# ANCO FAX News

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The ANCO FAX News focuses on ANCO's core activities—advocacy, clinical and professional education, and Association and membership news. While membership mailings and e-mail/FAX broadcasts continue, the ANCO FAX News summarizes this information in a regular forum of important news to members. Contact the ANCO office for additional information regarding any item published in the ANCO FAX News. Find the ANCO FAX News online at www.anco-online.org/pubs.html.

#### In this issue:

• CMS Part B Drug Reimbursement Experiment

- ASCO Responds to USP 800
- ANCO/MOASC Sponsor AB2209
- ANCO Positions on Other Legislation

The ANCO FAX News is FAXed to Individual Member practices, and e-mailed to Group, Institutional, and Corporate (contacts) Members. The next regular ANCO FAX News will be published on April 15<sup>th</sup>. Send your comments or contributions to ANCO, P.O. Box 151109, San Rafael, CA 94915-1109; Voice: (415) 472-3960; FAX: (415) 472-3961; execdir@anco-online.org.

The ANCO FAX News has information for every member of your practice or organization. Pass it along!

Physician Members

□ Nurses & Office Managers

Office Staff

**Colleagues & Representatives** 

The Association of Northern California Oncologists (ANCO) is an association of hematologists/oncologists dedicated to promoting high professional standards of cancer care by providing a forum for the exchange of ideas, data, and knowledge. The material contained in the ANCO FAX News is intended as general information for ANCO members. Because diagnostic, treatment, contracting, coding, and billing decisions should be made on a case-by-case basis, any such information contained in thve ANCO FAX News may not apply in any given situation. Members are encouraged to contact their own consultants or advisors to obtain specific advice on matters relating to contracting, coding, and billing. The information contained in the ANCO FAX News should not be used as a substitute for such advice.

# ADVOCACY

[Editor's Note: ANCO is a member of the Association of Community Cancer Centers (ACCC) and a state/regional affiliate of the American Society of Clinical Oncology (ASCO). ANCO and the Medical Oncology Association of Southern California (MOASC) are members of the California Medical Association's (CMA) Council on Legislation, House of Delegates, and specialty delegation. ANCO meets regularly with these and other organizations to discuss issues of importance to hematology/oncology practices and people living with cancer. We continually seek input from members on agenda items for these meetings. Send your issues to the ANCO office.]

## ACCC, ASCO, ASH, COA, and National Legislative & Regulatory Issues

CMS has proposed a Part B drug reimbursement experiment. Under the CMS proposed experiment, half of all oncology practices will be placed in a control group and continue to receive ASP + 6% (less the *Federal* sequester) as drug reimbursement for physician-administered drugs. The other half of oncology practices will be placed in an experimental group and receive ASP + 2.5% + 16.80/drug/patient/day (less the Federal sequester) as reimbursement for physician-administered drugs. The experiment is proposed to commence as early as the Fall 2016. Additional changes to drug reimbursement are proposed for as early as 2017. Read the CMS Fact Sheet at www.accc-cancer.org/ advocacy/pdf/2016-CMS-03-08-2016-FINAL-Medicare-Part-B-Demo-Technical-Fact-Sheet.pdf. Over 300 state and national oncology and other medical associations have already communicated their concern to CMS and Congressional leaders. Read the joint letters to Congress, CMS, and DHHS at www.asco.org/advocacy/asco-more-300advocacy-groups-request-withdrawal-medicarepart-b-drug-proposal. It is now time for all oncology practices to communicate their concerns to their Congressional Representatives. To do so:

• Use ASCO's ACT Network at http://cqrcengage.com/asco/ to find your elected *Representatives* and Take Action Now to Stop the CMS Proposed Part B Drug Demonstration Project! ASCO has been modeling CMS's proposed experiment to determine its impact on practices and they have prepared a template which you can use to get an idea of how the experiment will affect you. Download their Excel template at http://www.anco-online.org/ ASCOTemplate.xlsx, enter the requested data, and share the results with ASCO via e-mail at state affiliates@asco.org.

• Read **ASH's analysis** of the proposed experiment's implications for hematologists at www.hematology.org/ Advocacy/Policy-News/2016/5197.aspx.

• Use ACCC's advocacy portal at http://cqrcengage.com/accc/app/onestepwrite-a-letter?o&engagementId=181354 to communicate with your elected *Representatives.* Read ACCC's perspective about the proposed experiment at http://accc-cancer.org/mediaroom/ press\_releases/2016/ACCC-Voices-Strong-Opposition-to-CMS-Part-B-Drug-Payment-Model-3.9.16.asp.

