7
P8
P9
P10
P11
P12
Metabolism
M1
M2
M3
M4
M5
M6
M7
M8
M9
M10
M11
July 9, 2015
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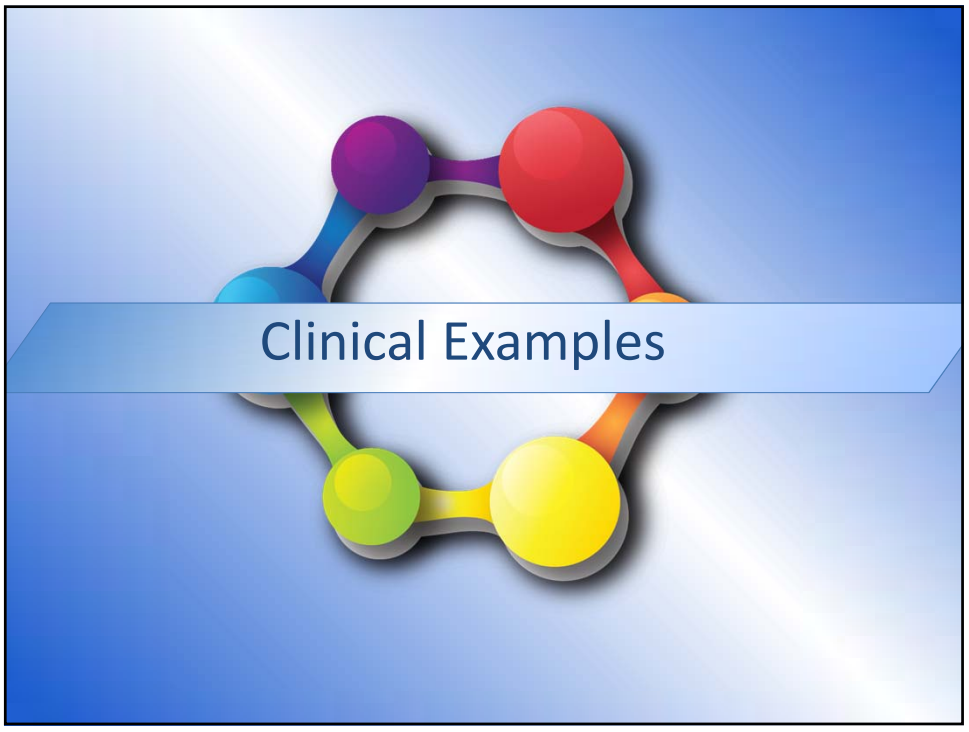
11


Clinical Examples

Case #1

- Around February 2014 – my partner calls and asks,
- "The NCCN says I should perform NGS on my patient with NSCLC. Where should I send the test?"

Case #1 - Background

- NCCN in early 2014 introduced in their NSCLC guidelines a recommendation to include NGS as part of the work up for patients with metastatic disease
- See the next 2 slides

NCCN January 30, 2014

NCCN Guidelines Version 3.2014
Non-Small Cell Lung Cancer

TARGETED AGENTS FOR PATIENTS WITH GENETIC ALTERATIONS

Genetic Alteration (ie, Driver event)	Available Targeted Agents with Activity Against Driver Event in Lung Cancer
EGFR mutations	erlotinib,[1] gefitinib,[2] afatinib[3]
ALK rearrangements	crizotinib[4]
HER2 mutations	trastuzumab,[5] afatinib[6]
BRAF mutations	vemurafenib,[7] dabrafenib[8]
MET amplification	crizotinib[9]
ROS1 rearrangements	crizotinib[10]
RET rearrangements	cabozantinib[11]

NCCN 2A+

16 ? Why – Every academic institution was running NGS?

LOE for NCCN Recommendations

TARGETED AGENTS FOR PATIENTS WITH GENETIC ALTERATIONS

Genetic Alteration (ie, Driver event)	Available Targeted Agents with Activity Against Driver Event in Lung Cancer
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MET amplification	crizotinib[9]
ROS1 rearrangements	crizotinib[10]
RET rearrangements	cabozantinib[11]

Retrospective – tissue only, no treatment

Case report

[1]Sequist LV, Joshi VA, Janne PA, et al. Response to treatment and survival of patients with non-small cell lung cancer undergoing somatic EGFR mutation testing. Oncologist 2007;12:90-98.
[2]Paez JG, Janne PA, Lee JC, et al. EGFR mutations in lung cancer: correlation with clinical response to gefitinib therapy. Science 2004;304:1497-1500.
[3]Sequist LV, Yang JC-H, Yamamoto N, et al. Phase III study of afatinib or cisplatin plus pemetrexed in patients with metastatic lung adenocarcinoma with EGFR mutations. J Clin Oncol 2013;31:3327-3334.
[4]Kwak EL, Bang YJ, Camidge DR, et al. Anaplastic lymphoma kinase inhibition in non-small-cell lung cancer. N Engl J Med 2010;363:1693-1703.
[5]Cappuzzo F, Bemis L, Varella-Garcia M. HER2 mutation and response to trastuzumab therapy in non-small-cell lung cancer. N Engl J Med 2006;354:2619-2621.
[6]Mazieres J, Peters S, Lepage B, et al. Lung cancer that harbors an HER2 mutation: epidemiologic characteristics and therapeutic perspectives. J Clin Oncol 2013;31:1997-2003.
[7]Gautschi O, Pauli C, Strobel K, et al. A patient with BRAF V600E lung adenocarcinoma responding to vemurafenib. J Thorac Oncol 2012;7:e23-24.
[8]Planchard D, Mazieres J, Riely GJ, et al. Interim results of phase II study BRF113928 of dabrafenib in BRAF V600E mutation-positive non-small cell lung cancer (NSCLC) patients [abstract]. J Clin Oncol 2013;31(Suppl 15): Abstract 8009.
[9]Ou SH, Kwak EL, Siwak-Tapp C, et al. Activity of crizotinib (PF02341066), a dual mesenchymal-epithelial transition (MET) and anaplastic lymphoma kinase (ALK) inhibitor, in a non-small cell lung cancer patient with de novo MET amplification. J Thorac Oncol 2011;6:942-946.
[10]Bergethon K, Shaw AT, Ou SH, et al. ROS1 rearrangements define a unique molecular class of lung cancers. J Clin Oncol 2012;30:863-870.
[11]Drilon A, Wang L, Hasanovic A, et al. Response to cabozantinib in patients with RET fusion-positive lung adenocarcinomas. Cancer Discov 2013; 3:630-635.

LOE By Literature

NCCN Guidelines Version 3.2014
Non-Small Cell Lung Cancer

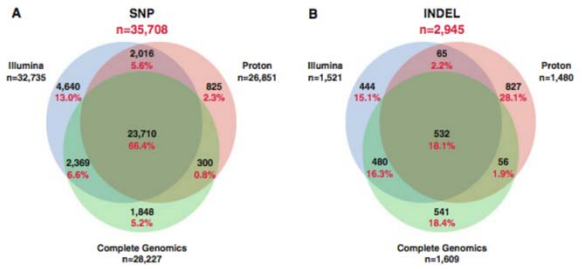
TARGETED AGENTS FOR PATIENTS WITH GENETIC ALTERATIONS

	Genetic Alteration (ie, Driver event)	Available Targeted Agents with Activity Against Driver Event in Lung Cancer
LOE +++	EGFR mutations	erlotinib,[1] gefitinib,[2] afatinib[3]
	ALK rearrangements	crizotinib[4]
LOE +	HER2 mutations	trastuzumab,[5] afatinib[6]
	BRAF mutations	vemurafenib,[7] dabrafenib[8]
LOE -	MET amplification	crizotinib[9]
	ROS1 rearrangements	crizotinib[10]
	RET rearrangements	cabozantinib[11]

Note – IN 2015 – Her2+ Bust, ROS1 is a homerun.

Which NGS Lab and Platform?

Different platforms yield different results



"True" + (All 3 hit)
SNP – 66.4%
INDEL – 18.1%

"False" + (Only 1)
SNP – 20.5%
Indel – 61.6%

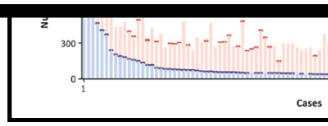
Reference: Boland JF, et al. *Hum Genet* 2013;132:1153-1163

Is NGS of Somatic Tissue Enough?

Targeted

C

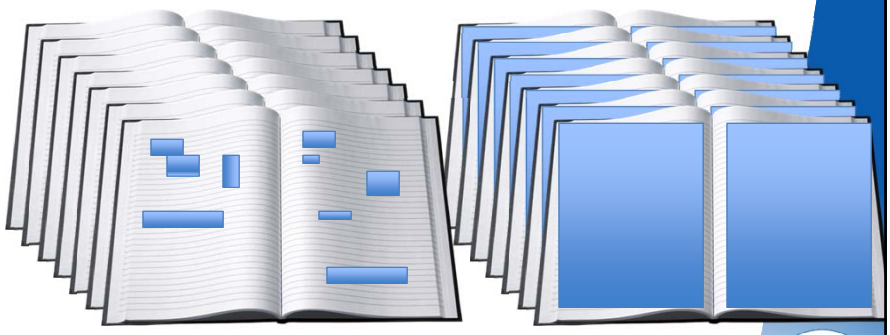
	Matched tumor/normal sample analyses			Tumor-only analyses			
	Total sequence coverage	Number of samples analyzed	Somatic mutations per tumor		Candidate mutations per tumor	Candidate mutations per tumor after removal of common germline variants (dbSNP)	Alterations in actionable genes after dbSNP filter
Whole exome	199×	100	135	Total alterations	1401	382	2.41
				True positives (somatic)	135 (10%)	133 (35%)	1.61 (67%)
				False positives (germline)	1266 (90%)	249 (65%)	0.80 (33%)
Targeted	1052×	58	4.34	Total alterations	11.53	6.28	2.31
				True positives (somatic)	4.34 (38%)	4.33 (69%)	1.79 (77%)
				False positives (germline)	7.19 (62%)	1.95 (31%)	0.52 (23%)



Jones S. Sci Transl Med 2015 April 15; 7 (283)

Massive Parallel Sequencing (NGS)

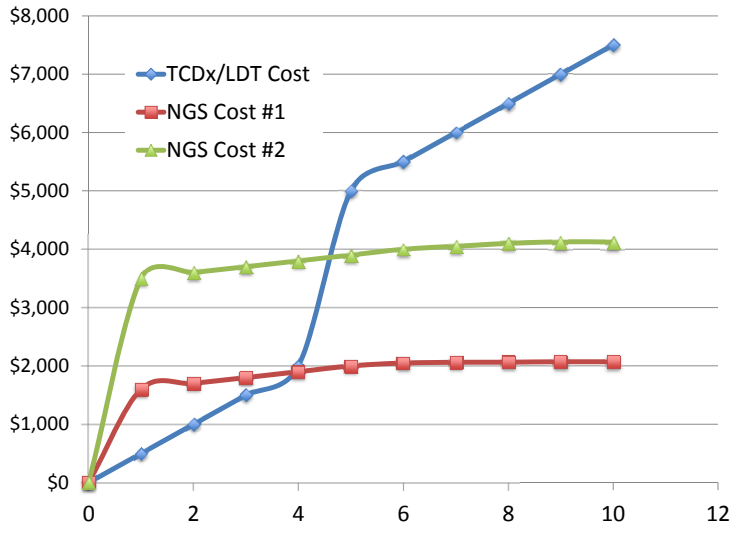
- Hot Spot Testing
- Comprehensive Genomic Profiling



Multiple genes – only certain segments

Multiple genes – all segments

Yet, NGS is the Future



Problems Exemplified by Case #1

- Non-Standardized NGS – Unable to trust one lab's result to another's
- Lack of LOE to know if and how to use the results
- Shunting of patients from possible clinical trials and other evidence collection

Case 2: Laboratory Developed Tests (LDTs) vs. Companion Diagnostics (CDx)

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Case #2

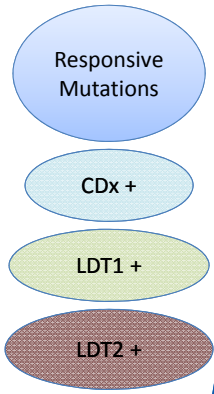
- 48 y.o. never-smoker
- Metastatic NSCLC
- Tumor sent for EGFR and ALK by LDT (major national lab)
- "Negative"

Case #2

- Failed first line chemo – with Carboplatin Paclitaxel
- Failed 2nd line chemo – with Alimta
- Based on Drillon Study with high quality NGS sent off original biopsy again
- EGFR Mutation Found Exon 19
- Companion Diagnostic usually would have found
- Patient placed on Erlotinib – near CR after 3 months with often patients responding for months to years on therapy.

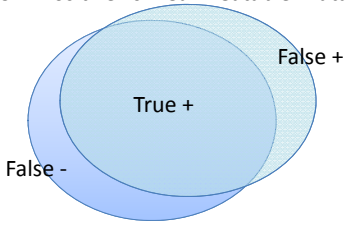
CDx vs. LDTs

- Complexity of Testing
  - Companion Diagnostics are the only test that have been proven to work with certain drugs.
  - There are mutations not picked up by CDx that likely would benefit from the drugs.
  - LDTs may pick up these additional mutations, but also may pick up mutations that don't respond

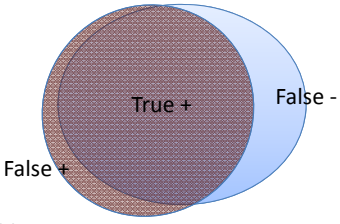


CDx vs. LDTs

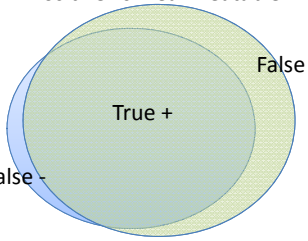
CDx Positive vs. Real Treatable Mutations



LDT2 Positive vs. Real Treatable Mutations



LDT1 Positive vs. Real Treatable Mutations



FDA Memo

- Compare LDTs to CDx
- "Ensuring that doctors and patients have access to safe, accurate and reliable diagnostic tests to help guide treatment decisions is a priority for the FDA. Inaccurate test results could cause patients to seek unnecessary treatment or delay and sometimes forgo treatment altogether. Today's action demonstrates the agency's commitment to personalized medicine, which depends on accurate and reliable tests to get the right treatment to the right patient."
- FDA Commissioner Margaret A. Hamburg M.D.

