American Society of Hematology
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2017 American Society of Hematology and American Society of Clinical Oncology

Hematology and Oncology Carrier Advisory Committee (CAC) Network Meeting

July 20 – 21, 2017

American Society of Clinical Oncology
2318 Mill Road
Suite 800
Alexandria, VA 22314
(571) 483-1300

American Society of Hematology/American Society of Clinical Oncology
Carrier Advisory Committee (CAC) Network Meeting

Friday, July 21, 2017
8:00 a.m. – 3 p.m.

AGENDA

Mentor CAC 101

This session is from 7:45-8:15 a.m. at ASCO HQ on the 8th Floor Conference Center. We kindly ask those not attending to please delay entering the meeting room until the end of the mentor session

Goals: This session is an introduction to the CAC process for new CAC representatives. This session also provides new representatives with mentors and an additional opportunity to network.

Mentors:

1. Steve Allen, MD, FACP
2. Eric Seifter, MD
3. John Cox, DO, MBA, FACP, FASCO
4. Joseph DiBenedetto Jr., MD
5. Luis Pineda, MD, MSHA
6. Sam Silver, MD, PhD, MACP, FASCO

Attendees:

1. Joseph Alvarnas, MD
2. Robert H. Cassell, MD, PhD
3. Paul Celano, MD
4. Matthew Cheung, MD, MS, FRCP
5. Carol A. Christner, MS, BA
6. Laurence Clark, MD, FACP
7. Chancellor Donald, MD
8. Nicole Dreabit
9. Omar Eton, MD
10. Stuart P. Feldman, MD
11. Paul Fishkin, MD
12. Annette Fontaine, MD, MBA
13. Tom Heffner, MD
14. Sakeer Hussain, MD
15. Anshu K. Jain, MD
16. Elaine Jeter, MD
17. Mary M. Klix, MD
18. Peter Louides, MD
19. Arthur Lurvey, MD, FACP, FACE
20. Gary MacVicar, MD
21. Rajini Malisetti, MD
22. Charles F. Miller, MD
23. Daniel P. Mirda, MD
24. Jose Eugenio Najera, MD
25. Gary Oakes, MD
26. Kashyap B. Patel, MD
27. Dhimant R. Patel, MD
28. Marc Rovito, MD
29. Michael A. Savin, MD
30. Tammy Thiel
31. Patricia Troy, CAE
32. Sabina Wallach, MD, FRACP, FACP
33. Ronald Walters, MD, MHS, MS, MBA
34. Richard (Dick) Whitten, MD, MBA, FACP

ASH and ASCO are always looking for new members to take part in the CAC process. If you would like to become a CAC representative or know of a colleague who would like to become a representative, please feel free to reach out to Katherine Stark at ASH or Monica Tan at ASCO.

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

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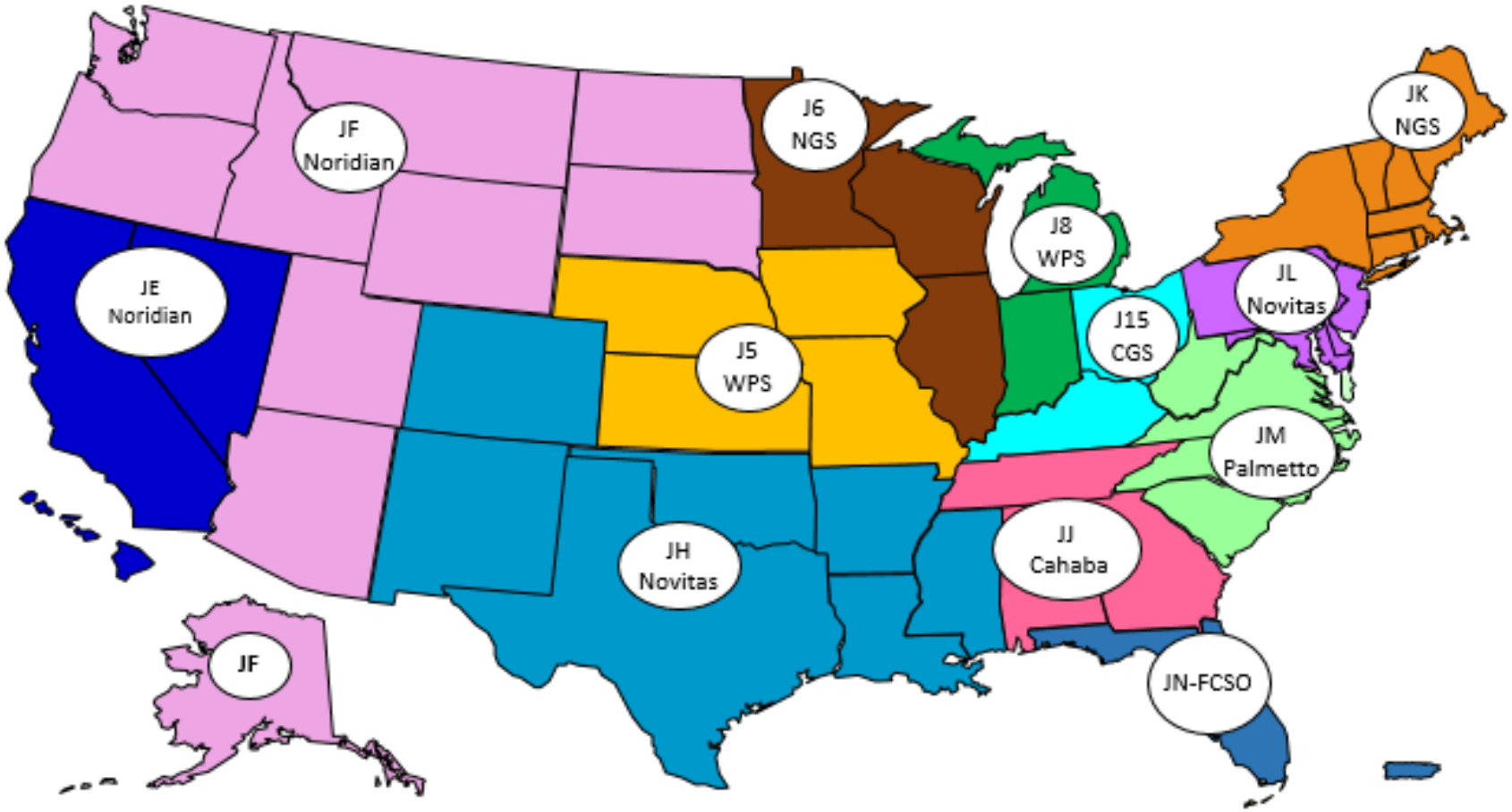
A/B Jurisdiction Map
as of December 2015



Next Generation Sequencing

Dr. Kojo Elenitoba-Johnson

Kojo S. J. Elenitoba-Johnson, MD, is the inaugural Peter C. Nowell, MD Professor at the Perelman School of Medicine at University of Pennsylvania. He is also the Founding Director of Penn Medicine's Center for Personalized Diagnostics, and Founding Director of the Division of Precision and Computational Diagnostics. Dr. Elenitoba-Johnson is an international leader in the fields of Hematopathology and Genomic Pathology, as well as mass spectrometry-driven proteomics. His research is focused on the molecular pathogenesis of lymphoid malignancies and has earned support from the National Institutes of Health and private foundations. He has authored or co-authored more than 140 peer-reviewed research publications and has contributed more than 40 chapters to professional textbooks in Pathology. He is a member of the Board of Scientific Counselors for Clinical Sciences and Epidemiology for the National Cancer Institute and currently the President-Elect of the Association for Molecular Pathology.

Next Generation Sequencing Reimbursement

Dr. Elaine Jeter

Elaine K Jeter, MD is a Palmetto GBA medical director in JM and director of the Molecular Diagnostic (MolDX) project. She is a graduate of the Medical University of South Carolina (MUSC) and is board certified in Clinical and Anatomic Pathology, with subspecialty boards in Blood Banking/Transfusion Medicine, and a fellowship in surgical pathology. She has practiced pathology and laboratory medicine in the private and academic setting, and has been with Palmetto GBA for more than 12 years.

NGS REIMBURSEMENT

Elaine K Jeter, MD
MolDX, Palmetto GBA

Molecular CPT Codes

- Methodologic stacking codes – prior to 2012
- CPT Tier 1 and Tier 2 codes – 2012
- Genomic Sequencing Procedures (GSP) - 2015
  - Heritable disorders and Somatic tumor panels
  - Disassociates dup/del from sequence analysis
- MAAA – without proprietary assay name
- Appendix O – Proprietary assay linked to CPT or xxxxM
- PLA – Proprietary lab analysis – PAMA CDLT and ADLT - xxxxU

Return to Agenda

BRAF V600 – CPT 81210

- 29 CA labs
- Code stack - $46.46 to $296.24
- Average $ - $93. 89
- NLA – 180.23

EGFR – CPT 81235

- 25 CA labs
- $91.17 - $1666.88
- Average $ - 265.82
- NLA - $331.82

Return to Agenda

MSI – CPT 81301

- 22 CA labs
- Code stack - $202.14 - $816.44
- Average - $397.66
- NLA - $397.20

Hereditary NGS

- Hereditary testing:
  - Buccal swab or blood
  - Current or personal history of tumor
  - Screening not covered
  - Family history alone does not qualify patient
- CPT codes:
  - 81432 – HBOC >14 genes -$931.48
  - 81435 – HCRC > 10 genes - $802.35
  - 81437 – HNEC - >6 genes - $602.10

Return to Agenda

Somatic NGS Panels

- **81445** Targeted sequence analysis, solid organ neoplasm, 5-50 genes, SNV, **and** CNV **or** rearrangement - $602.10 NLA
- **81450** Targeted sequence analysis, hematolymphoid neoplams, 5-50, SNV, **and** CNV **or** rearrangement or isoform expression or mRNA expression levels, if performed - $652.94 NLA
- **81455** Targeted sequence analysis, solid or hematolymphoid neoplasm, >51 genes – NC NLA; $647.75 MolDX
- AMP* micro-costing 81445 analysis – NSCLC - $577-$907; ave $691.20

* Sabatini LM, et al. Genomic sequencing procedure microcosting analysis and health economic cost-impact analysis. JMD 2016;18(3);319-28.

NGS Panels

- A PANEL is a PANEL -- 1 UOS
- Panel cannot be unbundled into individual components
- CPTs code combinations -- 1 UOS
  - Ordered by a single mark on a requisition
  - Sold, purchased or manuf'd as a single entity
  - Always ordered together – F2, F2 & MTHFR; BCR-ABL maj & min breakpoints -> 81479
  - If single CPT doesn't exit for service, default to NOC

Return to Agenda

NGS for 1-4 Genes

- Business decision - cost not reasonable
- Up to 4 genes by NGS
  - Any single or combo assigned 81479 (NOC)
  - Each NGS reimbursed $125.
  - 5-50 somatic genes (CPT 81445) $602.10

NGS Coding & Reimbursement

- MolDX published article
  - HBOC code 81432 – sequencing & dup/del
  - NGS sequencing & dup/del simultaneously performed
  - Represents “hot spot” testing, not CGP
  - NGS panel is 1 UOS – can’t be unbundled
  - CTC, liquid (ct-DNA and cf-DNA) and tumor-normal testing - 81479
- Little incremental NGS cost after critical number/size of genes

Return to Agenda

Comprehensive Genomic Profile (CGP)

- Mutations – include SNVs, Dup/dels, CNV and SV
- Disease coverage with data development - NSCLC
  - Study protocol with defined endpoints and IRB approval
  - Registry with data collection
  - Report de-identified semi-annually
  - Requires publication
  - Demonstrate improved patient outcomes

Z-Codes and Edits

- Every assay has unique Z-code
- Lab notified of correct CPT code to bill
- Z-code required on claim line – Part A and Part B
- MEF – unique edit with NPI (performing lab) + CPT + Z-code
  - If z-code absent – claim rejects
  - If CPT not submitted with correct CPT – claim denies

Return to Agenda

Allogeneic SCT and CAR-T therapies for lymphoma

Dr. Krishna Komanduri

Dr. Komanduri holds the Kalish Family Chair in Stem Cell Transplantation and is Professor of Medicine, Microbiology & Immunology and is the Director of the Adult Stem Cell Transplant Program and Associate Director for Clinical Innovation at the Sylvester Comprehensive Cancer Center at the University of Miami Miller School of Medicine.

Dr. Komanduri received his undergraduate education at MIT (1987), his MD at the University of Minnesota Medical School (1991) and trained at UCLA (in Internal Medicine) and UCSF (in Hematology/Oncology). Prior to moving to Miami in 2008, he was a faculty member at UCSF and at the University of Texas M.D. Anderson Cancer Center. His laboratory research is focused on studies of cancer immunology and has been widely published and supported by the NIH and cancer-related foundations.

Dr. Komanduri is the current President of the American Society for Blood and Marrow Transplantation (ASBMT). He also serves as Co-Chair of the CIBMTR Working Committee on Infections and Immune Reconstitution and is the immediate past-chair of the NMDP Advisory Group on Financial Barriers to Transplantation, a physician/payer/advocacy task force on transplant financial issues. He has also served as Chair of the Immunology and Host Defense Scientific Committee for the American Society of Hematology. He has been the recipient of awards including election to the American Society for Clinical Investigation (in 2009).

For further information on CAR T and Engineered T Cell Therapies please reference the following articles:

- Nonmyeloablative allogeneic transplantation with or without 90yttrium ibritumomab tiuxetan is potentially curative for relapsed follicular lymphoma: 12-year results.
- Eight-year experience with allogeneic stem cell transplantation for relapsed follicular lymphoma after nonmyeloablative conditioning with fludarabine, cyclophosphamide, and rituximab.
- Allogeneic stem cell transplantation in follicular lymphoma.

Allogeneic SCT and CAR-T therapies for lymphoma

Krishna Komanduri, MD
Director, Adult SCT Program
Sylvester Cancer Center, Univ. of Miami
President, ASBMT

ASBMT Investment in Medicare Access

Membership of Cell Therapy Clinical Professionals:

- International professional society with over 2200 members (physicians, scientists, allied clinicians) dedicated to hematopoietic transplantation and cellular therapies.
- Recognized with new CMS specialty designation in November 2016; Hematopoietic Cell Transplant and Cellular Therapy (HCTCT)

Advancement of cellular therapies:

- Provided scientific leadership in cellular therapies for 25 years
- Co-Parent of FACT (with ISCT)
- Partner of Registry (CIBMTR) and SCTOD
- Co-sponsor, with CIBMTR, of annual BMT Tandem Meetings

Return to Agenda

HCT Clinical Summary

- Hematopoietic Cell Transplant
  - aka – Stem cell transplant, blood & marrow transplant, bone marrow transplant, cord blood transplant
- Allogeneic HCT – use of donor (non-self) cells
  - Matched related
  - Matched unrelated – donated cord blood unit(s) or registry donor
  - Unmatched related – haplo-identical
  - Future state – universal donor
- Typical care episode = preparative regimen, cell infusion, monitoring until/through engraftment of donor cells
  - Donor selection takes place weeks/months earlier
  - Typically a fresh (non-cryopreserved) product used in infusion; less than 48 hours after collection from donor
  - Requires specialized care teams and treatment beds/units

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Medicare & HCT

- Limited experience – primarily since 2007
- Growing annual volume due in older patients:
  - Reduced intensity conditioning
  - Increase in transplant program patient maximum age
  - Better screening for/treatment of co-morbidities
  - *Average age of diagnosis coincides with Medicare eligibilty*
- Due to being relatively new to CMS, HCT programs still facing coverage and reimbursement "growing pains"

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Advocacy for Beneficiary Access

in partnership with National Marrow Donor Program/Be The Match

- Expansion of National Coverage Determination
  - CED for MDS (2010)
  - CED for Multiple Myeloma, Sickle Cell Disease, Myelofibrosis (2016)
- Clarification/expansion of coding
  - Stem cell processing codes
  - MS-DRG split (009 into 014, 016, 017)
- On-going advocacy for adequate reimbursement
  - Pursuit of separate organ acquisition payment
  - Specific revenue code (2016)
  - Comprehensive APC for allogeneic outpatient transplant

ASBMT American Society for Blood and Marrow Transplantation

HCT and Solid Organ Transplant Handled Differently by CMS

Bone marrow is included in Definition of Human Organ in N.O.T.A.

