2019 American Society of Hematology / American Society of Clinical Oncology

Hematology and Oncology Carrier Advisory Committee (CAC) Network Meeting

June 27 – 28, 2019

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

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

Friday, June 28, 2019
8:00 a.m. – 3:00 p.m.

AGENDA

8:00 a.m.	Breakfast		
8:30 a.m.	Welcome and Introductions	Co-Chairs	
	• ASH and ASCO Staff List		3
	• Attendee List		4
	• CAC Representatives		10
	• CMD List and Jurisdiction Map		17
8:45 a.m.	Background and Intention of the 21st Century Cures Act		
	• 21st Century Cures & LCD Reform	Robert Horne	24
9:30 a.m.	Recent Changes to CAC and LCD Process		
	• Local Coverage Determinations Development Process	Janet Brock	28
10:15 a.m.	Break		
10:30 a.m.	Panel Discussion with CMD and CAC Representatives		
	• Open discussion on how ASH and ASCO can help with the 21st Century Cures Act's impact on the CAC process	Larry Clark, MD, FACP, Gary Oakes, MD, FAAFP, Steve Allen, MD, and John Cox, DO, FASCO, FACP, MBA	
11:30 a.m.	Networking Lunch		
12:30 p.m.	The Changing Landscape of Opioid Policy	Kristina Novick, MD	36
1:30 p.m.	Next Generation Sequencing (NGS)		
	• NGS and Myeloid Malignancies: To Repeat or Not?	Jamile Shammo, MD	61
	• Update on NGS National Coverage Determination	Erika Miller, JD	72
2:30 p.m.	Closing Remarks and Reference Materials	Co-Chairs	
	• CMS Resources		76
	• ASH Choosing Wisely		77
	• ASCO Choosing Wisely		83
	• ASH Practice Resources		87
	• ASCO Clinical Affairs Brochure		90
	• Meeting Evaluation Form		98
	• Meeting Reimbursement Policy		101
	• Meeting Reimbursement Form		105
3:00 p.m.	Adjourn		

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CAC Acronyms

AMA – American Medical Association
AML - Acute Myeloid Leukemia
ALTO - Alternative to Opioids
CAC - Carrier Advisory Committee
CBC - Complete Blood Count
CDC – U.S. Centers for Disease Control and Prevention
CED - Coverage with Evidence Development
CMD - Contractor Medical Director
CMS – U.S. Centers for Medicare & Medicaid Services
ESA - Erythropoiesis-Stimulating Agent
FDA - U.S. Food and Drug Administration
Hgb - Hemoglobin
HHS – U.S. Department of Health and Human Services
HTN - Hypertension
ICD - International Statistical Classification of Diseases and Related Health Problems
LCD - Local Coverage Determination
MA – Medicare Advantage
MAC - Medicare Administrative Contractors
MAT - Medication-Assisted Treatment
MCD – Medicare Coverage Database
MEDCAC - Medicare Evidence Development & Coverage Advisory Committee
MDS - Myelodysplastic Syndrome
MDS-MPN - Myelodysplastic/ Myeloproliferative Neoplasms
MME - Milligram Morphine Equivalent
NASEM - National Academies of Sciences, Engineering, and Medicine
NCA - National Coverage Analysis
NCCN - National Comprehensive Cancer Network
NCD - National Coverage Determination
NGS - Next Generation Sequencing
OUD – Opioid Use Disorder
PDMP - Prescription Drug Monitoring Programs
PMF – Primary Myelofibrosis
REMS - Risk Evaluation and Mitigation Strategy
WHO – World Health Organization

CAC 101:
An Introduction to Carrier Advisory Committees

1

According to Medicare Coverage Rules

- The decision about whether to cover or, in some cases, not to cover various products and services is typically made at the local level, by Medicare Administrative Contractors (MACs)
- CMS rules require MACs to establish Carrier Advisory Committees (CACs) to advise the contractors about Local Coverage Decisions (LCDs) as long as the proposed coverage or non-coverage does not conflict with an existing National Coverage Decisions (NCDs).
- MACs must establish one CAC per state
- Where one MAC oversees multiple states, it must create a separate CAC for each state.

2

CAC Members

CAC Members are responsible for:

1. Disseminating proposed LCDs to colleagues for comment;
2. Disseminating information about the Medicare program obtained at the CAC meetings; and
3. Discussing inconsistent or conflicting Medical Review policies.
4. Contributing to help in other specialties' LCDs. This is helpful for the MAC and helps CAC Members gain credibility.

3

National Coverage Determination (NCD)

- Determined by CMS.
- CMS is advised, at its discretion, by Medicare Evidence Development & Coverage Advisory Committee (MEDCAC), or can conduct an external technology assessment.
- Supersedes MAC policies.
- Can specify services never and/or always covered.
- NCDs can change as science and research emerge.
- NCDs play a growing role in coverage, particularly for very expensive items and services

4

NCD Process

- Generally, CMS has six to nine months to complete the process after it is initiated (depending on whether technology assessment or MEDCAC review is needed).
- The MEDCAC process includes a public forum, including public testimony.
- Proposed decision is then posted to the CMS website for a 30 day comment period.
- Final decision posted within 60 days after the conclusion of the comment period.

5

Local Coverage Determinations (LCD)

- LCDs are decisions by a MAC, fiscal intermediary, or carrier on whether to cover or, in some cases, not to cover a particular service.
- LCDs specify under what clinical circumstances a service is considered reasonable and necessary.
- They can also provide administrative and educational tools to assist providers in submitting correct claims for payment.
- It is important to note: LCD is the typical mechanism for most Medicare coverage policies

6

Development of LCDs

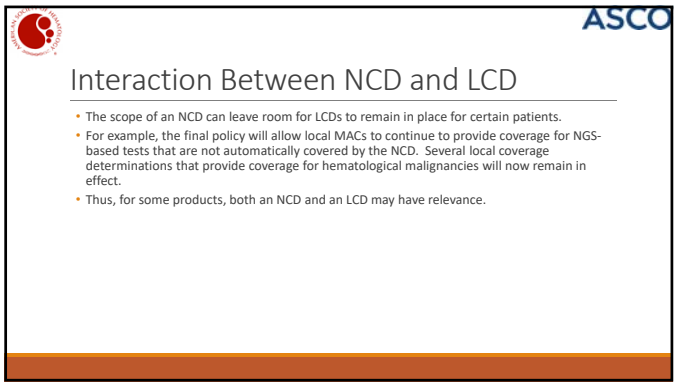
- MACs must develop new/revised LCDs when a service or item is never covered under certain circumstances and the MAC wants to establish an automated review in the absence of an NCD.
- MACs may develop an LCD if it identifies a widespread problem that poses a risk to Medicare trust funds.
- MACs may also develop a LCD if deemed necessary in order to ensure access to care for beneficiaries.

7

LCD Process: CAC Role

- MACs must solicit comments from the physician community, utilizing CACs at the state level.
- The comment period begins upon submission to the CAC at a regularly scheduled meeting or delivery in writing to all CAC members.
- The comment period is 45 days

8


ASCO
Interaction Between NCD and LCD
• The scope of an NCD can leave room for LCDs to remain in place for certain patients.
• For example, the final policy will allow local MACs to continue to provide coverage for NGS-based tests that are not automatically covered by the NCD. Several local coverage determinations that provide coverage for hematological malignancies will now remain in effect.
• Thus, for some products, both an NCD and an LCD may have relevance.

9

21st Century Cures & LCD Reform

Robert Horne

Robert Horne is a principal 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.

ASH/ASCO CAC Meeting:

21ST CENTURY CURES & LCD REFORM

June 28, 2019

LEAVITT PARTNERS

1

SECTION

The Concept of "21st Century Cures"

The 21st Century Cures Act was developed as a means of improving "the discovery, development, and delivery" of health care services and new technologies.

- **Discovery** – supporting basic and translational research to improve the science of health care and medical product/service development.
- **Development** – improving the development and approval pathway for medical products and services.
- **Delivery** – enhancing how patients access and receive health care products and services.

 2

2

SECTION

21st Century Cures: Some Notable Provisions

- Defining the regulatory approach for digital health/digital technologies
  - UPDATE: FDA released a "Proposed Regulatory Framework for Modifications to Artificial Intelligence/Machine Learning (AI/ML)-Based Software as a Medical Device" (April 2, 2019)
- Increasing the use of Real-World Evidence (RWE)
  - UPDATE: FDA has and continues to define the way forward for RWE use in health care. One recent and important milestone was the release of the "Framework for FDA's Real-World Evidence Program" (December 2018)
- Improving ONC/CMS Interoperability and the Meaningful Use Program
  - UPDATE: CMS and ONC recently released rules on information blocking and making data more available and useful in health care operations (e.g. The Interoperability and Patient Access Proposed Rule released Feb. 11 2019)
- Other Notable Provisions
  - Modernizing clinical trial designs, consent reform, and support for basic research among others

3

Spotlight: Sec. 4009 of 21st Century Cures

21st C.C. Act Statute: SEC. 4009. IMPROVING MEDICARE LOCAL COVERAGE DETERMINATIONS

(a) IN GENERAL.—Section 1862(l)(5) of the Social Security Act (42 U.S.C. 1395y(l)(5)) is amended by adding at the end the following new subparagraph:

''(D) LOCAL COVERAGE DETERMINATIONS.—The Secretary shall require each Medicare administrative contractor that develops a local coverage determination to make available on the Internet website of such contractor and on the Medicare Internet website, at least 45 days before the effective date of such determination, the following information:

''(i) Such determination in its entirety.

''(ii) Where and when the proposed determination was first made public.

''(iii) Hyperlinks to the proposed determination and a response to comments submitted to the contractor with respect to such proposed determination.

''(iv) A summary of evidence that was considered by the contractor during the development of such determination and a list of the sources of such evidence. ''(v) An explanation of the rationale that supports such determination.''.

(b) EFFECTIVE DATE.—The amendment made by subsection (a) shall apply with respect to local coverage determinations that are proposed or revised on or after the date that is 180 days after the date of enactment of this Act.

4

Spotlight: Sec. 4009 of 21st Century Cures

Congressional Intent

- The Affordable Care Act and other recent health care statutes had placed big responsibilities and great burden on CMS staff (e.g. CMMI).
- There were concerns that CMS coverage operations (NCDs, etc.) were suffering as a result due to lack of resources (staff).
- Some felt that real-world testing and data gathering requests were increasing as a direct result of this resource issue.
- The Local Coverage Determination (LCD) process was becoming increasingly important to organizations seeking revenue and CMS data to prove "reasonable and necessary" for purposes of national coverage determinations.
- Congress intended, as part of 21st Century Cures, that improvements to the local coverage determination (LCD) – with a focus on greater transparency – would help organizations and entities better navigate the LCD and NCD processes and help inform CMS work at the national level.