Problems Exemplified by Case #2

- What would have happened if we would not have tested this dear patient?
- Can we trust LDTs?– What it the problem with the LDT, or the increased sensitivity of the NGS?
- Do I need to re-test every patient?
- Would another lab have found the mutation given only 66% concordance in SNP

Clinical Scenario #3 & #4: Multiplex Testing

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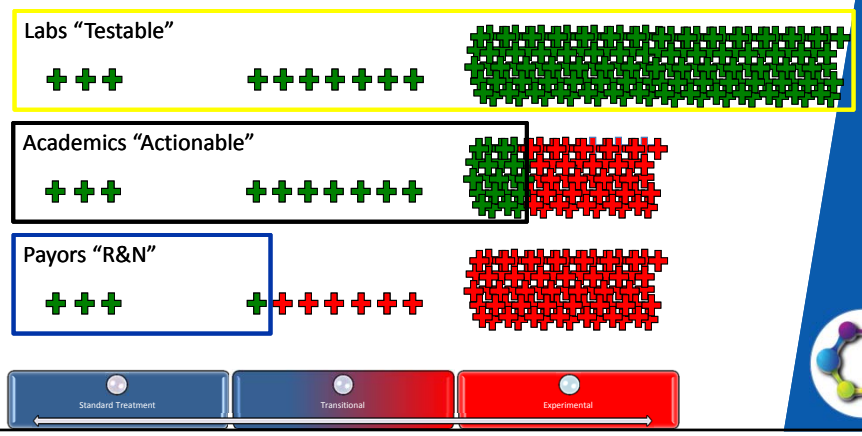
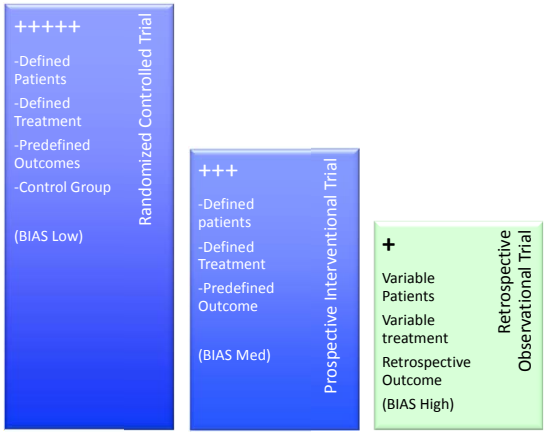
Observation #3

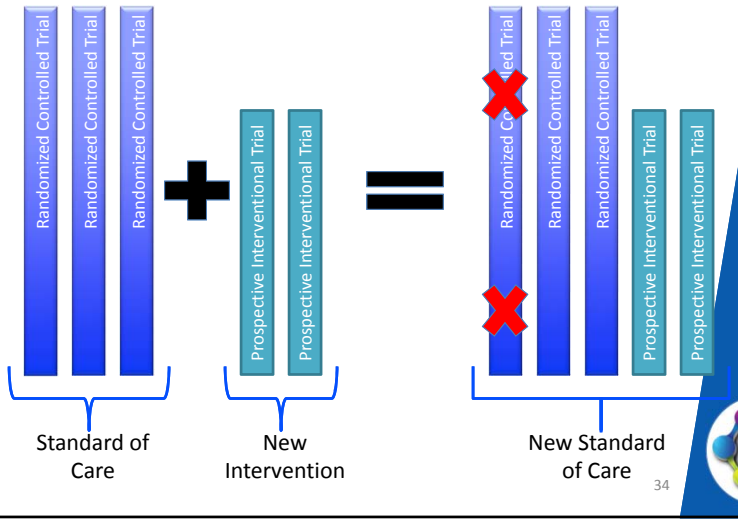
- Rapidly Expanding NGS Panels
- Academicians vs. Laboratory vs. Payors
- AMA – Codes somewhere between Testable and Actionable



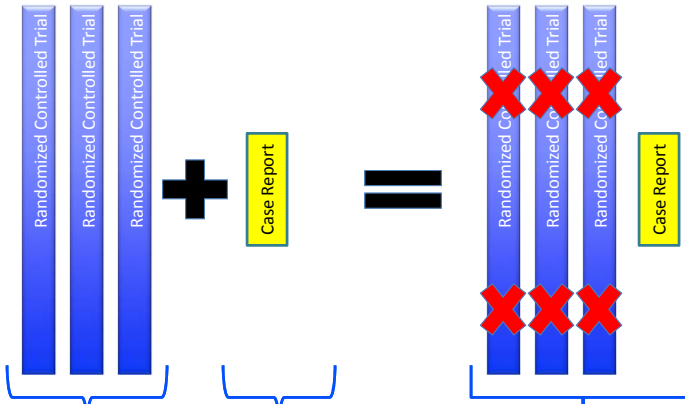
Observation #3 - Levels of Evidence



Obs#3 - Old School Care Migration



Erroneous Migration of Care



Obs #3 - The Problem with N of 1

- Estrogen receptors and Her2 in lung cancer
- How many patients does it take to really determine an effect?
- How many, “we could try X based on. . .” have data collected
- How many “N of 1” could have been on a clinical trial of “N of 30 or 50 or 100”
- How many clinics get reimbursed for the time and effort that it takes to get testing and drug for their “N of 1”

Medicare Oncology Care Model

Biography

Ron Kline is a board certified pediatric hematologist-oncologist. In his role as medical officer in the Patient Care Models Group at the Center for Medicare and Medicaid Innovation (CMMI), he is part of the program team directing CMS's new Oncology Care Model. As a Robert Wood Johnson Foundation Health Policy Fellow in 2013-14, he focused on health policy in the office of Senate Finance Committee Chair Ron Wyden and at CMMI.

He has been a clinical pediatric hematologist –oncologist for over 20 years, most recently serving as the medical director of the Pediatric Division of Comprehensive Cancer Centers of Nevada, the largest multispecialty oncology group in Nevada. He is a clinical associate professor at the University of Nevada School of Medicine.

Kline has held leadership positions in local and statewide organizations, primarily focusing on health policy and children's issues. He is past president of the Clark County Medical Society and the Nevada State Medical Association, a former alternate delegate to the American Medical Association House of Delegates, a past gubernatorial appointee to the Silver State Health Insurance Exchange board of directors, and a former member of the Nevada Board of Medical Examiners. He was the founding chair of the Children's Medical Advocacy Coalition and president elect of the Southern Nevada Medical Industry Coalition. In addition to his medical and health policy pursuits, Kline has a strong interest in history and international relations, having served as an officer of the World Affairs Council of Las Vegas from 2008-2013.

Kline has broad experience directing clinical programs in multiple states and in university, hospital-based, and private practice settings. He is the author of over 20 scientific publications, and the editor of a textbook on pediatric hematopoietic stem cell transplantation.

Kline received his MD and BA from the University of California, Los Angeles, and did his pediatric residency training at the Children's Hospital of Los Angeles. He completed a biotechnology fellowship at the National Cancer Institute and a clinical fellowship in pediatric hematology-oncology and hematopoietic stem cell transplantation at the University of California, San Francisco.

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Oncology Care Model Overview

Centers for Medicare & Medicaid Services

Innovation at CMS

Center for Medicare & Medicaid Innovation (Innovation Center)

- Established by section 1115A of the Social Security Act (as added by Section 3021 of the Affordable Care Act)
- Created for purpose of developing and testing innovative health care payment and service delivery models within Medicare, Medicaid, and CHIP programs nationwide

Innovation Center priorities:

- Test new payment and service delivery models
- Evaluate results and advancing best practices
- Engage a broad range of stakeholders to develop additional models for testing

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Innovation Center Models

Goals of Innovation Center models:

- Better care
- Smarter spending
- Healthier people

Models range in focus, including:

- Accountable Care Organizations
- Primary Care Transformation
- Bundled Payments for Care Improvement
- New emphasis on specialty care models

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3

Oncology Care Background

- One specialty practice area where the Innovation Center aims to improve effectiveness and efficiency is oncology care.
- More than 1.6 million people are diagnosed with cancer in the United States each year. Approximately half of those diagnosed are over 65 years old and Medicare beneficiaries. Cancer patients comprise a medically complex and high-cost population served by the Medicare program.
- About 50% of patients in oncology practices are Medicare beneficiaries
- The Innovation Center has the opportunity to further its goals of better care, smarter spending, healthier people through an oncology payment model.

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Oncology Care Model (OCM)

- The Innovation Center's Oncology Care Model (OCM) focuses on an episode of cancer care, specifically a chemotherapy episode of care
- The goals of OCM are to utilize appropriately aligned financial incentives to improve:
    1) Care coordination
    2) Appropriateness of care
    3) Access for beneficiaries undergoing chemotherapy
- Financial incentives encourage participating practices to work collaboratively to comprehensively address the complex care needs of beneficiaries receiving chemotherapy treatment, and encourage the use of services that improve health outcomes.

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OCM Overview

Episode-based

Payment model targets chemotherapy and related care during a 6-month period following the initiation of chemotherapy treatment

Emphasizes practice transformation

Physician practices are required to engage in practice transformation to improve the quality of care they deliver

Multi-payer model

Includes Medicare fee-for-service and other payers working in tandem to leverage the opportunity to transform care for oncology patients across the population

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Participants: Physician Practices

Physician practices that are Medicare providers and furnish chemotherapy may apply to participate in OCM.

Practices are expected to engage in practice transformation to improve the quality of care they deliver. This transformation is driven by OCM's 6 practice requirements:

1) Provide 24/7 patient access to an appropriate clinician who has real-time access to patient's medical records

Aim to better meet patients' needs by providing around-the-clock access to a clinician who can provide real-time, individualized medical advice

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Practice Requirements

2) Use an ONC-certified EHR and attest to Stage 2 of meaningful use (MU) by the end of the third model performance year

OCM Practices must demonstrate progress by attesting to MU Stage 1 by end of the first model performance year

3) Utilize data for continuous quality improvement

The Innovation Center will provide participating practices with rapid cycle data feedback reports to aid in quality improvement. Practices are expected to use this data to continuously improve OCM patient care management.

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Practice Requirements cont.

4) Provide core functions of patient navigation

Practices are required to provide patient navigation to all OCM patients. The National Cancer Institute provides a sample list of patient navigation activities (see Appendix B of the RFA)

5) Document a care plan for every OCM patient that contains the 13 components in the Institute of Medicine Care Management Plan

Plan components include treatment goals, care team, psychosocial support, and estimated patient out-of-pocket cost (see Appendix A of the RFA for full list)

6) Treat patients with therapies consistent with nationally recognized clinical guidelines

Practices must report which clinical guidelines (NCCN or ASCO) they follow for OCM patients, or provide a rationale for not following the clinical guidelines.

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Participants: Payers

OCM covers Medicare fee-for-service (OCM-FFS) and other payers (OCM-OP)

- Other payers may include commercial payers (including MA plans), state Medicaid agencies, or other governmental payers (including Tricare, FEHBP, and state employee health plans)

Payer participation will drive the geographical scope of the model

- The Innovation Center will publish lists of payers and practices who submit letters of intent to participate in OCM, and expects other payers to plan for OCM participation with their associated practices

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Payer Requirements

Operational

- Commit to participation in OCM for its 5-year duration
- Sign a Memorandum of Understanding with the Innovation Center
- Enter into agreements with OCM practices that include requirements to provide high quality care
- Share model methodologies with the Innovation Center
- Provide payments to practices for enhanced services and performance as described in the RFA

Quality Improvement Measures

- Align practice quality and performance measures with OCM, when possible

Data Sharing

- Provide participating practices with aggregate and patient-level data about payment and utilization for their patients receiving care in OCM, at regular intervals

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Target Beneficiary Population: OCM-FFS

Medicare beneficiaries who meet each of the following criteria will be included in OCM-FFS.

- Are enrolled in Medicare Parts A and B
- Have Medicare FFS as their primary payer
- Do not have end-stage renal disease
- Are not covered under United Mine Workers
- Receive an included chemotherapy treatment for cancer under management of an OCM participating practice

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Episode Definition: OCM-FFS

Types of cancer

- OCM-FFS includes nearly all cancer types

Episode initiation

- Episodes initiate when a beneficiary starts chemotherapy
- The Innovation Center has devised a list of chemotherapy drugs that trigger OCM-FFS episodes, including endocrine therapies but excluding topical formulations of drugs

Included services

- All Medicare A and B services that Medicare FFS beneficiaries receive during episode
- Certain Part D expenditures will also be included

Episode duration

- OCM-FFS episodes extend six months after a beneficiary's chemotherapy initiation.
- Beneficiaries may initiate multiple episodes during the five-year model performance period

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Two-Part Payment Approach: OCM-FFS

During OCM, participating practices will be paid Medicare FFS payments.

Additionally, OCM has a two-part payment approach:

(1) Per-beneficiary-per-month (PBPM) payment

- $160 PBPM payment for enhanced services required by OCM that is paid during the chemotherapy episode
- OCM-FFS practices are eligible for the PBPM monthly for each month of the 6-month episode, unless beneficiary enters hospice

(2) Performance-based payment

- Incentive to lower the total cost of care and improve quality of care for beneficiaries over the 6-month episode period
- Retrospective payment that is calculated based on the practice's historical Medicare expenditures and achievement on selected quality measures

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Performance-Based Payment: OCM-FFS

1) CMS will calculate **benchmark** episode expenditures for participating practices
   - Based on historical data
   - Risk-adjusted, adjusted for geographic variation
   - Trended to the applicable performance period
2) A discount will be applied to the benchmark to determine a **target price** for OCM-FFS episodes
   - Example: Benchmark = $100 → Discount = 4% → Target Price = $96
3) If **actual** OCM-FFS episode Medicare expenditures are **below target** price, the practice could receive a performance-based payment
   - Example: Actual = $90 → Performance-based payment up to $6
4) The amount of the performance-based payment may be reduced based on the participant's achievement and improvement on a range of **quality measures**

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Risk Arrangement Options: OCM-FFS

One-Sided

- Participants are NOT responsible for Medicare expenditures that exceed target price
- 5-year model duration
- Medicare discount = 4%
- *Must qualify for performance-based payment by end of Year 3*

Two-Sided

- Participants are responsible for Medicare expenditures that exceed target price
- Option to take downside risk, beginning in Year 3 (one-sided risk for Years 1 and 2)
- Medicare discount = 2.75%
- *Must qualify for performance-based payment by end of Year 3*

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Benchmarking: OCM-FFS

- Benchmarking will be based on **historical Medicare expenditure data**
  - Based on both practice data and regional/national data as necessary to increase precision
  - Risk adjusted, adjusted for geographic variation
  - Trended to applicable performance period
- Participants in the same risk arrangement structure will all receive the same **discount** (4% in one-sided risk; 2.75% in two-sided risk)
- **Clinical trial** participants will be included

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Risk Adjustment: OCM-FFS

OCM-FFS will risk adjust for several factors that affect episodic expenditures. Possible risk adjustment factors include:

1) **Beneficiary characteristics** (such as age strata or comorbidities)
2) **Episode characteristics** (such as whether an episode is the first for that beneficiary)
3) **Disease characteristics** (such as cancer type)
4) **Types of services furnished** (such as provision of radiation therapy or initiation with an endocrine therapy)

Risk adjustment in Year 1 will be based solely on information available in claims data. Risk adjustment in subsequent years may incorporate additional factors not captured in claims data, such as cancer staging.

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Winsorization: OCM-FFS

Practices may have a small number of **patients with unexpected events or outcomes that greatly increase their total cost of care**. To lessen the impact of these outlier cases on a practice's overall performance, CMS intends to utilize a process called Winsorization.

- Winsorization replaces extreme values above a certain threshold (e.g. 95th or 99th percentile) with less extreme values to lessen the potential impact of outliers.
- Ex: If a beneficiary were involved in a severe motor vehicle accident during an OCM episode, thus greatly increasing his/her costs, the total cost of care of the episode would be truncated at the Winsorization threshold based on the national distribution of expenditures for that type of episode.

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Quality Measures: OCM-FFS

Quality measure domains:

1) Clinical quality of care
2) Communication and care coordination
3) Person and caregiver centered experience and outcomes
4) Population health
5) Efficiency and cost reduction
6) Patient safety

Data sources:

1) Practice-reported
2) Medicare claims
3) Patient surveys

List still in progress – will be finalized prior to practices signing agreements

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Quality Measures: Performance-Based Payment Subset

See Appendix C of the RFA for full list of preliminary quality measures

Quality Domain	Recommended practice requirement or quality measurement	NQF #	Source
Communication and Care Coordination	# of ED visits per OCM-FFS beneficiary per episode		Claims data
Communication and Care Coordination	# of hospital admissions per OCM-FFS beneficiary per episode		Claims data
Communication and Care Coordination	% of all Medicare FFS beneficiaries managed by the practice admitted to hospice for < 3 days	#0216	Claims data
Communication and Care Coordination	% of all Medicare FFS beneficiaries managed by the practice who experience ≥1 ED visit in the last 30 days of life	#0211	Claims data
Person-and Caregiver-Centered Experience and Outcome	% of OCM-FFS beneficiary face-to-face encounters with the participating practice in which there is a documented plan of care for pain AND pain intensity is quantified	#2100	Reported by practice
Person-and Caregiver-Centered Experience and Outcome	Score on patient experience survey (modified CAHPS)		Administered by CMS contractor
Person-and Caregiver-Centered Experience and Outcome	% of OCM-FFS beneficiary face-to-face encounters in which the patient is assessed by an approved patient-reported outcomes tool		Reported by practice
Person-and Caregiver-Centered Experience and Outcome	% of OCM-FFS beneficiaries that receive psychosocial screening and intervention at least once per episode		Reported by practice

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Monitoring and Evaluation: OCM-FFS

Participant monitoring activities may include:

- Tracking of claims data
- Patient surveys
- Site visits
- Analysis of quality measurement data
- Time and motion studies
- Medical record audits, tracking of patient complaints, and appeals

OCM will employ a non-randomized research design using matched comparison groups to detect changes in utilization, costs, and quality that can be attributed to the model

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Learning and Diffusion (L&D)

The OCM Learning System will provide:

- Topic-specific webinars that allow OCM participants to learn from each other
- An online portal to support learning through shared resources, tools, ideas, discussions, and data-driven approaches to care
- Action Groups in which practices work together virtually to explore critical topic areas and build capability to deliver comprehensive oncology care
- Site visits to better understand how practices manage services, use evidence-based care, and practice patient-centered care
- Coaching to help practices overcome barriers to improvement

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Program and Payment Overlap

Shared Savings Programs

- Participation in shared savings programs and OCM is allowed
- Examples of shared savings programs are: Pioneer Accountable Care Organizations (ACOs), Medicare Shared Savings Program (MSSP), Comprehensive Primary Care (CPC)

Other Models

- Transforming Clinical Practice Initiative (TCPI): Significant overlap between TCPI and OCM is not expected, and dual participation in both TCPI and OCM is not allowed

Care Management Services

- Chronic Care Management (CCM) and Transitional Care Management (TCM) services: Practices that bill the OCM PBPM cannot also bill for CCM or TCM services in the same month for the same beneficiary.