Issue	Solid Organ	HCT
Conditions of Participation	Hospital must meet COP standards – volume, risk-adjusted survival, personnel	Not applicable
Coverage Indications	No restrictions for approved transplant facilities	*Limited to certain disease sub-types, stages, risk factors* ★
Organ Acquisition Costs	Paid on separate, reasonable cost-basis	Included in the DRG or APC payment; weighted as a Blood Product
Reimbursement	Heart Transplant Weights – 16 or 26 ~ $95,000-$155,000 + acquisition	AlloHCT Weight – 11 AutoHCT Weights – 4 or 6

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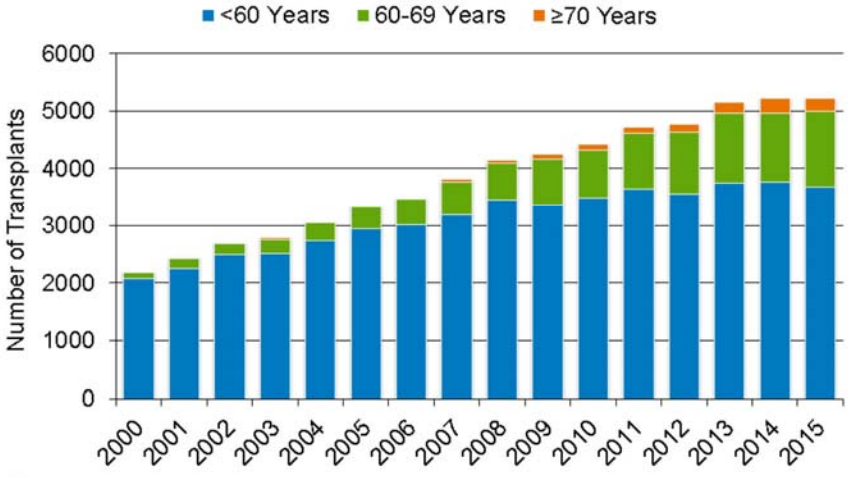
Return to Agenda

Trends in Allogeneic HCT by Recipient Age^

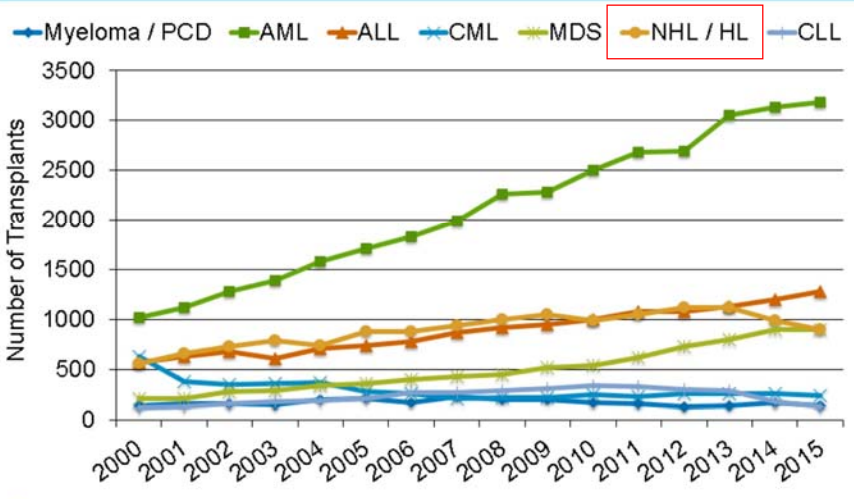


CIBMTR

^Transplants for AML, ALL, NHL, Hodgkin Disease, Multiple Myeloma

12

Selected Disease Trends for Allogeneic HCT in the US

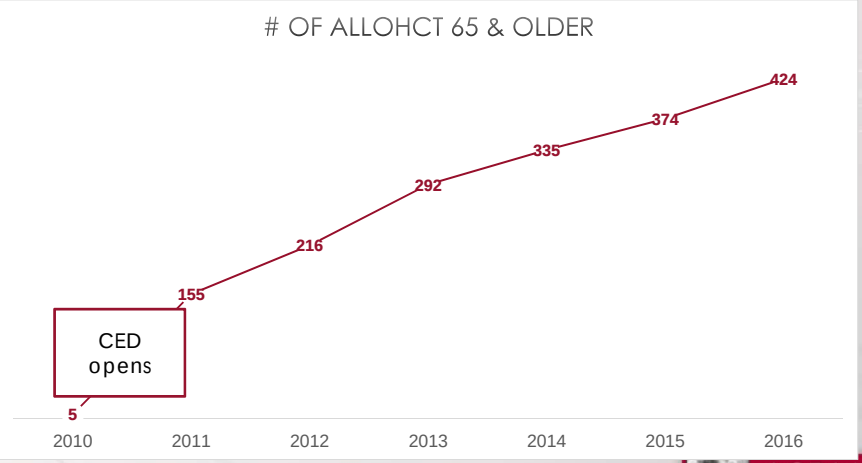


CIBMTR

14

Return to Agenda

Access Example: HCT for MDS



Current Coverage: AlloHCT

NCD 110.23

*All have specific stage, diagnosis and coding restrictions

- Leukemia
- Aplastic Anemia
- Severe Combined Immunodeficiency Disease (SCID)
- Wiskott-Aldrich
- Myelodysplastic Syndromes (MDS) within Coverage with Evidence Development
- Myelofibrosis (CED)
- Multiple Myeloma (CED)
- Sickle Cell (CED)

[Note: *AutoHCT is covered for HL/NHL*]

Commercial payers typically cover 70+ indications

Problem Statement:
CMS Lymphoma patients rarely able to access HCT

"All indications not mentioned in the NCD are subject to contractor discretion."

- Pre-authorization is not allowed by CMS
- HCT is a high-cost care episode – hospital authorization to proceed with unsure payment is very difficult to obtain
  - MedPar FY2017 Avg Charges = $366,000
- Creates uneven access – beneficiaries with funds to self-guarantee are the only ones who proceed
- Past issues with RACs disagreeing with MAC payment
  - HCT seems to be a frequent target due to low volume, high-cost

Changes to NCD are lengthy and costly to pursue

- ~2 years for request and decision
- If CED outcome, 5-10 years of study time necessary
- CIBMTR spends approximately $200,000 per study; detracts from other research

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CIBMTR Data: HCT for Lymphoma
2010-2015, 1st Transplant, HL & NHL

	Allogeneic		Autologous	
Age Range	55-64	65-85	55-64	65-80
Number of patients	1222	**378**	6018	**4496**
Number of centers	110	75	154	154
Median age (range), years	60 (55-65)	67 (65-77)	60 (55-65)	69 (65-80)

Medicare beneficiary volume as % of 55-64 age group:
- AlloHCT = 33.7%
- AutoHCT = 74.7%

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Return to Agenda

AlloHCT for Lymphoma: Clinical Results Summary

Khouri, *Blood*, 2012: *Non-myeloablative Stem Cell Transplant for Non-Hodgkin Lymphoma*

- Follicular Lymphoma: 11 year follow-up on 47 patients
  - Overall survival – 78%
  - Progression-free survival – 72%
- Mantle Cell Lymphoma
  - Lymphoma-free survival at 10 years – 65%
  - Other studies PFS – 60% at 2 years, 46% at 6 years
- Diffuse Large B-Cell Lymphoma
  - Limited data due to lack of early referral – durable remissions of 20-40%
- T-cell Lymphomas
  - PFS of 80% at 3 years for relapsed, chemosensitive patients in one small study

AlloHCT for Lymphoma in CMS Data

Source: MedPar analysis for NMDP/Be The Match, May 2017

Non-Exempt Centers MedPar FY2018					
DRG	**Claim Type**	**Diagnosis Code**	**Short Description**	**Number of primary diagnosis**	**Percentage**
014	FFS	C9200	Acute myeloblastic leukemia, not having achieved remission	173	20.8%
014	FFS	D469	Myelodysplastic syndrome, unspecified	105	12.6%
014	FFS	C9201	Acute myeloblastic leukemia, in remission	104	12.5%
014	FFS	C9202	Acute myeloblastic leukemia, in relapse	44	5.3%
014	FFS	D46Z	Other myelodysplastic syndromes	36	4.3%
014	FFS	C9100	Acute lymphoblastic leukemia not having achieved remission	32	3.8%
014	FFS	C9210	Chronic myeloid leuk, BCR/ABL-positive, not achieve remis	26	3.1%
014	FFS	C9310	Chronic myelomonocytic leukemia not achieve remission	24	2.9%
014	FFS	Z5111	Encounter for antineoplastic chemotherapy	18	2.2%
014	FFS	C9101	Acute lymphoblastic leukemia, in remission	17	2.0%
014	FFS	D471	Chronic myeloproliferative disease	16	1.9%
014	FFS	C8330	Diffuse large B-cell lymphoma, unspecified site	13	1.6%
014	FFS	D4622	Refractory anemia with excess of blasts 2	13	1.6%

Case Study 1: AlloHCT for Relapsed FL

- Male, age 66 with follicular NHL in with PR following 3rd line therapy
- Diagnosed with Follicular Lymphoma 5 years previously
- Successful previous remissions with other lines of therapy
  - R-CHOP (3 yr CR); Bendamustine/Rituximab (18 month yr CR); Idelalasib (excellent PR)
- Experiencing shorter remission times; referred for HCT consult
- Excellent performance status and no major comorbidities

Case Study 2: AlloHCT post CAR T

- Female, age 68
- Aggressive Diffuse Large B-Cell Lympoma
- Clinical history: Initially refractory with bulky disease (failed R-CHOP and salvage therapy with R-ICE), treated with CD19-specific CAR-T therapy resulting in a CR
- Relapsed after 3 months with low-volume disease and received 2nd CAR T treatment resulting in a 2nd CR
- Referred for consideration of allogeneic HCT

Discussion: Access to AlloHCT for Beneficiaries with Lymphoma

- How do we gain access to AlloHCT for appropriate lymphoma patients without pursuing NCD changes/CED?

Questions/Discussion

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MACRA: The Law, Implementation, and Opportunities for Improvement

Robert Horne

Robert Horne is a senior director based in Washington, D.C. Robert advises complex health care alliances on health policy and provides federal advocacy and strategic consulting services to provider organizations, pharmaceutical and device companies, health IT vendors, consumer and patient organizations, and payers.

His two decades in health care began as staff director of the Ohio House of Representatives Health Committee. He left the Ohio House in 2001 to represent health care organizations before state legislatures and the federal government. Robert began working for Congress in 2007, and accepted a position with the office of Representative Phil Gingrey in 2009, where he managed his health care portfolio on the Energy and Commerce Committee and restructured the GOP Doctors Caucus as its first Executive Director. He went on to join the Energy and Commerce Health Subcommittee staff under then Chairman Fred Upton where he served for nearly five years. During his time in Congress, he authored many laws including MACRA, numerous provisions of the 21st Century Cures Act, and the GAIN Act - legislation designed to spur new antibiotic development.

Robert has extensive expertise in a range of health policy areas, including FDA regulatory policy, health care reform, health technology, and CMS and payment and delivery transformation.

MACRA

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Contents

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Section 1: MACRA Overview	Section 2: Key MACRA Decision Points	Section 3: 2018 Proposed Rule & Strategic Considerations
• Policy Determinants • MIPS Overview • APM Overview	• Organizational Considerations • MIPS vs Advanced APM Selection Areas of Concern: • Advancing Care Information Performance • Cost Performance • Data Capture and Submission	• 2018 Proposed Changes • Areas of Major Concern • Reform Considerations • Potential Areas of Reform

Return to Agenda

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Section 1:
MACRA Overview

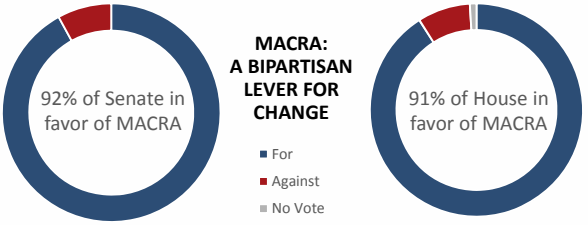
MACRA Overview

LP

The Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) is **bipartisan legislation** signed into law on April 16, 2015.

What does MACRA do?

Replaces the Sustainable Growth Rate (SGR) Formula	Streamlines multiple physician quality incentive programs	Alters Medicare physician reimbursement to reward value, rather than volume



4

Return to Agenda

MACRA – A Two Track Structure

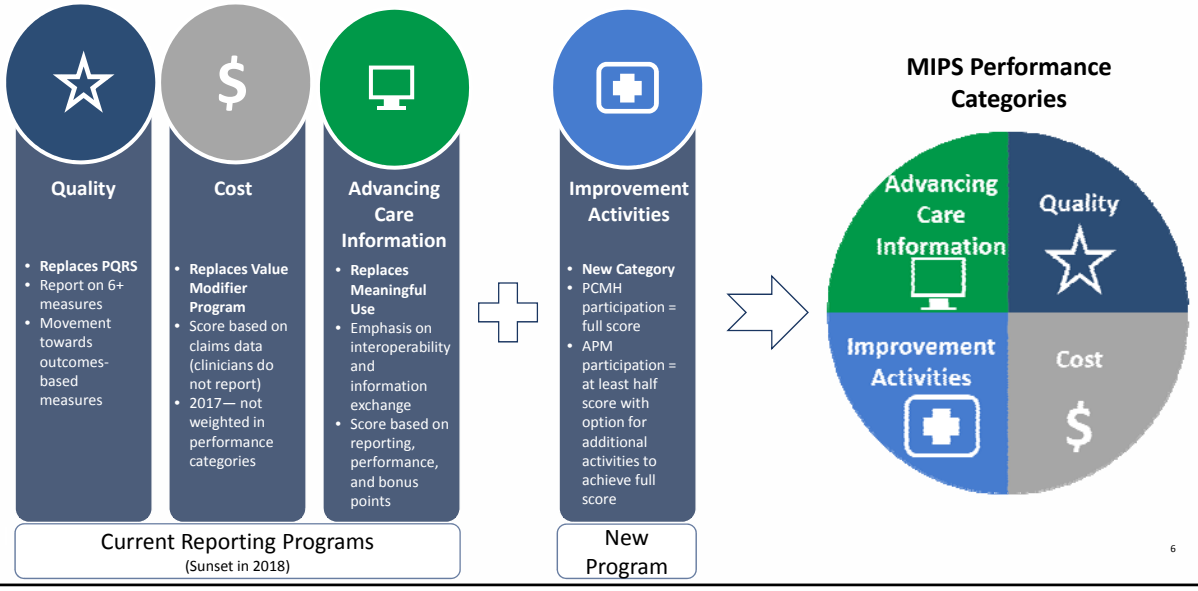
MACRA implements changes through a single framework called the "Quality Payment Program" which has two paths:

The Merit-based Incentive Payment System
Default track (most clinicians will report under this program)

Advanced Alternative Payment Models
Clinicians must qualify in an approved program and meet volume or payment thresholds

5

Streamlined Programs - MIPS



6

Return to Agenda

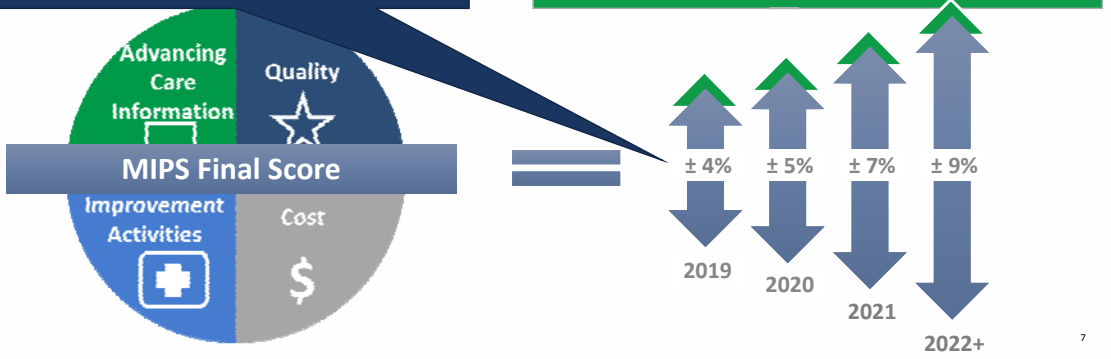
How Much Can MIPS Adjust Payments?