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6

Local Coverage Determinations (LCDs) Development Process

Janet Brock

Janet Brock is the Director of The Division of Policy Coordination and Implementation in the Coverage and Analysis Group in CMS. During her almost 19-year tenure at CMS, she has worked in various capacities to strengthen CMS's ability to increase access to promising clinical innovations. As a founding staff member of the Council of Technology and Innovation as well as its predecessor the Medical Technology Council (both at CMS), she worked to make sure that pathways to coverage, coding and payment were well articulated and navigable by all interested stakeholders. Most recently, she and her team shepherded a major redesign of the local coverage process, so it aligns fully with the priorities of CMS related to innovation and burden reduction.

Local Coverage Determinations (LCDs) Development Process

1

History

- When the Medicare program was enacted, there was recognition then, which is still supported by providers today, that an acceptable amount of local coverage is needed for the administration of the Medicare program.
- Thus Local Coverage Determinations (LCDs) are a deliberate and essential feature of the program.
- In the absence of national policy, the Medicare Administrative Contractors (MACs) have their own statutory authority to develop LCDs for their jurisdiction(s).

2

Current LCD Requirements

- 21st Century Cures Act requires:
- At least 45 days before the effective date of a new LCD determination, MACs must post the following information on their websites and in the Medicare Coverage Database (MCD):
  - The entire determination.
  - Where and when the proposed determination was first made public.
  - Web links to the proposed determination and a response to comments submitted to the MAC about the proposed determination.

3

Requirements - Continued

21st Century Cures Act – Continued:

- A summary of evidence considered by the MAC during the development of the determination, and a list of the sources of such evidence.

• In addition to Medicare law, LCDs must be consistent with Medicare regulations, NCDs and national guidance published in CMS's manuals.

4

LCD Development Process

1. Informal Meeting
   - Informal meetings for interested parties to discuss potential LCDs
2. New LCD Request
   - MACs could possibly use a consistent format (under development)
3. Contractor Advisory Committee (CAC)
   - MACs have the discretion to determine when a CAC is needed
   - CAC meeting may occur prior to, or after, the publication of a proposed LCD
   - Role of the CAC has changed – to review the quality of the evidence used to develop the LCD. MACs may pose evidentiary questions to the panel.
   - CAC members include all healthcare professionals along with a beneficiary representative
   - MAC have the discretion to assemble an expert panel and/or use the standing CAC members.
   - CAC meetings may be held via webinar, telephonically, or in-person
   - CAC meeting are open to the public to observe

5

LCD Development Process – Cont.

4. MAC published the Proposed LCD on the Medicare Coverage Database (MCD)
   - Proposed LCDs will be retired if not finalized within 1 year from the posting date
   - Most proposed LCD will be accompanied by a proposed article suggesting potential implementation of policy (i.e. codes)

5. LCD Comment Period
   - New and revised proposed LCD requires a comment period of 45 calendar days (note: all revised LCDs require comment/notice periods).

6. Proposed LCD Open Meetings
   - In addition to the comment period, Contractors hold meetings for interested parties within their jurisdiction to discuss the evidence used in their proposed determination.

6

Local Coverage Determination Process – Cont.

7. Post the Final LCD on the Medicare Coverage Database (MCD).
   - MACs will develop process to adequately notify public when the final LCD is posted
   - Response to Comment Articles will remain on the MCD indefinitely and will be linked to every Final LCD
   - Most final LCD will accompanied by linked articles that describe the coding and billing instructions

8. The Notice Period
   - After the MAC considered all the comments and finalized the LCD, a 45 calendar day period is required, unless extended by the contractor, to notify the public of the final LCD.

7

LCD Reconsideration Process

- LCD reconsideration process aligns with the NCD Reconsideration Process which requires the MACs to follow the full LCD process should a request be valid and opened
- Contractors post on their web site information on how someone goes about submitting a reconsideration request
- Contractors must consider LCD request from beneficiaries, providers and interested parties doing business in their jurisdiction
- Requests can only be for final LCDs and must be submitted in writing, identify the language the requestor wants changed, and submitted with supported evidence.
- Requests can be for all or portions of the LCD

8

LCD Challenges

- This process allows aggrieved parties to challenge LCD
- Aggrieved party is defined as a Medicare beneficiary, or the estate of a Medicare beneficiary, who is entitled to benefits under Part A, enrolled under Part B, or both and is in need of coverage for a service that would be denied by an LCD, as documented by the beneficiary's treating physician, regardless of whether the service has been received.

9

LCD Challenges – Cont.

ALJ → **DAB** → **Federal Court**

10

What's the future plan?

- All the Process to Evolve and Ensure Improvement Upon Transparency, Clarity, and Consistency
  - Remove all codes from LCDs and if appropriate include in a billing/coding Article
    - Explain how Codes are an operational function to implementing the policy??
  - Add a LCD Summary Sheet in the MCD
  - Add a LCD Landing Page
    - May include announcements for upcoming meetings (open, CAC)
    - May include news feed on Proposed or Final LCDs that have been published???

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Medicare Coverage Database (MCD)

- https://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx
- MCD houses all the NCDs, LCDs and Billing and Coding articles.

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References

- The LCD development process is outlined in the Program Integrity Manual, Chapter 13 (LCD) https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs.html.
- The LCD challenge process is outlined in the 42 CFR 426.

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The Changing Landscape of Opioid Policy

Kristina Novick, MD, MS

Kristina Novick, MD MS, is a Radiation Oncologist practicing in Rochester, NY. Dr. Novick received her undergraduate degree in Economics from Princeton University. She attended Columbia University College of Physicians & Surgeons and completed her residency in Radiation Oncology at University of Rochester, NY. She received a Master's of Science degree in Biostatistics from the University of Rochester. Dr. Novick is board certified in Radiation Oncology.

Since 2011, she has served as an Alternate Delegate from the American Society of Clinical Oncology (ASCO) to the AMA House of Delegates. In 2018, she was appointed ASCO representative to the AMA Opioid Task Force. She is Vice-Chair for the American Radium Society (ARS) Appropriate Use Criteria Breast Cancer Committee. Dr. Novick's interests include health policy, palliative care and supportive care.

The Changing Landscape of Opioid Policy

KRISTINA NOVICK, MD MS

ROCHESTER REGIONAL HEALTH SYSTEM

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About Me

- Radiation Oncologist, practicing in Rochester, NY.
- ASCO representative on the AMA Opioid Task Force.
- Alternate Delegate from ASCO to the AMA House of Delegates.
- No conflicts of interest to disclose.

2

Opioids for Cancer Pain

- 30% - 50% of patients with cancer experience moderate to severe pain
- Efficacy of opioids for cancer pain seen clinically and studied in Cochrane study of systematic reviews [Wiffen 2017]
  - 19 out of 20 patients with moderate to severe pain from cancer have reduction of pain to mild or no pain within 14 days with opioids
  - 1 to 2 out of 10 did not tolerate opioid treatment

3

Opioids for Cancer Pain

- Pain spans the entire time course of cancer, from diagnosis to death.
  - 55% of patients suffered pain during cancer treatment
  - 40% after curative treatment
  - 66% in advanced disease [van den Beuken-van Everdingen 2016]
- Cancer pain is neither acute nor chronic; it is episodic of varying intensity.

4

Dosing Opioids

- Morphine milligram equivalents (MME)

HOW MUCH IS 50 OR 90 MME/DAY FOR COMMONLY PRESCRIBED OPIOIDS?

50 MME/day:

- 50 mg of hydrocodone (10 tablets of hydrocodone/acetaminophen 5/300)
- 33 mg of oxycodone (~2 tablets of oxycodone sustained-release 15 mg)
- 12 mg of methadone (<3 tablets of methadone 5 mg)

90 MME/day:

- 90 mg of hydrocodone (9 tablets of hydrocodone/acetaminophen 10/325)
- 60 mg of oxycodone (~2 tablets of oxycodone sustained-release 30 mg)
- ~20 mg of methadone (4 tablets of methadone 5 mg)

U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

LEARN MORE | www.cdc.gov/drugoverdose/prescribing/guideline.html

Calculating morphine milligram equivalents (MME)

OPIOID (doses in mg/day except where noted)	CONVERSION FACTOR
Codeine	0.15
Fentanyl transdermal (in mcg/hr)	2.4
Hydrocodone	1
Hydromorphone	4
Methadone	
1-20 mg/day	4
21-40 mg/day	8
41-60 mg/day	10
≥ 61-80 mg/day	12
Morphine	1
Oxycodone	1.5
Oxymorphone	3

These dose conversions are estimated and cannot account for all individual differences in genetics and pharmacokinetics.

5

History

6

> We must appreciate that severe constant pain will destroy the morale of the sturdiest individual. . . . But . . . we are often loathe to give liberal amounts of narcotics because the drug addiction itself may become a hideous spectacle.
>
> Warren Cole, MD, FACS (1899-1990)

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History

- 1950s: morphine taken by mouth for cancer pain.
- 1986: morphine-like drugs recommended for moderate to severe pain from cancer by WHO.
- Kathleen Foley publishes on the low rate of addictive behavior in cancer and non-cancer patients in 1981 and 1986.
- 1999: 86% of opioids prescribed for non-cancer pain.
- 2001: Joint Commission released its Pain Management Standards, creating the idea of pain as the 5th vital sign.
- 2000's Purdue Pharma markets Oxycontin for chronic pain as a nonaddictive drug.

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Opioid Crisis- National Institute on Drug Abuse

- Roughly 21 to 29 percent of patients prescribed opioids for chronic pain misuse them [Vowles 2015].
- Between 8 and 12 percent develop an opioid use disorder [Vowles 2015].
- An estimated 4 to 6 percent who misuse prescription opioids transition to heroin.
- About 80 percent of people who use heroin first misused prescription opioids.
- Opioid overdoses increased 30 percent from July 2016 through September 2017 in 52 areas in 45 states.
- The Midwestern region saw opioid overdoses increase 70 percent from July 2016 through September 2017.
- Opioid overdoses in large cities increase by 54 percent in 16 states.