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Contact Information

Oncology Care Model

CMMI Patient Care Models Group

OncologyCareModel@cms.hhs.gov

http://innovation.cms.gov/initiatives/Oncology-Care/

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ASCO Medicare Oncology Payment Model Resources

Supporting the Oncology Community with Interpretation & Evaluation of CMMI's Oncology Care Model

This resource page is a service of ASCO, available to ASCO members and to the broader oncology community, providing an information source for the interpretation, evaluation and application process for oncology providers contemplating their participation in the Center for Medicare and Medicaid Innovation (CMMI) Oncology Care Model (OCM).

Should your practice embrace OCM or should it ignore OCM? What are the prospective benefits of participating in OCM? The OCM Support Center is available to support you in these deliberations.

What is the Oncology Care Model?

The Oncology Care Model is an oncology-specific initiative of CMMI that focuses on the total cost of care for cancer patients undergoing chemotherapy during a six-month episode of care. The OCM payment methodology incentivizes participating practices to meet certain quality and performance metrics and to comply with practice transformation requirements. The OCM program is five years in duration with an anticipated "go live" date in the spring 2016.

Physician group practices and solo practitioners that furnish chemotherapy for cancer are eligible to participate in OCM. As well, hospital owned practices, including provider-based departments and practices that partner with a hospital outpatient department for chemotherapy services are eligible to participate.

CMMI has posted **FAQs** about the model on its website.

Oncology Care Model Interpretation & Evaluation Support

Our staff and industry experts will respond to specific inquiries that you might have with regard to the feasibility and implications of OCM participation by your practice. **Submit an inquiry**.

Couldn't Make the ASCO Webinars on the Oncology Care Model?

A **recording**, the **slides,** and an **FAQ** from the April 28, 2015 webinar--and a **recording** and the **slides** from the June 4, 2015 webinar--are available now.

Breakout Session

Breakout Session Instructions

- Attendees will breakout into their MAC regions and the group lists can be found in the meeting binder. All groups will meet in the current meeting room. Tables are marked by region and MAC.

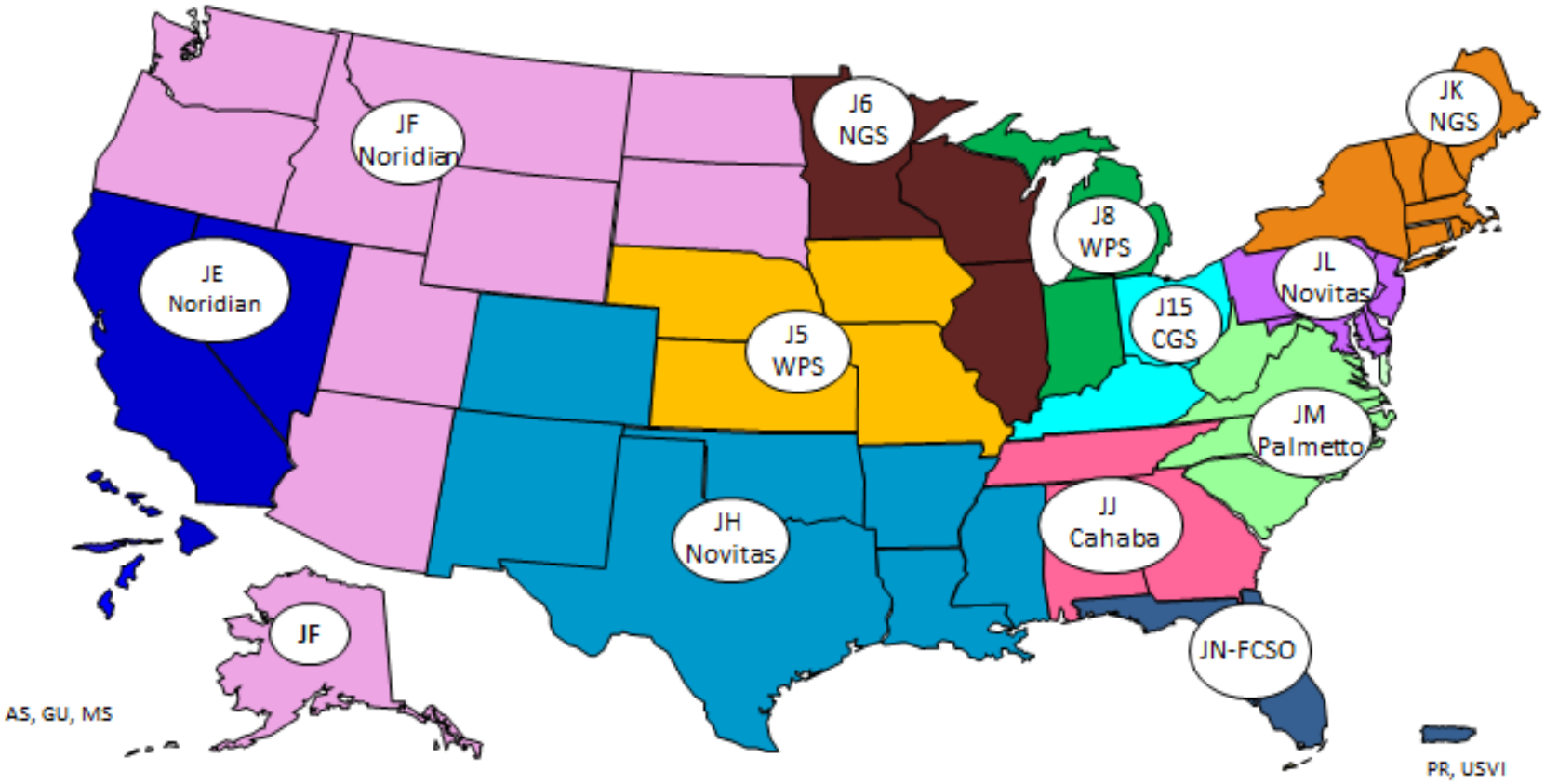
- Each group will have a facilitator and those are identified in the group lists with an asterisk on their name. There will be a thirty-minute discussion period.

- Groups are asked to consider one or two questions below during their breakout discussion:
    - How can we increase our communication on LCDs effecting hematology and/or oncology?
    - What was the most difficult coverage determination made in the past two years in the region?
    - What do you think will be addressed in LCDs in the near future and how should they be covered?

- After thirty-minutes, the identified facilitator will be asked to provide a brief summary of his/her group's discussion.

A/B MAC Current Jurisdictions

as of April 2015



MAC Region – Group List

Region E (Noridian)
Dr. Piyush Srivastava*
Dr. Sabina Wallach
Jose Gonzalez
Dr. Robert Robles
Dr. Warren Fong
Dr. Charles Miller
Dr. Heather Allen
Dr. Arthur Lurvey

Region F (Noridian)
Dr. Dan Zuckerman*
Dr. James Gajewski
Dr. Latha Subramanian
Tammy Thiel
Liz Cleland
Dr. Dane Dickson
Dr. Richard Whitten

Jurisdiction 5 (WPS)
Dr. Roscoe Morton*
Dr. Sukumar Ethirjan
Dr. Mark Hermann
Dr. Mary Klix

Jurisdiction 6 (WPS)
Dr. Gary MacVicar*
Dr. Paul Fishkin
Dr. Parameswaran Hari

Region H (Novitas)
Dr. Debra Patt*
Dr. Gregg Franklin
Dr. John Cox
Dr. Barbara McAneny
Dr. Debra Patterson
Dr. Shubam Pant

Jurisdiction 8 (WPS)
Dr. Samuel Silver*
Fuad Hammoudeh
Dr. Philip Kuriakose
Dr. Michael Stender
Carol Christner

Jurisdiction 15 (CGS)
Dave Dillahunt*
Dr. Joel Saltzman

Region J (Cahaba)
Dr. Luis Pineda*
Dr. Gregg Shepard
Dr. Thom Mitchell
Karen Beard

Region K (NGS)
Dr. Joseph DiBenedetto, Jr.*
Dr. Tracey Weisberg
Dr. Michael Willen
Dr. Eric Wong
Dawn Holcombe
Dr. Laurence Clark

Region L (Novitas)
Dr. Kenneth Adler*
Dr. Mark Pascal
Dr. Eric Seifter
Dr. Arturo Loaiza-Bonilla
Dr. Paul Celano
Dr. Steven Allen
Dr. Paul Celano

Region M (Palmetto)
Dr. Kashyap Patel*
Dr. Ahmed Khalid
Dr. Quillin Davis
Dr. Linda Sutton
Dr. Elaine Jeter

Region N (FCSO)
Dr. Michael Diaz*
Dorothy Green Phillips
Dr. Jose Davila
Dr. Juan L. Schaening

Dr. Mitchell Burken
Marci Cali (J5, J6, E, H, M)
David Richards (E, F, H, I)
Mary Jo Richards (E, F, H, I)

ICD-10: What It Means for Hematologists-Oncologists

SHORT BIO: ARTHUR N. LURVEY; MD, FACP, FACE

Arthur Lurvey is a board certified internist and endocrinologist, and has been a Medicare Contractor Medical Director for 18 years---initially working for the Medicare carriers: Transamerica Occidental Life Insurance Company, National Heritage Insurance Company, National Government Services; Palmetto GBA and most recently for Noridian Healthcare Solutions, the Medicare Contractor in Jurisdiction JE. He was in clinical practice for 35 years.

Dr. Lurvey received his MD degree from the University of Illinois, and had his post doctorate and fellowship training at Los Angeles County-USC Medical Center. He is a Fellow of the American College of Physicians and the American College of Endocrinology.

He is a delegate to both the California Medical Association and American Medical Association, has been a past Hospital Chief of Staff and served on several committees of the Hospital Council of Southern California. He also is on the Board of the California Region of the American College of Physicians and on several committees of the American Association of Clinical Endocrinologists. Other medical activities include service as a CMA surveyor for both the Joint Commission hospital survey program and the CME accreditation program in California.

noridian
Healthcare Solutions

ICD-10: What It Means For Hematologists-Oncologists July 10, 2015

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ICD-10-CM

- What Is It:
  - International Statistical Classification of Diseases and Related Health Problems, 10th revision, Clinical Modification (ICD-10-CM)
  - Across Most Countries with some local modification (Canada ICD-10 CA; Germany ICD-10-GM)
  - Published / run by the World Health Organization
- The term "clinical" is used to emphasize the modification's intent: to serve as a useful tool in the area of classification of morbidity data for indexing of health records, medical care review, and ambulatory and other health care programs, as well as for basic health statistics.
- To describe the clinical picture of the patient the codes must be more precise than those needed only for statistical groupings and trend analysis.

Characteristics of ICD-10-CM

- ICD-10-CM far exceeds its predecessors in the number of concepts and codes provided. The disease classification has been expanded to include health-related conditions and to provide greater specificity at the sixth and seventh character level.
- The sixth and seventh characters are not optional and are intended for use in recording the information documented in the clinical record.

ICD-9 Versus ICD-10

Comparisons

ICD-9	ICD-10
3-5 characters in length	3-7 characters in length
Approximately 13,000 codes	Approximately 68,000 available codes
First digit may be alpha (E or V) or numeric; digits 2-5 are numeric	Digit 1 is alpha; digits 2 and 3 are numeric; digits 4-7 are alpha or numeric

Limited space for adding new codes	Flexible for adding new codes
Lacks detail	Very specific
Lacks laterality	Has laterality (i.e., codes identifying right vs. left)

Structure

ICD-10 Code Structure:
Characters 1-3 – Category
Characters 4-6 – Etiology, anatomic site, severity, or other clinical detail
Characters 7 – Extension

CMS Reasons for ICD-10

- **Greater specificity of diagnosis-related groups**
- **Improve quality measurement and reporting capabilities**
- **improve tracking of illnesses**
- **Reflects greater accuracy of payment for medical services**
- **Improved data capture & analytics of public health surveillance**
- **Provide detailed data for healthcare delivery and healthcare policy decisions**
- **Reflects advances in medicine and medical technology**
- **Improvement in coding primary care encounters, external causes of injury, mental disorders, and preventive health.**
- **Reflects improved diagnosis of chronic illness and identifies underlying causes, complications of disease, and conditions that contribute to the complexity of a disease**

ICD-10-CM Tabular List of Diseases & Injuries

Table of Contents

10	J00-J99	Diseases of the respiratory system (J00-J99)
11	K00-K95	Diseases of the digestive system (K00-K95)
12	L00-L99	Diseases of the skin and subcutaneous tissue (L00-L99)
13	M00-M99	Diseases of the musculoskeletal system and connective tissue (M00-M99)
14	N00-N99	Diseases of the genitourinary system (N00-N99)
15	O00-O9A	Pregnancy, childbirth and the puerperium (O00-O9A)
16	P00-P96	Certain conditions originating in the perinatal period (P00-P96)
17	Q00-Q99	Congenital malformations, deformations and chromosomal abnormalities (Q00-Q99)
18	R00-R99	Symptoms, signs and abnormal clinical and laboratory findings, not elsewhere classified (R00-R99)
19	S00-T88	Injury, poisoning and certain other consequences of external causes (S00-T88)
20	V00-Y99	External causes of morbidity (V00-Y99)
21	Z00-Z99	Factors influencing health status and contact with health services (Z00-Z99)

Neoplasms--C00-D49

- Notes: Functional activity
- All neoplasms are classified in this chapter, whether they are functionally active or not. An additional code from Chapter 4 may be used, to identify functional activity associated with any neoplasm.
- Morphology [Histology]
- Chapter 2 classifies neoplasms primarily by site (topography), with broad groupings for behavior, malignant, in situ, benign, etc. The Table of Neoplasms should be used to identify the correct topography code. In a few cases, such as for malignant melanoma and certain neuroendocrine tumors, the morphology (histologic type) is included in the category and codes.
- Primary malignant neoplasms overlapping site boundaries
- A primary malignant neoplasm that overlaps two or more contiguous (next to each other) sites should be classified to the subcategory/code .8 ('overlapping lesion'), unless the combination is specifically indexed elsewhere. For multiple neoplasms of the same site that are not contiguous, such as tumors in different quadrants of the same breast, codes for each site should be assigned.
- Malignant neoplasm of ectopic tissue
- Malignant neoplasms of ectopic tissue are to be coded to the site mentioned, e.g., ectopic pancreatic malignant neoplasms are coded to pancreas, unspecified (C25.9).