# • Visit the *Community Oncology Alliance* (COA) at

http://www.communityoncology.org > Breaking News to read about the CMS experiment. **Watch and listen to a recent COA webcast** at

http://can.communityoncology.org/ site/forms.htm (CAN Meeting Recording 3/17/2016). Download, complete, and **submit COA's modeling tool** at http://can.communityoncology.org/site/ forms.htm (COA CMS Proposal April 16 - Version 2) to estimate the impact of CMS's experiment on your practice and share the data with COA for advocacy with *Congress*. **Go to www.cancerexperiement.com to contact** *Congress* and to download resources for providers and patients (including an Advocacy Toolkit).

Grassroots action with respect to CMS's proposed experiment will be key to stopping CMS from implementing their plans in 2016!

ASCO has launched a readiness assessment survey intended to help practices identify areas where additional preparation may be needed for the transition to MACRA. This short survey should be completed by April 15<sup>th</sup> by someone familiar with practice operations, generally the oncology administrator or the physician leader. The aggregate results of this survey will help direct ASCO's advocacy and education efforts on these issues, and will guide ASCO in developing resources and tools for members preparing for practice changes under MACRA. Take the survey at

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www.asco.org/advocacy/take-macrareadiness-assessment-survey-help-guideresource-development.

MACRA encourages the development of alternatives to the current Medicare fee-forservice payment system as a means to achieve higher quality and more affordable care. ASCO believes that its *Patient-Centered Oncology Payment* (PCOP) model meets MACRA's definition of an alternative payment model (APM) and will actively advance PCOP as a certified APM. ASCO is offering practices a unique opportunity to test PCOP and will provide tools and assistance in modeling data to help practices be successful. To learn more about this opportunity, please read *Transforming Oncology Payment* at www.asco.org/sites/ www.asco.org/files/2016-pcop-brochure.pdf.

The United States Pharmacopeia Convention (USP) released a final version of General Chapter <800> Hazardous Drugs–Handling in Healthcare Settings with an official implementation date of July 1<sup>st</sup>, 2018 to provide practices with time to implement the changes in the Chapter. Few substantive edits were made to the final version of the Chapter and many of the requirements presented in the draft Chapter remain unchanged. ASCO disagrees with many of the specific requirements, including:

• Closed system transfer devices (CSTDs) are required for administration of antineoplastic hazardous drugs when dosage form allows.

• Antineoplastic hazardous drugs must be stored in an externally vented room that is under negative pressure. They must be stored separately from other inventory, including in a dedicated, separate refrigerator.

• Sterile preparation of hazardous drugs must occur in a containment primary engineering control (C-PEC), like a biological safety cabinet (BSC) that is externally vented.

• Protections for pregnant workers are minimal. Workers of reproductive capability must confirm in writing that they understand the risks of handling hazardous drugs.

• Housekeeping and maintenance staff are not acknowledged as workers that may be at potential risk for exposure to hazardous drugs. ASCO has numerous concerns with the final USP *General Chapter <800>*, including the fact that no practicing oncologists were involved with its development. Many of the requirements are overly burdensome without adequate scientific evidence to support their necessity. The complete body of evidence used to develop the standards was not shared with stakeholders and the evidence behind each recommendation was not provided when requested. Additionally, the scope of the *Chapter* is outside the traditional and appropriate jurisdiction of USP and overlaps with existing recommendations by the Occupational Safety and Health Administration (OSHA) and the National Institute for Occupational Safety and *Health* (NIOSH). Finally, the *Chapter* refers to the process of mixing and diluting drugs as compounding. According to the Food and Drug *Administration* (FDA), these activities do not fall under the definition of compounding. It is unclear at this point whether and to what extent state and local governments or private accreditation organizations will adopt USP General Chapter <800> in whole or in part, or whether these entities will draw from other standards in the future. Although the USP has set a specific implementation date, state or private entities could establish implementation dates that start before or after the USP's recommendation. Adoption could arise by action through the state legislature or by a state agency. ASCO has developed an FAQ on USP General Chapter <800> and the safe handling of hazardous drugs for its members at asco1.sharefile.com/share?cmd=d&id=

seb75f4b2fe142908#/view/seb75f4b2fe142908? \_k=bxuj3n and will continue to work to develop evidence-based recommendations, collaborate with other stakeholders, educate policymakers, and develop educational materials for ASCO members on these issues.

CMS has released a *Next Steps Toolkit* to help providers track and improve ICD-10 progress. The *Toolkit* includes information and resources on how to assess ICD-10 progress using key performance indicators to identify potential productivity or cash flow issues, address opportunities for improvement, and maintain progress and keep up-to-date on ICD-10. The *Toolkit* is available online at www.cms.gov/ Medicare/Coding/ICD10/Downloads/ ICD10NextStepsToolkit20160226.pdf.

# CMA, MOASC, and State Legislative & Regulatory Issues

The *California Oncology Political Action Committee* (or CalCancerPAC), formed by ANCO and MOASC, supports candidates sensitive to the needs of hematologists/oncologists and people living with cancer in California. ANCO membership dues include a contribution to CalCancerPAC.