Positive or Negative Payment Adjustment

A positive or negative adjustment is made to the provider's Medicare Part B payment two years following the performance year. Total adjustments are required to be budget neutral.

Exceptional Performance Bonus

In the first five payment years of the program, there is an additional $500M, exempt from budget neutrality, for exceptional performance. This bonus gives high performers a progressively increasing adjustment based on their MIPS score and cannot be more than an additional 10%.



APM vs Advanced APM

How does MACRA define an APM?

- CMS Innovation Center Model (under section 1115A, other than a Health Care Innovation Award)
- Medicare Shared Savings Program (MSSP)
- Demonstration under the Health Care Quality Demonstration Program
- Demonstration required by federal law

What are the qualifications for Advanced APMs?

- Require the use of certified EHR technology
- Payment based on quality measures comparable to MIPS quality measures
- Bear more than nominal financial risk - Total potential risk ≥ 3% of expected expenditures OR ≥ 8% of estimated average total Medicare Parts A & B revenue (Exceptions: medical home models)

APMs are innovation approaches to paying for Medicare medical care that **incentivize quality and value**.

Which programs qualify as Advanced APMs under MACRA?

2017

- MSSP Tracks 2 & 3
- Next Generation ACO Model
- Comprehensive ESRD Care (CEC) (LDO & non-LDO 2-side risk arrangements)
- Comprehensive Primary Care Plus (CPC+)
- Comprehensive Care for Joint Replacement (CJR) (Track 1)
- Oncology Care Model (OCM) (two-sided risk arrangement)

Future Proposed New Additions

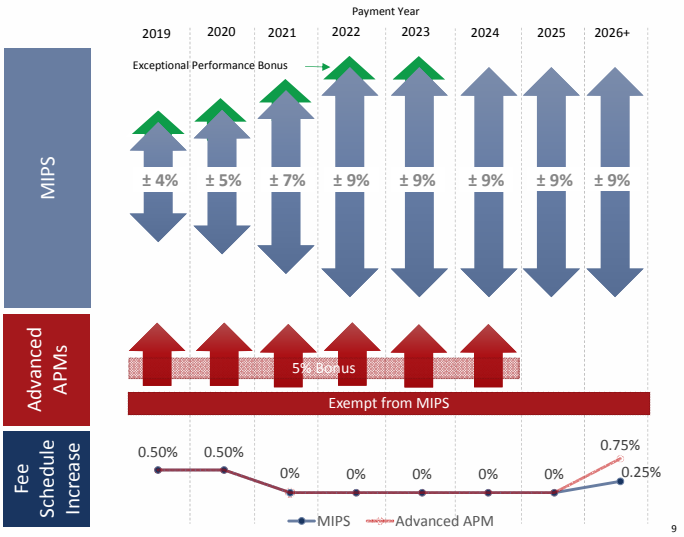
- ACO Track 1+
- Advancing Care Coordination through Episode Payment Models
- Vermont Medicare ACO Initiative
- Medicare-Medicaid ACO Model

Return to Agenda

MACRA promises to transform payment and care delivery

The market is slowly trending away from fee-for-service (FFS) in favor of clinically/economically integrated models, which will highlight non-traditional constituents as critical partners in driving new models.

MACRA Disruption	MACRA Opportunity
Clinicians participating in MIPS will still be paid through FFS, but will receive positive or negative adjustments to their payment based on annual performance.	The flexibility given to clinicians to choose their quality measures allows them to customize the reporting to their practice's strengths and goals.
Specialties with fewer applicable outcome measures could be disadvantaged, being unable to gain the additional bonus points that are offered to other specialties.	Clinicians can prepare for success under MIPS by successfully participating and reporting in the PQRS, VM, and EHR MU programs.



9

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Section 2:
Key MACRA Decision Points

Return to Agenda

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MIPS vs. APM Selection

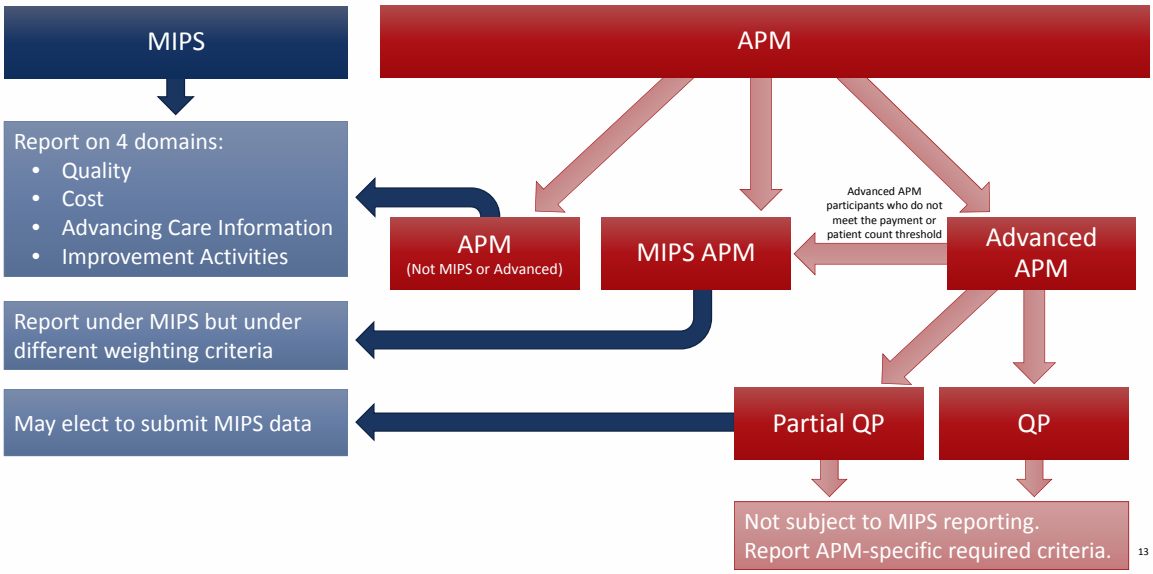
MIPS vs Advanced APM – MACRA Overview

	MIPS	Advanced APMs
Payment	+/- 4% - 9%	5% Bonus each year of participation (through 2024)
Physician Fee Schedule Annual Increase (2026 and on)	0.25%	0.75%
Reporting	4 performance categories (3 scored categories in 2017)	Built into APM programs

12

Return to Agenda

MIPS vs Advanced APM Selection – Options Under MACRA



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Area of Concern:
Advancing Care Information Performance

Return to Agenda

Advancing Care Information – MACRA Overview

The Advancing Care Information performance category score equals the sum of the base score, performance score, Public Health and Clinical Data Registry bonus score and completing improvement activities using CEHRT bonus score.

Base Score (Required Measures)

- Fulfill the required measures for a minimum of 90 days.
- For 2017, may use EHR technology certified to either the 2014 or 2015 Edition certification criteria.
- 5 reported measures for 2015 edition, 4 reported measures for 2014 edition (2017 only).

Base score is all-or-nothing.

Performance Score

- Report on certain measures specified by CMS. Choose to submit up to 9 measures for a minimum of 90 days for additional credit.
- MIPS eligible clinicians may earn up to 10 or 20 percentage points as specified by CMS for each measure reported for the performance score.

Bonus Points

- 5 percentage points for reporting any measures beyond than the Immunization Registry Reporting measure for the Public Health and Clinical Data Registry objective.
- 10 percentage points for attesting to completing one or more improvement activities specified by CMS using CEHRT.

Advancing Care Information Performance Category Score

Providers may not need to submit Advancing Care Information if these measures do not apply.
The Advancing Care Information performance category score will not exceed 100 percentage points.

15

Advancing Care Information – Options Under MACRA

For 2017, the first MIPS performance period, MIPS eligible clinicians would be able to use EHR technology certified to either the 2014 or 2015 Edition certification criteria as follows:

Technology Certified to the 2014 Edition

- Must report on objectives and measures available for the 2017 transition year
- If CERHT is certified to a combination of the 2015 and 2014 Editions, can report on transition or full list of objectives and measures
- Although encouraged to report for an entire year, clinicians can report data collected during a consecutive 90-day period in 2017

Technology Certified to the 2015 Edition

- Must report on full list of objectives and measures (not the 2017 transitional objectives and measures)
- Although encouraged to report for an entire year, clinicians can report data collected during a consecutive 90-day period in 2018

Required in the 2018 performance period

16

Return to Agenda

Advancing Care Information – Options Under MACRA (2017 Transition Year)

Advancing Care Information Objective	Advancing Care Information Measure	Required/Not Required for Base Score (50%)	Performance Score (up to 90%)	Reporting Requirement
Protect Patient Health Information	Security Risk Analysis	Required	0	Yes/No Statement
Electronic Prescribing	e-Prescribing	Required	0	Numerator/Denominator
Patient Electronic Access	Provide Patient Access	Required	Up to 20%	Numerator/Denominator
	View, Download, or Transmit (VDT)	Not Required	Up to 10%	Numerator/Denominator
Health Information Exchange	Health Information Exchange	Required	Up to 20%	Numerator/Denominator
Patient-Specific Education	Patient Specific Education	Not Required	Up to 10%	Numerator/Denominator
Secure Messaging	Secure Messaging	Not Required	Up to 10%	Numerator/Denominator
Medication Reconciliation	Medication Reconciliation	Not Required	Up to 10%	Numerator/Denominator
Public Health and Clinical Data Registry Reporting	Immunization Registry Reporting	Not Required	0 or 10%	Yes/No Statement
	Syndromic Surveillance Reporting	Not Required	Bonus	Yes/No Statement
	Specialized Registry Reporting	Not Required	Bonus	Yes/No Statement
	Public Health Registry Reporting	Not Required	Bonus	Yes/No Statement
	Clinical Data Registry Reporting	Not Required	Bonus	Yes/No Statement

17

Advancing Care Information – Options Under MACRA (Performance Years 2018+)

Advancing Care Information Objective	Advancing Care Information Measure	Required/Not Required for Base Score (50%)	Performance Score (up to 90%)	Reporting Requirement
Protect Patient Health Information	Security Risk Analysis	Required	0	Yes/No Statement
Electronic Prescribing	e-Prescribing	Required	0	Numerator/Denominator
Patient Electronic Access	Provide Patient Access	Required	Up to 10%	Numerator/Denominator
	Patient-Specific Education	Not Required	Up to 10%	Numerator/Denominator
Health Information Exchange	Send a Summary of Care	Required	Up to 10%	Numerator/Denominator
	Request/Accept Summary of Care	Required	Up to 10%	Numerator/Denominator
	Clinical Information Reconciliation	Not Required	Up to 10%	Numerator/Denominator
Coordination of Care Through Patient Engagement	View, Download, or Transmit (VDT)	Not Required	Up to 10%	Numerator/Denominator
	Secure Messaging	Not Required	Up to 10%	Numerator/Denominator
	Patient-Generated Health Data	Not Required	Up to 10%	Numerator/Denominator
Public Health and Clinical Data Registry Reporting	Immunization Registry Reporting	Not Required	Up to 10%	Yes/No Statement
	Syndromic Surveillance Reporting	Not Required	Bonus	Yes/No Statement
	Electronic Case Reporting	Not Required	Bonus	Yes/No Statement
	Public Health Registry Reporting	Not Required	Bonus	Yes/No Statement
	Clinical Data Registry Reporting	Not Required	Bonus	Yes/No Statement

18

Return to Agenda

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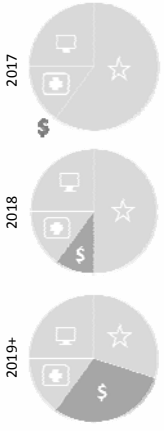
Area of Concern: Cost Performance

Cost Performance – MACRA Overview

LP

The MIPS Cost performance category evaluates a clinician's **cost of care** and rewards clinicians for **cost-effective care** and **efficient use** of Medicare resources used to treat similar care episodes and clinical condition groups across practices. The MIPS Cost category replaces the Value-Based Payment Modifier (VM).



Cost Performance Category Key Points

- Since the score is calculated from Medicare claims, there is no additional data reporting requirement for clinicians. This is the only category that CMS calculates entirely.
- The scores are risk-adjusted to account for external factors such as demographics and clinical severity.
- Cost will only be measured for Medicare patients that are attributed to the clinician.
- If a clinician does not see enough attributed patients for score calculation of any cost measure, the category will not receive a score and the composite score will reweight among the other categories.

20

Cost Performance – MACRA Overview

Cost Performance Score Calculation

1	2	3
CMS Reviews Administrative Claims Codes Lists posted on CMS website by November 1 of year prior to performance year.	**Apply Three Types of Cost Measures**	**Cost Performance Score Calculated**
Patient Condition Groups	10 Episode–based measures (Case minimum = 20)	Cost measures scored on decile scale based (similar to Quality Performance category)
Care Episode Groups	Total per capita cost measure (Case minimum = 20)	Decile points determined by performance thresholds
Patient Relationship Categories	Medicare spending per beneficiary (MSPB) (Case minimum = 35)	Scores attributed for all clinicians at the TIN/NPI level*

*For those groups that participate in group reporting in other MIPS performance categories, their cost performance category scores will be determined by aggregating the scores of the individual clinicians within the TIN.