Neoplasms--C00-D49

C7A	Malignant neuroendocrine tumors
C7B	Secondary neuroendocrine tumors
C76-C80	Malignant neoplasms of ill-defined, other secondary and unspecified sites
C81-C96	Malignant neoplasms of lymphoid, hematopoietic and related tissue
D00-D09	In situ neoplasms
D10-D36	Benign neoplasms, except benign neuroendocrine tumors
D3A	Benign neuroendocrine tumors
D37-D48	Neoplasms of uncertain behavior, polycythemia vera and myelodysplastic syndromes
D49	Neoplasms of unspecified behavior

Malignant neoplasms of lip, oral cavity and pharynx (C00-C14)

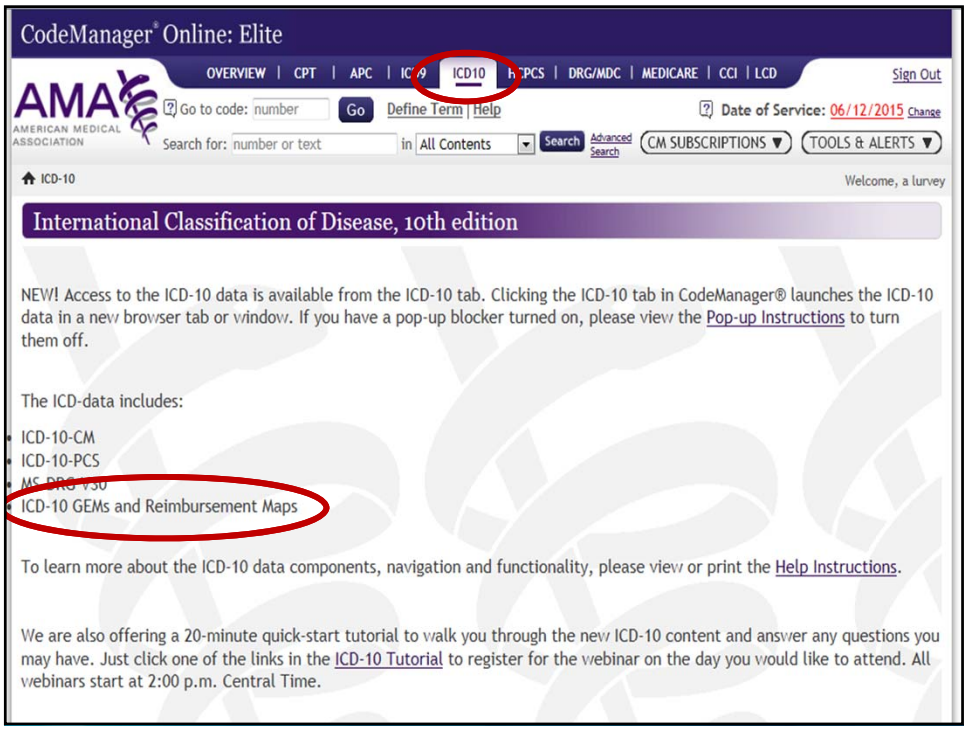
C08	Malignant neoplasm of other and unspecified major salivary glands
C09	Malignant neoplasm of tonsil
C10	Malignant neoplasm of oropharynx
C11	Malignant neoplasm of nasopharynx
C12	Malignant neoplasm of pyriform sinus
C13	Malignant neoplasm of hypopharynx
C14	Malignant neoplasm of other and ill-defined sites in the lip, oral cavity and pharynx

C00 Malignant neoplasm of lip

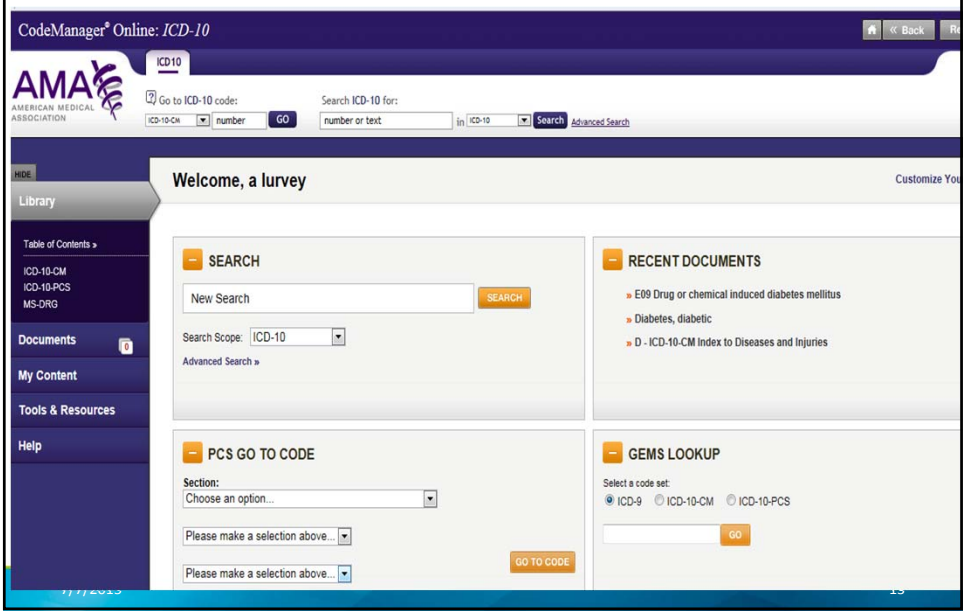
C00.0	Malignant neoplasm of external upper lip MORE INFO
C00.1	Malignant neoplasm of external lower lip MORE INFO
C00.2	Malignant neoplasm of external lip, unspecified MORE INFO
C00.3	Malignant neoplasm of upper lip, inner aspect MORE INFO
C00.4	Malignant neoplasm of lower lip, inner aspect MORE INFO
C00.5	Malignant neoplasm of lip, unspecified, inner aspect MORE INFO
C00.6	Malignant neoplasm of commissure of lip, unspecified
C00.8	Malignant neoplasm of overlapping sites of lip
C00.9	Malignant neoplasm of lip, unspecified

And The Coding Goes On

- Code Structure
  - Digits 1-3: Letter plus 2 numbers: Category
  - Digits 4-6: Letter or number: Define etiology, anatomic site, severity, or other clinical detail
  - Digit 7: Extension
- Letter X usually means space for further expansion of some aspect of code
- All that information is a blessing? curse? For coding but must be present on October 1, 2015 and after. ICD-9 CM used through date of service September 30



GEMS Lookup Tool and More Info



Help From AMA CPT

- GEMS lookup comparing ICD-9-CM to ICD-10-CM (CPT and CMS website)

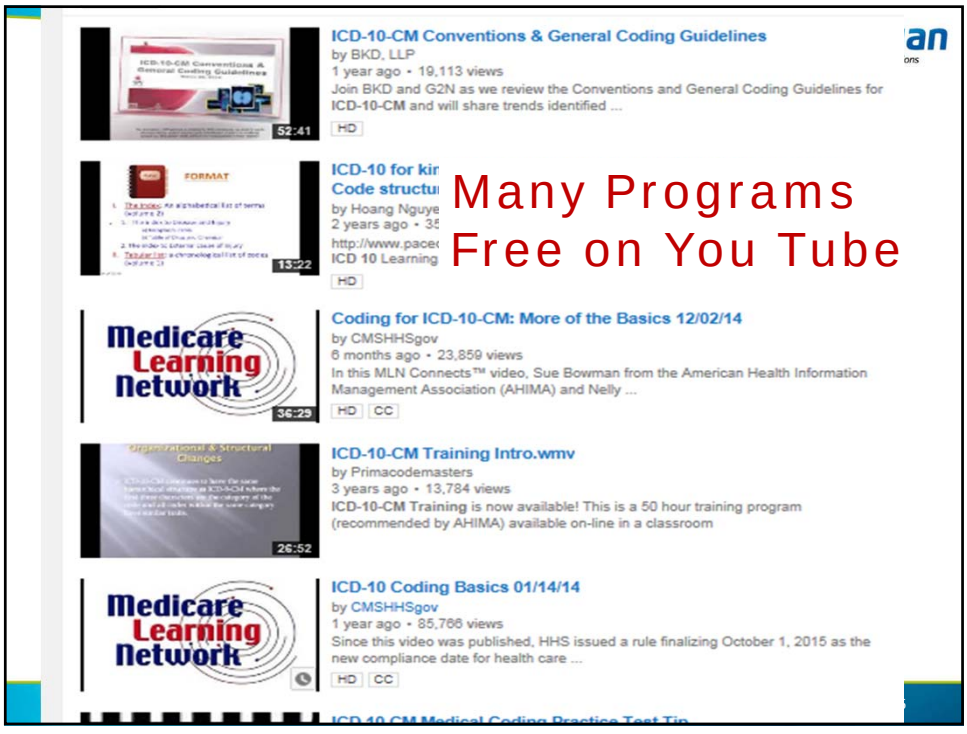
Top 10 Documents

Name	Count
ICD-10-CM Neoplasms Table	47
ICD-10-PCS Body Part Key	20
A02 Other salmonella infections	19
ICD-10-PCS Device Key	18
ICD-10-CM Tabular List of Diseases and Injuries	12
A - ICD-10-CM Index to Diseases and Injuries	12
H40 Glaucoma	11
E10 Type 1 diabetes mellitus	8
ICD-10-PCS Device Aggregation Table	7
Conventions	7

Small Practice Physicians

- Small practice physicians “Road to 10” no-cost tool: Obtain overview of ICD-10
- Explore Specialty References by selecting your specialty
- Click “BUILD YOUR ACTION PLAN” to create your personal plan
- Webcasts, Events, FAQs, Quick References & Template Library
- Specialty References: Select profile to explore common codes, clinical documentation/scenarios and additional specialty resources
- Family Practice, Pediatrics, OB/GYN,

http://www.roadto10.org/



HOW IT AFFECTS HEMATOLOGISTS AND ONCOLOGISTS

- Increases specificity of cancer diagnoses and locations
  - ICD-9 may have several varieties in 1 code
  - ICD-10 codes for each variant or diagnoses
- Increases amount and specificity of treatment effects and causations
- Has many more codes that you will need
- Does have crosswalks from former ICD-9 codes you currently use

BUT CMS PROMISES LENIENCY FOR FIRST YEAR

- Announcement by AMA sent Monday, July 6, 2015…
- "In response to our extensive communication of physicians' concerns, the Centers for Medicare and Medicaid Services (CMS) announced today that it is making several critical changes to the transition period so that physicians can continue to provide high-quality patient care without risking their livelihood"

CMS PROPOSALS

- Claim denials: For the first year ICD-10 is in place, Medicare claims will not be denied solely based on the specificity of the diagnosis codes as long as they are from the appropriate family of ICD-10 codes.
  - Medicare will not deny payment for these unintentional errors as practices become accustomed to ICD-10 coding. and Medicare claims will not be audited based on the specificity of the diagnosis codes as long as they are from the appropriate family of codes. Both Medicare Administrative Contractors and Recovery Audit Contractors will be required to follow this policy.
- Quality-reporting penalties: Similar to claim denials, CMS will not subject physicians to penalties for the PQRS, the value-based payment modifier or meaningful use based on the specificity of diagnosis codes as long as they use a code from the correct ICD-10 family of codes.
  - In addition, penalties will not be applied if CMS experiences difficulties calculating quality scores for these programs as a result of ICD-10 implementation.

CMS PROPOSALS

- Payment disruptions. If Medicare contractors are unable to process claims as a result of problems with ICD-10, CMS will authorize advance payments to physicians.
  - Have not established mechanism as yet for advanced pay
- Navigating transition problems. CMS will establish a communication center to monitor issues and resolve them as quickly as possible. This will include an “ICD-10 ombudsman” devoted to triaging physician issues.
- Contractors have not as yet heard the details of CMS actions…but will let physicians know as soon as they are told.

ICD-10: WHAT YOU NEED TO DO

- Prepare for October 1, 2015
  - Understand differences in codes (ICD-9 & ICD-10)
  - Learn most common codes for your office / specialty
  - Help from AMA, specialty societies, CMS available
- Testing your system-make sure it works
  - Check with vendors and clearinghouses
  - ICD-10 Acknowledgement Testing with trading partners during separate testing weeks, and to collect data about the testing
    - June 1-5 and other days to be announced (Front end)
    - Noridian and other MACs will publish information (end to end)
- Switch to ICD-10 October 1, 2015
  - LCDs and NCDs will have coding in ICD-10
  - Watch notices in Noridian website / CMS website
  - Separate claims before and after 10/01/15

HELP IS AVAILABLE

- No-cost tool that will help you:
  - Get an overview of ICD-10
  - Explore Specialty References
  - Create your personal action plan
- Resources:
  - ICD-10 Overview
  - Physician Perspectives
  - Webcasts: CMS & contractors
  - FAQs
  - Quick References
  - Template Library
  - Events

CMS ICD-10 Webpage: http://www.cms.gov/Medicare/coding/ICD10/index.html

CMS Resources

- Check out the updated CMS ICD-10 Resources Flyer.
- Access three new Medscape Education resources that provide guidance around the transition to ICD-10. Continuing medical education (CME) and nursing continuing education (CE) credits are available to health care professionals who complete the learning modules. Anyone can earn a certificate of completion. If you are a first-time visitor to Medscape, you will need to create a free account to access these resources.
  - Video: ICD-10: Getting From Here to There -- Navigating the Road Ahead
  - Video: ICD-10 and Clinical Documentation
  - Expert Column: Preparing for ICD-10: Now Is the Time
- View the ICD-10 Introduction fact sheet.
- Find official resources designed to help providers, payers, vendors, and non-covered entities with the transition to ICD-10.

Stay up to date on ICD-10!

Sign up for CMS ICD-10 Industry Email Updates and follow us on Twitter.

Logos

This official CMS ICD-10 logo (displayed on the top of this page) signifies that these materials were developed by CMS, and are intended for general industry use.

CMS materials intended solely for providers in the Medicare Fee-for-Service program feature the Medicare Learning Network logo.

http://www.cms.gov/Medicare/coding/ICD10/index.html

Learning Network®

Official CMS Information for

noridian Healthcare Solutions

REAL ICD-10 CODES

- W56.21xD: Bitten by orca, subsequent encounter
- Z62.891: Sibling rivalry
- V97.33XD: Sucked into jet engine, subsequent encounter
- W61.92: Struck by other birds
- Z63.1: Problems in relationship with in-laws
- W45.8XXA: Other foreign body or object entering through skin, initial encounter
- V52.2XXA: Person on outside of pick-up truck or van injured in collision with two- or three-wheeled motor vehicle in nontraffic accident, initial encounter
- X92.0: Assault by drowning and submersion while in bathtub
- W00.1: Fall from stairs and steps due to ice & snow

Testing For ICD-10

- Front-end (acknowledgement testing)
  Pass EDI front-end edits
  - Determine if codes used are valid
- End-to-End
  - End-to-end testing takes testing a step further, processing claims through all Medicare system edits to produce and return an accurate Electronic Remittance Advice (ERA)
    - Testers should be verifying payment or denial
    - Some are looking at payment amounts, especially on Part A
- Early Front End Testing Results Mixed
  - March 3-7, 2014: 127,000 claims and 2,600 participants
  - Nov. 17-21 2014: 13,700 claims and more than 500 participants
  - March 2-6, 2015: 9,000 claims and 775 submitters
  - Acceptance rate nationally of 91.8%, a higher acceptance rate than the previous two testing weeks
  - Excluded from these statistics are 8.2% of claims that were rejected because testers used future dates which are not accepted during acknowledgement testing

LCD/NCD CHANGES

- LCD changes for ICD-10 codes have been available on contractor websites or the CMS coverage database since 4/10/14 (CR8348)
- NCD changes are completed and controlled by CMS and are listed on their website.
- Physicians have lots of time to review and comment on any "missing" ICD-10 diagnoses.
  - CMS asked for comments on some Part B policies from Industry and received very few comments.
  - Suggested changes by physicians will be reviewed by all contractors
  - Existing Policies will not go to CACs as there will be no changes to coverage---just coding

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IN MY OPINION

- ICD-10 Will Come October 1, 2015
  - Delay very unlikely but ???
- Most of us will be mostly prepared
  - Our computer systems
  - Our office staffs

Except for some surly surgeons

- There will be some CMS leniency in terms of transition time
  - We will see how that plays out…
- We will be here, our patients will be here and ICD-10-CM will be here…

ASCO ICD-10 Resources

http://www.asco.org/practice-research/icd-10

- Introduction to ICD-10
- Anatomy of an ICD-10 Code
- Finding an ICD-10 Code
- General Equivalence Mappings
- Taking Control of the Transition to ICD-10
- Selecting the Appropriate ICD-10 Training Program

Centers for Medicare and Medicaid Services (CMS) ICD-10 Resources

Provider Resources

http://www.cms.gov/Medicare/Coding/ICD10/ProviderResources.html

The ICD-10 transition will affect every part of your practice, from software upgrades, to patient registration and referrals, to clinical documentation and billing. With the compliance date quickly approaching, now is the time to get ready. Resources include:

- Medscape Education Resources
- Understanding the Basics
- Communicating about ICD-10
- Educational ICD-10 Videos
- Conferences, Meetings, and Webinars

2016 ICD-10 CM and GEMS

http://www.cms.gov/Medicare/Coding/ICD10/2016-ICD-10-CM-and-GEMs.html

The 2016 ICD-10-CM files below contain information on the new diagnosis coding system, ICD-10-CM, that is a replacement for ICD-9-CM, Volumes 1 and 2.

2016 ICD-10 PCS and GEMS

http://www.cms.gov/Medicare/Coding/ICD10/2016-ICD-10-PCS-and-GEMs.html

The 2016 ICD-10 Procedure Coding System (ICD-10-PCS) files contain information on the new procedure coding system, ICD-10-PCS, that is a replacement for ICD-9-CM, Volume 3.

CMS Sponsored ICD-10 Teleconferences

http://www.cms.gov/Medicare/Coding/ICD10/CMS-Sponsored-ICD-10-Teleconferences.htm

MLN Connects® National Provider Calls and videos help prepare the provider community for the U.S. health care industry's change from the ICD-9 to ICD-10 medical coding system.