#### The ANCO *Board of Directors* has voted to sponsor AB2209 that would prohibit health insurance plans from developing and implementing clinical care pathways. Additional legislative positions taken by ANCO are:

• AB1668, would permit a manufacturer of an investigational drug, biological product, or device to make the product available to eligible patients with an immediately lifethreatening disease or condition— OPPOSE

• AB1763, would require a health plan contract to provide coverage for colorectal cancer screening examinations and laboratory tests—SUPPORT

• AB1795, would provide breast and cervical cancer screening and treatment to Medi-Cal patients for the duration of the period of treatment as long as the patient meets all other Medi-Cal eligibility requirements—SUPPORT

• AB1823, would increase access to cancer clinical trials and establish the *California Cancer Clinical Trials Program* at the *University of California*—SUPPORT

• AB2325, would make changes to the physician reporting requirements for the *California Cancer Registry*—SUPPORT IF AMENDED

• AB2588, would link the *California Cancer Registry*, a database of oncologists, and public and private payer claims data in order to report on the quality of cancer care in California—WATCH

• SB923, would prohibit health plans from changing any cost sharing requirements during the plan year or policy year— SUPPORT

The *California Medical Association* (CMA) has released guidance for prescribing lethal

doses of medication under California's new physician-assisted death law (ABX2-15). CMA's The California End of Life Option Act is available at www.cmanet.org/resourcelibrary/detail/?item=the-california-end-of-lifeoption-act. The *End of Life Option Act* becomes law on June 9<sup>th</sup>. The CMA guidance details the legal and medical steps physicians must take before prescribing life-ending medications and physicians' legal rights to participate or opt out based on their moral or religious beliefs. The guidelines are written in a Q&A format and provide detailed information about the new law. However, they do not currently recommend the drug physicians should use to facilitate aid-indying and they state that physicians can choose not to assist patients to end their own lives.

Under California law, all individuals practicing in California who possess both a state regulatory *Board* license authorized to prescribe, dispense, furnish, or order controlled substances and a Drug Enforcement Administration Controlled Substance Registration Certificate (DEA Certificate) must register for the Controlled Substance Utilization Review and Evaluation System (CURES) by July 1st. The California Medical Association (CMA) recently co-hosted a webinar with the *Department of Justice* (DOJ) to help physicians navigate the CURES 2.0 registration process. The webinar is now available on demand at www.cmanet.org/resource-library/ detail/?item=cures-20-navigating-the-statesnew0&r\_search=&r\_page=&return\_to=list.

The California Medical Association (CMA) has published a guide and will host a webinar to help physicians prepare for payor contract negotiations. The guide, entitled Contract Renegotiations: Making Your Business Case, is designed to help physicians review an existing contract to determine timing of the renegotiation, how to identify negotiating leverage and the uniqueness of your practice, how to pinpoint your "bread and butter" codes, how to draft an attention-getting written request for renegotiation, and how to understand what a fee change would mean to your practice. Download the guide at www.cmanet.org/ resource-library/detail/?item=contractrenegotiations-making-yourbusiness&r\_search=&r\_page=&return\_to=list. The webinar, entitled *Contract Renegotiations:* How to Get Past No with a Payor, will take place

on May 4<sup>th</sup> at 12:15PM. Go to www.cmanet.org/events/detail/?event=contractrenegotiaions-how-to-get-past-no for more information and to register.

## Noridian/JEMAC, DHCS/MediCal, & Private Payers

Noridian Administrative Services is the Jurisdiction E (JE) Medicare Administrative Contractor (MAC). Jurisdiction E includes California. Regularly review postings at the Noridian/JEMAC website at med.noridianmedicare.com/web/jeb. Recent updates include:

• MLN Connects Provider eNews Announcements—Major Commitments from Healthcare Industry to Make Electronic Health Records Work Better; Program Integrity Enhancements to the Provider Enrollment Process; EHR Incentive Program Hardship Application Deadline Extended to July 1; EHR Incentive Programs: FAQs on Public Health Reporting Requirements; ICD-10 Next Steps Toolkit; CMS Proposes to Test New Medicare Part B Prescription Drug Models; 2016 Value Modifier Results and Upward Payment Adjustment Factor; 2015 PQRS Data Submission Deadlines; ICD-10: Track and Improve Your Progress; 2016 PQRS Educational Materials Available Claims, Pricers, and Codes—Mandatory Payment Reduction of 2% Continues until Further Notice for the Medicare FFS Program-"Sequestration"; April 2016 Average Sales Price Files Available Publications & Videos-Provider Enrollment Revalidation: Cycle 2 MLN Matters Article-New; CMS Quality Conference 2015: Industry Leaders Discuss IMPACT Act Video-New; Home Health Prospective Payment System Booklet-Revised; Diagnosis Coding: Using the ICD-9 Web-Based Training-Revised; SNF Consolidated Billing Web-Based Training Course-Reminder; PECOS for Physicians and Non-Physician-Practitioners-Reminder; Medicare Enrollment for Institutional Providers Fact Sheet-Reminder