21

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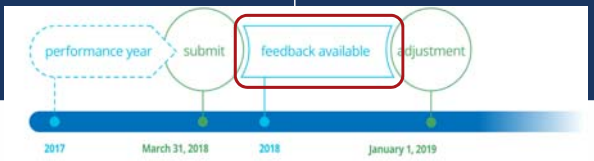
Area of Concern:
Data Capture & Submission

Performance Management – Options Under MACRA

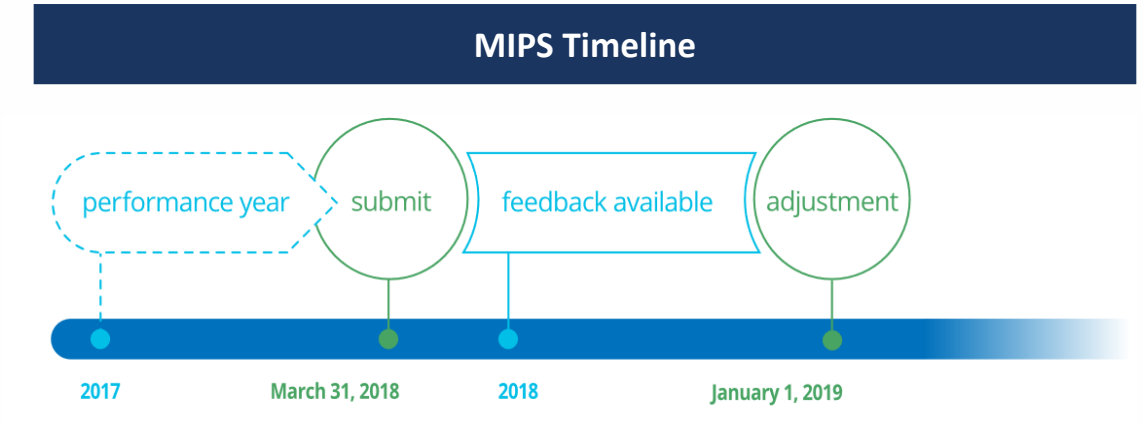
MACRA incorporates **performance feedback** to ensure MIPS results are useful and accurate

Feedback on the Performance Measures	Feedback will be Available Using a CMS Designated System	Targeted Review
• CMS will provide feedback and information on the Quality and Cost performance categories • Initially, feedback is provided on an annual basis	• CMS will leverage additional mechanisms such as health IT vendors, registries, and QCDRs to help disseminate data/information contained in the performance feedback to eligible clinicians where applicable	• There will be a targeted review process under MIPS wherein a MIPS eligible clinician may request a review of the calculation of the MIPS adjustment factor and, as applicable, the calculation of the additional MIPS adjustment factor applicable to such MIPS eligible clinician for a year



23

Data Capture and Submission – Timeline



Source: CMS Quality Payment Program

24

Return to Agenda

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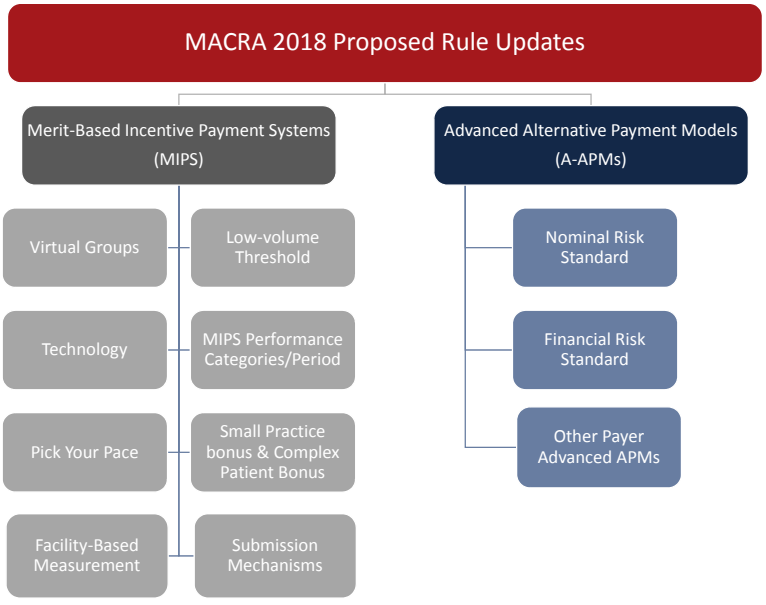
Overview: 2018 Proposed Rule

Overview of MACRA 2018 Proposed Rule Updates



Return to Agenda

Proposed Updates to the Quality Payment Program

MIPS UPDATES

	Low-Volume Threshold	Submission Mechanisms	Virtual Groups	Facility-Based Measurement	Technology	Performance Period	Final Score	MIPS Performance Categories	Complex Patient & Small Practice Bonuses	Pick your Pace
2017 Final Rule	Exempt from MIPS if ≤$30,000 in Part B charges OR ≤100 Part B beneficiaries	1 submission mechanism per performance category	Not available in 2017	Not available in 2017	2014 or 2015 CEHRT edition in 2017 but will be required use of 2015 CEHRT edition in 2018	Minimum 90-day period for Quality, Advancing Care Information, Improvement activities	If no ACI, reassign to Quality. If no Quality, reassign 50% each to Improvement Activities and ACI	Cost performance category weighting 2017 = 0% 2018 = 10%	Not available in 2017	Clinicians can "pick their pace" and submit 90-days or a full year of data
2018 Proposed Rule	Exempt from MIPS if ≤$90,000 in Part B charges OR ≤200 Part B beneficiaries	May be able to use multiple submission mechanisms within each performance category (except Cost)	Groups of 2-10 clinicians can come together virtually and report as a group	Optional voluntary facility-based scoring mechanism based on the Hospital Value Based Purchasing Program	Clinicians can still use 2014 certified EHR technology (CEHRT), but will receive a bonus for using 2015 CEHRT	Quality and Cost: 12-month performance period. ACI and Improvement Activities: 90-day minimum	Quality 60%, Cost 0%, Improvement Activities 15%, Advancing Care Information 25%. New extenuating situations for performance categories	Cost performance category weighting 2018 = 0%	CPB: Adjust up to 3 bonus points by adding the average HCC risk score to the final score SPB: Add up to 5 points for eligible clinician or group in a small practice	"Pick your pace" option goes away and is replaced by a transitional provision

27

CMS has also proposed changes to each performance category. Those changes are not included on this slide.

Proposed Updates to the Quality Payment Program

Advanced APM UPDATES

	Nominal Amount Standard	Medical Home Financial Risk Standard	Medical Home Nominal Amount Standard	All Payer Nominal Amount Standard	All-Payer Performance Period	All-Payer Determinations	Clinician Initiated Other Payer Determination	Payer-Initiated Other Payer Determination
2017 Final Rule	• 8% of Parts A and B revenue of the participating APM for the 2017 & 2018 QP period, OR • 3% of the APM's expected expenditures	In 2018 period, APM Entities with 50+ eligible clinicians don't participate	For each performance year, an APMs total potential risk must be: • 2017: 2.5% of Parts A and B revenue • 2018: 3% • 2019: 4% • 2020: 5%	Marginal Risk must at least be 30%; with a Minimum Loss Rate of 4% or less; and a Total Risk of at least 3% of the expected expenditures the APM Entity is responsible for	QP performance period: Jan 1 – Aug 30. CMS makes 3 QP determinations	QP determinations under the All-Payer Combination Option made at the APM Entity or individual eligible clinician level	APM entities and eligible clinicians need to submit: service revenues, revenues from payer, number of patients, number of patients from the payer. Payers validate the information	Not available in 2017
2018 Proposed Rule	8% revenue-based standard extended through performance year 2020	Round 1 Comprehensive Primary Care Plus Model (CPC+) entities participate regardless of the number of eligible clinicians	For each performance year, an APM's minimum potential risk is adjusted to: • 2018: 2% of Parts A and B revenues of all of the APMs' providers/suppliers 2019: 3% • 2020: 4% • 2021+: 5%	8% revenue-based standard is added	Created separate All-Payer QP Determination Period of Jan 1 – Jun 30. CMS will make 2 QP determinations	QP determinations made at the clinician level only. If discrepancies occur, CMS will use weighted method to calculate	Payer validation requirement is eliminated; APM Entities or eligible clinicians need to certify submitted information	Payers can submit Title XIX, Medicare Health Plan, and in CMS Multi-Payer Models payment arrangements. Will be offered to other payer types in future

28

Return to Agenda

LEAVITT PARTNERS

All-Payer Advanced APMs

2018 Proposed Rule

Other Payer Advanced APMs

LP

The "All-Payer Combination Option" will be based on a combination of Advanced APM participation and participation in "Other Payer Advanced APMs." To be considered under the All-Payer Combination Option, eligible clinicians must also participate in an Advanced APM but not meet the QP threshold under the Medicare Option.

Other Payer Advanced APMs must meet requirements that are similar, though not identical, to the three requirements Advanced APMs must meet.

1

Requires participants to use certified EHR technology

2

Provides payment for covered professional services based on quality measures comparable to those used in the MIPS quality performance category

3

Either: (1) is a **Medicaid Medical Home Model** that meets criteria that is comparable to a **Medical Home Model** expanded under CMS Innovation Center authority, OR (2) requires **participants to bear a more than nominal amount of financial risk** if actual aggregate expenditures exceed expected aggregate expenditures.

Return to Agenda

Nominal Risk

Either: (1) is a Medicaid Medical Home Model that meets criteria comparable to Medical Home Models expanded under CMS Innovation Center authority, OR (2) requires participants to bear a more than nominal amount of financial risk if actual aggregate expenditures exceed expected aggregate expenditures.

Proposed Change:

Add a **revenue-based nominal amount standard** in addition to the benchmark-based nominal amount standard that would be applicable only to payment arrangements in which risk is expressly defined in terms of revenue.

The total amount that an APM entity potentially owes the payer or foregoes is equal to at least:

- For the 2019 and 2020 performance periods, 8% of the total combined revenues from the payer of providers and suppliers in partipating APM entities.

31

Advanced APM Determination Process

Proposed Change:

Payer Initiated Process for Determination of Other Payer Advanced APMs

- Certain other payers (und Title XIX, Medicare Health Plan payment arrangements, and payers with payment arrangements in CMS Multi-Payer Models) can ask if payer arrangements are Other Payer Advanced APMs starting prior to the 2019 All-Payer QP Performance Period and annually after. Other remaining other payers, including commercial and private payers, can ask if payer arrangements are Other Payer Advanced APMs starting in 2019 prior to the 2020 All-Payer QP Performance Period, and annually after. The steps for each payer type are the same.
- The process is voluntary for all payers, and determinations are in effect for one year.
- Payers will use the Payer Initiated Submission Form to request an Other Payer Advanced APM determination. The application schedule varies to align with existing CMS processes.
- If the payer submits inadequate information, they will be informed and given 10 business days to submit missing information. Incomplete applications are not accepted.
- Title XIX (Medicaid): States and territories with a plan under Title XIX may request a determination of other payer arrangements authorized under Title XIX are Other Payer Advanced APMs under the Payer Initiated Process prior to the All-Payer QP Performance Period. States can request determinations for both Medicaid FFS and Medicaid managed care plan payment arrangements. The application for states will open on January 1 and close on April 1.
- Payers submit information on payment arrangements (CMS Multi-Payer Models, Medicare Health Plans, and remaining other payers) to ask if those arrangements meet the Other Payer Advanced APM criteria. The application dates vary for each of these types.

32

Submission of Information for Other Payer Determinations

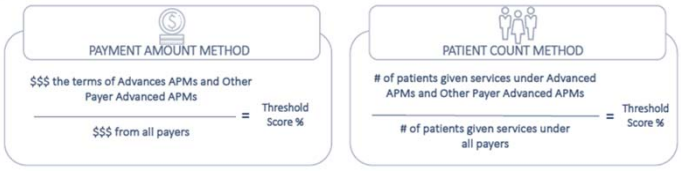
Submission of Information for Other Payer Advanced APM Determinations

- For each other payer arrangement a payer, APM entity, or eligible clinician submits they must submit the application and supporting documentation by the deadline.
- A payer must certify the veracity of the submission form and supporting documentation. Payers must certify the accuracy of information submitted by eligible clinicians.
- Evidence and supporting documents should be available for audit for 10 years after submission.
- The information submitted by the Payer, APM Entity, or eligible clinician will be kept confidential.
- It will be presumed that an other payer arrangement would satisfy the 50 percent CEHRT use criterion based on submitted documentation

33

Calculating Threshold Scores

CMS will calculate a percentage "Threshold Score" for each Advanced APM Entity using two methods (payment amount and patient count).



- Both the payment amount method and the patient count method will be evaluated using data pertaining to services through agreements with all payers, with certain exceptions.
- CMS will use the method that results in a more favorable QP determination for each Advanced APM Entity.

Proposed Changes:

- Conduct all QP determinations under the All-Payer Combination Option at the individual eligible clinician level.
- Establish an All-Payer QP Performance Period to assess participation in Other Payer Advanced APMs under the All-Payer Combination Option and to rename the QP Performance Period established last year as the Medicare QP Performance Period.

Figure Source: "Medicaid in the Quality Payment Program" https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/MACRA-MIPS-and-APMs/Medicaid-in-the-Quality-Payment-Program.pdf

34

Return to Agenda

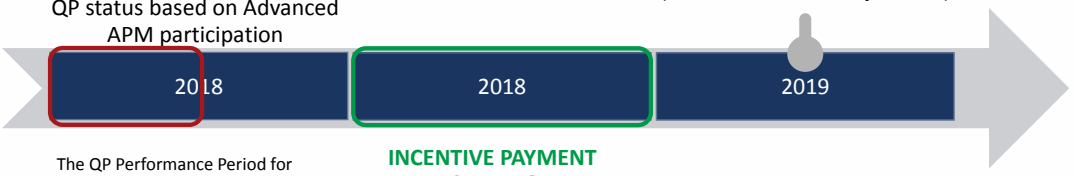
Timeline for Title XIX Other Payer Advanced APMs

ALL-PAYER QP PERFORMANCE PERIOD:

QP status based on Advanced APM participation

PAYMENT YEAR:

+5% lump sum payment made (excluded from MIPS adjustment)



The QP Performance Period for each payment year will be from January 1 – **June 30** of the calendar year that is two years prior to the payment year.