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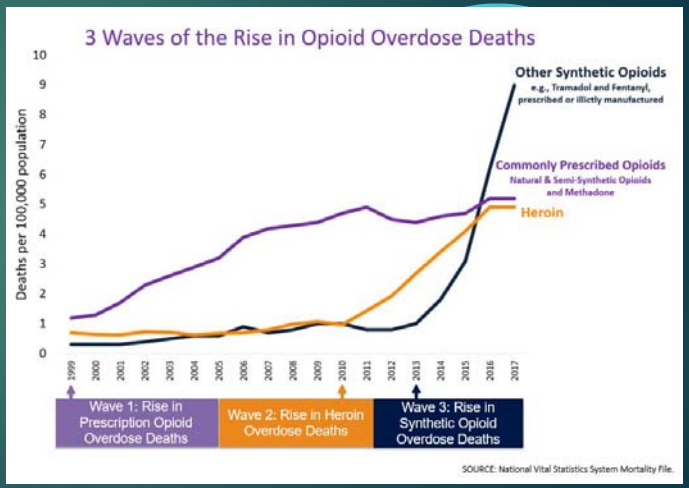
Opioid Crisis- CDC

- From 1999 to 2017, more than 700,000 people have died from a drug overdose.
- Around 68% of the more than 70,200 drug overdose deaths in 2017 involved an opioid.
- In 2017, the number of overdose deaths involving opioids (including prescription opioids and illegal opioids like heroin and illicitly manufactured fentanyl) was 6 times higher than in 1999.
- On average, 130 Americans die every day from an opioid overdose.



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Ending the Opioid Epidemic

- Decline in annual opioid prescriptions from 252 million to 169 million from 2013 to 2018.
- Decline in MME by 43% since 2011.
- Congress allocated $4 billion for prevention, treatment and law enforcement efforts addressing the opioid epidemic.
- Barrier of prior authorization for treatment of opioid use disorder (OUD) removed in 9 states and DC.
- A 290% increase since 2014 in number of physicians registered to state prescription drug monitoring programs (PDMPs) to nearly 2 million physicians.
- 460 million queries of state PDMPs in 2018.
- Nearly 600,000 prescriptions of naloxone in 2018, double the number in 2017.

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AMA Opioid Task Force

- Remove barriers to care for opioid use disorder (OUD) with medication-assisted treatment (MAT)
- Support mental health treatment
- Remove barriers to comprehensive, multimodal, multidisciplinary pain care
- Increase access to non-punitive evidence-based treatment for the betterment of maternal and child health
- Support civil and criminal justice reforms to increase assess to treatment for OUD

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Clinical Review & Education

Special Communication

CDC Guideline for Prescribing Opioids for Chronic Pain—United States, 2016

- The "CDC Guideline for Prescribing Opioids for Chronic Pain—United States, 2016," is intended for primary care clinicians (eg, family physicians, internists, nurse practitioners, and physician assistants) who are treating patients with chronic pain (ie, pain conditions that typically last >3 months or past the time of normal tissue healing) in outpatient settings.
- **The guideline is intended to apply to patients 18 years and older with chronic pain outside of active cancer treatment, palliative care, and end-of-life care.**
- Some of the recommendations might be relevant for acute care settings or other specialists, such as emergency physicians or dentists, but use in these settings or by other specialists is not the focus of the guideline."

Dowell 2016

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CDC Guidelines, 2016

Table 1
Summary of CDC guidelines for prescribing opioids for chronic pain.*

Category	Recommendation
Determining when to initiate or continue opioids for chronic pain	1. Encourage use of nonpharmacologic and nonopioid pharmacologic therapies for chronic pain. 2. Assess patient goals and align with treatment goals for pain and function. 3. Prior to initiating opioids, clinicians provide education on risks and benefits with intermittent reassessment.
Opioid selection, dosage, duration, follow-up, and discontinuation	4. Opioid therapy should be initiated with short-acting opioids as opposed to long-acting opioids. 5. Use lowest possible effective dose. Avoid dose ≥90 MME/day and *IF* considering dose above this limit justify clinical rationale. 6. For acute pain, use lowest possible effective dose for shortest effective duration (3–7 days suggested for acute pain). 7. When initiating opioid therapy, evaluate effectiveness and benefit/harm within 1–4 weeks and at least every 3 months thereafter. Discontinue when harm outweighs benefit.
Assessing risk and addressing harms of opioid use	8. Consider co-prescribing naloxone in high-risk patients (ie, history of overdose, history of OUD, ≥50 MME/day, concurrent benzodiazepine use). 9. Clinicians are encouraged to review PDMP frequently. 10. Check urine drug test before initiating opioids and at least annually. 11. Avoid concurrent use of opioids and benzodiazepines. 12. Consider medication-assisted treatment, such as buprenorphine or methadone with behavioral therapy, for patients with OUD.

* Guideline excludes patients receiving active cancer treatments, palliative care, and end-of-life care.
Abbreviations: MME, morphine milligram equivalents; OUD, opioid use disorder; PDMP, prescription drug monitoring program.
Data from Dowell et al.[8]

Foxwell 2019

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Perspective

No Shortcuts to Safer Opioid Prescribing

Deborah Dowell, M.D., M.P.H., Tamara Haegerich, Ph.D., and Roger Chou, M.D.

- Efforts to implement prescribing recommendations to reduce opioid-related harms are laudable. Unfortunately, some policies and practices purportedly derived from the guideline have in fact been inconsistent with, and often go beyond, its recommendations.
- A consensus panel has highlighted these inconsistencies, which include:
  - Inflexible application of recommended dosage and duration thresholds;
  - Policies that encourage hard limits and abrupt tapering of drug dosages, resulting in sudden opioid discontinuation or dismissal of patients from a physician's practice;
  - Misapplication of the guideline's dosage thresholds to opioid agonists for treatment of opioid use disorder; and
  - The potential for misapplication of the recommendations to populations outside the scope of the guideline…[including] pain associated with cancer, surgical procedures, or acute sickle cell crises.

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Impact of Opioid Crisis on Cancer Care

- Primary Effects
  - Patients presenting with personal history of OUD
  - Risk of OUD in the cancer patient
- Secondary Effects
  - Family members or associates with addiction
  - Changing perceptions on opioid use
  - Reluctance to prescribe opioid medication when needed
  - Uncontrolled non-cancer pain affecting ability to receive treatment
- Tertiary Effects
  - Societal constraints on access to opioids affecting availability

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Primary Effects- OUD in the Cancer Patient

- Pre-existing history of addiction creates challenges when treating cancer pain.
- Patient and/or caretakers may be reluctant to prescribe opioid medication, thereby affecting pain and possibly ability to complete cancer treatment.
- Patients with pre-existing use of high MME use of opioids are less likely to achieve control of cancer-related pain.

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Primary Effects- OUD in the Cancer Patient

- Challenges in quantifying risk of OUD in the cancer patient.
- Historically thought to be very low.
- Attempts to quantify risk of death from overdose depend on the accuracy of the coroner's report, which may list the primary cancer diagnosis as cause of death.
- Death from opioids is 10 times less likely as primary cause of death on the death certificate in cancer patients [Chino 2018].
- From 2006 to 2016, opioid deaths increased from 0.52 to 0.66 per 100,000 in cancer patients compared to increase from 5.33 to 8.97 in the general population [Chino 2018].

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Primary Effects- Risk Assessment and Monitoring

- Include a risk assessment during evaluation of pain.
- Implement risk mitigation strategies:
  - Universal precautions
  - Ongoing monitoring
  - Referral to addiction specialists if opioid or substance use disorder is suspected.

Table 1. Structure employed in prescribing opioids based on risk

Minimal Structure	High Structure
Annual urine toxicology	Frequent urine toxicology – may be conducted with each refill in some cases
Review of PDMP every 3 months[a]	Review of PDMP with each refill
Clinic appointments every 3 months	Reassess pain, function and aberrant behaviors frequently; reconsider need for controlled substances regularly
Prescriptions provided for 30-day supply – may provide 3 prescriptions and notate earliest fill dates for each prescription to receive a total of up to 90 days (e.g., "may fill on or after June 1, 2019")[b,c]	Prescriptions provided for short periods (e.g., 1- or 2-week supply)
	Engage family or responsible person to dispense medications
	Taper medications when indicated (e.g., change in pain, aberrant behaviors)
	Refer to addiction specialist

[a]More frequently if mandated by state regulations.
[b]If permissible by state law.
[c]For more information regarding prescribing of controlled substances, see the following: Issuance of multiple prescriptions for Schedule II controlled substances. Web site of the Diversion Control Division, Drug Enforcement Agency, U.S. Department of Justice. Available at https://www.deadiversion.usdoj.gov/faq/mult_rx_faq.htm. Accessed April 28, 2019.
Abbreviation: PDMP, prescription drug monitoring program.

Paice 2016

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Secondary Effects- Attitudes and Perceptions

- Patients
  - Poor understanding of cancer pain management and opioids
  - Rising fear of addiction
- Caretakers
  - Negative view of opioids can affect the ability to treat cancer pain
- Physicians or other healthcare professionals
  - Knowledge about cancer pain differs between oncologists and non-oncologists
  - Many prescribers reluctant to prescribe opioids
  - "Hot potato" opioid prescribing

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Secondary Effects- Attitudes and Perceptions

- Changes in prescription trends seen in outpatient palliative care after reclassification of hydrocodone [Haider 2017]
  - DEA reclassified schedule III to schedule II in October 2014
  - From 2010 to 2015, MME before referral decreased from 78 mg/d (IQR 30 to 150) to 40 mg/d (IQR 19 to 80) (p = 0.001)
  - 87% had advanced cancer
  - Rates of hydrocodone prescription decreased while tramadol (schedule IV) increased

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Tertiary Effects

- Pharmacy restrictions
  - Partial filling at pharmacies lacking full supply
  - Refusal to honor 3 day emergency supply when allowed by state law
  - Refusal to fill when ICD10 diagnosis code is omitted
- Insurance restrictions
  - Limits on quantity per fill, requiring extra copays
  - Use of prior authorization to increase dose or refill sooner than original prescription allowed
  - No mechanism for authorizing pain medication on weekends

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Ongoing Federal Policy

- Congressional legislation
- Centers for Disease Control (CDC)
- Federal Drug Administration (FDA)
- Department of Health and Human Services (HHS)