• MolDX: Genetic Testing for BCR-ABL Negative Myeloproliferative Disease Final LCD-Effective April 19 • Positron Emission Tomography (PET) Scans Coverage-R3 and R4

• Remittance Advice Messages Update-Pub. 100-04, Medicare Claims Processing Manual, Chapters 4 and 5 CR9424

• CPT Category III Non Covered and Covered Codes Coverage Article Retired-Effective March 1

• Non-Covered Services LCD

• MolDX: Breast Cancer Assay: Prosigna Final LCD-Effective May 3

• Telehealth Services CR9428

*Noridian/JEMAC's* Electronic Data Interchange Support Services (EDISS) invites you to subscribe to its e-mail distribution list to receive current information at www.edissweb.com/cgp/news/index.html.

# Forthcoming *Noridian/JEMAC* meetings/workshops include:

- Modifier 59 (March 30)
- Signatures (April 5)
- Modifier 59 (April 14)
- Part B Ask the Contractor
- Teleconference (ACT; April 20)
- DME Documentation (April 27)
- In-Person Seminars (May 7)
- Open Public Meeting (June 2)

Visit med.noridianmedicare.com/web/ jeb/education/training-events for more information and to register.

Subscribe today to receive the DHCS/Medi-Cal Subscription Service (MCSS) via e-mail. The MCSS is a free service that can help keep you upto-date on the latest DHCS/MediCal news. Go to the MCSS Subscriber Form (files.medical.ca.gov/pubsdoco/mcss/mcss.asp) to subscribe.

A list of DHCS/MediCal webinars is at files.medi-cal.ca.gov/pubsdoco/newsroom/ newsroom\_23149.asp?utm\_source= iContact&utm\_medium=email& utm\_campaign=Medi-Cal%20NewsFlash& utm\_content=23149.

Anthem (formerly Wellpoint) is offering California oncologists a monetary incentive for each patient who receives treatment as specified by one of the insurer's recommended regimens. Learn more about the Anthem program at www.cancercarequalityprogram.com. ANCO members are encouraged to review Anthem's Cancer Care Quality Program Treatment Pathways

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and send their comments to ANCO at execdir@anco-online.org. ANCO's comments on the *Program* and *Anthem's* response are available online at www.anco-online.org/index.html.

# **EDUCATION**

[Editor's Note: ANCO organizes clinical and professional education meetings throughout the year and throughout Northern California.]

# ASCO Annual Meeting

Registration and housing for the 2016 ASCO *Annual Meeting*, June 3<sup>rd</sup> -7<sup>th</sup>, at *McCormick Place* in Chicago is now open. Reserve your room and register at am.asco.org/.

# Additional Education Meetings

Other meetings of possible interest to ANCO member practices are:

March 28<sup>th</sup> Update on Polycythemia Vera (Part I of Living with Polycythemia Vera) Cancer*Care* Connect Education Workshop

March 30<sup>th</sup> Managing Aches and Pains, and Treatment Side Effects from Myeloproliferative Neoplasms (MPN; Part II of Living with Myeloproliferative Neoplasms) CancerCare Connect Education Workshop

#### April 1<sup>st</sup>

*The Role of Immuno-Oncology in the Treatment of Melanoma (Part III of Living with Advanced Skin Cancer)* Cancer*Care* Connect Education Workshop

April 4<sup>th</sup> *Managing Eye and Vision Changes Related to Cancer Treatments* Cancer*Care* Connect Education Workshop

April 8<sup>th</sup> Advances in the Treatment of Renal Cell Cancer CancerCare Connect Education Workshop

#### April 11<sup>th</sup>

Coping with the Stresses of Caregiving When Your Loved One Has Polycythemia Vera (Part II of Living with Polycythemia Vera) Cancer*Care* Connect Education Workshop

April 12<sup>th</sup>

*Advances in the Treatment of Lung Cancer (Part I of Living with Lung Cancer)* Cancer*Care* Connect Education Workshop

#### April 13th

The Role of Nutrition, Exercise and Meditation in Coping with Myeloproliferative Neoplasms (MPN; Part III of Living with Myeloproliferative Neoplasms) CancerCare Connect Education Workshop

April 14<sup>th</sup> Progress in the Treatment of Multiple Myeloma (Part I of Living with Multiple Myeloma) Cancer*Care* Connect Education Workshop

April 14-15<sup>th</sup> *The COA 2016 Community Oncology Conference—Innovation in Cancer Care: Moving from Theory to Practice* Community Oncology Alliance Orlando, FL (www.coaconference.org)