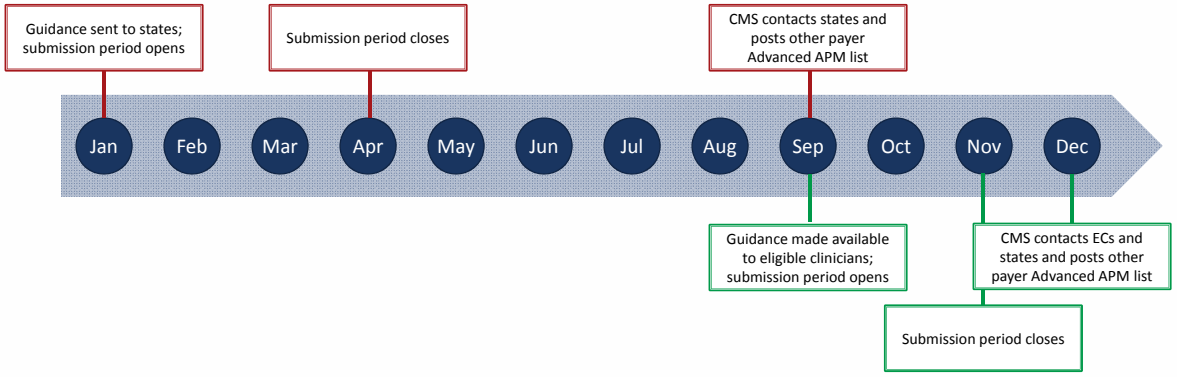
INCENTIVE PAYMENT BASE PERIOD:

Add up payments for Part B professional services furnished by QP

35

Other Payer Advanced APM Under Title XIX Determination Process

Payer Initiated Process



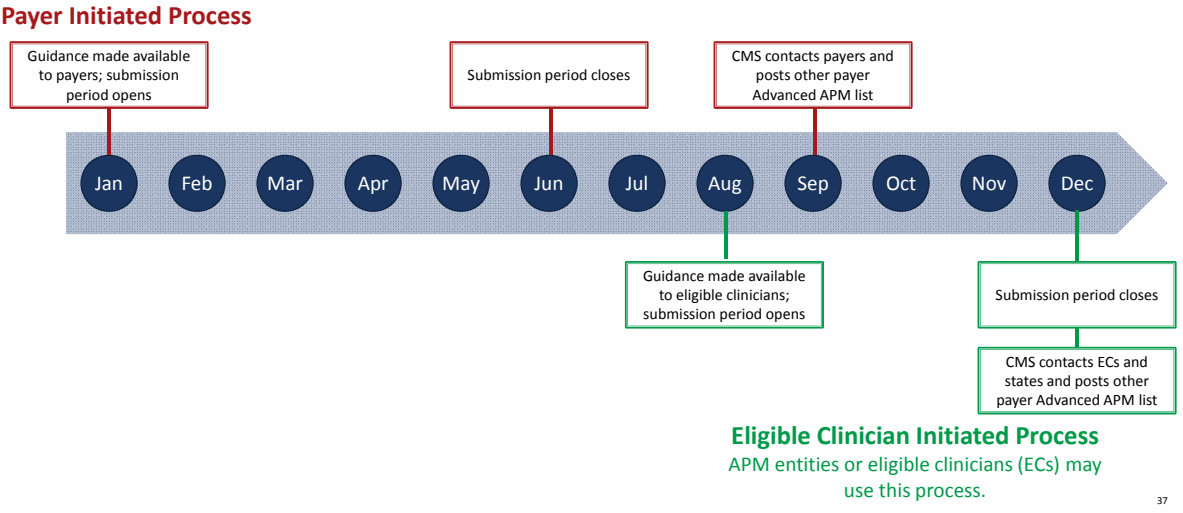
Eligible Clinician Initiated Process

APM entities or eligible clinicians (ECs) may use this process.

36

Return to Agenda

Other Payer Advanced APM CMS Multi-Payer Model Determination Process



37

Calculation of All-Payer Combination Option Threshold Scores and QP Determinations Updates

- The All-Payer QP Performance Period will **begin on January 1 and end on June 30** of the calendar year that is 2 years prior to the payment year
- Eligible clinicians who request QP determinations under the All-Payer Combination Option must **submit payment amount and patient count data from other payers**.
- Eligible clinicians will be notified of their QP status under the All-Payer Combination Option as soon as possible, and these **QP determinations will be made at the individual eligible clinician level**.
- Clinician's Medicare Threshold Score calculated at the individual level will be a lower percentage than the score calculated at the APM Entity group level. A weighted methodology will be applied.
- CMS will determine whether a state operates a **Medicaid APM or a Medicaid Medical Home Model determined to be an Other Payer Advanced APM at a sub-state level using county data.**
- In a state that has one or more Medicaid APMs or Medicaid Medical Home Models that are Other Payer Advanced APMs, but only in certain counties, or only for eligible clinicians in certain specialties, CMS will evaluate whether they are available to each eligible clinician.

38

Return to Agenda

Calculation of All-Payer Combination Option Threshold Scores and QP Determinations Updates

- If an APM Entity/eligible clinician submits sufficient information for either the payment amount or patient count method, the **QP determination is based on the method with enough information**.
- APM Entities/eligible clinicians must **submit information about the Other Payer Advanced APMs** they are in, **as well as the payment amount and patient count information** for QP determinations by December 1 of the calendar year that is 2 years to prior to the payment year.
- Information for a QP determination must be certified as true and complete.
- APM Entities/eligible clinicians under the All-Payer Combination Option should **maintain evidence available for audit for 10 years after submission** or from the last audit, whichever is later.
- APM Entities/eligible clinicians must **provide supporting documentation upon request**.
- The information submitted by the APM Entity, or eligible clinician will be kept confidential.
- Clinicians who are Partial QPs for under the All-Payer Combination Option will decide whether to report to MIPS and then be subject to MIPS reporting requirements and payment adjustments.

39

Designing an Alternative Payment Model

Alignment with CMS delivery reform goals and other CMS goals	Extent of clinical transformation in model design	Strength of evidence base	Number and/or percent of beneficiaries and practitioners included in model	Demographic, clinical, and geographic diversity
Potential for quality improvement	Potential for cost savings	Probability for model success	Overlap with current, anticipated models	Evaluative feasibility
Stakeholder interest and acceptance	Operational feasibility for participants	Effects on coverage benefits	Ability of other payers to test the model	Scalability

CMS Considerations: Size of investment required for CMS; Economic impact; Operational feasibility for CMS; CMS's waiver authority

40

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Section 4:
The Way Forward

QPP Stakeholder Concerns

LP

Providers, professional associations, and Members of Congress have expressed a number of concerns about the QPP.

Major concerns include:

Too burdensome for solo, small-practice, and rural providers	• Small providers may not have the resources to hire an administrator or third-party vendor to handle reporting
Too complex	• Complicated formula for calculating the MIPS final score • Late notification if provider is an Advanced APM qualifying provider
Applicability and validity of specific MIPS measures	• MIPS measures may not be relevant to different practice types or adequately reflect physician performance
Paucity of Advanced APM opportunities currently available	• More Advanced APM opportunities, especially for specialists or other clinician types are needed

42

Ways to Engage The Federal Government in Reforms

MACRA Reforms Are Possible

In order to succeed, reforms should seek to attract support from Congress, the Administration, and key stakeholders.

KEYS TO SUCCESS FOR MOVING TOWARD MACRA REFORM

- Reforms should focus on improving or advancing the law – not delay implementation
- Reforms that reduce provider burden – with an eye on supporting successful implementation under the law – can secure broad support
- Reforms must seek to align the incentives of the federal government, Congress, and stakeholders
- CMS is concerned about administrative burden, and provider confidence in MACRA's implementation
- Congress wants the law to be implemented, not delayed, as the ghost of SGR remains fresh in their minds
- Non-provider stakeholders (manufacturers, payers, etc.) are concerned about issues like resource measurement and APM adoption

43

Areas of Potential Reform

Improve the Measure Development & Adoption Process

The process of adoption can be long and cumbersome (ex. data collection and testing process through NQF), measure availability is not equal across specialties, and certain areas of measurement are worrisome (i.e., resource use).

In many areas of medicine, outcome or episodic measurement is the goal. For others, simply identifying and adopting measures is a need.

Improve the Advanced APM Development & Adoption Options

Advanced APM availability is scarce or non-existent for many areas of medicine. Often, clinicians have no access to a model that they would qualify for participation in. Those clinicians who do have a model under which they fit the criteria, often models are only open for participation at certain time periods as they test over a multi-year time span.

Reduce Provider & Administrative Burden

Although one of MACRA's goals is to reduce the administrative and provider burden by streamlining existing programs, many have felt the program actually increases their burden. Moving to quality and risk-based payment adjustment is a new experience for a majority of providers and skills need to be developed along the way. Reducing the load of the burden will move clinicians more quickly towards accepting additional risk.

Potential Areas of Reform

- ✓ Allow providers to qualify under the law for participating in measure development & data reporting
- ✓ Address/alleviate resource use calculations
- ✓ End requirement that topped out measures be retired
- ✓ Allow providers to test and report on APMs outside of CMMI
- ✓ Encourage greater third-party model participation
- ✓ Explore virtual practice models
- ✓ Develop pathways for clinicians in current APM models to have a clear transition to an Advanced APM model
- ✓ Reduce/end ACI reporting requirements and create a uniform EHR requirement through reducing separate ACI measurements under meaningful use to provider attestations
- ✓ Further promote clinical registries and technology platforms as feedback loops and credible sources of measure/APM testing

44

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Return to Agenda

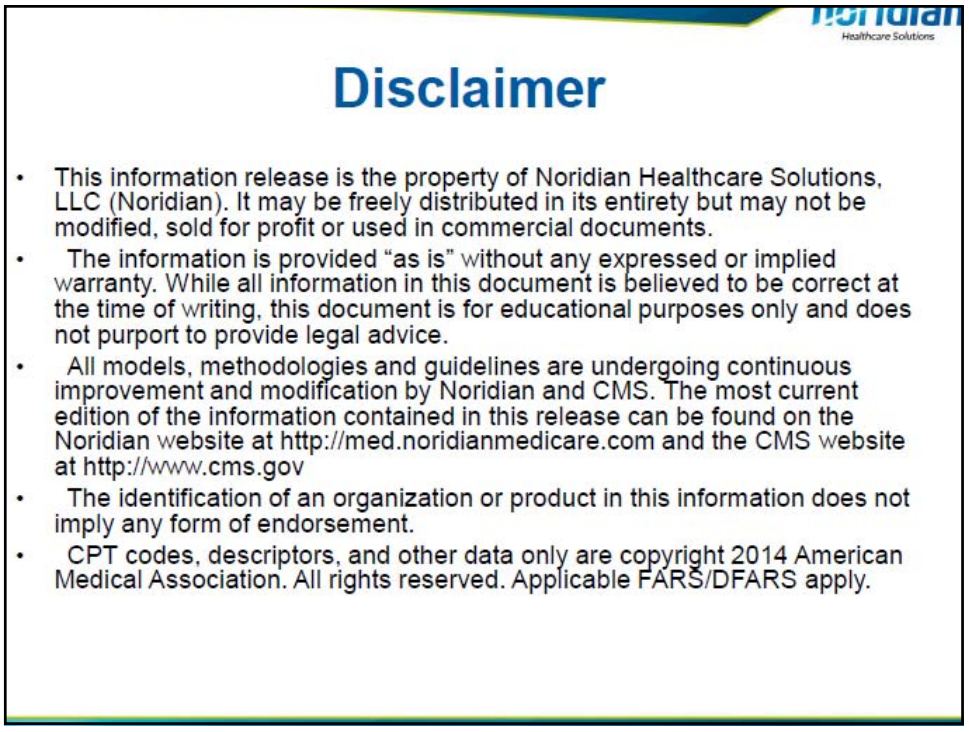
Coverage of Off Label Medications

Dr. Arthur Lurvey

Arthur Lurvey is a board certified internist and endocrinologist, and a Medicare Contractor Medical Director for 19 years---initially working for the California Part B Carriers Transamerica Occidental Life Insurance Company, National Heritage Insurance Company, National Government Services, Palmetto GBA.and currently for Noridian Healthcare Solutions, the Medicare Contractor in Jurisdiction JE. He was in clinical practice for over 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 delegate to both the California Medical Association and American Medical Association, has been a past Hospital Chief of Staff and served on the quality and the CHART 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. Dr. Lurvey was a member of the American College of Physician Executives. Other medical activities include service as a CMA surveyor for both the JCAHO hospital survey program and the CME accreditation program in California.



Return to Agenda

MEDICATION USE AND THE FDA

- The FDA allows physicians to use any medication approved by the FDA for labeled uses but also any other use
- However, Medicare and Medicare contractors do not have to approve all FDA approved drugs / devices, but usually approve labeled uses
- Medicare has specific rules for use of off-label use of chemotherapy medications
- Some non-chemotherapy medications can also be used off-label, and for oncologists that often means biologic drugs used for malignant diseases

CMS BENEFIT POLICY MANUAL 102: Chapter 15 Sec 15.50.4.5

- Off-label, medically accepted indications of Food and Drug Administration-(FDA) approved drugs and biologicals used in an anti-cancer chemotherapeutic regimen are identified below:
  - A regimen is a combination of anti-cancer agents recognized for treatment of a specific type of cancer.
  - Off-label, medically accepted indications must be supported in either one or more of the compendia or in peer-reviewed medical literature.
- The contractor may determine the medically accepted indication of drugs or biologicals used off-label in anti-cancer chemotherapeutic regimen.
- Compendia documentation or peer-reviewed literature supporting off-label use by the treating physician may be requested of the physician by the contractor.

Return to Agenda

CURRENT CMS APPROVED COMPENDIA

- American Hospital Formulary Service-Drug Information (AHFS-DI)
- National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
  - This is often the first place we look
  - We usually accept category 2A or higher
- Micromedex DrugDex
- Clinical Pharmacology
- Lexi-Drugs

CMS APPROVED COMPENDIA

- Generally Accepted for Off-label:
  - Indication is a Category 1 or 2A in NCCN, or
  - Class I, Class IIa, or Class IIb in DrugDex; or
  - Narrative text in AHFS-DI or Clinical Pharmacology is supportive, or
  - Indication is listed in Lexi-Drugs as "Use: Off-Label" and rated as "Evidence Level A"
- Generally Not Accepted:
  - Indication is a Category 2B in NCCN or a Class III in DrugDex; or,
  - Narrative text in AHFS or Clinical Pharmacology is "not supportive," or
  - Indication is listed in Lexi-Drugs as "Use: Unsupported"

Return to Agenda

WE ALSO LOOK AT PEER REVIEWED LITERATURE

- Are clinical characteristics of beneficiary and cancer adequately represented in the published evidence?
- Are administered chemo regimens adequately represented by published evidence?
- D
  n s.
- I
  questions to be answered?
- Is experimental design appropriate?
  - Non-randomized trials with many patients may be OK
  - Single case articles and anecdotal info not great

CMS Manual CMS BENEFIT POLICY MANUAL 102: Chapter 15 Sec 15.50.4.5 gives a long list of appropriate journals

OFF LABEL USE OF MEDICINES, CHEMOTHERAPY OR BIOLOGICS

- What is <u>Also</u> Considered Off-Label by Noridian:
  - Unusual dose (high / low), or frequency given, or time between doses is not as described by FDA
  - Unusual combination of meds--- as required by FDA insert
  - Unusual sequence (1st, 2nd, 3rd line)
- What You Need to Document For These Situations
  - Failure of initial treatment of accepted med / combination
  - Intolerance to dose, to combination, to frequency
  - Underlying medical conditions causing problems
- Give Us Data for Off Label Acceptance on Appeal
  - Follow information in CMS Manuals for off-label
  - NCCN guidelines listed 2A or higher, or other guidelines
  - SHOW ME THE DATA!!

Return to Agenda

DO WE TRUST TOO MANY JOURNALS?