Infusions, DMEPOS, Oral Meds

Short bio 2015

* * * * * * * *

Dick Whitten is a Medical Director for Medicare and remains a practicing general internist with the University of Washington at Harborview Medical Center after a prior eighteen years in critical care. He was Medical Director for 12 years for Washington's Health Care Authority and its Basic Health Plan, becoming a Contractor Medical Director for Medicare in 2000 and Vice President for Medical Policy in 2013. He was on the American Medical Association's Relative Value System (RVS) Update Committee (“RUC”) for 12 years, its Vice Chair as well as Chair of the Health Care Professionals Advisory Committee for six and on the CPT Assistant Editorial Panel from 2007-2010.

Dick graduated from Yale with a degree in economics, worked in Chicago, then went to Harvard Business School receiving an MBA with Distinction. His Internship and Residency were in Internal Medicine, then two years as a Robert Wood Johnson Clinical Scholar, all at the University of Washington, where he remains an Associate Clinical Professor.

Infusions, DMEPOS, Oral Meds

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Disclosure of Financial Relationships

Richard W. Whitten, MD

Has no relationships with any entity producing, marketing, re-selling, or distributing health care goods or services consumed by, or used on, patients.

"Medicare is a law,
…enacted by Congress in 1965,
…that Congress has tried to 'fix'
some seven hundred times since."

Tom Grissom, Deputy CMS Administrator ~ 2002

Sources of Information

- "The Statute" (Congress)
  Social Security Act: Title XVIII Section
  - Section 1861: Benefits, e.g., hospital services
  - Section 1862: Exclusions, e.g., dental services
- CMS (Cabinet Sub-department) www.cms.hhs.gov
  - National Coverage Determinations (NCDs)
  - Manuals/Websites
- Individual Medicare Administrative Contractors (MAC)
  - Local Coverage Determinations (LCDs, Articles)
  - Websites

Issues Today

- **"Chemotherapy" and regular infusion codes**
- **"DME" ≡ Durable Medical Equipment, Prosthetics, Orthotics & Supplies**
- **"Oral drugs related to chemotherapy"**

"Infusions"

- **Standard Infusion & Injection Codes**
  vs.
- **"Chemotherapy Administration" Codes**

- **96365** Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); initial, up to 1 hour
- **96366** Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); each additional hour (List separately in addition to code for primary procedure)
- **96367** Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); additional sequential infusion of a new drug/substance, up to 1 hour (List separately in addition to code for primary procedure)
- **96372** Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); subcutaneous or intramuscular
- **96374** Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); intravenous push, single or initial substance/drug
- **96375** Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); each additional sequential intravenous push of a new substance/drug (List separately in addition to code for primary procedure)

- **96401** Chemotherapy administration, subcutaneous or intramuscular; non-hormonal anti-neoplastic
- **96409** Chemotherapy administration; intravenous, push technique, single or initial substance/drug
- **96411** Chemotherapy administration; intravenous, push technique, each additional substance/drug (List separately in addition to code for primary procedure)
- **96413** Chemotherapy administration, intravenous infusion technique; up to 1 hour, single or initial substance/drug
- **96415** Chemotherapy administration, intravenous infusion technique; each additional hour (List separately in addition to code for primary procedure)
- **96417** Chemotherapy administration, intravenous infusion technique; each additional sequential infusion (different substance/drug), up to 1 hour (List separately in addition to code for primary procedure)

CHEMOTHERAPY ADMINISTRATION (directly from CPT):

Chemotherapy administration codes 96401-96549 apply to parenteral administration of non-radionuclide anti-neoplastic drugs; and also to anti-neoplastic agents provided for treatment of noncancer diagnoses (eg, cyclophosphamide for auto-immune conditions) or to substances such as certain monoclonal antibody agents, and other biologic response modifiers. The highly complex infusion of chemotherapy or other drug or biologic agents requires physician work and/or clinical staff monitoring well beyond that of therapeutic drug agents (96360-96379) because the incidence of severe adverse patient reactions are typically greater. These services can be provided by any physician. Chemotherapy services are typically highly complex and require direct physician supervision for any or all purposes of patient assessment, provision of consent, safety oversight, and intraservice supervision of staff. Typically, such chemotherapy services require advanced practice training and competency for staff who provide these services; special considerations for preparation, dosage, or disposal; and commonly, these services entail significant patient risk and frequent monitoring. Examples are frequent changes in the infusion rate, prolonged presence of the nurse administering the solution for patient monitoring and infusion adjustments, and frequent conferring with the physician about these issues. When performed to facilitate the infusion of injection, preparation of chemotherapy agent(s), highly complex agent(s), or other highly complex drugs is included and is not reported separately. To report infusions that do not require this level of complexity, see 96360-96379.

Variance

- **96365** Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); initial, up to 1 hour
- **96413** Chemotherapy administration, intravenous infusion technique; up to 1 hour, single or initial substance/drug

CPT	RVW	RVPE	RVPL	RV Total
96365	0.21	1.98	0.03	2.22
96413	0.28	3.88	0.05	4.21

- Clinical Staff minutes: **96365** – 50 minutes **96413** – **98** minutes
- **96413** includes 20 minutes under a biohazard hood

Issues for CPT/RUC

- **Not the general economics of practice or of running an infusion service**

  but rather

- **Do the services being provided meet the CPT specifications distinguishing chemotherapy administration from regular injections & infusions**

CMS Comments – Jan. 2014 Steve Phurrough, MD:

- **"CMS Central Office does not maintain lists of non-ChemoRx drugs that can use the ChemoAdmin codes. CMS CO allows contractors to determine which drugs for which they will provide payment using ChemoAdmin codes. In general, contractors attempt to follow criteria in the CPT Manual. CMS CO currently limits its involvement to assuring that appropriate processes are followed by the contractors in making those determinations...**

Steve Phurrough, MD – cont'd

"...Entities that believe that a contractor did not follow an appropriate process for a particular drug or who believe that the proper process results in an obviously incorrect conclusion may address that with CMS CO. Entities that wish to change the criteria should initially address that with the CPT Editorial Panel."

Chemo Admin – Who want's this changed

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 218
(I-14)

Introduced by: American College of Rheumatology
American Academy of Allergy, Asthma and Immunology
American Gastroenterological Association

Subject: Parity of Payment for Administration of Medications Within the Same Category of Drug

Chemo Admin – Who want's this changed$_2$

AMA House of Delegates: R-218:

"... that CMS issue guidance requiring parity of payment for administration of medications within the same *category* of drug"

(Emphasis mine; note that this implies the concern is a "category of drug" like "biologic", "monoclonal" or "anti-infective")

Chemo Admin – Who want's this changed$_3$

- **American College of Rheumatology's Delegate statement at AMA HOD:**

  "...concern is discrimination by one or more MACs, paying for the *same drug* differently based on the provider's specialty ...or the diagnosis being treated." (T

Feb. 2015 e-mail to CMDs

Sent: February XX, 2015
Subject: American College of Rheumatology Call Request

Good afternoon Dr. _____,

I'm writing to follow up on the attached letter sent by the ACR in November. ACR leadership would like the opportunity to speak with you regarding access to biologics for Medicare patients in your region. Is there a convenient time in the next few weeks when we could schedule a conference call?

Thank you very much for your time.

Meredith Freed Strozier
Director, Practice Advocacy
American College of Rheumatology
2200 Lake Boulevard NE
Atlanta, GA 30319
(404)633-3777
mstrozier@rheumatology.org

Issue: Rx that *would* qualify as ChemoRx, but conditions don't

- **To be "incident to" must have *both* the drug and an administration code**
- **If drug qualifies as a ChemoRx and all conditions are met (including *direct supervision*), then bill ChemoRx admin code**
- **If all conditions not met, but the drug still R&N, bill routine infusion/injection code (which only requires *general supervision*)**

"DME"

- **Durable Medical Equipment, Prosthetics, Orthotics & Supplies**

Benefit Category

- **FFS is a defined benefit program**
- **No benefit = no coverage**
- **Range from general to specific**
  - Physician Services (broad & general)
    - Include supplies and services "incident to"
  - IVIG – drug only, specific dx, etc.

Medicare DMEPOS

LCD Title	LCD ID Number and Effective Date	Policy Article and Effective Date	HCPCS
Oral Anticancer Drugs	L11574 Effective 11/1/13	A25372 Effective 3/1/14	A9270, J8498, J8597, J8999, Q0511, Q0512, Busulfan, Capecitabine, Cyclophosphamide, Etoposide, Fludarabine phosphate, Melphalan, Methotrexate, Temozolomide, Topotecan
Oral Antiemetic Drugs (Replacement for Intravenous Antiemetics)	L11575 Effective 10/31/14	A25373 Effective 10/31/14	J8501, J8540, J8650, Q0161, Q0162, Q0163, Q0164, Q0166, Q0167, Q0169, Q0173, Q0174, Q0175, Q0177, Q0180, Q0181, Q0511, Q0512

LCDs with ICD-10 translations may be found on the Future LCD webpage

DMEPOS: Drugs used with an external infusion pump

Infusion drug - four possible scenarios:

1. **Billing for an infusion drug alone (no pump being used). There is <u>no statutory infusion drug benefit</u> to allow coverage. All infusion drugs and any associated supplies will be denied as statutorily noncovered.**

DMEPOS: Drugs used with an external infusion pump 2

2. **Billing for a pump with an infusion drug not listed in the LCD. The pump is eligible for coverage under the DME benefit, but because the drug is not listed in the LCD, all items (the pump, drug, and any associated supplies) will be denied as not reasonable and necessary.**

DMEPOS: Drugs used with an external infusion pump 3

3. **Billing for a pump with a drug listed in the LCD but the R&N criteria for the drug are not met. The pump, drug, and any associated supplies will be denied as not reasonable and necessary.**

DMEPOS: Drugs used with an external infusion pump 4

4. Billing for a pump with a drug listed in the LCD where the R&N criteria for the drug are met. The pump, drug and any associated supplies are payable if other conditions of coverage are met.

DMEPOS: Immune Globulins

- **Subcutaneous immune globulin**
  - Coverage is under the DME benefit (of the pump)
  - See DMEPOS External Infusion Pump LCD & PA
- **Intravenous immune globulin (IVIG)**
  - Has it's own benefit under Medicare
  - See the DMEPOS IVIG LCD & PA

Drugs Provided "Incident To" a Physician Service (ie not DMEPOS)

- **Pharmacy dispenses drug administered through implanted DME**
  - Generally incident to a physician's service to fill the pump with the drug
  - & "*rarely* even when *not* directly filled by a physician's service"
- **Claim is submitted to the A/B MAC ("carrier") for coverage determined reasonable & necessary**

Drugs Provided "Incident To" a Physician Service 2

- **MLN Matters® Number: MM7397 Revised**
- **Related Change Request (CR) #: 7397**
- **Related CR Release Date: July 1, 2011**
- **Related CR Transmittal #: R2251CP**
- **Effective Date: August 15, 2011**
- **Implementation Date: August 15, 2011**

Prescription Drug Coverage

- **Over and above that offered by Medicare A, B and/or C**

  https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/index.html

Prescription Drug Coverage2

- **"Entities that provide prescription drug coverage to Medicare Part D eligible individuals must notify these individuals whether the drug coverage they have is creditable or non-creditable."**

Office of Inspector General Reporting

- **Phone: 1-800-HHS-TIPS (1-800-447-8477)**
- **Fax: 1-800-223-2164**
  (no more than 10 pages please)
- **E-Mail: HHSTips@oig.hhs.gov**
- **Mail: Office of the Inspector General**
  HHS TIPS Hotline
  P.O. Box 23489
  Washington, DC 20026

Thank you. Comments/questions welcome:

Please remember to 1st check
www.noridianmedicare.com &
Provider Call Center: **877-908-8431**

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Issues in Coverage and Payment for Biosimilars

John Warren
Senior Director
McDermott+ Consulting

John Warren is a highly experienced Medicare Veteran with wide ranging experience in traditional Medicare fee-for-service, Medicare program integrity, and Medicare contracting issues. With over 22 years of experience inside the Centers for Medicare and Medicaid Services (CMS), John brings a unique perspective to clients of all types and sizes. As the former CMS director of the Divisions responsible for payment policy and program integrity, John is uniquely qualified to speak on matters related to Medicare payment for clinical laboratory services, Part B prescription drugs, and the Medicare Physician fee schedule.

Issues in Coverage and Payment for Biosimilars

ASH/ASCO Hematology and Oncology Carrier Advisory Committee
July 10, 2015

John Warren,
Senior Director,
McDermottPlus Consulting

Introduction

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McDermottPlus Consulting is a wholly owned subsidiary of McDermott, Will & Emery LLP. McDermottPlus provides consultative advice to clients in the Diagnostics and Life Sciences industries as well as to Hospitals and Providers.

Statutory Requirements

The New Authorities

- Created as a part of the Affordable Care Act in 2010
- Established “abbreviated licensure pathway” for products that are biosimilar to or interchangeable with a previously approved biological
- Similar to the pathway created under Hatch-Waxman Act for abbreviated approval of generic drugs.

What BPCIA Permits

- Approval of highly similar biologic products can be granted based on certain existing data already verified and addressing the purity, safety, and potency of the reference product
- Licensure of biosimilar product can now be based on less that the full complement of product-specific data.

Biosimilarity

- A product is biosimilar to an already licensed biologic product when:
  - The biological product is **highly similar** to the reference product notwithstanding minor differences in clinically inactive components;

    and
  - There are **no clinically meaningful differences** between the biological product and the reference product in terms of the safety, purity, and potency of the product.

Interchangeability

- A product is interchangeable with an already licensed biologic product when:
  - the biological product is **biosimilar** to the reference product;
  - it can be expected to produce the **same clinical result** as the reference product **in any given patient**; and
  - for a product administered more than once, the **safety and reduced efficacy risks of alternating or switching** are not greater than with repeated use of the reference product without alternating or switching.

Regulatory Guidance

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FDA Guidance's

- April 2015, FDA published 3 guidance documents to help manufacturers navigate the 351(k) approval process
  - Scientific Considerations in Demonstrating Biosimilarity to a Reference Product
  - Quality Considerations in Demonstrating Biosimilarity to a Reference Protein Product
  - **Biosimilars**: Questions and Answers Regarding Implementation of the Biologics Price Competition and Innovation Act of 2009

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Scientific Considerations

- Discusses
  - The approach that sponsors should take when developing the evidence needed to demonstrate biosimilarity to a reference product
  - **FDA**'s "totality-of-the-evidence" approach for reviewing biosimilar applications
  - General scientific principles for sponsors to consider when performing product analysis, studies and assessments

Quality Considerations

- Includes factors to consider when showing that a biosimilar is "*highly similar*" to a reference biologic
  - Expression System
  - Manufacturing Process
  - Assessment of Physiochemical Properties
  - Functional Activities
  - Receptor Binding and Immunochemical Properties
  - Impurities
  - Reference Product and Reference Standards
  - Finished Drug Product
  - Stability

Questions & Answers

- Intended to be a "living document" addressing issues which arise
  - Biosimilarity & Interchangeability
  - Process for submitting a BLA under 351(k)
  - Exclusivity

Draft Guidance

- FDA has issued four additional draft guidance documents
  - Formal Meetings between the FDA and Biosimilar Biological Product Sponsors or Applicants (March 2013)
  - Clinical Pharmacology Data to Support a Demonstration of Biosimilarity to a Reference Product (May 2014)
  - Biosimilarity Reference Product Exclusivity for Biological Products Filed Under Section 351(a) of the Public Health Service Act (August 2014)
  - Biosimilars: Additional Questions and Answers Regarding Implementation of the Biologics Price Competition and Innovation Act of 2009 (May 2015)

Key Issues - Interchangeability

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Interchangeability

- Sandoz was first company is US to receive FDA approval of a biosimilar
- Zarxio™ (filgrastim-sndz) approved as biosimilar to NEUPOGEN®
  - Approved for same set of indications
  - Approval based on information that demonstrates biosimilarity to NEUPOGEN®
- Zarxio™ was not approved by the FDA as an interchangeable biosimilar,
  - Remains unclear how FDA will review and ultimately approve interchangeable biologics