April 20<sup>th</sup> *Treatment Update on Pancreatic Cancer* Cancer*Care* Connect Education Workshop

# April 26th

For Caregivers: Practical Tips for Coping with Your Loved One's Lung Cancer (Part II of Living with Lung Cancer) CancerCare Connect Education Workshop

#### April 27th

Understanding the Role of Immuno-Oncology in Treating Cancer (Part I of Immuno-Oncology: A Promising New Approach to Treating Cancer) CancerCare Connect Education Workshop

#### April 28th

Coping with the Stresses of Caregiving When Your Loved One Has Multiple Myeloma (Part II of Living with Multiple Myeloma) CancerCare Connect Education Workshop

May 10<sup>th</sup> Managing the Side Effects of Immuno-Therapy (Part II of (Part I of Immuno-Oncology: A Promising New Approach to Treating Cancer) CancerCare Connect Education Workshop

May 17<sup>th</sup> Understanding Diagnostic Technologies and Biomarkers in the Treatment of Lung Cancer CancerCare Connect Education Workshop

May 18th

Updates in the Treatment of Estrogen Receptor (ER) Positive, Progesterone Receptor (PR) Positive & HER2 Positive Breast Cancer CancerCare Connect Education Workshop

Please contact the ANCO office for more information about these meetings.

# ASSOCIATION & MEMBERSHIP NEWS, RESOURCES,& BENEFITS

# **Board of Directors**

The ANCO *Board of Directors* meets by teleconference and occasionally in person to discuss issues affecting the *Association*, clinical and professional education, and ways to better serve the membership. *Board* teleconferences/meetings are open to individual physician members. The **next regularly scheduled ANCO** *Board of Directors* teleconference is scheduled for April 12<sup>th</sup>. Please call José Luis González, *ANCO Executive Director*, at (415) 472-3960 if you wish to participate in a future teleconference/meeting.

#### Individual Member News

A current *Directory of Members* is available online at www.anco-online.org/pubs.html as a .pdf document. We urge all ANCO members to download their own edition of *The ANCO Directory of Members*. Please verify your *Directory* entry and contact the ANCO office at execdir@anco-online.org with any corrections, additions, and/or deletions.

# Group Member News

ANCO initiated a **Group Membership** in 2008 based on a mutual set of perceived values and benefits and a mutual set of interests. The ANCO *Board* believes that the *Association* and *The Permanente Medical Group* (TPMG) will each receive value from Group Membership. ANCO initiated a **Multi Site Group Membership** in 2010 to encourage all physicians (medical and radiation oncologists) from multi-site and multidisciplinary practices to join. ANCO thanks Annadel Medical Group/St Joseph's Heritage Healthcare, California Cancer Associates for Research and Excellence, Diablo Valley Oncology & Hematology Medical Group, EPIC Care, Pacific Cancer Care, Palo Alto Medical Foundation, and Valley Medical Oncology Consultants for their multi site group memberships.

## Institutional Member News

ANCO initiated an **Institutional Membership** in 2002. *Department(s) of Hematology and/or Oncology* of accredited, degree granting teaching universities or research institutions are eligible for institutional membership. ANCO thanks the following Institutional Members for their support:

• Stanford Cancer Center

- University of California, Davis, Cancer Center
- University of California, San Francisco

Stanford and UC San Francisco, in collaboration with the National Cancer Institute, Consortium of Universities for Global Health, and Global Health, are co-hosting the 4<sup>th</sup> Annual Symposium on Global Cancer Research on April 8<sup>th</sup> at the Hilton Union Square Hotel in San Francisco. For more information and to register, visit www.eventbrite.com/e/4th-annual-symposiumon-global-cancer-research-tickets-19192248532.

#### **Corporate Member News**

ANCO thanks the following **Corporate Members** for their generous support that enables ANCO to provide services to the hematology/oncology community in northern California, and to provide its members and their patients with substantial benefits in the areas of advocacy, education, and information dissemination:

AbbVie • Alexion Pharmaceuticals • AMGEN Astellas Oncology • AstraZeneca Bayer Healthcare Pharmaceuticals Biodesix • Boehringer Ingelheim Pharmaceuticals Bristol-Myers Squibb Oncology Cardinal Health Specialty Solutions Celgene • Clovis Oncology • Daiichi Sankyo Dendreon • Eisai • Foundation Medicine Genoptix Medical Laboratory Genentech BioOncology • Genomic Health Gilead Sciences • Helsinn Oncology Incyte • Infinity Pharmaceuticals Ipsen Biopharmaceuticals Janssen Oncology • Jazz Pharmaceuticals Lilly Oncology • Merrimack Pharmaceuticals Medivation • Merck nanoString • Novartis Oncology Oncology Supply/ION • Onyx Pharmaceuticals Pfizer Oncology • Pharmacyclics Prometheus Therapeutics & Diagnostics Sandoz Biopharmaceuticals • Sanofi Genzyme Sargas Pharmaceutical Adherence & Compliance (SPAC) International Seattle Genetics • Taiho Oncology Takeda Oncology • Tesaro • TEVA Oncology