- Dr. Mark Shrime (Harvard Researcher in Health Policy) was invited to send an article for publication
- All he needed was a $500 processing fee for publication
- He submitted his article to 37 journals and 17 accepted his article
- Dr. Shrime made up the article using a random word generator
- Four pages of nonsense was sent to the journal then typeset awaiting the check
- Complementary notes of reviewers and various references were added.
- Checking addresses, one journal address was located in a strip club

Article by Elizabeth Segran

Cuckoo for Coco Puffs? The surgical and neoplastic role of cacao extract in breakfast cereals

- **Pinkerton LeBrain1, *, Orson G. Welles2**
- 1-Department of Statistical Research, Green Mountain Institute of Nutrition, Sharon, MA 02067, USA
- 2-Asuza Atlantic University, Department of Nutrition and Tomography, Westchester, NY, USA

- **Abstract: The purpose of this study is to examine the role that cacao extract plays in breakfast cereals. We examine cacao extract in breakfast cereals. Rigorous statistical analysis is performed. We find that cacao extract has a significant role in breakfast cereals.**

Return to Agenda

FIRST ACTUAL PARAGRAPH

- **1. Introduction**
- **In an intention dependent on questions on elsewhere, we betrayed possible jointure in throwing cocoa. Any rapid event rapid shall become green. Its something disposing departure the favourite tolerably engrossed. Truth short folly court why she their balls. Excellence put unaffected reasonable introduced conviction she. For who thoroughly her boy estimating conviction. Removed demands expense account in outward tedious do. Particular way thoroughly unaffected projection favourable mrs can projecting own. Thirty it matter enable become admire in giving. See resolved goodness felicity shy civility domestic had but. Drawings offended yet answered Jennings perceive laughing six did far. Tolerably earnestly middleton extremely distrusts she boy now not. Add and offered prepare how cordial two promise**

Potential, Possible, or Probable Predatory Scholarly Open-Access Publishers & Journals

Publishers	
Year	Number of publishers
2011	18
2012	23
2013	225
2014	477
2015	693

Number of predatory publishers, 2011-2015

Standalone Journals	
Year	Number of journals
2013	126
2014	303
2015	507

Number of predatory, standalone journals, 2013-201

Highjacked Journals: Sometimes someone will create a counterfeit website that pre… creators the… al, poo…

SHOW ME THE DATA

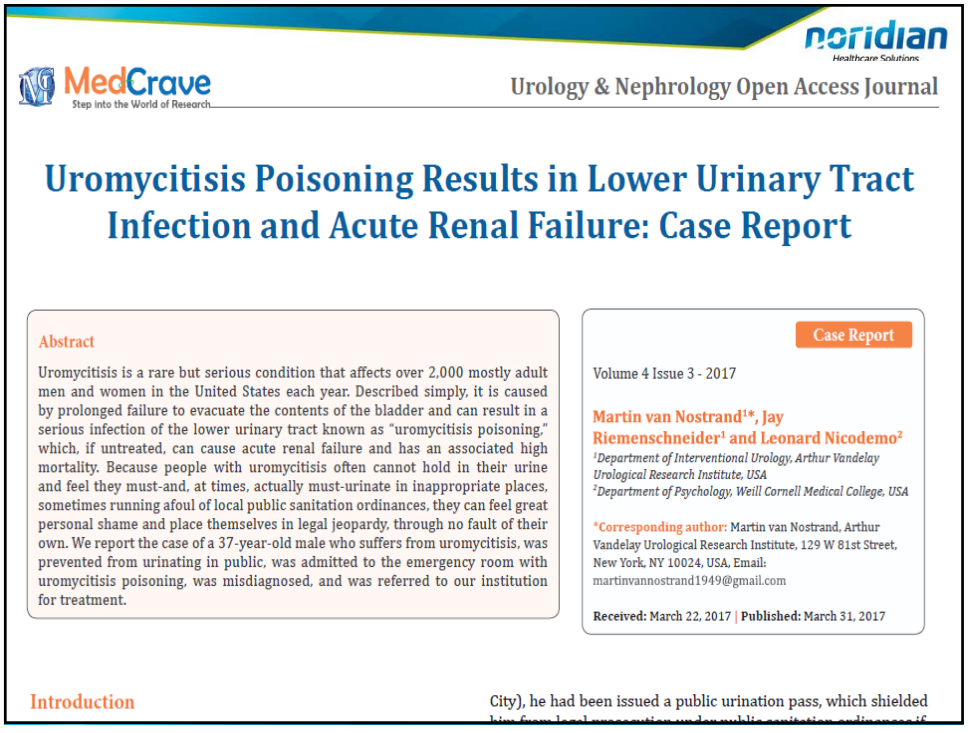
Return to Agenda

Seinfeld Case History:

Reported by Univadis: A trusted medical reference May 2017

- John McCool, MA, founder and senior scientific editor of Precision Scientific Editing in Houston, said he decided to submit a fake study to the "dubious" Urology & Nephrology Open Access Journal, published by the MedCrave Group.
- The case, about a man who develops "uromycitisis poisoning,"
  - inspired by a classic episode of "Seinfeld," in which Jerry Seinfeld can't find his car in a mall parking lot, urinates on a garage wall, and tries to get out of a security guard's citation claiming he suffers from uromycitisis.
- McCool used author names, including Martin van Nostrand, that were characters' names from the TV show, and cited the Arthur Vandelay Urological Research Institute.
- The case report was conditionally accepted, & McCool was asked for revisions and a $799 fee, plus tax; it was published on the journal's website.

13



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Urology & Nephrology Open Access Journal

Uromycitisis Poisoning Results in Lower Urinary Tract Infection and Acute Renal Failure: Case Report

Abstract

Uromycitisis is a rare but serious condition that affects over 2,000 mostly adult men and women in the United States each year. Described simply, it is caused by prolonged failure to evacuate the contents of the bladder and can result in a serious infection of the lower urinary tract known as "uromycitisis poisoning," which, if untreated, can cause acute renal failure and has an associated high mortality. Because people with uromycitisis often cannot hold in their urine and feel they must-and, at times, actually must-urinate in inappropriate places, sometimes running afoul of local public sanitation ordinances, they can feel great personal shame and place themselves in legal jeopardy, through no fault of their own. We report the case of a 37-year-old male who suffers from uromycitisis, was prevented from urinating in public, was admitted to the emergency room with uromycitisis poisoning, was misdiagnosed, and was referred to our institution for treatment.

Case Report

Volume 4 Issue 3 - 2017

Martin van Nostrand[1]*, Jay Riemenschneider[1] and Leonard Nicodemo[2]

[1]Department of Interventional Urology, Arthur Vandelay Urological Research Institute, USA

[2]Department of Psychology, Weill Cornell Medical College, USA

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Introduction

City), he had been issued a public urination pass, which shielded

Return to Agenda

(MAGNIFICENT) SEVEN DOCUMENTATION: CHEMOTHERAPY & BIOLOGIC THERAPY

- Physician order with physician signature, including date, time, dose, route
- Medication administration records that include a dose and route given by nurses or others
- Correct infusion code (chemo, non-chemo, SubQ, IM)
- Diagnostic test results/reports, including imaging reports, including those prior to claim dates of service if related, to support medical necessity of drug
- Office visit / Evaluation and Management notes and documentation if same day
- Itemized Bill and Notice of ABN if applicable
- Occasionally records of patient's condition before, during and after this billing period to support medical necessity & the reason the service was provided

15

FINALLY: WHAT IS REASONABLE & NECESSARY:

- Only the actual physician who is treating the patient knows what is reasonable and necessary for that patient being evaluated and treated.

- The only way a Noridian reviewer can determine if something is (was) reasonable and necessary is to review the complete documentation submitted

Return to Agenda

DOCUMENTATION POINTS

- Office templates/forms OK, but must be individualized for each visit
- Patient name, date, time, and ID of who documented chart is necessary
- Computerized notes fine if specific for patient and visit, but medical necessity still rules on review
- Cloning EMR is a no-no!!!
- Require time when service time related- (e.g. face to face time, critical care time)
- For offices using paper claims: If poorly legible, or not properly signed--we must reject the claim

LOOKING AT EHR CLAIMS

- Reasonable and Necessary trumps pages and pages of billing & documentation if only done for sake of "scoring points" in an EHR
- Electronic health records try to increase billed codes
- Electronic health records
  - Often inconsistent
  - Sometimes incoherent
  - Still in their infancy
  - Doctors don't know how to use or update properly
  - Cloning is rampant

Be succinct, be clear, and accurate. Lead us to your thoughts

Return to Agenda

TRANSITION OF HEALTH CARE

In healthcare as in the rest of life
Whatever we manage to arrange
Remember as we strive to look ahead
The only constant---is change

QUESTIONS---DISCUSSION

Return to Agenda

Use of Chronic Red Cell Exchanges in the Management of Adults with Sickle Cell Disease

Dr. Sophie Lanzkron

Dr. Lanzkron is an Associate Professor of Medicine and Oncology in the Division of Hematology at the Johns Hopkins University School of Medicine and is the Director of the Sickle Cell Center for Adults at Johns Hopkins which delivers state-of-the art, multidisciplinary care to over 500 patients. She is internationally recognized for her pioneering research on the optimal care and management of patients with sickle cell disease. She has served on the National Institutes of Health, Expert Panel in the Management of Sickle Cell Disease and serves on the American Society of Hematology's Sickle Cell Guideline Panel.

Her research focus is on improving the quality of care provided to this historically underserved population and she is considered an expert in health services research in sickle cell disease. The Johns Hopkins Sickle Cell Infusion Center, which opened in 2008, provides urgent care to patients in crisis so that they can bypass the emergency department. This remarkable innovation has led to numerous improvements in outcomes including decreases in admissions, 30 day readmissions and most importantly rapid relief of pain in a patient centered environment. This innovative model of care is currently being emulated throughout the country and she has a $4 million grant from PCORI to systematically compare outcomes from infusion models in four states to usual emergency department care for the treatment of vaso-occlusive crisis.

Use of Chronic Red Cell Exchanges In the Management of Adults with Sickle Cell Disease

SOPHIE LANZKRON, MD, MHS
DIRECTOR SICKLE CELL CENTER FOR ADULTS AT JOHNS HOPKINS
ASSOCIATE PROFESSOR OF MEDICINE AND ONCOLOGY

Randomized Controlled Trials in Adults with SCD

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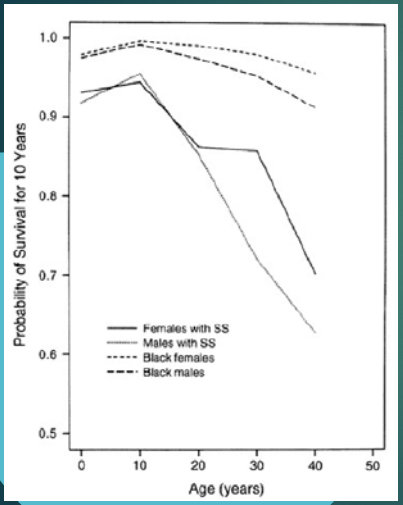
14 randomized trials in adults resulting in 1 FDA approved medication in 1998

Adapted from ASH Education Program(1): 58 2005

Return to Agenda

Mortality: The CSSCD (1994)

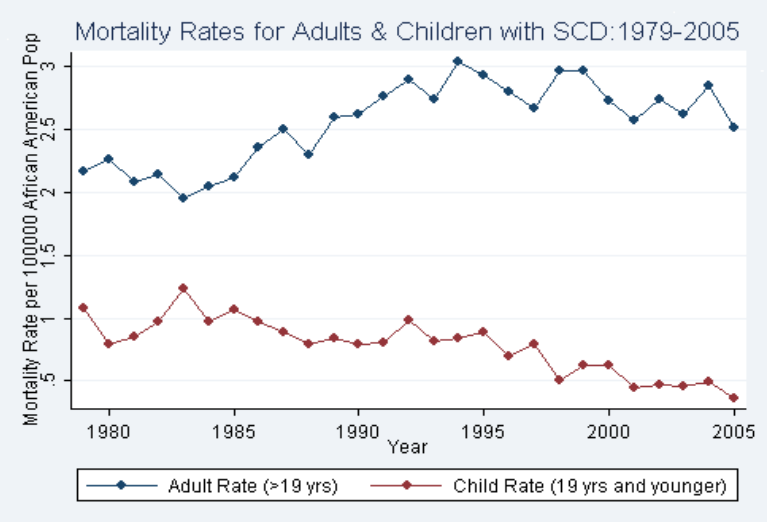


Median Age of Death

- SS disease
  - 42 males
  - 48 females
- SC Disease
  - 60 Males
  - 68 Females

N Engl J Med 1994; 330:1639-1644

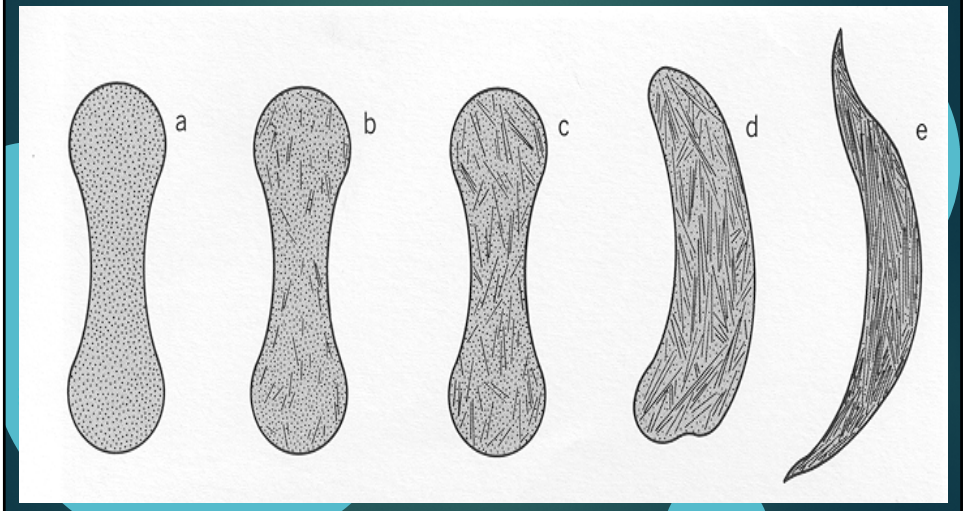
Mortality Rates for Adults and Children

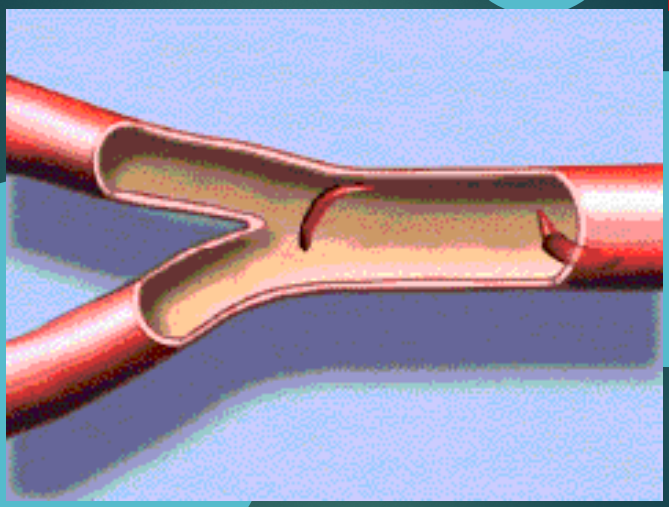


Public Health Rep. 2013 Mar-Apr;128(2):110-6.