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Federal Policy- Congress

- H.R. 6, the "SUPPORT for Patients and Communities Act" in Oct. 2018
  - Multiple provisions to address treatment of OUD
  - Provides funding to encourage R&D for non-opioid treatments for pain
  - Requires HHS to study federal and state laws and regulations limiting prescriptions of opioid medications (length, quantity or dosage)
  - Mandates electronic prescription of controlled substances (EPCS) schedule II-V for Medicare Part D and Medicare Advantage (MA)
    - Requires DEA to update regulations on authentication of prescriptions using biometrics
  - HHS to establish electronic prior authorizations for Part D and MA drugs
  - Requires FDA to develop indication-specific prescribing guidelines for acute pain

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Federal Policy- CDC

- CDC Guideline Clarification
  - Letter to 3 medical societies on April 9th
    - NCCN, ASCO, ASH
    - Recommends 2016 publication ASCO Clinical Practice Guideline on Management of Chronic Pain in Survivors of Adult Cancers and 2018 publication NCCN Clinical Practice Guidelines in Oncology: Adult Cancer Pain provide "useful guidance"
    - Also recognizes the unique considerations for management of pain in the sickle cell patient, recommending use of NIH publication, National Heart, Lung, and Blood Institute's Evidence Based Management of Sickle Cell Disease Expert Panel Report
  - Transitional materials and training for providers
    - Assessing Benefits and Harms of Opioid Therapy
    - Web-based training, Applying CDC's Guideline for Prescribing Opioids

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Federal Policy- CDC

- Further clarification of the intent of the guidelines in response to a letter from 300+ "Health Professionals for Patients in Pain" on April 10th
  - "The guideline does not endorse mandated or abrupt dose reduction or discontinuation…[and recommends] to taper or reduce dosage only when patient harm outweighs patient benefit.'
- Media statement on April 24th:
  - Advise against misapplication of the 2016 guideline
  - "Examples of misapplication include applying the Guideline to patients in active cancer treatment, patients experiencing acute sickle cell crises, or patients experiencing post-surgical pain."

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Federal Policy- FDA

- FDA issues Drug Safety Communication on safe opioid tapering
  - No standard opioid tapering schedule
  - Gradual reduction to avoid withdrawal symptoms, worsening of pain and psychological distress
  - Close monitoring during taper
  - Appropriate treatment of substance use disorder if suspected
- Update on storage and disposal of opioid medications, Disposal of Unused Medicines
- Work with National Academies of Sciences, Engineering, and Medicine (NASEM) to develop indication-specific guidelines on opioids for acute pain
- Finalized revision of REMS (Opioid Analgesic Risk Evaluation and Mitigation Strategy)
  - Will apply to immediate release opioid analgestics in outpatient setting

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Committee on Pain Management and Regulatory Strategies to Address Prescription Opioid Abuse

- Collaboration between FDA and NASEM
- Submit comments to opioids@nas.edu
- Evidence-based Clinical Practice Guidelines for Prescribing Opioids for Acute Pain
- Workshop Feb 4, rwedge@nas.edu

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Federal Policy- HHS

- Pain Management Best Practices Inter-Agency Task Force Members
  - 29 members – 12 special government employee members, 9 organization representative members, 8 federal members
  - Created out the Comprehensive Addiction and Recovery Act of 2016 (CARA)
  - Charged to identify, review and resolve inconsistencies in best practices for pain management
  - Unless extended by Congress, with terminate on July 22, 2019
  - Met 3 times, next meeting June 26th, 2019
  - 2.7.3 Patients with Cancer-Related Pain and Patients in Palliative Care
    - GAPS AND RECOMMENDATIONS
      - Gap 1: Oncologists and PCPs are not trained in pain palliative care
      - Recommend that clinicians assess and address pain at every encounter
      - Gap 2: Persistent cancer pain in setting of limited prognosis is often inadequately treated
      - Recommend that multimodality and multi disciplinary care be used

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"Various health insurance plans, retail pharmacies, and local and state governments are implementing the CDC Guideline as policy, limiting the number of days a patient can receive prescription opioids even when the seriousness of the injury or surgery may require opioids for adequate pain management for a longer period. A more even-handed approach would balance addressing opioid overuse with the need to protect the patient-provider relationship by preserving access to medically necessary drug regimans and reducing the potential for unintended consequences."

U.S Department of Health and Human Services (May 2019). Pain Management Best Practices Inter-Agency Task Force Report: Updates, Gaps, Inconsistencies, and Recommendations.

30

State Policy

- National Academy of State Health Policy Palliative Care Resource Hub: State Strategies to Address Palliative Care
- 2017 Colorado Opioid Safety Pilot Results
  - Colorado Hospital Association initiative to reduce opioid administration in the emergency department (ED) through use of alternative to opioids (ALTOs) for treatment of pain

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The Colorado Opioid Safety Collaborative

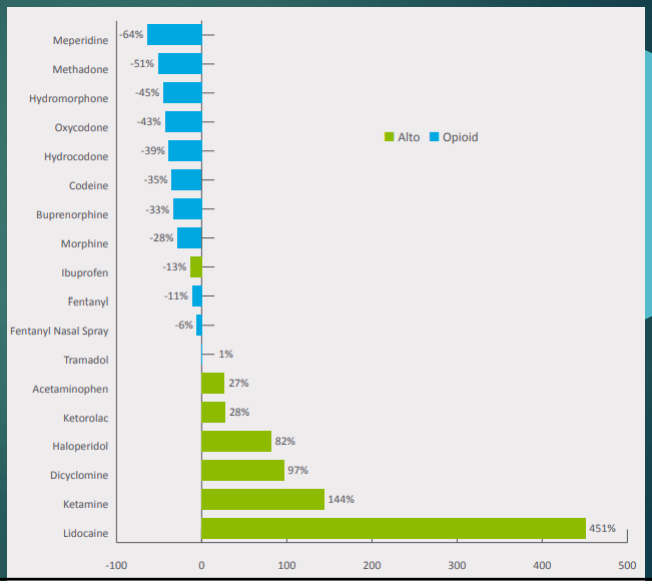
The Colorado Hospital Association, Colorado Chapter of American College of Emergency Physicians, Colorado Consortium for Prescription Drug Abuse Prevention, Telligen and the Colorado Emergency Nurses Association

Pilot Snapshot	
Number of Hospitals	10 EDs
Number of ED Visits During 2017 Intervention Period	130,631
Projected Decrease in Opioid Doses in 2017 Intervention Period Over 2016 Baseline Period (adjusted for number of visits)	35,000
Percent Change in Morphine Equivalent Units	36 percent decrease
Percent Increase ALTO Administrations	31.4 percent increase

32

Colorado Opioid Safety Pilot Study

- Reduction of MME seen across all opioid subtypes
- Greatest increased use of Lidocaine



33

Colorado Opioid Safety Pilot Study

- Although ALTO use doubled, opioid use was the highest for malignant neoplasms
- 84% of patients still required opioid

34

Colorado Opioid Safety Pilot Study

- Although ALTO use doubled, opioid use was the highest for malignant neoplasms
- 84% of patients still required opioid

35

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2018 ABPM Barriers to Pain Care Pain Medicine Specialists Survey

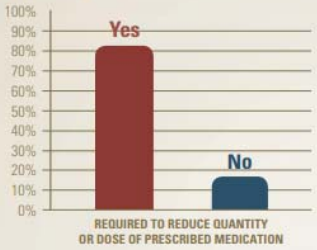
Survey design and methodology

A 10 question, web based survey of ABPM Diplomates was conducted by ABPM in January 2018 and again in April 2018 until a total of 100 responses were received. The survey was completed by 100 practicing pain medicine specialists in the United States.

The survey was conducted to to help identify how the nation's opioid epidemic is affecting patients with pain and the physicians who treat them.

Opioid prescription limits

Q: When prescribing opioid analgesics for chronic pain, have you or your patients been required to reduce the quantity or dose of the medication?



83% of pain medicine specialists said that they – or their patients – have been required to reduce the quantity or dose of medication they have prescribed

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Walmart's Opioid Stewardship Initiative

The health and safety of our patients is a critical priority. Walmart Inc., including Walmart and Sam's Club pharmacies in the United States and Puerto Rico, has taken the following actions in our pharmacies to be part of the solution to our nation's opioid epidemic.

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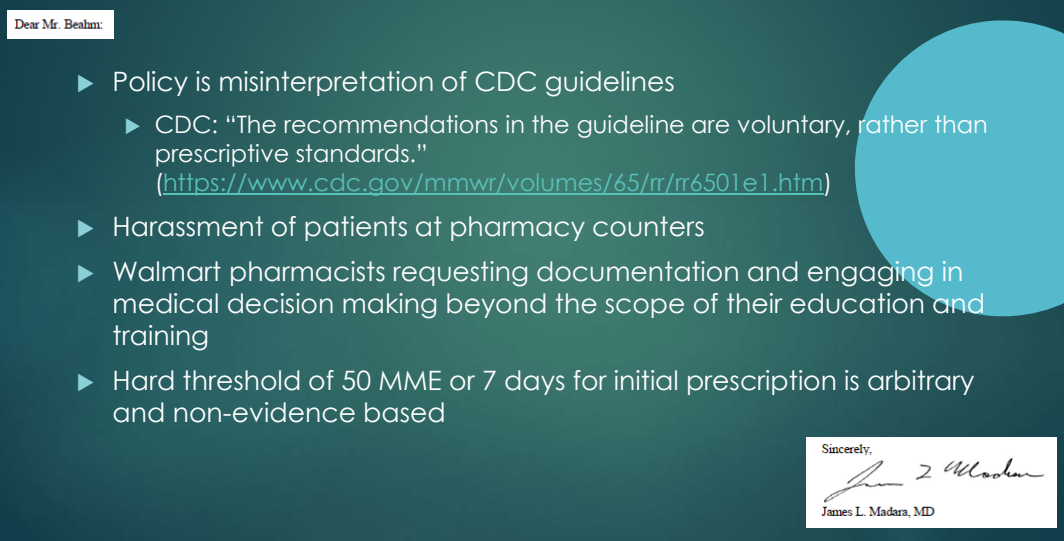
Walmart Initiative

- Requires e-prescriptions for controlled substances as of Jan. 1, 2020 at all Walmarts and Sam's Clubs
- Pharmacists using NarxCare since Aug. 2018 to track opioid dispensing
  - Trained to check for "indicators of potential concern"
- Restrict initial acute opioid prescriptions to ≤ 7 day supply, ≤ 50 MME/day
  - "This policy is in alignment with the Centers for Disease Control and Prevention's (CDC) guidelines for opioid use."