We especially wish to thank and welcome AbbVie, Biodesix, Clovis Oncology, Infinity Pharmaceuticals, Ipsen Pharmaceuticals, Jazz Pharmaceuticals, Merrimack Pharmaceuticals, Prometheus Therapeutics & Diagnostics, Sandoz Biopharmaceuticals, Taiho Oncology, and Tesaro as new Corporate Members for 2016. Please visit www.anco-online.org/assistance.html for Corporate Member drug reimbursement and patient assistance program information. ANCO encourages all member practices to use this resource and enroll all patients at the start of treatment in all available and appropriate patient assistance programs.

*Janssen Biotech* informs ANCO that the *United States Food and Drug Administratin* has approved Imbruvica capsules for treatment-naïve patients with chronic lymphocytic leukemia (CLL).

Janssen Biotech previously informed ANCO that *Noridian/JEMAC* has published an FAQ on Yondelis at med.noridianamedicare.com/ web/jeb/education/act/act-qa-012016 in which they state that Yondelis is a covered drug by Noridian/JEMAC using J9999. A decision on whether the pump will be covered is still being discussed. In an update, Janssen Biotech reports that in response to a letter from the *Community Oncology Alliance* (COA), CMS states that directional guidance and rationale will be shared with both the *Contractor Medical Directors* and the DMERC to clearly define the appropriate agency for billing both drug and route of administration, either collectively or separately, for patients receiving Yondelis for the treatment of specific soft tissue sarcomas unresectable or metastatic. CMS urges physicians not to delay or withhold treatment until such guidance becomes available. COA has been given every assurance that both drug and service will be covered and reimbursed.

Janssen Biotech is hosting a series of dinner programs entitled Value-Based Care and Quality Measures in Oncology: Current and Future Approaches with Richard McGee, M.D., First Choice Health Network, in Sacramento on April 26<sup>th</sup> (meeting code 2016-01000), Berkeley on May 5<sup>th</sup> (meeting code 2016-01008), and San Jose on May 18<sup>th</sup> (meeting code 2016-00999). To register for these programs, visit www.MyDomeProgramRegistration.com.

*Pfizer Oncology* informs ANCO that the *United States Food and Drug Administration* has approved Xalkori for the treatment of patients with metastatic non-small cell lung cancer (NSCLC) whose tumors are ROS1-positive.

#### **Clinical Trial News**

The ASCO Clinical Trial Assessment Tool, developed by ASCO's Community Research Forum (CRF), is a unique Tool to assess clinical trialassociated workload, based on the complexity of research protocols and the number of patients. An article recently published in the Journal of Oncology Practice summarizes findings from a pilot study conducted prior to the Tool's release. The findings demonstrate that the Tool is easy to use and supported its long-term feasibility and utility for research sites. The Tool is available for free at workload.asco.org

# *Stanford Cancer Center* brings the following oncology clinical trials (not previously listed or changed) to the attention of the ANCO membership:

• A First-In-Human Phase I, Dose Escalation, Safety and Pharmacokinetic Study of PF-06647020 in Adult Patients with Advanced Solid Tumors [VAR0130; clinicaltrials.gov/ct2/show/NCI02222922]. Principal Investigator: Shivaani Kummar, MD; Contact: Gagan Grewal, (650) 721-4084, ggrewal@stanford.edu

• A Phase Ib/II, Multicenter, Open-label Study of ACP-196 in Subjects with Recurrent Glioblastoma Multiforme [GBM; BRN0031; med.stanford.edu/cancer/trials/results.html?ctid= NCT02586857]. Principal Investigator: Lawrence Recht, MD; Contact: Cathy Recht, (650) 723-6095, ckrecht@stanford.edu.

• Randomized Phase III Trial of Memantine and Whole-Brain Radiotherapy with or without Hippocampal Avoidance in Patients with Brain Metastases [NRGCC001;

med.stanford.edu/clinicaltrials/trials/NCT023602 15]. Principal Investigator: Scott Soltys, MD; Contact: Polly Young, (650) 497-7499, polly14@stanford.edu. • Phase 2 Study of Alisertib as a Single Agent in Recurrent or Progressive Central Nervous System SJATRT: (SNS) Atypical Teratoid Rhabdoid Tumors (AT/RT) and Extra-CNS Malignant Rhabdoid Tumors (MRT) and in Combination Therapy in New Diagnosed AT/RT [Up to 21 years of age; PEDSBRNCNS0006; med.stanford.edu/clinicaltrials/NCT02114229]. Principal Investigator: Sonia Partap, MD; Contact: Prianka Kumar, (650) 724-3866, prianka@stanford.edu.