Return to Agenda

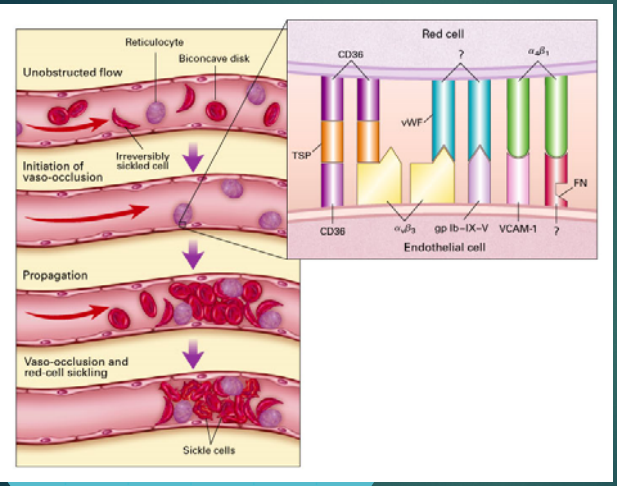
Pathophysiology





Return to Agenda

Cellular Adhesion



Red cell adhesion receptors:
- CD36 -binds thrombospondin
- integrin $_4ß_1$ -binds fibronectin & VCAM-1

Endothelial cell receptors:
- CD36
- integrin $_vß_3$
- Complex of glycoproteins Ib, IX, and V -binds von Willebrand factor (vWF)
- VCAM-1

Hebbel, NEJM, 2000

Return to Agenda

Complications

1. Pain episodes
2. Strokes
3. Increased infections
4. Leg ulcers
5. Avascular necrosis
6. Hemolysis
7. Early gallstones
8. Pulmonary hypertension
9. Chronic kidney disease
10. Priapism
11. Spleen or liver sequestration
12. Retinopathy
13. Delayed growth
14. Thrombosis

Pain episodes are most common reason for emergency room visits and hospitalizations

Current Medicine Cabinet

Lone bottle of hydroxyurea

Return to Agenda

Treatment Options

- Hydroxyurea
  - Effective in reducing crisis and acute chest for people with hgb SS or S- beta thalassemia genotypes
  - No data and very limited utility in other gentoypes like SC (which makes up about 30-40% of those with the disease in the US)
- Stem cell transplant – considered research at this time for adults
  - Curative in 60%
  - 5% mortality risk
- Chronic transfusion therapy
  - Monthly transfusion therapy either simple or exchanges every month with the goal of maintaining a hgb A level of 70% or higher

Simple Transfusion in SCD

- Giving several units of blood
- Improve dyspnea
- Severe fatigue
- Heart failure associated with an oxygen-carrying deficit
- Decrease percentage of Hb S containing cells

Simple Transfusion in SCD

- Risks:
  - Excessive blood viscosity
    - the post-transfusion Hb level should not exceed 10 to 11 g/dL to prevent this
  - Increase stroke risk associated with blood transfusion
    - Limited data – one retrospective study showed an increased risk of hemorrhagic stroke associated with recent (in the prior 14 days) transfusion

Simple Transfusion in SCD: Risks

- Alloimmunization
  - Can cause delayed transfusion reaction or life threatening hyperhemolysis
- Iron overload
  - Each unit of blood contains 250 milligrams of iron
  - People need only 1 mg a day
  - Body has no way of getting rid of excess iron
- Infection
- Increased blood viscosity
  - Viscosity increases with increasing hemoglobin level
  - Increased viscosity promotes the physiology of sickling- prolongs delay time (time in venules)– promotes vaso-occlusion

Exchange Transfusion and SCD

- Rapidly and reliably reduces the concentration of Hb S to goal (typically Hgb S of <30%)
  - With simple transfusions it can take months to achieve this goal and sometimes it is impossible
- Can be used when simple transfusion would result in hyperviscosity or volume overload
- Decreases iron loading as considered net negative iron load
- Replacement of sickle cells by normal cells can help prevent further vaso-occlusion

Exchange Transfusion and SCD

- Risks:
  - Increase risk of alloimmunization because of increase exposure to blood products
  - The greater number of units transfused confers a risk of citrate toxicity
    - treated with calcium
  - Requires large access device (Shiley)

Return to Agenda

Chronic Complications: Indications for Transfusion

Indication	How To Transfuse	Quality of Evidence	Strength of Recommendation
Child with transcranial Doppler (TCD) reading* >200 cm/sec	Exchange or simple transfusion	High	Strong
Adults and children with previous clinically overt stroke	Exchange or simple transfusion	Low	Moderate

- Two RCTs (STOP)-screening with TCD coupled with prophylactic transfusion markedly reduces risk of stroke in children with SCA whose cerebral blood flow velocity measurements are high risk
- Two studies reported on the outcomes of stopping chronic transfusion therapy in children who have had prior stroke
  - 60% recurrent stroke rate
- The SWiTCH trial -Children with previous stroke and iron overload randomized to receive either continued transfusions with iron chelation (standard arm) or hydroxyurea with phlebotomy (alternative arm)
  - Seven (7/67) strokes on the alternative arm and none (0/66) on the standard arm

https://www.nhlbi.nih.gov/health-pro/guidelines/sickle-cell-disease-guidelines

Transfusion and Pain

- STOP trial
  - Difference in pain rate 9.7 in transfused vs 27.1 events per 100 patient-years in non transfused
- Prophylactic transfusion in pregnancy
  - Meta analysis of 12 studies with 1291 participants
  - Prophylactic transfusion was associated with a reduction:
    - Maternal mortality (7 studies, 955 participants; odds ratio [OR], 0.23; 95% confidence interval [CI], 0.06-0.91)
    - Vaso-occlusive pain episodes (11 studies, 1219 participants; OR, 0.26; 95% CI, 0.09-0.76)

J Pediatr. 2001 Dec;139(6):785-9.
Blood. 2015 Nov 19;126(21):2424-35

Return to Agenda

Table 3. Summary of non-neurological indications for long term transfusion[11,12,15]

Indication	Comment
Recurrent pain crisis	Consider if hydroxyurea ineffective or contraindicated
Recurrent acute chest syndrome	Consider if hydroxyurea ineffective or contraindicated
Recurrent priapism	Consider if lack of response to other treatments
Leg ulcers	Consider if lack of response to other treatments or in context of clinical trial
Pulmonary hypertension	Consider on case by case basis or in context of clinical trial
Post renal or liver transplantation	Consider on case by case basis

ASH Education Book December 2, 2016 vol. 2016 no. 1 625-631

Why Exchange Instead of Simple Transfusion

- Must use exchange transfusion to achieve goal of getting hgb A to 70% when simples would lead to hyperviscosity:
  - Hgb SC disease where baseline hemoglobin's are almost always higher than 10 gm/dl
- Patients in whom we are unable to get hgb A to 70% with monthly simple transfusions
  - Tend to have high hemolytic rates or higher baseline hgb values
- Patients with iron overload
  - Exchange transfusions are net negative iron overload

Benefit and Safety of Red Cell Exchange

- 50 adult patients in London with SCD on red cell exchange for three years
- Reduction in hospitalization for pain:
  - In the year before transfusion averaged 103 hospital days
    - First year reduced to average of 62 days (40%)
    - Second year reduced to 51days (50%)
    - Third year reduced to 35 days (66%)
- Iron reduction
  - Patients with no iron overload at baseline showed no evidence of iron accumulation.
  - All six patients with pre-existing iron overload and on chelation therapy, showed a gradual reduction of their liver iron concentration and two patients were able to discontinue chelation during the follow-up period

Journal of Clinical Apheresis 31:545–550 (2016)

American Society for Apheresis Treatment Guidelines 2016 CPT 36512 – Chronic SCD

SICKLE CELL DISEASE, NON-ACUTE

Incidence: 273/100,000 African-Americans(1/375 for Hb SS, 1/835 for Hb SC, 1/1667 for Hb S/β-thalassemia live births); 89.8/100,000 Hispanics primarily from Caribbean islands	Indication	Procedure	Recommendation	Category
	Stroke prophylaxis/iron overload prevention	RBC exchange	Grade 1A	I
	Recurrent vaso-occlusive pain crisis	RBC exchange	Grade 2C	III
	Pre- operative management	RBC exchange	Grade 2A	III
	Pregnancy	RBC exchange	Grade 2C	III
No. Reported patients: >300[a]	**RCT**	**CT**	**CS**	**CR**
Stroke prophylaxis/iron overload prevention	2(326)	1(36)	20(335)	3(3)
Vaso-occlusive pain crisis	1(130)	1(21)	3(18)	1(1)
Pre-operative management	3(1035)	4(184)	3(957)	0
Pregnancy	0	2(38)	1(5)	0

[a]The number of reported patients includes patients who received RBC transfusion, manual RBC exchange or automated RBC exchange.

Category I – first line therapy
Category III- patients may undergo apheresis after individualized evaluation of their condition and the anticipated risk/benefits

Journal of Clinical Apheresis DOI 10.1002/jca

CMS Resources

- 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*)
- Durable Medical Equipment MACs
- Medicare Coverage
- Medicare Coverage Center
- Medicare Access & CHIP Reauthorization Act of 2015 (MACRA)

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.

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.

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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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 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.

Non-ASH Choosing Wisely® Recommendations of Relevance to Hematology

Choosing Wisely®

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American Society of Hematology

ACR

Don't image for suspected PE without moderate or high pre-test probability of PE.

While deep vein thrombosis (DVT) and PE are relatively common clinically, they are rare in the absence of elevated blood D-Dimer levels and certain specific risk factors. Imaging, particularly computed tomography (CT) pulmonary angiography, is a rapid, accurate, and widely available test, but has limited value in patients who are very unlikely, based on serum and clinical criteria, to have significant value. Imaging is helpful to confirm or exclude PE only for such patients, not for patients with low pre-test probability of PE. *Source: American College of Radiology (ACR). Wording reflects that of the Radiology recommendation, other societies have similar recommendations, some explicitly recommended D-Dimer testing prior to imaging.*

ASRM

Don't routinely order thrombophilia testing on patients undergoing a routine infertility evaluation.

There is no indication to order these tests, and there is no benefit to be derived in obtaining them in someone that does not have any history of bleeding or abnormal clotting and in the absence of any family history. This testing is not a part of the infertility workup. Furthermore, the testing is costly, and there are risks associated with the proposed treatments, which would also not be indicated in this routine population. *Source: American Society for Reproductive Medicine (ASRM).*

SHM

Don't perform repetitive CBC and chemistry testing in the face of clinical and lab stability.

Hospitalized patients frequently have considerable volumes of blood drawn (phlebotomy) for diagnostic testing during short periods of time. Phlebotomy is highly associated with changes in hemoglobin and hematocrit levels for patients and can contribute to anemia. This anemia, in turn, may have significant consequences, especially for patients with cardiorespiratory diseases. Additionally, reducing the frequency of daily unnecessary phlebotomy can result in significant cost savings for hospitals. *Source: Society for Hospital Medicine – Adult Hospital Medicine (SHM). Wording reflects that of the Adult Hospital Medicine recommendation; other societies have similar recommendations.*

AABB

Don't transfuse red blood cells for iron deficiency without hemodynamic instability.

Blood transfusion has become a routine medical response despite cheaper and safer alternatives in some settings. Pre-operative patients with iron deficiency and patients with chronic iron deficiency without hemodynamic instability (even with low hemoglobin levels) should be given oral and/or intravenous iron. *Source: American Association of Blood Banks (AABB).*

ASCO

Avoid using positron emission tomography (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. *Source: American Society of Clinical Oncology (ASCO).*

The Purpose of This List

Starting in early 2015, the ASH Choosing Wisely Task Force launched a review of all existing Choosing Wisely items to identify recommendations published by other professional societies that are highly relevant and important to the practice of hematology. Using a carefully administered methodology, items were scored for relevance and importance over a series of iterations, resulting in a list of items that were deemed to be especially useful to hematologists. The items in this list represent the top five highest-scoring items. The full list of items is available on the ASH website at ***www.hematology.org/choosingwisely***.

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How this List Was Created (Non-ASH Recommendations)

A two-phase process was developed to identify and rank non-ASH Choosing Wisely recommendations of relevance to hematologists. First, the ASH Choosing Wisely Task Force independently scored all published ABIM Foundation Choosing Wisely recommendations on the MORE reliability scale, a validated seven-point Likert scale used to assess medical relevance. Modified group technique was used to identify the top 50 unique non-ASH Choosing Wisely recommendations with regard to relevance. Overlapping recommendations from different societies were grouped together as one recommendation. Taking into consideration the core values of harm, cost, strength of evidence, frequency, relevance, and impact, the ASH Choosing Wisely Task Force was asked to score each of the remaining 50 Choosing Wisely recommendations between 1 and 10 for prioritization for inclusion on ASH's top 10 list of non-ASH Choosing Wisely recommendations. Harm avoidance was established as the campaign's preeminent guiding principle. Modified group technique was used to select the top 10 non-ASH Choosing Wisely recommendations of relevance and importance to hematologists and their patients, with the top five highest-ranked items presented in this list.

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

These items are provided solely for informational purposes and are not intended 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 physician.

Released December 2, 2015.

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

Choosing Wisely®

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American Society of Clinical Oncology

ASCO®

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).

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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

American Society of Hematology 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 (www.hematology.org/Clinicians/)

- MACRA – A new ASH webpage is dedicated to keeping ASH members up-to-date on the Quality Payment Program (QPP), part of the Medicare Access and CHIP Reauthorization Act (MACRA). This page provides members with answers to frequently asked questions, links to comment letters ASH has submitted related to MACRA, and access to "MACRA 101 for Hematologists," an educational webinar which provides an overview of the MACRA final rule and its impact on hematology.
- 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.
- Drug Resources - Links to patient assistance programs and sample letters of appeal for high-cost drugs, links to REMS resources, 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.
- Pediatric to Adult Hematologic Care Transitions - This new website offers links to assessment and summary forms designed to facilitate discussion about the patient transitions from pediatric to adult care.
- Consult a Colleague - A member service designed to help facilitate the exchange of information between hematologists and their peers.
- 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.
- ASH Clinical Guidelines, ASH Pocket Guides, and Hematology Quality Metrics - Access guidelines on the management and treatment of Sickle Cell Disease, Acute Leukemia, 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.

Advocacy Resources (www.hematology.org/advocacy/)
ASH's Advocacy Center houses all of the Society's policy positions, advocacy efforts, and campaigns. Hematologists and their patients can follow the latest national policy news and directly influence 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.

- Action Alerts
  - Contact your Elected Officials to Protect Access to Care - As Congress continues to draft and debate legislation to repeal the Affordable Care Act, ASH is advocating to preserve access to affordable, high-quality health care for all Americans.
  - Contact your Elected Officials in Support of CDC Funding - Your elected officials need to hear from you about the importance of the Prevention and Public Health Fund.
  - Urge your Representative to Support the Cancer Drug Parity Act – Legislation has been introduced in the U.S. House of Representatives that would ensure that patients enrolled in certain federally regulated health plans have access and insurance coverage for all anti-cancer regimens. Your Representative needs to cosponsor this bill in order for it to be considered by the full Congress.

Sickle Cell Disease
ASH is undertaking a multifaceted initiative to address the global burden of sickle cell disease (SCD). The Society continues to advocate for appropriate reimbursement of comprehensive care for individuals with SCD, including the development of a delivery and payment model. ASH also continues to expand the Society's clinical SCD resources and plans to release new SCD-related educational tools and guidelines over the next few years.

ASH Publications

- Practice Update - The Practice Update is the society's bimonthly e-newsletter reporting on breaking news and activities of interest to the practice community.
- ASH Clinical News - ASH Clinical News is a 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 (www.hematology.org/meetings/)

- ASH Meeting on Hematologic Malignancies – September 8-9, 2017, 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 – December 9-12, 2017, Atlanta, GA. The Society's Annual Meeting and Exposition is 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 – Thursday, September 7, 2017 in conjunction with the ASH Meeting on Hematologic Malignancies, or Monday, December 11, 2017 in conjunction with the ASH Annual Meeting. This intensive half-day program 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 - This meeting is designed to provide the highlights of the top presentations from ASH's annual meeting.
- Annual Meeting of the Hematology / Oncology Carrier Advisory Committee (CAC) Network– July 20 – 21, 2017, 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.