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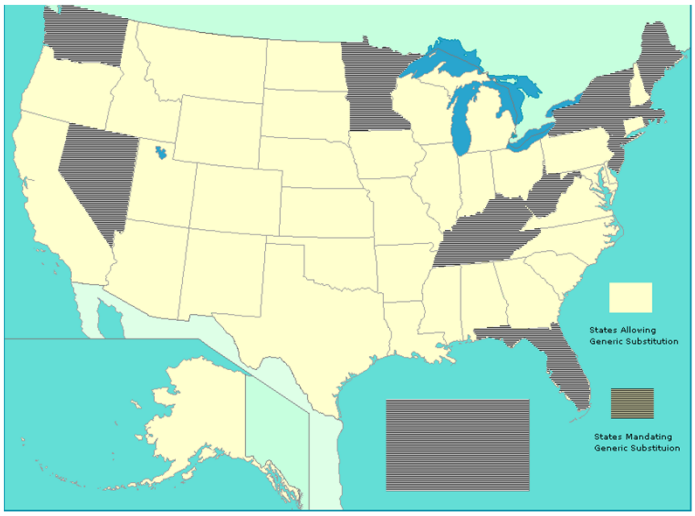
Implications of Interchangeability

- Interchangeability implicates prescribing and dispensing decisions
- FDA has not indicated how it will review an application for an interchangeable biosimilar
- As such, the FDA's scrutiny of an interchangeable application will impact providers, pharmacists and patients alike

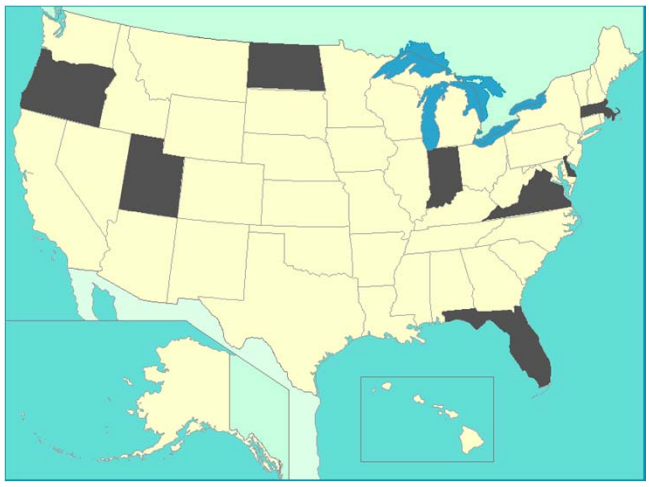
State Level Activity

- State laws can vary on pharmacist's ability to automatically substitute biosimilar
- State laws vary in addressing substitution
  - FDA determination of interchangeability
  - Doctor and patient notification
  - "Brand Medically Necessary"
  - Records kept on file
  - Interchangeable products posted

State Substitution Laws as of 2010



States with Biosimilar Laws - 2015



Key Issue - Labeling

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Why Labeling is Critical

- Consistency
  - "Organic" will have the same meaning on each package where it appears
- Safety
  - Consumers can understand what ingredients were used in a product
- Consumer protection
  - Prevent false or misleading statements that could impact consumer knowledge

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Medical Product & Drug Labeling

- Should provide the information necessary for the prescriber to make informed prescribing decisions
- Biosimilar labeling guidance fails to include proposed language addressing whether the product was
  - Approved as a biosimilar
  - Approved as interchangeable with the reference product
- FDA did not require information used by FDA to grant approval under 351(k)

Importance of Labeling

- Prescribers will not have the information or data used to approve the biosimilar and reference product
- Prescribers may not recognize different immunogenicity of biosimilar and reference biologic products
- Inadequate labeling could lead to misbranding and/or inadequate ability to differentiate between products and approved indications of each product

Key Issue - Extrapolation

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Role of Extrapolation

- A reduced number of clinical and nonclinical comparative studies may be used to approve a biosimilar
- Sponsor can use data from one indication to support approval for use in other indications for which the reference product has been approved

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Key Issue - Nomenclature

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Product Naming is Critical

- Help to identify differences and similarities between products
- Can help in prescribing decisions and reporting of adverse events
- Can also help in product marketing and consumer recognition

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Naming as a Prescribing Tool

- Studies have shown that 10% or more of prescribers use the nonproprietary name of a drug or biologic when making prescribing decision
- Shared nonproprietary names increased prescriber confidence in making interchangeability decisions
  - 74.6% confident or very confident with shared nomenclature
  - 37.3% confident or very confident with shared nomenclature with suffix
  - 25.3% confident or very confident when name is not shared

Naming as a Safety Tool

- Differentiate the Biosimilar and the Reference Product
- Prevent “sound-alike” mistakes
- Allow for ability to track and trace biosimilar apart from the reference product
- Enable correct assignment and tracking of adverse events.

Issues

- Significant controversy and disagreement on both sides of naming argument
- FDA naming on Zarxio™ is a place-holder
  - "The provision of a placeholder nonproprietary name for this product should not be viewed as reflective of the agency's decision on a comprehensive naming policy for biosimilar and other biological products."

Key Issues – Medicare Reimbursement

Average Sales Price

- Single Source Drugs (Brand without generic alternatives) and biologics
  - Average Sales Price of Branded Drug (or biologic) + 6%
- Multiple Source Drugs (Brand and Generic Drugs)
  - Weighted Average Sales Price of all Branded and Generic Drugs + 6%
- Biosimilars
  - Average Sales Price of Biosimilar + 6% of Average Sales Price of Reference Biologic

Payment Implications

- Pricing of biosimilars will not result in same level of price deflation as with generic drugs
  - Medicare payment for reference biologic not impacted by sales of biosimilar
- CMS decision on pricing multiple biosimilars could affect price competition
  - If CMS keeps all pricing separate, biosimilars must compete on price

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Meeting Wrap Up

American Society of Hematology
www.hematology.org

American Society of Clinical Oncology
www.asco.org

ASH/ASCO CAC Resources from CMS

- Medicare's Program Integrity Manual, Chapter 13, which outlines the local coverage determinations, the Carrier Advisory Committee (CAC), and contractor responsibilities surrounding CACs
- General Information on CMS' Contracting Reform
- Medicare Administrative Contractors (MAC) Regions and updates
- Map of Current Jurisdictions
- Map of Consolidated Regions (*what CMS is moving toward*)
- Information on MAC Implementation (*last updated April 2015*)
- Documents relating to the procurement and implementation of MACs
- Durable Medical Equipment MACs
- Medicare Coverage
- Medicare Coverage Center

American Society of Clinical Oncology

Making a world of difference in cancer care

ASCO Advocacy

ASCO in Action (AiA) –ASCO has dedicated a portion of its website to spotlight timely information on research policy, clinical affairs, government relations, and quality of care issues that affect oncology practice, cancer care, and cancer research. ASCO publishes AiA briefs and alerts and these are all available at http://ascoaction.asco.org/

AiA Beat - The ASCO in Action Beat is a bi-weekly newsletter which shares timely information on ASCO's policy priorities – be sure to subscribe on ASCO.org.

ASCO's ACT Network – This network provides members different opportunities to become engaged in advocacy. The ASCO ACT Network allows individuals to send a message using the pre-drafted editable alerts, find phone numbers and mailing addresses for elected officials, see how members of Congress voted on key issues, and draft a message (e-mail or letter) to a member of Congress. http://www.asco.org/actnetwork

Advocacy Toolkit – The toolkit provides information about effectively communicating and establishing a relationship with members of Congress. It includes details on how to effectively organize a visit, schedule and participate in a meeting with a member of Congress, and how to write a meaningful letter/e-mail that will get the member's attention. (The toolkit is for members only.) http://www.asco.org/advocacy/ascos-advocacy-toolkit

Practice-Related Items

Coding & Reimbursement Service - ASCO offers a service to answer oncology-related coding, billing and reimbursement inquiries. The coding and reimbursement service is offered electronically and can be accessed at www.asco.org/billingcoding. The service is available to ASCO members and their office staff as a member benefit, and a valid ASCO member number must be provided when using the online e-form. The service is also available to non-members for a nominal fee per inquiry.

Oncology Practice Insider - The Oncology Practice Insider is a bi-weekly e-communication specifically devoted to oncology practice management issues. The Insider provides updates on Medicare initiatives, drug shortages, regulations affecting physician practices, legislative activities, coverage information billing and coding, and more. The Insider launched in the spring of 2009 and currently has over 800 subscribers. To subscribe to this free oncology management e-communication e-mail practice@asco.org.

Journal of Oncology Practice - The *Journal of Oncology Practice (JOP)* provides oncologists and other oncology professionals with information, news, research and tools to enhance practice efficiency and promote quality in cancer care. The JOP includes original research, feature articles, and columns on various issues pertinent to daily practice operations, all of which are subject to peer review. For more information about JOP visit http://jop.ascopubs.org.

Practical Tips for the Oncology Practice - ASCO published *Practical Tips for the Oncology Practice, 6th Edition* in 2015. This book is one of ASCO's best resources for your practice with useful content that answers the most commonly asked billing, coding, and reimbursement questions related to oncology services. The book is directed at both physicians and their office staff. Its practical content can be applied in day-to-day operations and features discussions on common coverage and reimbursement issues.

The 6th edition of Practical Tips will be the first edition published in electronic format only. Updates from the 5th edition include information on ICD-10, Medicare quality reporting programs, and safety guidelines. The new electronic format of Practical Tips allows for enhanced search capabilities direct access of information listed in the publication's appendices.

As an eBook, users can access Practical Tips from a Kindle or other readers and mobile devices, such as an iPad or a Nook. Users can also download eBook readers for their computers if they want to access the content of Practical Tips from their desktop computers. The 6th edition of Practical Tips is $275; however, ASCO members receive a 20% discount of this price.

To learn more about *Practical Tips* or to order the 6th edition, go to http://university.asco.org/PracticalTips.

ASCO PracticeNET - PracticeNET is a learning collaborative where practices can share and receive insights to enhance their business operations and quality of care in order to assist practices in providing high quality, high value cancer care to patients. Participating practices will submit data for quarterly trend analysis and will be able to request reports to meet their individual practice needs. For more information, please visit www.asco.org/PracticeNet or contact PracticeNET@asco.org.

CAC Program

A national meeting for oncology and hematology Medicare Carrier Advisory Committee (CAC) representatives is held every year. Oncology and hematology CAC representatives from across the states are invited as well as Medicare Administrative Contractor Medical Directors (CMDs). The goal of the meeting is to educate attendees on the local coverage process as well as provide opportunities to strengthen communication and collaboration between CAC representatives and Contractor Medical Directors. (The meeting has been co-hosted by ASCO and the American Society of Hematology for the last few years.) Dedicated information for Carrier Advisory Committee (CAC) representatives and related CAC activities can be found on the ASCO website at http://www.asco.org/advocacy-practice/medicare-program under the CAC Program.

Institute for Quality

ASCO has developed the Institute for Quality which compiles the organization's quality projects and initiatives under one umbrella. Some of the initiatives are highlighted below.

Clinical practice guidelines, Provisional Clinical Opinions (PCOs) and guideline endorsements are available for practitioners outlining appropriate methods of treatment and care. ASCO expert panels identify and develop practice recommendations for specific areas of cancer care that would benefit from using practice guidelines. http://www.asco.org/institute-quality/guidelines

ASCO's Quality Oncology Practice Initiative (QOPI®) is an oncologist-led practice-based quality assessment and improvement program. http://qopi.asco.org/

ASCO's QOPI® Certification Program (QCP) provides a three-year certification for outpatient hematology-oncology practices that are committed to delivering high quality cancer care. http://qopi.asco.org/certification.html

CancerLinQ – The Learning Intelligence Network for Quality is ASCO's multi-phase initiative that promises to change the way cancer is treated. This learning health system will connect oncology practice, measure quality and performance, and provide physicians with decision support in real time. http://www.asco.org/institute-quality/cancerlinq

ASCO State of Cancer Care

This year, ASCO released the *State of Cancer Care in America: 2015*. This annual publication provides a comprehensive look at demographic, economic, and oncology practice trends that will impact cancer care in the United States over the coming years.

With recommendations for addressing the cancer care delivery system's most pressing concerns, this landmark ASCO report also examines the rapid expansion of health information technology and the growing emphasis on quality measurement and value.

ASCO developed the *State of Cancer Care in America: 2015* report to help cancer care providers, policy makers, and other more effectively shape the future of cancer care during these uncertain times. The Society will issue annual updates that will track trends and identify emerging issues.

For a full report published in the *Journal of Oncology Practice* and additional report content, visit www.asco.org/stateofcancercare.

ASCO PracticeNET
Networking for Education and Transformation

- A new collaborative learning network for oncology practice knowledge
  - Business knowledge, dynamic standards, best practices
  - Especially important as healthcare transitions from fee for service to value and other new payment models
- Practices share and receive insights to enhance business operations and quality of care
  - Quarterly reports measuring your practice against a national database of similar practices
  - Annual report on key practice indicators

ASCO PracticeNET
Networking for Education and Transformation

- Participation is at the practice level, with all physicians participating
- Simple, streamlined data submission
  - Submit data monthly; existing data from practice management system
- Enrollment is open now!
- For more information
  - www.asco.org/practicenet or PracticeNet@asco.org

American Society of Hematology's Practice-Related Resources

ASH offers a wide range of practice-related resources on its website (*www.hematology.org*). Below, please find a list of resources that may be of interest to you.

Resources for Clinicians **Section on the ASH Website** ***(http://www.hematology.org/Clinicians/)***

This page on the ASH website consolidates information for practitioners and provides the following links:

- ***ASH Practice Partnership*** – The ASH Practice Partnership (APP) is a group within the Society that was formed to better represent the interests of practicing hematologists. The APP is comprised of practicing hematologists from across the nation; participants must be board-certified in hematology and active members of ASH. Ideal candidates should be interested in malignant and nonmalignant hematology.

- ***Evidence-based Guidelines, Quick Reference Tools, Including Mobile Downloads*** – Access guidelines on the management and treatment of Sickle Cell Disease, Idiopathic Thrombocytopenic Purpura, Antithrombotic Drug Dosing and Management, Heparin-Induced Thrombocytopenia (HIT), Immune Thrombocytopenia (ITP), von Willebrand Disease, Red Blood Cell Transfusion, and Thrombocytopenia in Pregnancy.

- ***The ASH Choosing Wisely List*** **–** Evidence-based recommendations about the necessity and potential harm of certain practices developed as part of Choosing Wisely®, an initiative of the ABIM Foundation.

- ***The ASH Academy*** – The ASH Academy provides hematologists with easy-to-use options for knowledge testing (for both MOC and CME purposes), completing practice improvement modules, as well as evaluating ASH meetings you attend and claiming CME credit for participating. The fifth edition of the ASH Self-Assessment Program (ASH-SAP) is also available on the ASH Academy.

- ***ASH On Demand*** **–** ASH On Demand is multimedia platform in which users can browse, purchase, and view a variety of ASH educational content. The portal includes PowerPoint slides, audio, and/or video from a number of ASH-wide programs – including annual meetings, regional meetings, and webinars.

- ***Physician Quality Reporting System (PQRS) Resources*** – Up to date information on Medicare's PQRS and measures appropriate for use by hematologists.

- ***Drug Resources*** – Links to patient assistance programs and sample letters of appeal for high-cost drugs, an up-to-date list of hematologic drug shortages, resources for physicians dealing with shortages, and links to ASH/FDA webinars featuring an unbiased discussion of newly approved drugs and their uses.

- ***ICD-10 Conversion for Hematology Resource Page*** – This resource help members prepare for the transition by providing complete conversion charts for all disorders related to hematology.

- ***Open Payments Program (Sunshine Act) Resource Page*** – This page provides resources to help members understand the program, important dates, and links to the CMS Open Payments webpage and registration instructions.

- ***Consult a Colleague*** – A member service designed to help facilitate the exchange of information between hematologists and their peers.

ASH Advocacy Resources

ASH's redesigned Advocacy Center houses all the Society's policy positions, advocacy efforts, and campaigns. Hematologists and their patients can follow the latest national policy news and directly campaign their representatives through ASH Action Alerts. The Center also displays ASH's official policy statements along with testimony and correspondence related to federal regulation and private insurance developments.

ASH Publications

- ***ASH Practice Updates*** – The *Practice Update* is the society's bi-monthly e-newsletter reporting on breaking news and activities of interest to the practice community.

- ***ASH Clinical News*** **–** *ASH Clinical News* is a new magazine for ASH members and non-members alike – offering news and views for the broader hematology/oncology community.

- ***The Hematologist: ASH News and Reports*** – An award-winning bimonthly publication that updates readers about important developments in the field of hematology and highlights what ASH is doing for its members.

Meeting Information

- ***ASH Meeting on Hematologic Malignancies*** – September 17 – 19, 2015, Chicago, IL. This event will allow you to hear top experts in hematologic malignancies discuss the latest developments in clinical care and to find answers to your most challenging patient care questions.