• A Phase I Multicenter, Open-Label, ,Dose-Escalation, and Dose-Expansion Study to Evaluate the Safety, Pharmacokinetics, Immunogenicty, and Antitumor Activity of MEDI4276 in Subjects with Select HER2-expressing Advanced Solid Tumors [VAR0128;

med.stanford.edu/cancer/trials/results.html?ctid= NCT02576548]. Principal Investigator: Mark Pegram, MD; Contact: Karen Lau, (650) 723-0658, kkwlau@stanford.edu.

• PM1183-C-004-14 Phase III Randomized Clinical Trial of Lurbinectedin (PM01183) versus Pegylated Liposomal Doxorubicin or Topotecan in Patients with Platinum-resistant Ovarian Cancer [CORAIL Trial; GYNOVA0035; med.stanford.edu/cancer/trials/results.html?ctid= NCT02421588]. Principal Investigator: Oliver Dorigo, MD; Contact: Aarti Kale, (650) 723-0622, aartik@stanford.edu.

• A Phase I/IIa, Open Label, Clinical Trial Evaluating the Safety and Efficacy of Autologous T Cells Expressing Enhanced TCRs Specific for NY-ESO-1 in Patients with Recurrent or Treatment Refractory Ovarian Cancer [GYNOVA0036;

med.stanford.edu/cancer/trials/results.html?ctid= NCT01567891]. Principal Investigator: Oliver Dorigo, MD; Contact: Alma Gonzalez, (650) 498-0624, alma.gonzalez@stanford.edu.

• A Randomized Phase 2 Trial of Neoadjuvant and Adjuvant Therapy with the IRX-2 Regimen in Patients with Newly Diagnosed Stage III or IVA Squamous Cell Carcinoma of the Oral Cavity [ENT0045;

clinicaltrials.gov/ct2/show/NCT02609386]. Principal Investigator: Michael Kaplan, MD; Contact: Priya Hegde, (650) 723-0920, phegde@stanford.edu.

• A Phase III Randomized, Open-Label, Multi-Center, Global Study of MEDI4736 Monotherapy and MEDI4736 in Combination with Tremelimumab Versus Standard of Care Therapy in Patients with Recurrent or Metastatic Squamous Cell Carcinoma of the Head and Neck [SCCHN; ENT0046;

med.stanford.edu/cancer/trials/results.html?ctid= NCT02369874]. Principal Investigator: A. Dimitrios Colevas, MD; Contact: Mary May, (650) 721-4079, mmay2@stanford.edu.

• A Phase II Clinical Trial of MK-3475 (Pembrolizuman) in Subjects with Relapsed or Refractory (R/R) Classical Hodgkin Lymphoma [cHL; LYMPHD0013; med.stanford.edu/cancer/trials/results.html?ctid= NCT02453594]. Principal Investigator: Ranjana Advani, MD; Contact: Jean Sabile, (650) 723-0530, jsabile@stanford.edu.

• A Randomized Phase II Trial of Brentuximab Vedotin (SGN35, NSC#749710), or Crizotinib (NSC#749005, commercially available) in Combination with Chemotherapy for Newly Diagnosed Patients with Anaplastic Large Cell Lymphoma [ALCL; up to 21 years of age; COGANHL12P1;

med.stanford.edu/cancer/trials/results.html?ctid= NCT01979536]. Principal Investigator: Neyssa Marina, MD; Contact: Christin New, (650) 497-8815, newc@stanford.edu.

• Open Label, Multicenter Phase I Study of IPH4102, a Humanized Anti-KIR3DL2 Monocloncal Antibody, in Patients with Relapsed/Refractory Cutaneous T-cell Lymphomas [CTCL; LYMNHL0131; med.stanford.edu/cancer/trials/results.html?ctid= NCT02593045]. Principal Investigator: Youn Kim, MD; Contact: Illisha Rajasansi, (650) 421-1397, illisha@stanford.edu.

• A Single Arm, Open-Label Study to Evaluate the Safety, Tolerability and Preliminary Efficacy of NM-IL-12 (rHuIL-12) in Patients with Cutaneous T Cell Lymphoma (CTCL) Undergoing Low Dose Total Skin Electron Beam Therapy [TSEBT; LYMNHL0133; med.stanford.edu/cancer/trials/results.html?ctid= NCT02542124]. Principal Investigator: Youn Kim, MD; Contact: Eric Hong, (650) 725-2142, ekjhong@stanford.edu.

• Detection of Integrin Alpha-v-Beta 6 in Pancreatic Cancer with [18F]R01-MG-F2: A First in Human Study [PANC0020; med.stanford.edu/cancer/trials/results.html?ctid= NCT02683824]. Principal Investigator: Sanjiv Gambhir, MD; Contact: Krithika Rupnarayan, (650) 736-0959, krupnara@stanford.edu.