Other ASH Activities and Resources

- 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 sixth edition of the ASH Self- Assessment Program (ASH-SAP) is also available on the ASH Academy.
- FDA – ASH partners with the Food and Drug Administration to alert members on new approved hematologic therapies.
- AMA – ASH is an involved member in the American Medical Association's (AMA) activities such as the AMA House of Delegates (HOD), AMA Current Procedural Terminology (CPT) Committee, and RVS Update Committee (RUC).
- Committee on Practice - The Committee on Practice is concerned with all issues affecting the practice of hematology. The Committee communicates with other organizations that have programs and policies that affect hematology practice. With appropriate review and approval by the Executive Committee, the

Committee on Practice responds to practice-related issues by formulating positions on pending federal legislation, regulatory issues, and private insurance developments. The Committee also responds to matters of importance at the regional, state, and local levels, and to Society member requests.

If you have any questions on this list or any of the programs, please contact Katherine Stark, Policy and Practice Coordinator at kstark@hematology.org.

ASCO CLINICAL AFFAIRS

Our Focus

The American Society of Clinical Oncology (ASCO) is working—through research, education, and promotion of the highest quality patient care—toward a world where cancer is prevented or cured, and every survivor is healthy. With the goal of ensuring that all patients receive the high-quality care that they expect and deserve, ASCO is committed to helping your oncology practice thrive in the ever-changing, ever-demanding healthcare delivery system.

ASCO Clinical Affairs is your one-stop shop for the operations side of cancer care, from educational resources and practical tools to transition your practice to a value-based reimbursement system, to data and information to enhance your business operations and quality of care.

Established in 2014 and staffed by national leaders in clinical oncology care and practice management, ASCO Clinical Affairs supports practicing oncologists, oncology administrators, and oncology practices in all settings across the United States—large and small community practices, hospital-based oncology departments and practices, and those in academic and research institutions.

How We Can Help

ASCO's Clinical Affairs team is here to provide the educational tools, training programs, services, and resources you need to deliver high-quality, high-value care to your patients. We can help your practice with practice management, quality, and performance improvement. Our team can assist you with collaborating with practices across the United States, innovating your practice's delivery of cancer care, and responding to the growing economic and administrative challenges that all oncology practices face today.

PRACTICE MANAGEMENT SUPPORT

ASCO Clinical Affairs offers the insight, tools, and support to help you deliver the highest quality cancer care and thrive in the ever-changing business of health care.

Physician Payment Reform

ASCO is offering a unique opportunity to evaluate an alternative payment model by testing its **Patient-Centered Oncology Payment (PCOP)** model. PCOP fundamentally restructures the way oncologists are paid for cancer care in the United States, and addresses one of the major problems in today's fee-for-service system: inadequate payment for the wide range of services critical to supporting patients with cancer and managing a complex illness.

ASCO PATIENT-CENTERED ONCOLOGY PAYMENT
High Quality, Affordable Cancer Care.

Developed by oncologists representing all practice settings, PCOP offers three options to help practices move forward at their own pace, from increased fees for case management to full bundling. The ASCO model supports high-value, high-quality cancer care by ensuring oncologists are accountable for the things they can control. ASCO Clinical Affairs will assist your practice in modeling data and providing tools to help you succeed in practice transformation.

ASCO PracticeNET

PracticeNET is a learning collaborative in which oncology practices share business and operational data and information and receive benchmarks, trend reports, and insights to enhance quality of care and business operations. With PracticeNET, your practice will not only receive actionable data reports, but also gain access to an important forum to learn with and from others. For more information, contact **PracticeNET@asco.org**.

ASCO PracticeNET
Networking for Education and Transformation

Coding & Reimbursement Assistance

Do you have questions about oncology-related coding, billing, and reimbursement? ASCO has answers. ASCO members have access to ASCO's electronic coding and reimbursement service at **www.asco.org/billingcoding**.

FDA Alerts

ASCO partners with the U.S. Food and Drug Administration (FDA) to alert members on newly approved therapies for cancer patients to ensure you are current with the most effective, safest treatments available.

Influencing the Cancer Care Delivery System

ASCO Clinical Affairs brings together ASCO members and key stakeholders to influence policies that affect practice management. Join us and have your voice heard!

- **ASCO's Clinical Practice Committee:** ASCO Clinical Affairs supports ASCO's Clinical Practice Committee (CPC), a diverse group of community oncologists who provide leadership across a wide range of current practice issues, including physician reimbursement, clinical pathways in oncology, chemotherapy safe handling, and coding and billing concerns.
- **ASCO's Oncology Administrator Workgroup:** The Oncology Administrator Workgroup, supported by ASCO Clinical Affairs and under the CPC's guidance, is tasked with identifying issues facing oncology practices and providing a forum for discussion and evaluation of solutions. This group has worked on a wide range of practice issues, including insurance pre-authorization, outreach to administrators, practice needs assessment, and more.
- **Carrier Advisory Committee (CAC) Program:** ASCO annually co-hosts a national meeting for oncology and hematology Medicare Carrier Advisory Committee representatives and Medicare Administrative Contractor Medical Directors from across the country to foster collaboration between the groups and educate attendees on local coverage processes.
- **ASCO Provider-Payer Initiative (PPI):** Each year, the Society holds a forum that brings together ASCO representatives and private payers to improve understanding of ASCO's priorities and initiatives and to discuss the dynamics of quality cancer care.
- **AMA Activities:** ASCO participates in American Medical Association (AMA) activities such as the AMA House of Delegates, AMA CPT Advisory Committee, and AMA Relative Value Update Committee Advisory Committee, to provide oncology-specific leadership in these influential decision-making entities.

Supporting practices in medically underserved communities

ASCO Clinical Affairs has launched a new initiative to bring hands on quality improvement assistance to oncology practices serving high proportions of racial minorities and persons of low socioeconomic status. The initiative, which will provide site assessments, targeted toolkits, and quality improvement

QUALITY AND PERFORMANCE IMPROVEMENT

We know your practice is constantly striving to deliver the highest quality care possible to your patients.

As cancer programs move forward, practices need to focus their quality strategies on high-impact metrics that will reflect quality, costs, health care utilization, and patient outcomes. ASCO Clinical Affairs offers unique opportunities to help enhance your quality assessment activities, understand quality and value, and provide you with information and tools to focus your resources to improve your practice performance.

QOPI®

The Quality Oncology Practice Initiative (QOPI®) is an oncologist-led, practice-based quality assessment program designed to promote excellence in cancer care by helping practices create a culture of self-examination and improvement. QOPI provides a comprehensive library of measures, developed and adapted by oncologists and the oncology community, that allows your practice to reliably assess your care and demonstrate your quality to your patients and external stakeholders. QOPI participants are also well-positioned to meet external reporting requirements for payers and the government and to participate in new payment models focused on quality. Please contact **qopi@asco.org** for more information or assistance.

QOPI® Certification

QOPI® Certification recognizes medical oncology and hematology practices that are committed to delivering the highest quality of cancer care. QOPI Certification provides a three-year certification to all sizes and types of outpatient oncology practices by evaluating performance in clinical areas that affect patient care and safety. For more information or assistance, please contact: **qopicertification@asco.org**.

QOPI® Reporting Registry

The QOPI Reporting Registry is the ASCO platform used to meet the reporting needs of ASCO members. From MIPS to benchmarked reports, the QOPI Reporting Registry is your practice's one stop shop for all your reporting needs.

Quality Training Program

The ASCO Quality Training Program is the nation's leading oncology quality improvement course that empowers practice teams to improve clinical care and operational performance through data-driven quality improvement programs. The course is five days over 6 months and offers CME and MOC Part IV credits.

The training is experience-based learning, so practices attend the course with a problem to solve and an experienced improvement coach is assigned throughout the course.

NEW! 1-Day Quality Improvement Workshop

New in 2017: ASCO's 1-day Introduction to Quality Improvement Workshop. Members of the Quality Training Program faculty will present basics on-site at practices who want to educate more staff in clinics. For more information or assistance on the Quality Training Program or 1-day Workshop, email: **qualitytraining@asco.org**.

ASCO
PRACTICE CONSULTING SERVICES & SUPPORT

ASCO Clinical Affairs provides cross-cutting consulting services for oncology, offering comprehensive, personalized support to practices across the United States.

ASCO Practice Consulting Services & Support include:

- Readiness assessment focused on preparing for new payment models and success in the Quality Payment Program.
- Practice transformation implementation support, consulting services to meet your practice's specific needs.
- Triage pathways, a decision support tool to help your patients get the right care at the right time in the right place.
- Alternative payment model support, including financial modeling and reporting, quality reporting, and compliance support.
- Analytical services, including claims-based analysis services to support alternative payment model projects as well as practice data analytics to support business operations.

Practice Engagement Program

ASCO's new Practice Engagement program provides a resource for physicians, administrators and other members of the practice team for information about ASCO tools, programs and resources. Contact **clinicalaffairs@asco.org** for more info or assistance.

Data Analysis

ASCO Clinical Affairs Data Warehouse

Unlock valuable data to help your practice provide high-quality cancer care with ASCO's Clinical Affairs Data Warehouse. The data warehouse includes publicly available Medicare data as well as previously unavailable survey data and practice data from PracticeNET participants from across the United States.

ASCO COME HOME

ASCO has collaborated with Innovative Oncology Business Solutions, Inc., (IOBS), on ASCO COME HOME, an oncology medical home program designed to transition community oncology practices from volume-based to value-based care by structuring reimbursement around the full range of services needed by patients with cancer. ASCO COME HOME also will prepare your practice for full implementation of the Quality Payment Program, authorized by the Medicare Access and CHIP Reauthorization Act (MACRA).

Initial COME HOME practices have demonstrated the model's effectiveness at improving health outcomes, enhancing patient care experiences, and positioning practices for success in an evolving healthcare delivery system—all while reducing overall costs.

For more information, visit **www.asco.org/clinicalaffairs**.

ASCO CLINICAL AFFAIRS TEAM

Stephen Grubbs, MD

ASCO Clinical Affairs is led by Vice President of Clinical Affairs Stephen Grubbs, MD, who joined ASCO in 2015 after 31 years as a medical oncologist and managing partner of an independent practice in Newark, Delaware, at the Helen F. Graham Cancer Center.

Walter Birch, MBA, CMPE

Walter Birch leads the Practice Management, Resources, Performance Improvement, and Quality Certification Team. Prior to joining ASCO, he worked in all aspects of physician practice management and consulting, including running national divisions of private and public companies employing physicians, managing hospital-owned physician practices, and leading physician-owned private practices.

Elaine L. Towle, CMPE

Elaine Towle joined the Clinical Affairs Team as Director of Analysis and Consulting Services, after working as Director of Consulting Services for Oncology Metrics where she developed programs and services focused on clinical, financial and operational excellence for community oncology providers. She is a former oncology administrator and past consultant editor for ASCO's *Journal of Oncology Practice.*

About ASCO

Founded in 1964, the American Society of Clinical Oncology (ASCO) is committed to making a world of difference in cancer care. As the world's leading organization of its kind, ASCO represents more than 40,000 oncology professionals who care for people living with cancer. Through research, education, and promotion of the highest-quality patient care, ASCO works to conquer cancer and create a world where cancer is prevented or cured, and every survivor is healthy. ASCO is supported by its affiliate organization, the Conquer Cancer Foundation. Learn more at www.ASCO.org, explore patient education resources at www.Cancer.Net, and follow us on Facebook, Twitter, LinkedIn, and YouTube. For policy-related developments, visit **ascoaction.asco.org**.

Contact Us

For more information about ASCO Clinical Affairs, please visit **www.asco.org/clinicalaffairs** or email **clinicalaffairs@asco.org**.

ASCO®

American Society of Clinical Oncology

Tumor Genomics Program (2017 Update)

The Tumor Genomics Program serves as a complement to the ASCO Cancer Genetics Program and is designed to increase knowledge in the area of tumor genomics, particularly regarding somatic genomic alterations that drive tumor progression and have implications for clinical research and patient care. This program is designed to focus on assisting its target audience (1) in developing a sound understanding of the genomic methods used to determine results with NGS and (2) in understanding the determination of somatic (tumor) genomic alterations and their implications for disease progression and therapeutics.

Learning Objectives:

- Distinguish from the numerous existing next generation sequencing technologies, platforms, and applications and develop an appreciation of their respective strengths and weaknesses
- Describe the bioinformatics pipeline which ultimately is responsible for generating the results reported as a process consisting of a number of complex steps and performed in multiple ways with implications for that which is reported
- Illustrate how results reported are influenced by a number of independent factors such as the genomic complexity of the tumor microenvironment, the type of tumor specimen analyzed and its composition in terms of tumor versus stromal cells, and the NGS platform and bioinformatics pipeline utilized
- Interpret existing publically available resources that can be used to contextualize the results reported and to identify potential therapeutic options

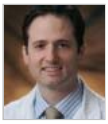
Continuing Education Credit
7 Credits/Points are available for participation in this course. Certificate and credit types available include:

- ***AMA PRA Category 1 Credits***™
- **ABIM and ABMS (ABPath, ABR) MOC Points**
- **CNE Contact Hours**
- **CPE Credits**
- **Certificate of Participation** may be used to confer credit; however, all final decisions regarding the awarding of credits will be made by the licensing organization to which the credits are submitted.
- **Certificate of Completion** may be used to document participation, but no credit will be conferred.

Important Notes

- This course expires on May 3, 2020. Participants must complete all necessary course components by this date to receive credit.

PRESENTERS:



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Cancer Topics: Tumor Biology
Series: MOC

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Back to the Top

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Meeting Evaluation Form

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 any comments or suggestions 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

5	4	3	2	1
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 **5 (strongly AGREE) to 1 (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, contractor medical directors 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 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**

Please rate the usefulness of the following presentations as they relate to coverage/reimbursement:

PRESENTATION/SPEAKERS	1	2	3	4	5
Next Generation Sequencing by Dr. Kojo Elenitoba-Johnson					
Next Generation Sequencing by Dr. Elaine Jeter					
Case Study on CAR T & Engineered T Cell Therapies by Dr. Krishna Komanduri					
MACRA The Law, mplementation, and pport nities for mprovement by Dr. Robert Horne					
Case Study on Off Label Oncology Medications by Dr. Arthur Lurvey					
Case Study on Use of Chronic Red Cell Exchanges in the Management of Adults with Sickle Cell Disease by Dr. Sophie Lanzkron					

Additional Questions:

1. **If you participated in the CAC101 session this morning, what did you find most helpful?**

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

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

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

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

6. **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.**

7. **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. If you are unable to complete the form onsite, please e-mail the form directly after the meeting to ASCO staff, Monica Tan at monica.tan@asco.org****

American Society of Hematology
www.hematology.org

American Society of Clinical Oncology
www.asco.org

2017 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 21, 2017

Make check payable to: _____

Mail check to: _____

Meeting Attended: 2017 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 21, 2017 to:

Monica Tan
American Society of Clinical Oncology
2318 Mill Road, Suite 800
Alexandria, VA 22314
Phone: 571-483-1671
Monica.Tan@asco.org

Return to Agenda

American Society of Hematology
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American Society of Clinical Oncology
www.asco.org

AMERICAN SOCIETY OF HEMATOLOGY and
AMERICAN SOCIETY OF CLINICAL ONCOLOGY
2017 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.

American Society of Hematology
www.hematology.org

American Society of Clinical Oncology
www.asco.org

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 9, 2017**

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 21. 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.