39

AMA Response to Walmart Initiative


Dear Mr. Beahm:

- Policy is misinterpretation of CDC guidelines
  - CDC: "The recommendations in the guideline are voluntary, rather than prescriptive standards." (https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm)
- Harassment of patients at pharmacy counters
- Walmart pharmacists requesting documentation and engaging in medical decision making beyond the scope of their education and training
- Hard threshold of 50 MME or 7 days for initial prescription is arbitrary and non-evidence based

Sincerely,

James L. Madara, MD

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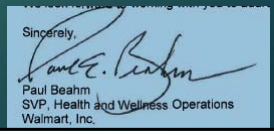
Walmart Response to AMA

Dear Dr. Madara:

- CDC recommendation, "more than seven days will rarely be needed [for acute pain]" is a Category A recommendation, which indicates that "most patients should receive the recommended course of action."
- Johns Hopkins publication April 2017 in the *Journal of Pain*
  - Inpatient orthopedic surgery
    - Mean days of opioid use was 7 +/- 7 (median 5, interquartile range 2-9)
    - Opioids stored unlocked (75%), patients did not dispose of excess (85%)
- Policy "applies to initial acute opioid prescriptions, not to those who are managing chronic pain or patients receiving palliative care."

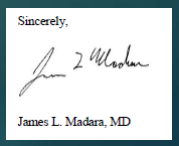


41

AMA Response to Walmart Response to AMA Response

Dear Mr. Beahm:

- Article cited was a 101-patient review and had no mention of MME
- Average of 7 days needed, many patients needing more
- Different surgical procedures noted to have different length of pain medicine requirements
- Patients have been adversely affected by arbitrary prescription limits



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Access to Non-Opioid Treatments

- Coverage policies for non-opioid treatments are restrictive
- Prior authorization (PA) more frequent for non-opioid treatments for pain than opioid treatments for Medicare advantage plans
- 93% of pain specialists report PA for non-opioid pain care [American Board of Pain Specialists], including:
  - Physical therapy limits, psychiatric services, occupational therapy.
  - Pain creams and patches (e.g. lidocaine, Lidoderm, Voltaren, topical NSAIDs).
  - Non-opioid prescription medications (e.g. Cymbalta, Lyrica, Celebrex).
  - Non-opioid pain treatments (e.g., TENS, facet blocks, spinal cord stimulators, epidural injections).
- Non-opioid treatments often not on formulary, or on high-cost specialty tier

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ASCO Opioids Toolkit

- Cancer patients are a special population
- Provider education
- Prescription limits
- Patient education
- Prescription Drug Monitoring Programs
- Patient screening and assessment before and during opioid treatment
- Abuse deterrent formulations
- Treatment for misuse, abuse or addiction
- Wider availability of naloxone
- Prescription "Take-Back" programs

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Eye of the Storm

- Patients with pain due to cancer face unique challenges in pain management
- Application of CDC Guideline to cancer pain management is inappropriate and often harmful
- Although guidelines and regulations explicitly provide exceptions for cancer pain management, patients are experiencing decreased access to necessary medications and treatments
- Education and advocacy are necessary

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"We are at a crossroads in our nation's efforts to end the opioid epidemic. It is time…for payers, PBMs and pharmacy chains to reevaluate and revise policies that restrict opioid therapy to patients based on arbitrary thresholds…Physicians must continue to demonstrate leadership, but unless and until these actions occur, the progress we are making will not stop patients from dying."

Patricia A. Harris, MD, MA, Chair AMA Opioid Task Force, AMA President

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NGS and Myeloid Malignancies To Repeat or Not?

Jamile M. Shammo, MD, FASCP, FACP

Jamile M. Shammo, MD, FASCP, FACP, is Professor of Medicine and Pathology, Section of Hematology and Stem Cell Transplantation, Division of Hematology/Oncology, at Rush University Medical Center in Chicago, Illinois, where she has been practicing since 2000. In her current position, she spearheads the MDS/MPN/Bone Marrow Failure Program. As principal investigator of clinical trials in her area of expertise, and as chair of the protocol review and monitoring committee at Rush Cancer Institute, she is heavily involved in education, research and administrative activities in the division of Hematology/Oncology.

Dr. Shammo earned her medical degree from Aleppo Medical School in Syria, after which she completed residencies in Anatomic, and Clinical Pathology, as well as Internal Medicine at McGaw Medical Center of Northwestern University, in Evanston, Illinois. She then completed a 3-year fellowship in the Division of Hematology/Oncology at University of Chicago.

Dr. Shammo is board certified in anatomic and clinical pathology as well as hematology, and is board eligible in internal medicine, and oncology. She is a fellow of both, the American Society of Clinical Pathologists and American College of Physicians. She received the Department of Medicine Service and Teaching Award from Rush University Medical Center in 2003 and was a finalist in the Department of medicine positive environment learning award in 2014. She was chosen by the MDS foundation to receive the 'Nobility in Science Award" on 6/22/2019. She founded the Chicago MDS/ MPN group in 2011 and has chaired several educational events to facilitate scientific exchange between academic medical centers in Chicago. She has developed and chaired multiple online CME activities pertaining to MDS as well as MPN. She has authored, and contributed to over 100 publications; including abstracts, posters, and book chapters. Her articles are published in Blood, American Journal of Hematology, Journal of Clinical Oncology, Clinical Lymphoma, Journal of Heart and Lung Transplantation, Cytotherapy, and American Journal of Clinical Pathology, among others. She served as a reviewer for several medical journals including Journal of Clinical Oncology. She has designed and conducted several investigator-initiated trials and is currently involved as principal investigator for many clinical trials related to chronic myelogenous leukemia, myeloproliferative neoplasms, paroxysmal nocturnal hemoglobinuria, and myelodysplastic syndromes. As an invited speaker, Dr. Shammo lectured at national and international meetings and conferences.

NGS and Myeloid Malignancies To Repeat or Not?

Jamile M. Shammo MD, FASCP, FACP
Professor of Medicine and Pathology
Rush University Cancer Center, Chicago

ASH/ASCO CARRIER ADVISORY COMMITTEE MEETING

ALEXANDRIA, VA

6/28/2019

1

Next Generation Sequencing (NGS)

- NGS is a new method for sequencing DNA which allows for the ability to process millions of genome-wide sequence reads in parallel.
- It is a rapidly evolving and complex methodology that can interrogate multiple regions of genomic tumor DNA in a single assay.
- Many hematologic neoplasms are characterized by morphologic or phenotypic similarities, but can have characteristic somatic mutations in many genes.

2

NGS

- Millions of small fragments of DNA are immobilized on a solid surface,
- Amplified (copied), and sequenced simultaneously
- During sequencing a signal (light, pH change) is detected when a base is incorporated
- Short contiguous sequences (reads) are generated
- Reads are aligned to a reference sequence to be analyzed
- Analysis is computationally intense

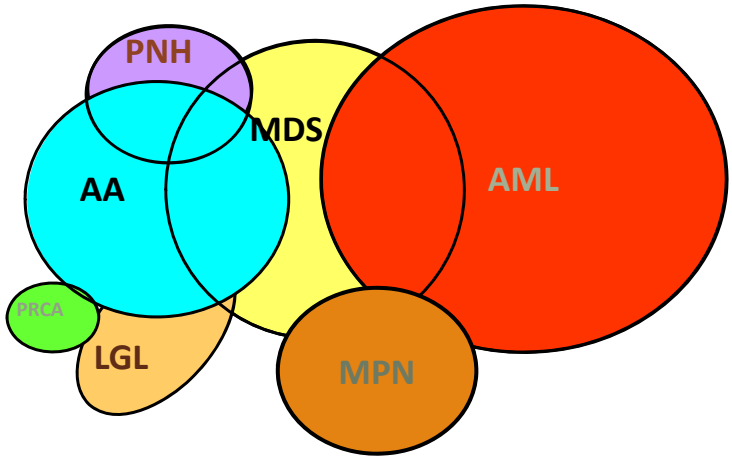
3

The Myeloid Neoplasms

- A group of heterogeneous hematopoietic stem cell disorders with variable overlapping clinical presentations.
- Diagnosis relies on evaluating bone marrow biopsies , cytogenetic data and molecular tests, (such as NGS).
- They are uniformly characterized by a tendency for progression to more advanced forms of the disease with subsequent bone marrow failure , need for transfusions and propensity for infections.
- Progression is typically associated with acquisition of new cytogenetic abnormalities.

4

Overlapping Clinical Presentation of Myeloid neoplasms :



Young NS. Ann Intern Med. 2002;136:534-46.

5

B). The 2016 WHO Diagnostic Criteria of Overt Primary Myelofibrosis (PMF):

Major criteria:

1. **Megakaryocytic proliferation** and atypia, accompanied by either reticulin and/or collagen fibrosis grades 2 or 3.
2. Not meeting WHO criteria of BCR/ABL+ CML, PV, ET, MDS or other myeloid neoplasms.
3. Presence of **JAK2**, **MPL** or **CALR** mutation or in the absence of these mutations, presence of **another clonal marker or absence of minor reactive BM reticulin fibrosis**.

Minor criteria:

Presence of at least one of the following, confirmed in two consecutive determinations:

a. **Anemia** not attributed to a comorbid condition.

b. **Leukocytosis** ≥11 x 10^9/L.

c. **Palpable splenomegaly.**

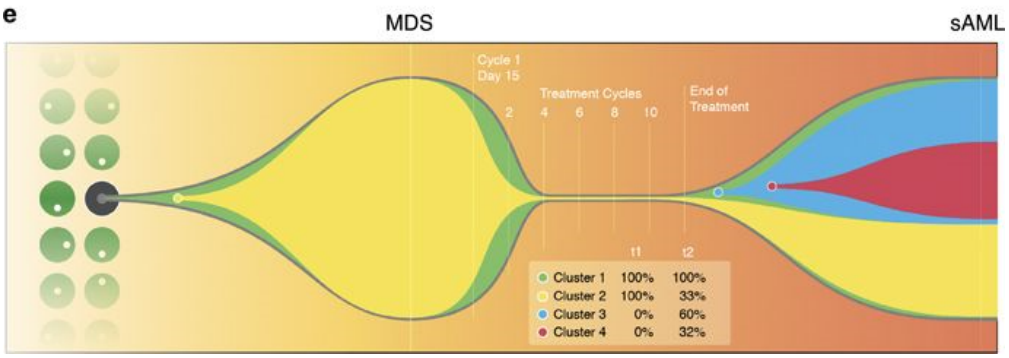
d. **LDH increased** to above upper normal limit of institutional reference range.

e. **Leucoerythroblastosis.**

Diagnosis of Overt PMF requires meeting all three major criteria and at least one minor criterion.