• A Phase 1/2 Study of FPA008, an Anti-CSF1 Receptor Antibody, in Patients with Pigmented Villonodular Synovitis (PVNS)/Diffuse Type Tenosynovial Giant Cell Tumor [dt-TGCT; SARCOMA0019;

med.stanford.edu/cancer/trials/results.html?ctid= NCT02471716]. Principal Investigator: Kristen Ganjoo, MD; Contact: Maria Ahern, (650) 725-6413, mahern@stanford.edu.

#### Publications, Resources, Services, & Surveys

ASCO's *Clinical Affairs Department* is dedicated to providing services, education, and resources to support oncology practices. It offers hands-on assistance in areas such as practice management, quality care assessment and improvement, and efficiency and business intelligence to meet the needs and demands of the current oncology landscape. Resources on the business of oncology,

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practice management (staffing, technology), practice transformation, and market analysis are available from the *Department*. For more information, visit www.asco.org/practiceresearch.

ASCO's PracticeNET is a collaborative network in which practices share and receive insights to enhance their business operations and quality of care. PracticeNET is the first initiative of ASCO's *Clinical Affairs Department*. This new initiative uses existing data from your practice management system to offer customizable reports that measure practice-wide and individual performance against a national database of other PracticeNET participants. Go to www.asco.org/PracticeNET for more information.

A new original contribution published in the Journal of Oncology Practice (JOP) details the evaluation of the feasibility of interface development between Survivorship Care Plans (SCPs) and an electronic medical record (EMR) representing a new approach for widespread implementation of SCPs. The study, entitled A Feasibility Study of an Electronic Interface between Internet Based Survivorship Care Plans and Electronic Medical Records, is available at jop.ascopubs.org/content/early/2016/03/17/JOP. 2015.006841.abstract.

The March 2016 issue of ASCO's Journal of Oncology Practice (JOP) is available online and features an article entitled American Society of Clinical Oncology Policy Statement on Clinical Pathways in Oncology; Physician Experience and Attitudes Toward Addressing the Cost of Cancer Care; The State of Cancer Care in America, 2016: A Report by the American Society of Clinical Oncology. Visit jop.ascopubs.org for more information.

The American Board of Internal Medicine (ABIM) has approved Maintenance of Certification (MOC) points for physicians whose practices have received accreditation through ASCO's Quality Oncology Practice Initiative (QOPI) Certification Program (QCP). In addition, MOC points are available for physicians whose practices are participating in QOPI if the individual oncologist attests that he or she has been part of the quality improvement effort.

CMS has approved ASCO's *Quality Oncology Practice Initiative* (QOPI) as a qualified clinical data registry (QCDR), a pathway for oncologists to meet the agency's current quality reporting requirements. Oncology practices registered with QOPI will have the opportunity to fulfill CMS's PQRS or QCDR reporting requirements through QOPI. Go to www.asco.org/advocacy/cmsapproval-new-platform-making-qopi<sup>®</sup>participation-easier for more information. QOPI is designed to promote excellence in cancer care by helping oncologists create a culture of selfexamination and improvement. ASCO offers the *QOPI Certification Program* to recognize QOPI participants who achieve rigorous standards for cancer care. The *QOPI Certification* designation can be used by certified practices to demonstrate an advanced commitment to quality.

# ACCC is excited to announce a complete redesign of its annual *Trends in Cancer Programs*

*Survey.* This year ACCC is rolling out four surveys, one each of cancer program administrators, oncology nurses, pharmacists, and medical directors/physician leaders. Just launched is the cancer program administrator's survey at www.accc-cancer.org/surveys/ CancerProgramTrends-2016-Overview.asp.

The March/April issue of ACCC's Oncology Issues includes articles entitled Developing a Navigation and Psychosocial Support Program from the Ground Up; Developing an Oncology IT Strategy; and, Exploring the Issue of of Cancer Drug Parity. Visit www.accc-cancer.org/oncology\_issues to read this issue.

NCCN has updated their *Clinical Practice Guidelines in Oncology* and/or *Drugs & Biologics Compendium* for myeloid growth factors (V1.2016), non-small cell lung cancer (V4.2016), and prostate cancer early detection (V1.2016).

# Individual Membership Dues for 2016

Second notices of membership renewal for 2016 were mailed to all members in early February. If you have not yet done so, then please return your 2016 membership dues to ANCO now to ensure your inclusion in *The ANCO Directory of Members*. Be sure to provide ANCO with your email address and the name(s) and e-mail address(es) of office and/or nurse manager contact(s). Those not renewing their membership by June 30<sup>th</sup> will be deleted from the *Directory of Members*, and will no longer be eligible for any ANCO benefits. Contact the ANCO office if you do not receive or misplaced your membership dues renewal notice.