- ***ASH Annual Meeting and Exposition*** – Information concerning registration, housing, and meeting content for the Society's Annual Meeting and Exposition designed to provide hematologists from around the world a forum for discussing critical issues in the field. Abstracts presented at the meeting also contain the latest and most exciting developments in hematology research.

- ***Consultative Hematology Course*** – Information concerning registration, housing, and meeting content for this intensive half-day program, which focuses on updates in non-malignant hematology designed for practitioners who are trained as hematologists or hematologist-oncologists, but now see patents with non-malignant hematologic conditions on a less frequent basis.

- ***Highlights of ASH*** – Information concerning registration, housing, and meeting content for this ASH-sponsored meeting designed to provide the highlights of the top presentations from the recent annual meeting.

- ***Annual Meeting of the Hematology / Oncology Carrier Advisory Committee (CAC) Network*** – July 9 – 10, 2015, Alexandria, VA. This annual event brings together the hematologists and oncologists who serve as representatives to regional Medicare Contractors, Medicare Contractor Medical Directors, leaders from hematology and oncology state societies, and members of ASH and ASCO practice committees. The meeting is intended to provide attendees with a better understanding of the CAC process; discuss issues of common concern and develop solutions; and improve the overall CAC process throughout the year.

Choosing Wisely®

An initiative of the ABIM Foundation

American Society of Clinical Oncology

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American Society of Clinical Oncology

Five Things Physicians and Patients Should Question

The American Society of Clinical Oncology (ASCO) is a medical professional oncology society committed to conquering cancer through research, education, prevention and delivery of high-quality patient care. ASCO recognizes the importance of evidence-based cancer care and making wise choices in the diagnosis and management of patients with cancer. After careful consideration by experienced oncologists, ASCO highlights ten categories of tests, procedures and/or treatments whose common use and clinical value are not supported by available evidence. These test and treatment options should not be administered unless the physician and patient have carefully considered if their use is appropriate in the individual case. As an example, when a patient is enrolled in a clinical trial, these tests, treatments and procedures may be part of the trial protocol and therefore deemed necessary for the patient's participation in the trial.

These items are provided solely for informational purposes and are not intended to replace a medical professional's independent judgment or as a substitute for consultation with a medical professional. Patients with any specific questions about the items on this list or their individual situation should consult their health care provider. New evidence may emerge following the development of these items. ASCO is not responsible for any injury or damage arising out of or related to any use of these items or to any errors or omissions.

1 Don't use cancer-directed therapy for solid tumor patients 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 anti-cancer treatment.

- Studies show that cancer directed treatments are likely to be ineffective for solid tumor patients who meet the above stated criteria.
- Exceptions include patients with functional limitations due to other conditions resulting in a low performance status or those with disease characteristics (e.g., mutations) that suggest a high likelihood of response to therapy.
- Implementation of this approach should be accompanied with appropriate palliative and supportive care.

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

- Imaging with PET, CT, or radionuclide bone scans can be useful in the staging of specific cancer types. However, these tests are often used in the staging evaluation of low-risk cancers, despite a lack of evidence suggesting they improve detection of metastatic disease or survival.
- Evidence does not support the use of these scans for staging of newly diagnosed low grade carcinoma of the prostate (Stage T1c/T2a, prostate-specific antigen (PSA) <10 ng/ml, Gleason score less than or equal to 6) with low risk of distant metastasis.
- Unnecessary imaging can lead to harm through unnecessary invasive procedures, over-treatment, unnecessary radiation exposure, and misdiagnosis.

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

- Imaging with PET, CT, or radionuclide bone scans can be useful in the staging of specific cancer types. However, these tests are often used in the staging evaluation of low-risk cancers, despite a lack of evidence suggesting they improve detection of metastatic disease or survival.
- In breast cancer, for example, there is a lack of evidence demonstrating a benefit for the use of PET, CT, or radionuclide bone scans in asymptomatic individuals with newly identified ductal carcinoma in situ (DCIS), or clinical stage I or II disease.
- Unnecessary imaging can lead to harm through unnecessary invasive procedures, over-treatment, unnecessary radiation exposure, and misdiagnosis.

4 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.

- Surveillance testing with serum tumor markers or imaging has been shown to have clinical value for certain cancers (e.g., colorectal). However for breast cancer that has been treated with curative intent, several studies have shown there is no benefit from routine imaging or serial measurement of serum tumor markers in asymptomatic patients.
- False-positive tests can lead to harm through unnecessary invasive procedures, over-treatment, unnecessary radiation exposure, and misdiagnosis.

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

- ASCO guidelines recommend using white cell stimulating factors when the risk of febrile neutropenia, secondary to a recommended chemotherapy regimen, is approximately 20 percent and equally effective treatment programs that do not require white cell stimulating factors are unavailable.
- Exceptions should be made when using regimens that have a lower chance of causing febrile neutropenia if it is determined that the patient is at high risk for this complication (due to age, medical history, or disease characteristics).

Choosing Wisely®

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Five More Things Physicians and Patients Should Question

6

Don't give patients starting on a chemotherapy regimen that has a low or moderate risk of causing nausea and vomiting antiemetic drugs intended for use with a regimen that has a high risk of causing nausea and vomiting.

- Over the past several years, a large number of effective drugs with fewer side effects have been developed to prevent nausea and vomiting from chemotherapy. When successful, these medications can help patients avoid spending time in the hospital, improve their quality of life and lead to fewer changes in the chemotherapy regimen.
- Oncologists customarily use different antiemetic drugs depending on the likelihood (low, moderate or high) for a particular chemotherapy program to cause nausea and vomiting. For chemotherapy programs that are likely to produce severe and persistent nausea and vomiting, there are new agents that can prevent this side effect. However, these drugs are very expensive and not devoid of side effects. For this reason, these drugs should be used only when the chemotherapy drugs that have a high likelihood of causing severe or persistent nausea and vomiting.
- When using chemotherapy that is less likely to cause nausea and vomiting, there are other effective drugs available at a lower cost.

7

Don't use combination chemotherapy (multiple drugs) instead of chemotherapy with one drug when treating an individual for metastatic breast cancer unless the patient needs a rapid response to relieve tumor-related symptoms.

- Although chemotherapy with multiple drugs, or combination chemotherapy, for metastatic breast cancer may slow tumor growth for a somewhat longer time than occurs when treating with a single agent, use of combination chemotherapy has not been shown to increase overall survival. In fact, the trade-offs of more frequent and severe side effects may have a net effect of worsening a patient's quality of life, necessitating a reduction in the dose of chemotherapy.
- Combination chemotherapy may be useful and worth the risk of more side effects in situations in which the cancer burden must be reduced quickly because it is causing significant symptoms or is life threatening. As a general rule, however, giving effective drugs one at a time lowers the risk of side effects, may improve a patient's quality of life, and does not typically compromise overall survival.

8

Avoid using PET or PET-CT scanning as part of routine follow-up care to monitor for a cancer recurrence in asymptomatic patients who have finished initial treatment to eliminate the cancer unless there is high-level evidence that such imaging will change the outcome.

- PET and PET-CT are used to diagnose, stage and monitor how well treatment is working. Available evidence from clinical studies suggests that using these tests to monitor for recurrence does not improve outcomes and therefore generally is not recommended for this purpose.
- False positive tests can lead to unnecessary and invasive procedures, overtreatment, unnecessary radiation exposure and incorrect diagnoses.
- Until high level evidence demonstrates that routine surveillance with PET or PET-CT scans helps prolong life or promote well-being after treatment for a specific type of cancer, this practice should not be done.

9

Don't perform PSA testing for prostate cancer screening in men with no symptoms of the disease when they are expected to live less than 10 years.

- Since PSA levels in the blood have been linked with prostate cancer, many doctors have used repeated PSA tests in the hope of finding "early" prostate cancer in men with no symptoms of the disease. Unfortunately, PSA is not as useful for screening as many have hoped because many men with prostate cancer do not have high PSA levels, and other conditions that are not cancer (such as benign prostate hyperplasia) can also increase PSA levels.
- Research has shown that men who receive PSA testing are less likely to die specifically from prostate cancer. However when accounting for deaths from all causes, no lives are saved, meaning that men who receive PSA screening have not been shown to live longer than men who do not have PSA screening. Men with medical conditions that limit their life expectancy to less than 10 years are unlikely to benefit from PSA screening as their probability of dying from the underlying medical problem is greater than the chance of dying from asymptomatic prostate cancer.

10

Don't use a targeted therapy intended for use against a specific genetic aberration unless a patient's tumor cells have a specific biomarker that predicts an effective response to the targeted therapy.

- Unlike chemotherapy, targeted therapy can significantly benefit people with cancer because it can target specific gene products, i.e., proteins that cancer cells use to grow and spread, while causing little or no harm to healthy cells. Patients who are most likely to benefit from targeted therapy are those who have a specific biomarker in their tumor cells that indicates the presence or absence of a specific gene alteration that makes the tumor cells susceptible to the targeted agent.
- Compared to chemotherapy, the cost of targeted therapy is generally higher, as these treatments are newer, more expensive to produce and under patent protection. In addition, like all anti-cancer therapies, there are risks to using targeted agents when there is no evidence to support their use because of the potential for serious side effects or reduced efficacy compared with other treatment options.

Abbreviations

CT, computed tomography; DCIS, ductal carcinoma in situ; PET, positron emission tomography; PSA, prostate-specific antigen.

How This List Was Created (1–5)

The American Society of Clinical Oncology (ASCO) has had a standing Cost of Cancer Care Task Force since 2007. The role of the Task Force is to assess the magnitude of rising costs of cancer care and develop strategies to address these challenges. In response to the 2010 New England Journal of Medicine article by Howard Brody, MD, "Medicine's Ethical Responsibility for Health Care Reform – the Top Five List," a subcommittee of the Cost of Cancer Care Task Force began work to identify common practices in oncology that were both common as well as lacking sufficient evidence for widespread use. Upon joining the Choosing Wisely campaign, the members of the subcommittee conducted a literature search to ensure the proposed list of items were supported by available evidence in oncology; ultimately the proposed Top Five list was approved by the full Task Force. The initial draft list was then presented to the ASCO Clinical Practice Committee, a group composed of community-based oncologists as well as the presidents of the 48 state/regional oncology societies in the United States. Advocacy groups were also asked to weigh in to ensure the recommendations would achieve the dual purpose of increasing physician-patient communication and changing practice patterns. A plurality of more than 200 clinical oncologists reviewed, provided input and supported the list. The final Top Five list in oncology was then presented to, discussed and approved by the Executive Committee of the ASCO Board of Directors and published in the Journal of Clinical Oncology. ASCO's disclosure and conflict of interest policies can be found at www.asco.org.

How This List Was Created (6–10)

To guide ASCO in developing this list, suggestions were elicited from current ASCO committee members (approximately 700 individuals); 115 suggestions were received. After removing duplicates, researching the literature and discussing practice patterns, the Value in Cancer Care Task Force culled the list to 11 items, which comprised an ASCO Top Five voting slate that was sent back to the membership of all standing committees. Approximately 140 oncologists from its leadership cadre voted, providing ASCO with an adequate sample size and perspective on what oncologists find to be of little value. The list was reviewed and finalized by the Value in Cancer Care Task Force and ultimately reviewed and approved by the ASCO Board of Directors and published in the *Journal of Clinical Oncology*. ASCO's disclosure and conflict of interest policies can be found at www.asco.org.

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About the ABIM Foundation

The mission of the ABIM Foundation is to advance medical professionalism to improve the health care system. We achieve this by collaborating with physicians and physician leaders, medical trainees, health care delivery systems, payers, policymakers, consumer organizations and patients to foster a shared understanding of professionalism and how they can adopt the tenets of professionalism in practice.

To learn more about the ABIM Foundation, visit www.abimfoundation.org.

About the American Society of Clinical Oncology

The American Society of Clinical Oncology (ASCO) is the world's leading professional organization representing physicians who care for people with cancer. With more than 30,000 members, ASCO is committed to improving cancer care through scientific meetings, educational programs and peer-reviewed journals. ASCO is supported by its affiliate organization, the Conquer Cancer Foundation, which funds ground-breaking research and programs that make a tangible difference in the lives of people with cancer. ASCO's membership is comprised of clinical oncologists from all oncology disciplines and sub-specialties including medical oncology, therapeutic radiology, surgical oncology, pediatric oncology, gynecologic oncology, urologic oncology, and hematology; physicians and health care professionals participating in approved oncology training programs; oncology nurses; and other health care practitioners with a predominant interest in oncology.

For more information, please visit www.asco.org.

For more information or to see other lists of Five Things Physicians and Patients Should Question, visit www.choosingwisely.org.

Choosing Wisely®

An initiative of the ABIM Foundation

American Society of Hematology

Ten Things Physicians and Patients Should Question

1 Don't transfuse more than the minimum number of red blood cell (RBC) units necessary to relieve symptoms of anemia or to return a patient to a safe hemoglobin range (7 to 8 g/dL in stable, non-cardiac in-patients).

Transfusion of the smallest effective dose of RBCs is recommended because liberal transfusion strategies do not improve outcomes when compared to restrictive strategies. Unnecessary transfusion generates costs and exposes patients to potential adverse effects without any likelihood of benefit. Clinicians are urged to avoid the routine administration of 2 units of RBCs if 1 unit is sufficient and to use appropriate weight-based dosing of RBCs in children.

2 Don't test for thrombophilia in adult patients with venous thromboembolism (VTE) occurring in the setting of major transient risk factors (surgery, trauma or prolonged immobility).

Thrombophilia testing is costly and can result in harm to patients if the duration of anticoagulation is inappropriately prolonged or if patients are incorrectly labeled as thrombophilic. Thrombophilia testing does not change the management of VTEs occurring in the setting of major transient VTE risk factors. When VTE occurs in the setting of pregnancy or hormonal therapy, or when there is a strong family history plus a major transient risk factor, the role of thrombophilia testing is complex and patients and clinicians are advised to seek guidance from an expert in VTE.

3 Don't use inferior vena cava (IVC) filters routinely in patients with acute VTE.

IVC filters are costly, can cause harm and do not have a strong evidentiary basis. The main indication for IVC filters is patients with acute VTE and a contraindication to anticoagulation such as active bleeding or a high risk of anticoagulant-associated bleeding. Lesser indications that may be reasonable in some cases include patients experiencing pulmonary embolism (PE) despite appropriate, therapeutic anticoagulation, or patients with massive PE and poor cardiopulmonary reserve. Retrievable filters are recommended over permanent filters with removal of the filter when the risk for PE has resolved and/or when anticoagulation can be safely resumed.

4 Don't administer plasma or prothrombin complex concentrates for non-emergent reversal of vitamin K antagonists (i.e. outside of the setting of major bleeding, intracranial hemorrhage or anticipated emergent surgery).

Blood products can cause serious harm to patients, are costly and are rarely indicated in the reversal of vitamin K antagonists. In non-emergent situations, elevations in the international normalized ratio are best addressed by holding the vitamin K antagonist and/or by administering vitamin K.

5 Limit surveillance computed tomography (CT) scans in asymptomatic patients following curative-intent treatment for aggressive lymphoma.

CT surveillance in asymptomatic patients in remission from aggressive non-Hodgkin lymphoma may be harmful through a small but cumulative risk of radiation-induced malignancy. It is also costly and has not been demonstrated to improve survival. Physicians are encouraged to carefully weigh the anticipated benefits of post-treatment CT scans against the potential harm of radiation exposure. Due to a decreasing probability of relapse with the passage of time and a lack of proven benefit, CT scans in asymptomatic patients more than 2 years beyond the completion of treatment are rarely advisable.

Released December 4, 2013

Choosing Wisely®

An initiative of the ABIM Foundation

American Society of Hematology

Ten Things Physicians and Patients Should Question

6 Don't treat with an anticoagulant for more than three months in a patient with a first venous thromboembolism (VTE) occurring in the setting of a major transient risk factor.

Anticoagulation is potentially harmful and costly. Patients with a first VTE triggered by a major, transient risk factor such as surgery, trauma or an intravascular catheter are at low risk for recurrence once the risk factor has resolved and an adequate treatment regimen with anticoagulation has been completed. Evidence-based and consensus guidelines recommend three months of anticoagulation over shorter or longer periods of anticoagulation in patients with VTE in the setting of a reversible provoking factor. By ensuring a patient receives an appropriate regimen of anticoagulation, clinicians may avoid unnecessary harm, reduce health care expenses and improve quality of life. This *Choosing Wisely*® recommendation is not intended to apply to VTE associated with non-major risk factors (e.g., hormonal therapy, pregnancy, travel-associated immobility, etc.), as the risk of recurrent VTE in these groups is either intermediate or poorly defined.