6

Clonal Evolution in Myeloid Neoplasms



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Clinical impact of somatic mutations

- Samples from 738 patients with MDS, MDS-MPN were analyzed

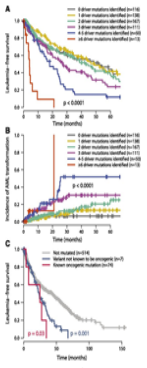
-111 cancer associated genes were sequenced by NGS

-78% of patients had 1 or more oncogenic mutations

-No systematic differences between DNA derived from bone marrow or peripheral blood

- Higher overall number of oncogenic mutations correlated with worse outcome

Relationship between number of oncogenic mutations and outcome.



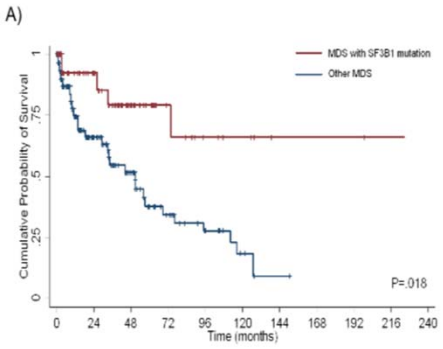
Elli Papaemmanuil et al. Blood 2013;122:3616-3627

blood

Papaemmanuil E et al. Blood 2013;122:3616-3627

8

NGS and Risk assessment



- Data derived from 308 pts with myeloid neoplasms
  - MDS: 245
  - MDS/MPN: 34
  - AML-MDS: 29
- 111 gene mutation panel was utilized
- Almost all patients with
  - RARS (refractory anemia with ring sideroblasts) had an SF3B1 mutation
- SF3B1 mutations are associated with favorable outcome

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Case Study

- A 67 year old retired physician who presented to the hematology clinic for a second opinion regarding his recent diagnosis of MDS.
- He was first noted to be pancytopenic on CBC in January of 2018, (though he has not had CBC for several years prior to 1/2018) .
- A marrow biopsy was performed at the end of January of 2018 which was consistent with a diagnosis of myelodysplastic syndrome with single lineage dysplasia. No increase in blasts or fibrosis.
- Cytogenetic testing revealed a normal male karyotype
- His disease was classified as low–risk MDS.

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Case Study

- He was initially started on ESA's without response despite dose escalation.
- He became transfusion dependent and came to see me for a second opinion.
- Hgb: 6.6 gm/dl, PLt 78 K, ANC 1400.
- We repeated his bone marrow biopsy to rule out disease progression
- His bone marrow biopsy was again C/W myelodysplastic syndrome with single lineage dysplasia.
- We ordered a next generation sequencing panel which showed several mutations involving SRSF-2, TET-2 and ASXL-1.

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Case Study

- He was started on low-dose chemotherapy with hypomethylating agent azacitidine.
- He continued to be transfusion dependent, and is now extremely fatigued.
- A repeat bone marrow biopsy was performed after 4 cycles of azacitidine.
- The patient did not agree to have a repeat NGS panel, as his first panel was not covered under his insurance policy.

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Case Study 2

- A 68 year old man with HTN, degenerative joint disease, and Atrial fibrillation, was Initially diagnosed with MDS in 4/2015.
- He was initially transfusion-independent and did not require treatment.
- On 3/15/2018 he presented to the clinic with severe headache which he rated at 7/10. CBC demonstrated worsening blood counts . MRI was negative for bleed/lesions.
- He underwent a bone marrow biopsy to further investigate his pancytopenia on 3/21/2018 which showed 43% blasts reported on aspirate differential, consistent with progression to acute leukemia.
- An NGS panel was performed initially demonstrating 6 somatic mutations including ASXL-1, IDH-1, JAK-2, PHF6, RUNX1 and U2AF1.
- -IDH1 VAF* (11%)

*VAF: Variant allele frequency

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Case Study 2

- He was initially treated with 3 cycles of dacogen but progressed through that regimen and ended up receiving induction chemotherapy.
- His disease went into remission after induction, but he declined consolidation chemotherapy.
- Repeat NGS testing after induction chemotherapy harbored 4/6 initial mutations , and negative for the IDH-1, and PHF6 mutations.
- He was treated with Azacitidine and venetoclax but later progressed.
- He had to be hospitalized on multiple occasions while on aza/venetoclax for febrile neutropenia.
- A repeat panel at his third relapse re-demonstrated all 6 mutations , all at a higher VAF including IDH-1 (13.8%)
- He was started on an IDH-1 inhibitor (Ivosidinib) and had a remarkable response.
- He has not been hospitalized since initiation of therapy.

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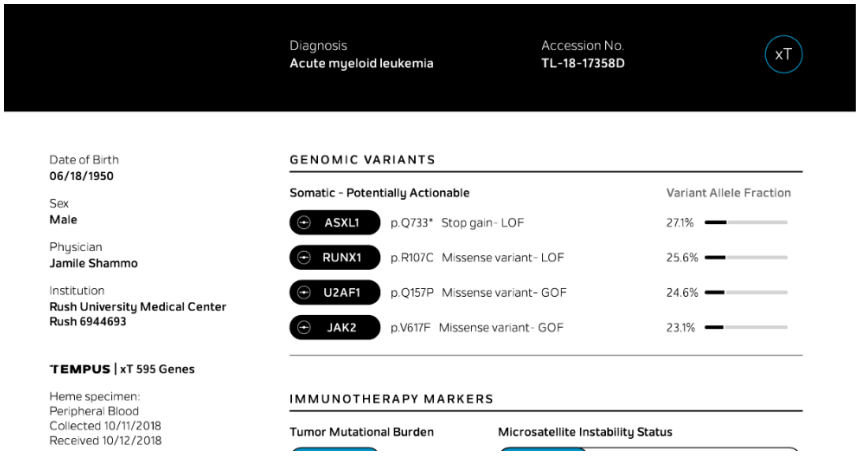
Post - chemotherapy



Diagnosis
Acute myeloid leukemia

Accession No.
TL-18-17358D

xT

Date of Birth
06/18/1950

Sex
Male

Physician
Jamile Shammo

Institution
Rush University Medical Center
Rush 6944693

TEMPUS | xT 595 Genes

Heme specimen:
Peripheral Blood
Collected 10/11/2018
Received 10/12/2018

GENOMIC VARIANTS

Somatic - Potentially Actionable		Variant Allele Fraction
ASXL1	p.Q733* Stop gain - LOF	27.1%
RUNX1	p.R107C Missense variant - LOF	25.6%
U2AF1	p.Q157P Missense variant - GOF	24.6%
JAK2	p.V617F Missense variant - GOF	23.1%

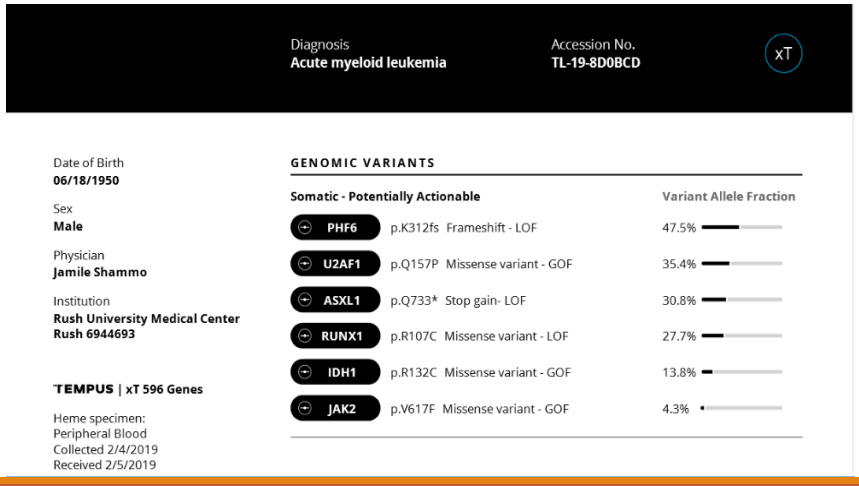
IMMUNOTHERAPY MARKERS

Tumor Mutational Burden

Microsatellite Instability Status

15

Pre-Ivosidenib



Diagnosis
Acute myeloid leukemia

Accession No.
TL-19-8D0BCD

xT

Date of Birth
06/18/1950

Sex
Male

Physician
Jamile Shammo

Institution
Rush University Medical Center
Rush 6944693

TEMPUS | xT 596 Genes

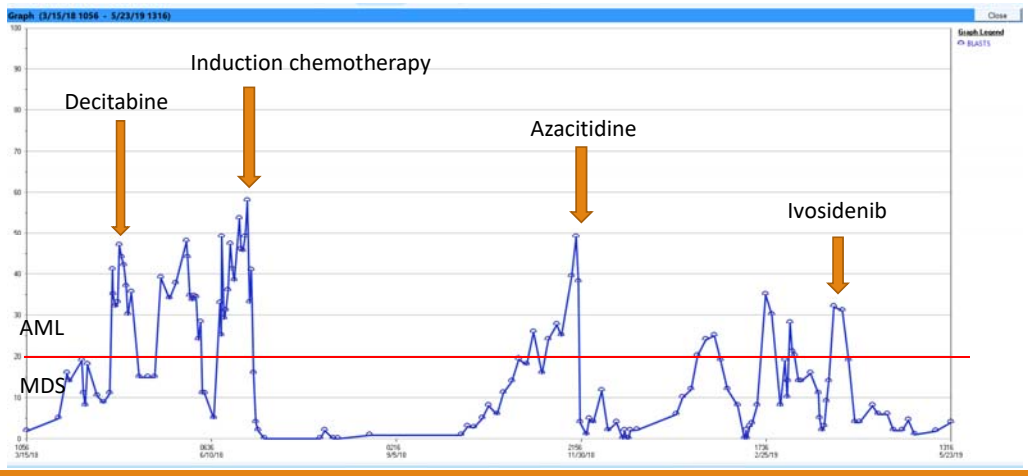
Heme specimen:
Peripheral Blood
Collected 2/4/2019
Received 2/5/2019

GENOMIC VARIANTS

Somatic - Potentially Actionable		Variant Allele Fraction
PHF6	p.K312fs Frameshift - LOF	47.5%
U2AF1	p.Q157P Missense variant - GOF	35.4%
ASXL1	p.Q733* Stop gain - LOF	30.8%
RUNX1	p.R107C Missense variant - LOF	27.7%
IDH1	p.R132C Missense variant - GOF	13.8%
JAK2	p.V617F Missense variant - GOF	4.3%

16

Case 2: Blast Count



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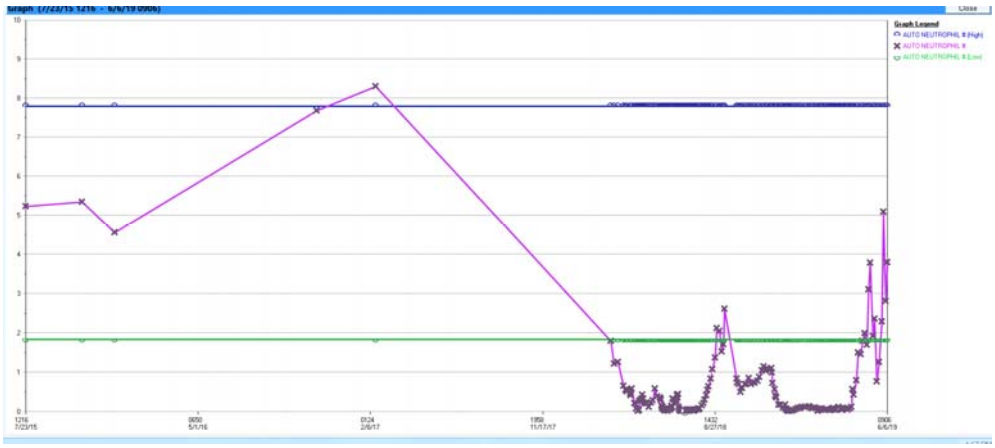
Case 2: Hematological improvement - Neutrophils



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NGS and Myeloid Neoplasms

- An important tool for diagnostic and prognostic purposes.
- Cost of panel is less than that incurred upon testing for multiple single genes.
- Helps to detect actionable mutations and allows for the use of targeted therapies.
- Repeat testing at the time of disease relapse is essential to determine trial eligibility and to identify a therapeutic target.

19

NGS: Conclusions

- NGS is revolutionizing our approach to diagnosis, risk assessment and treatment of myeloid neoplasms .
- It allows for personalization of therapy
- It facilitates use of targeted therapeutic strategies
- Cost of test is declining

- Ongoing Challenges:
  - It may not be reimbursed by insurance companies.
  - Not all reported mutations are actionable
  - Uncertainty re. mutations of unknown significance

20

Update on the Next Generation Sequencing National Coverage Determination

Erika Miller, JD

Erika A. Miller joined CRD Associates, LLC in 2005. Her practice includes physician specialty organizations; groups interested in Medicare reimbursement and policy; institutions of higher education and related associations; biomedical research related interests; and health and education appropriations.

Erika has expertise in the intricacies of physician reimbursement and the work of the American Medical Association (AMA)/Specialty Society Relative Value Scale Update Committee and provides guidance to clients as they navigate the evolving area of alternative payment models and health care quality initiatives, like the physician quality reporting system, accountable care organizations and the Medicare and Medicaid Incentive Programs. She advocates before the legislative and executive branches to innovate within the health workforce programs, like Title VII, and the Medicare graduate medical education program to ensure that there is a physician workforce available to meet the health needs of Americans.

Erika is a co-author of a chapter entitled, "Lobbying the Appropriations Process" in the American Bar Association Lobbying Manual. A New Jersey native, Erika worked in the office of Congressman Steve Rothman of New Jersey, a member of the House Appropriations Committee, where she handled immigration issues. Erika also worked in the U.S. Department of Health and Human Services Office on Women's Health, where she monitored grant awards. Prior to joining CRD Associates, Erika worked at the lobbying firm of Broydrick & Associates representing health care interests. Erika received her law degree from The American University, where she was an editor of the Administrative Law Review. She earned an undergraduate degree in Political Science from Colgate University.

American Society *of* Hematology
Helping hematologists conquer blood diseases worldwide

Update on the Next Generation Sequencing National Coverage Determination

June 28, 2019

1

CMS National Coverage Determination for NGS

CMS finalized the National Coverage Determination for *Next Generation Sequencing for Medicare Beneficiaries with Advanced Cancer* in March of 2018.

- Reconsideration process underway based on stakeholder concerns.

Background: CMS initiated the NCA for NGS to determine whether a diagnostic lab test using NGS will be covered. This was part of the parallel review process for FoundationOne CDx (companion diagnostic for all solid tumors).

2

Timeline for Original NCD and Reconsideration

Original Timeline for NGS NCD

- **Foundation Medicine Requests NCA:** 11/17/2017
- **Proposed Decision Memo:** 11/30/2017
  - **Public Comment Period:** 11/30/2017-1/17/2018 (extension granted)
- **Final Decision Memo:** 3/16/2018
- **Implementation Instructions to MACs:** 11/2018

Timeline for Reconsideration

- **CMS Initiates Formal Review**: 04/29/2019
- **Public Comment Period**: 04/29/2019 - 05/29/2019
- **Proposed Decision Memo Due Date**: 10/29/2019
- **Expected NCA Completion Date**: 01/27/2020

3

Comparison of Proposed and Final NCD

- **Scope of Proposed Decision**:
  - Coverage:
    - Nationally Covered Indications
    - Coverage with Evidence Development (CED)
  - Non-covered Indications
- **ASH's Key Concerns:**
  - Concern that the proposal would drastically limit patient access to NGS-based testing through CED and by eliminating coverage provided under LCDs
- **Final Coverage Decision:**
  - Expanded coverage portion for when NGS-based tests are covered under NCD.
  - Removed CED requirements and non-coverage portion of proposal.
  - Allows MACs to continue to provide coverage for NGS-based tests that are not covered by NCD.

4

Issues with Implementation

- November 2018: CMS transmittal to MACs eliminating coverage for non-advanced cancers
- ASH one of 63 organizations to sign letter to CMS expressing concerns about the implementation instructions
  - Effort led directly to reconsideration process

- **ASH Comments on Scope of Review:**
  - Limitation on NGS-based testing for repeat testing and only providing coverage for advanced cancer

5

CMS Resources

- Medicare's Program Integrity Manual, Chapter 13 (*Revised 2/12/19: 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 Centers
- Patients over Paperwork: 9th Issue - Modernization Update: Local Coverage Determination (LCD)

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.

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*.

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AMERICAN SOCIETY OF CLINICAL ONCOLOGY

Five Things Physicians and Patients Should Question

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

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

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

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

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

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

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

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

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

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

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

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

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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/)

- 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.
- Drug Resources - This page provides 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.
- MACRA – The ASH MACRA 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 other resources.
- Pediatric to Adult Hematologic Care Transitions - This webpage offers links to assessment and summary forms designed to facilitate discussion about 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. ASH is also excited to announce the release of the ASH Clinical Practice Guidelines on Venous Thromboembolism (VTE). The VTE Guidelines, along with other tools and resources, including pocket guides, apps, teaching slides, webinars, and podcasts, can be found at hematology.org/VTE.
- Well-Being and Resilience - Well-being is a critical factor in the strength of the workforce, and the Society is committed to helping hematologists address the myriad factors impacting well-being through interventions such as openly addressing burnout in live meetings and in publications, advocating on behalf of hematologists to streamline administrative work, and sharing approaches to building resilience among hematologists.

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.

- In August 2017, ASH launched a new online advocacy toolkit to provide members with the information and guidance necessary to communicate with elected officials in support of hematology. The new toolkit clearly and concisely explains how members can undertake a number of actions to support ASH's advocacy efforts.
- ASH recently launched a survey of all U.S. members to learn about what advocacy topics matter most to the Society's membership and the ways in which members would like to engage with their elected officials. If

you have not yet taken the survey but would like the opportunity to help shape the future of ASH's advocacy and policy efforts in Washington, please click here.

- Action Alerts
    - Tell Congress to Raise the Budget Caps in Support of NIH Funding for FY 2020 - The Society needs the help of all its members to urge lawmakers to reach a bipartisan agreement to raise the budget caps! This will allow Congress to support the robust, sustained, and predictable funding increases for NIH that are currently proposed in the House Labor-HHS spending bill. You can help spread this message by quickly sending an email to your legislators.
    - Urge Your Senators and Representative to Support the Cancer Drug Coverage Parity Act - Legislation has been reintroduced in the U.S. House of Representatives and U.S. Senate that would ensure that patients enrolled in certain federally regulated health plans have access and insurance coverage for all anti-cancer regimens. The Cancer Drug Coverage Parity Act would require any health plan that provides coverage for cancer chemotherapy treatment to provide coverage for orally administered and self-injectable anticancer medications at a cost no less favorable than the cost of IV, port administered, or injected anticancer medications.
- Get involved with ASH's Advocacy Activities!
    - ASH Advocacy Leadership Institute - The ASH Advocacy Leadership Institute was created in 2011 to provide additional opportunities for ASH members to learn more about advocacy, health policy, the legislative process and to become engaged in the Society's activities. This two-day workshop is an opportunity for ASH members to gain a better understanding of the Society and to learn about legislation and health policy affecting hematology research and practice.
    - ASH Congressional Fellowship Program - The ASH Congressional Fellowship offers a unique opportunity for a hematologist to work in a Congressional office on Capitol Hill for an academic year, starting in September, in order to help shape health care and hematology policy. The fellowship aims to provide education about the policymaking process, including Congress' relationship to the hematology community, as well as an opportunity to educate Congressional members and staff about hematology.

Sickle Cell Disease

ASH is undertaking a multifaceted initiative to address the global burden of sickle cell disease (SCD). In September 2016, the Society issued *the State of Sickle Cell Disease: 2016 Report*, which can be found on the ASH SCD Initiative page along with other ASH SCD priorities. This report outlines the most pressing areas of need and provides a blueprint to advance these actions. To address issues related to access to care, ASH is (1) implementing a strategy to educate hematologists and other health care providers in all settings to recognize and properly respond to SCD complications; and (2) pursuing payment reforms to encourage appropriate care for individuals with SCD. 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 for Clinicians

- 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 6-7, 2019, Chicago, IL. This event will allow an opportunity 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 7-10, 2019, Orlando, FL. 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 5, 2019 in conjunction with the ASH Meeting on Hematologic Malignancies, or Monday, December 9, 2019 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 –Attend Highlights of ASH to get a synopsis of the top hematology research presented at the latest ASH annual meeting and learn how it can help improve your patient management and care strategies. These meetings are a chance to discuss rapidly evolving developments in hematology and hematology-oncology with leading faculty in the field, discover new treatments for patients, and improve overall practice methods.