7 Don't routinely transfuse patients with sickle cell disease (SCD) for chronic anemia or uncomplicated pain crisis without an appropriate clinical indication.

Patients with SCD are especially vulnerable to potential harms from unnecessary red blood cell transfusion. In particular, they experience an increased risk of alloimmunization to minor blood group antigens and a high risk of iron overload from repeated transfusions. Patients with the most severe genotypes of SCD with baseline hemoglobin (Hb) values in the 7-10 g/dl range can usually tolerate further temporary reductions in Hb without developing symptoms of anemia. Many patients with SCD receive intravenous fluids to improve hydration when hospitalized for management of pain crisis, which may contribute to a decrease in Hb by 1-2 g/dL. Routine administration of red cells in this setting should be avoided. Moreover, there is no evidence that transfusion reduces pain due to vaso-occlusive crises. For a discussion of when transfusion is indicated in SCD, readers are referred to recent evidence-based guidelines from the National Heart, Lung, and Blood Institute (NHLBI) (see reference below).

8 Don't perform baseline or routine surveillance computed tomography (CT) scans in patients with asymptomatic, early-stage chronic lymphocytic leukemia (CLL).

In patients with asymptomatic, early-stage CLL, baseline and routine surveillance CT scans do not improve survival and are not necessary to stage or prognosticate patients. CT scans expose patients to small doses of radiation, can detect incidental findings that are not clinically relevant but lead to further investigations and are costly. For asymptomatic patients with early-stage CLL, clinical staging and blood monitoring is recommended over CT scans.

9 Don't test or treat for suspected heparin-induced thrombocytopenia (HIT) in patients with a low pre-test probability of HIT.

In patients with suspected HIT, use the "4T's" score to calculate the pre-test probability of HIT. This scoring system uses the timing and degree of thrombocytopenia, the presence or absence of thrombosis, and the existence of other causes of thrombocytopenia to assess the pre-test probability of HIT. HIT can be excluded by a low pre-test probability score (4T's score of 0-3) without the need for laboratory investigation. Do not discontinue heparin or start a non-heparin anticoagulant in these low-risk patients because presumptive treatment often involves an increased risk of bleeding, and because alternative anticoagulants are costly.

10 Don't treat patients with immune thrombocytopenic purpura (ITP) in the absence of bleeding or a very low platelet count.

Treatment for ITP should be aimed at treating and preventing bleeding episodes and improving quality of life. Unnecessary treatment exposes patients to potentially serious treatment side effects and can be costly, with little expectation of clinical benefit. The decision to treat ITP should be based on an individual patient's symptoms, bleeding risk (as determined by prior bleeding episodes and risk factors for bleeding such as use of anticoagulants, advanced age, high-risk activities, etc.), social factors (distance from the hospital/travel concerns), side effects of possible treatments, upcoming procedures, and patient preferences. In the pediatric setting, treatment is usually not indicated in the absence of mucosal bleeding regardless of platelet count. In the adult setting, treatment may be indicated in the absence of bleeding if the platelet count is very low. However, ITP treatment is rarely indicated in adult patients with platelet counts greater than 30,000/microL unless they are preparing for surgery or an invasive procedure, or have a significant additional risk factor for bleeding. In patients preparing for surgery or other invasive procedures, short-term treatment may be indicated to increase the platelet count prior to the planned intervention and during the immediate post-operative period.

Released December 3, 2014

How This List Was Created (1–5)

The American Society of Hematology (ASH) *Choosing Wisely*® Task Force utilized a modified Delphi technique to collect suggestions from committee members and recipients of its clinically focused newsletter, the *ASH Practice Update*. Respondents were asked to consider the core values of harm, cost, strength of evidence, frequency and control. Fifty-nine of 167 ASH committee members (35%) and 2 recipients of the *ASH Practice Update* submitted 81 unique suggestions. The Task Force used a nominal group technique (NGT) to identify the top 20 items, which were scored by ASH committee and practice community members, with a 46 percent participation rate. ASH's Task Force reviewed all scores to develop a 10-item list. A professional methodologist conducted a systematic literature review on each of the 10 items; the Task Force chair served as the second reviewer. Evidence reviews and source material for the 10 items were shared with ASH's Task Force, which ranked the items according to the core values. The Task Force then identified the top 5 items plus 1 alternate. ASH member content experts provided external validation for the veracity and clarity of the items.

How this List was Created (6–10)

Suggestions for the second ASH *Choosing Wisely* list were solicited from members of the ASH Committee on Practice, the ASH Committee on Quality, the ASH *Choosing Wisely* Task Force, ASH Consult-a-Colleague volunteers and members of the ASH Practice Partnership. Six principles were used to prioritize items: avoiding harm to patients, producing evidence-based recommendations, considering both the cost and frequency of tests and treatments, making recommendations in the clinical purview of the hematologist, and considering the potential impact of recommendations. Harm avoidance was established as the campaign's preeminent guiding principle. Guided by the 6 principles, the ASH *Choosing Wisely* Task Force scored all suggestions. Modified group technique was used to select 10 semi-finalist items. Systematic reviews of the literature were then completed for each of the 10 semi-finalist items. Guided by the 6 core principles outlined above, and by the systematic reviews of the evidence, the ASH *Choosing Wisely* Task Force selected 5 recommendations for inclusion in ASH's second *Choosing Wisely* Campaign.

ASH's disclosure and conflict of interest policy can be found at www.hematology.org.

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To learn more about the ABIM Foundation, visit www.abimfoundation.org.

About the American Society of Hematology

The American Society of Hematology (ASH) is the world's largest professional society of hematologists, serving more than 14,000 clinicians and scientists from around the world who are dedicated to furthering the understanding, diagnosis, treatment and prevention of disorders affecting the blood.

For more than 50 years, the Society has led the development of hematology as a discipline by promoting research, patient care, education, training and advocacy in hematology. By providing a forum for clinicians and scientists to share the latest discoveries in the field, ASH is helping to improve care and possibly lead to cures for diseases that affect millions of people, including leukemia, lymphoma, myeloma, anemias and various bleeding and clotting disorders.

For more information, visit www.hematology.org.

For more information or to see other lists of Five Things Physicians and Patients Should Question, visit www.choosingwisely.org.

MEETING EVALUATION FORM – ASH/ASCO CAC NETWORK MEETING
JULY 9 – 10, 2015 – Alexandria, VA

ASH and ASCO are committed to providing the highest quality for the CAC Network meeting. To assist in meeting that goal, we ask that you please complete the following confidential survey and provide and comments or suggestions that you may have.

DEMOGRAPHIC INFORMATION

I am (please check all that apply):

- ☐ The oncology CAC representative/alternate for my state.
- ☐ The hematology CAC representative/alternate for my state.
- ☐ The president (or another physician representative) of my state oncology society.
- ☐ The executive director/administrator of my state oncology society.
- ☐ A member of ASCO's Clinical Practice Committee.
- ☐ A member of ASH's Committee on Practice or ASH's Subcommittee on Reimbursement.
- ☐ A Medicare contractor medical director.
- ☐ An invited meeting speaker.

Evaluation Key

1	2	3	4	5
Strong Agree	Agree	Neutral	Disagree	**Strongly Disagree**

Please indicate the degree to which you agree with the statements in each section below by placing a check mark on **1 (strongly AGREE) to 5 (strongly disagree) for each statement.**

1. Welcome Reception

WELCOME RECEPTION	1	2	3	4	5
The Welcome reception provided an opportunity to network with other CAC representatives, state society representatives, and committee members.					
The format of the Welcome reception was a valuable addition to the meeting.					

2. Group Dinners

GROUP DINNERS	1	2	3	4	5
The group dinners provided the additional opportunity to network with other CAC representatives, state society representatives, committee members, and contractor medical directors.					
The size of the dinner group was appropriate for networking.					
I enjoyed the additional opportunity to network with other CAC meeting attendees.					

3. General Meeting

GENERAL MEETING	1	2	3	4	5
I learned new information or obtained a better understanding of a particular issue or topic.					
The topics discussed are important to my role as a CAC representative, state society representative or committee member.					
There were adequate opportunities for questions and answers or discussions of topics.					
The contractor medical director participation in the meeting was helpful in obtaining feedback on important issues.					
The open microphone session was helpful in understanding CAC-related issues/topics and fostered communication between CAC representatives and CMDs.					
The written materials and resources provided in the binder were a helpful supplement to the discussions.					
The length of the meeting was appropriate.					
The meeting facility was conducive for the meeting format/structure.					

4. Presentations/Speakers

PRESENTATIONS/SPEAKERS	1	2	3	4	5
I found the presentation on Molecular Diagnostics – Coverage with Evidence Development/ Data Development, Role of FDA, Panels by Elaine Jeter, MD and Dane Dickson, MD interesting.					
I found the presentation on Medicare Oncology Care Model – Practice Implications and Potential Pitfalls by Ronald Kline, MD educational.					
The breakout session, Ways to Improve the CAC Process in Your Region was useful.					
The ICD-10 Transition Issues presentation by Arthur Lurvey, MD was helpful.					
The presentation on Infusions/DME/Orals by Richard (Dick) Whitten, MD was educational.					
The presentation on Biosimilars – FDA Interchangeability Coverage by John Warren was informative.					
The Open Forum Panel with the Contractor Medical Directors was educational.					

5. What aspect(s) of the CAC Network Meeting do you find most valuable?

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6. What aspect(s) of the CAC Network Meeting are most in need of improvement? (Please be specific.)

7. **What topics or themes would you like to see addressed at future meetings?**

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8. **Overall, how would you rate the CAC Network Meeting? (Please choose one.)**
   a) Excellent b) Good c) Fair d) Poor

9. **Is the current format of the CAC Network Meeting effective? (Please circle one): YES or NO**
   - **If you circled NO, please provide additional/alternative ways ASH and ASCO can make the meeting more effective.**

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10. **Are there any additional resources ASH and ASCO can provide to assist you with the local coverage process?**

**** Thank you for your input! Please leave the evaluation form on your table or on the table outside the meeting room. If you are unable to complete the form onsite, please e-mail the form directly after the meeting to ASH staff, Deon Nelson at dnelson@hematology.org ****

American Society of Hematology
www.hematology.org

American Society of Clinical Oncology
www.asco.org

2015 ASH/ASCO CAC Network Meeting
Expense Reimbursement Form

Please fill out the information below and attach original receipts.
All forms must be submitted by August 10, 2015

Make check payable to: _____

Mail check to: _____

Meeting Attended: 2015 ASH/ASCO CAC Network Meeting

Signature: _____ **Date:** _____

Itemized Expenses:

Date	Description of Expense	Account (*internal use only*)	Amount
_____	_____	_____	$_____
_____	_____	_____	$_____
_____	_____	_____	$_____
_____	_____	_____	$_____
_____	_____	_____	$_____
_____	_____	_____	$_____

For ASCO Use Only:
Approval: _____ Date Submitted to Accounting: _____

Please return completed form and original receipts by August 10, 2015 to:

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American Society of Hematology
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American Society of Clinical Oncology
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AMERICAN SOCIETY OF HEMATOLOGY and
AMERICAN SOCIETY OF CLINICAL ONCOLOGY
2015 CAC Network Meeting
Travel Reimbursement Policy

The ASH-ASCO CAC Network Meeting Travel Reimbursement Policy is provided to travelers regarding reimbursement for costs incurred in order to participate in the CAC Network Meeting. It is expected that the policy will be adhered to explicitly.

ASCO and ASH will reimburse the following groups for their attendance:

- CAC representatives and alternate representatives for hematology and oncology;
- Members of the ASCO Clinical Practice Committee and ASH Committee on Practice;
- Two representatives from the Hematology/ Oncology State Society*
- Medicare Contractor Medical Directors (CMDs) for all A/B MAC jurisdictions.

**Only two representatives from the state society (excluding CAC representatives) will be reimbursed for attending the ASH/ASCO CAC Network Meeting. State hematology/oncology society presidents and administrators/executive directors should determine who will attend the meeting. If more than two individuals from the state society (excluding CAC representatives) attend the meeting, reimbursement will be the responsibility of the state society or individual.*

Coverage begins at the actual start of a trip, whether it is from the traveler's regular place of employment, home, or other location, and terminates when the traveler reaches his/her original destination. Expenses for spouses and/or dependents are personal expenses and are not reimbursable.

Original receipts for all expenditures (including E-ticket passenger receipts, taxis, and parking) of **$25.01 or more** must be included with the CAC Network Meeting Expense Reimbursement Form. Requests for reimbursement must be submitted within **thirty (30)** days of the meeting for which reimbursable expenses were incurred. The approved reimbursement will be issued by check.

Air/Train Travel

ASH and ASCO will pay for coach class airline tickets (not business or first class), preferably purchased through the ASCO travel agency MacNair Travel. To book your travel online, please visit http://travel.asco.org and use cost code "Carrier Advisory 20-822". If you need assistance with your flight purchase, please contact ASCO's travel specialist, Michelle Rowley at mrowley@macnairtravel.com or (877) 410-8198 or (202) 360-4674. Domestic airline reservations are recommended to be made at least 30 days in advance of the meeting. Flight reservations made less than 30 days in advance will require approval from ASH/ASCO staff.

ASH and ASCO will reimburse the most economical non-refundable coach fares available on a major airline carrier (American, Delta, Southwest, United, U.S. Airways, etc.). When a significantly less expensive option is available, reservations made with a particular carrier to benefit the traveler will not be reimbursed in full; rather, the amount reimbursed will equal the amount of the equivalent ticket on the most economical carrier.

If an approved traveler wants to bring a guest, they must provide the ASCO travel agent with a personal credit card for the guest's travel.

Ground Transportation

ASH and ASCO encourage the use of the most economical ground transportation to and from the airport or train station and will reimburse such expenses.

Use of a personal or university vehicle will be reimbursed at the mileage rate consistent with IRS rules and regulations (**57 cents per mile as of 1/1/15, including gasoline**) plus toll and parking charges. (ASH and ASCO will reimburse parking charges and mileage as long as this amount is not greater than the cost of roundtrip taxi or shuttle service.)

If ASH and ASCO approve the use of a rental car, limits will be set and communicated to the traveler by the appropriate ASCO representative. The maximum rates set by ASH and ASCO take into account the cost of the rental, mileage, gasoline, parking, tolls, and any other expenses related to the use of the rental in order to attend the meeting.

Hotel

One night hotel stay will be provided for by ASH and ASCO. Additional nights can be reserved but the attendee will be responsible for the extra stay. (Individuals that would require two nights based on flight options and/or destinations must contact ASH or ASCO staff prior to making the reservation.)

The traveler is responsible for promptly submitting the RSVP Survey as requested by the ASCO representative handling hotel room block arrangements. **Surveys are due Friday, June 5, 2015**

Meals

Meals that are not provided during the meeting will be covered with the following limits including tax and tip:

Dinner	$75.00
Lunch	$40.00
Breakfast	$25.00

ASCO and ASH provides breakfast and lunch for Friday, July 10. Expenses incurred by attendees for either of these meals will not be reimbursed.

Cancellations and Changes

When a traveler needs to change or cancel an airline reservation, he/she must contact the issuing agent and notify the appropriate ASH or ASCO representatives **immediately**. Unless the change or cancellation is approved by ASH or ASCO, the traveler is responsible for all penalty fees and any other charges incurred due to such changes or cancellations. If the traveler does not inform the travel agency or airline of the cancellation prior to the scheduled departure time, and the ticket is thereby rendered unusable for future travel, then the traveler will be held responsible for the cost of the original ticket.

If a traveler needs to change or cancel a hotel reservation, he or she must contact the appropriate ASH or ASCO representative at least 72 hours prior to his/her originally scheduled arrival. The traveler is responsible for reimbursing ASH and ASCO for expenses incurred due to last-minute changes, cancellations, no-shows, and early departures.

Miscellaneous Expenses

- Baggage service, up to a maximum of one checked bag per flight and similar expenses are reimbursable.
- Internet service, up to $14 per day is reimbursable while attending the CAC Network Meeting.
- Tips not included with meals or cab fare should be listed separately on the CAC Network Meeting Expense Reimbursement Form.
- When a trip involves traveling for both the CAC Network Meeting and other purposes, the traveler must reasonably allocate the costs between CAC Network Meeting and the other activity.

If a traveler has any questions concerning any other reimbursable expenses, he/she should contact the appropriate ASH or ASCO representative.