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

FOCUSING ON PRACTICE HEALTH

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 practice health and 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—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 help you collaborate with practices across the United States, innovate your practice's delivery of cancer care, and respond to the growing economic and administrative challenges that all oncology practices face today.

To support ASCO's global initiatives, ASCO also offers a selection of programs to support quality improvement in oncology practices on a global scale.

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.

ASCO PracticeNET

Compare performance to other practices of similar size and setting. **Improve operations** through sharing and receiving insights with your peers.

ASCO PracticeNET™
Networking for Education and Transformation

PracticeNET is ASCO's premier learning network focused on improving your practice's business operations. PracticeNET analyzes practice data to tell to you how your practice performance is trending, the effectiveness of your business practices, and how your practice compares to others. PracticeNET participation helps practices bolster practice operations and productivity; better allocate resources; identify billing and coding opportunities; and discuss best practices in oncology practice management. For more information, contact **PracticeNET@asco.org**.

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 **practice.asco.org/billing-coding-reporting**.

MACRA & the Quality Payment Program

The Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) established the Quality Payment Program (QPP), which is transforming the way physicians are reimbursed for services provided under Medicare Part B. As your partner in preparing for these changes, ASCO has assembled a library of tools and information to help you implement the Quality Payment Program in your practice. Visit **asco.org/macra**.

Physician Payment Reform

ASCO® Patient-Centered Oncology Payment

ASCO has developed the Patient-Centered Oncology Payment (PCOP) model, an alternative payment model designed for oncology. 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 complex illnesses. PCOP also includes a much more streamlined quality reporting requirement than the Oncology Care Model. ASCO is proposing to Centers for Medicare & Medicaid Services (CMS) that PCOP be approved as an Advanced Alternative Payment Model and has developed tools to help practices achieve success under PCOP or any other alternative payment model.

Practice Engagement Program

ASCO Practice Engagement Program

ASCO's Practice Engagement Program provides a single point of contact for practices to help them identify and connect with the ASCO tools, programs, and resources that can best support their needs. After understanding the needs of each specific practice, the Practice Engagement Team can identify the ASCO resources to help resolve outstanding challenges, prepare for pending changes, and succeed in an ever-changing practice environment. Contact **clinicalaffairs@asco.org** for more information or assistance.

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 make 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.
- **CPC's Oncology Administrator Professionals Task Force:** The task force, supported by ASCO Clinical Affairs and guided by the CPC, is tasked with identifying issues facing oncology practices and providing a forum for discussion and evaluation of solutions. This group has addressed a wide range of practice issues, including insurance pre-authorization, outreach to administrators, practice needs assessment, and more.
- **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.

Survey of Oncology Practice Operations

ASCO Survey of Oncology Practice Operations

ASCO conducts an annual Survey of Oncology Practice Operations (SOPO) to capture the current state of business and operational issues in oncology to help practices navigate the evolving cancer delivery system. Participation in this survey allows practices to compare their operations to national benchmarks. For more information contact **clinicalaffairs@asco.org**.

ASCO® Practice Consulting Services & Support

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

Operational Services Include:

- **Readiness assessment**, preparing practices for value-based care, new payment models and success in the Quality Payment Program
- **Practice operational assessment**, focused on the highest standards of care with review of patient flow, practice services, personnel, and physical space—resulting in actionable recommendations for practice success
- **Analytical services**, providing support with practical data analytics - clinical, financial and operational
- **Triage pathways**, a decision support tool to help your patients get the right care at the right time in the right place. ASCO Consulting Services can help you prepare for effective implementation of triage pathways
- **Customized consulting**, practice transformation support and personalized consulting services designed to meet your practice's specific needs

Clinical Services Include:

- **Clinical Care Delivery Assessment:** Provides a practice review that uses a standardized tool to evaluate quality patient care, safety, and readiness for value-based care, including patient-centered services such as patient navigation, access to care, team-based care and continual improvement
- **Nurse Training Support:** Supports implementation of ASCO/Oncology Nursing Society (ONS) Chemotherapy Administration Safety Standards
- **Advanced Practice Provider Program Development:** Optimizes workforce, focusing on role of advanced practice providers
- **Value-based Care Delivery Model:** Provides support for Centers for Medicare & Medicaid Services (CMS) Quality Payment Programs, including the Merit-based Incentive Payment System (MIPS), Oncology Care Model (OCM), and other alternative payment models and payer quality initiatives

ASCO Practice Central

ASCO® Practice Central

ASCO Practice Central is the first ASCO website dedicated to the business of oncology. The new website provides one centralized, convenient place for oncology professionals to easily find resources on business services, quality improvement, hiring and recruitment, staff burnout, reimbursement, and other topics to help their practice succeed. Visit **practice.asco.org**.

QUALITY AND PERFORMANCE IMPROVEMENT

Assuring high-quality care for every cancer patient is a key component of ASCO's mission. In keeping with this goal, ASCO offers oncology providers the resources to help deliver high-quality cancer care to every patient.

Cancer programs and 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.

ASCO Quality programs are expanding internationally. QOPI® is available to ASCO member practices in a number of countries outside the United States. Several international practices have achieved QOPI® Certification and have also participated in the Quality Training Program. For more information on how to participate in ASCO Quality programs from outside of the United States contact **globalquality@asco.org**.

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 Program

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 outpatient oncology practices of all sizes and types 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, a Qualified Clinical Data Registry (QCDR), brought to you by ASCO and the American Society for Radiation Oncology (ASTRO) is the one-stop shop for MIPS reporting. Practices can use either the System Integrated Approach to report electronically via their EHR or the Web Interface Tool to enter data manually to satisfy MIPS reporting requirements in the Quality, Improvement Activities, and Promoting Interoperability categories. Please contact **qopi@asco.org** for more information or assistance.

Quality Training Program

The ASCO Quality Training Program empowers practice teams to improve clinical care and operational performance and teaches teams how to balance quality improvement projects with demanding schedules and competing priorities. The training employs proven experiential learning techniques with a quality issue selected by the oncology team. It will enhance practical team skill-building, help teams prepare for a changing reimbursement environment, and includes support when the team returns to the primary institution. The course is five days over six months and offers CME, CNE, MOC Part II, and MOC Part IV credits/points.

1-Day Quality Improvement Workshop

ASCO's 1-day Introduction to Quality Improvement Workshop focuses on defining a problem, mapping the process for improvement, identifying the cause, implementing the solution and sustaining the gain. Members of the Quality Training Program faculty will present basics on-site at practices who want to educate more staff in clinics.

The Quality Training Program also has opportunities to host a regional course and to license course content.

For more information on the Quality Training program contact **qualitytraining@asco.org**.

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 is Division Director for Analysis and Consulting Services where her team develops programs and services focused on clinical, financial and operational excellence for community oncology practices. Before joining ASCO, she worked as Director of Consulting Services for Oncology Metrics and managed a medical oncology practice in the northeast.

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 nearly 45,000 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 ASCO Practice Central at **practice.asco.org** or email **clinicalaffairs@asco.org**.

For information about all ASCO programs and resources visit **asco.org**.

ASCO®
AMERICAN SOCIETY OF CLINICAL ONCOLOGY
MAKING A WORLD OF DIFFERENCE IN CANCER CARE

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	5	4	3	2	1
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	5	4	3	2	1
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	5	4	3	2	1
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	5	4	3	2	1
21st Century Cures Act – Impact on the CAC Process by Robert Horne					
21st Century Cures Act – Impact on the CAC Process by Janet Brock					
Panel Discussion with Drs. Clark, Oakes, Allen and Cox					
Opioid Policy Session by Dr. Kristina Novick					
Next Generation Sequencing by Dr. Jamile Shammo					
NGS National Coverage Determination by Erika Miller					

Additional Questions:

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

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

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

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

5. **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.**

6. **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

AMERICAN SOCIETY OF HEMATOLOGY and
AMERICAN SOCIETY OF CLINICAL ONCOLOGY
2019 CAC Network Meeting
Travel Reimbursement Policy

The ASH-ASCO CAC Network Meeting Travel Reimbursement Policy is provided to travelers to provide guidance on the 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, ASH Committee on Practice and ASH Subcommittee on Reimbursement;
- 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), purchased through the ASCO travel agency Direct Travel. Airline or train reservations should be made using ASCO's travel agency, Direct Travel. Tickets are to be booked at least 30 days in advance of the meeting dates for attendees (no later than May 27). Please contact Michelle Rowley at Direct Travel via email at

mrowley@dt.com or by phone at (877) 410-8198 or (202) 360-4674. You will need the following information when contacting ASCO travel agent; which meeting you are attending and/or the 9-digit cost code your travel will be billed to. Please use cost code "**ASCO ASH CAC Mtg 208220000**". Please refer to the volunteer instruction guide for more information.

ASH and ASCO will reimburse the most economical non-refundable coach fares available on a major airline carrier (American, Delta, Southwest, United, 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.

Train travel must be booked through the ASCO travel agency. ASH and ASCO will pay for business class seats on Amtrak regional trains. Where Amtrak's Acela Express trains are available, ASH and ASCO will pay for business class seats since this is the most economical option on Acela Express. It is required that tickets be purchased through the ASCO travel agent.

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. Examples of acceptable options include taxis, airport shuttle services, and ride-sharing services (i.e. Uber and Lyft) provided that the most economical option of these services (i.e. UberX or UberXL or equivalent) is utilized. Please note that ASH and ASCO will not cover the cost of luxury transportation, including limousine or black car services, UberSelect or UberBlack, Lyft Lux, Lux Black, or Lux Black XL, or their equivalents. Travelers should be aware of any surge pricing that is in effect with these services and select more economical options during these peak demand periods.

Use of a personal or university vehicle will be reimbursed at the mileage rate consistent with IRS rules and regulations (**$0.58 cents per mile as of 1/1/19, 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.). For mileage reimbursement, please include proof of mileage by submitting a map of the route (i.e., Google Maps).

If ASH and ASCO approve the use of a rental car, limits will be set and communicated to the traveler by the appropriate ASH or 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 May 20.**

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 provide breakfast and lunch for Friday, June 28. 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.

American Society of Hematology
www.hematology.org

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2019 ASH/ASCO CAC Network Meeting
Expense Reimbursement Form

Please fill out the information below and attach original receipts.
All forms must be submitted by July 28, 2019

Make check payable to: _____

Mail check to: _____

Meeting Attended: 2019 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 JULY 28, 2019 TO:

Monica Tan
2318 Mill Road, Suite 800
Alexandria, VA 22314
Monica.Tan@asco.org