

# 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](http://www.anco-online.org/pubs.html).

#### In this issue:

- Final rules CY PFS, HOPPS, QPP
- Update: IV fluid shortage
- *Medicare Reimbursement for Oncology*
- *Multidisciplinary Management of Cancers*
- Vote in the ASCO annual election

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 December 1<sup>st</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](mailto: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 the *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 released the CY2018 *Physician Fee Schedule (PFS)* and *Outpatient Prospective Payment System (OPPS)* final rules on November 2<sup>nd</sup>. Read the final rules at:

- 2018 PFS

[www.federalregister.gov/documents/2017/11/15/2017-23953/medicare-programs-revisions-to-payment-policies-under-the-physician-fee-schedule-and-other-revisions](http://www.federalregister.gov/documents/2017/11/15/2017-23953/medicare-programs-revisions-to-payment-policies-under-the-physician-fee-schedule-and-other-revisions)

- 2018 OPPS

[www.federalregister.gov/documents/2017/11/13/2017-23932/medicare-program-hospital-outpatient-prospective-payment-and-ambulatory-surgical-center-payment](http://www.federalregister.gov/documents/2017/11/13/2017-23932/medicare-program-hospital-outpatient-prospective-payment-and-ambulatory-surgical-center-payment)

- QPP

[www.federalregister.gov/documents/2017/11/16/2017-24067/medicare-programs-cy-2018-updates-to-the-quality-payment-program-and-quality-payment-program-extreme](http://www.federalregister.gov/documents/2017/11/16/2017-24067/medicare-programs-cy-2018-updates-to-the-quality-payment-program-and-quality-payment-program-extreme)

According to ASCO, the *2018 Physician Fee Schedule*:

- establishes a conversion factor of approximately \$36 resulting in an anticipated impact on hematology/oncology of 0% and radiation oncology of 1%.
- separates billing codes and payments for newly approved biosimilars paid under Medicare Part B.

Effective January 1<sup>st</sup>, biosimilars with a common reference product will no longer be grouped into the same billing code.

- defers the new Appropriate Use Criteria (AUC) rule for diagnostic imaging until 2010.

The 2017 OPPS:

- reduces 340B reimbursement for separately paid drugs to ASP minus 22.5%.
- finalizes revisions to the 14-day rule for molecular pathology and advanced diagnostic laboratory tests by unbundling lab tests ordered at discharge and permitting labs to bill CMS directly for the tests.

And, the *2018 Quality Payment Program*:

- moves forward with applying the MIPS adjustment to Medicare Part B items and services, including Part B drugs.
- weights the Cost category at 10% with no risk adjustment in the methodology.
- weights the Quality category at 50% of total MIPS scores.

Read Bobbi Buell's analysis of the final rules at [www.anco-online.org/BBMPFS2018Analysis.pdf](http://www.anco-online.org/BBMPFS2018Analysis.pdf). Join ACCC for its *CMS Final CY2018 Outpatient Prospective Payment System (OPPS) & Physician Fee Schedule (PFS) Rules: What You Need to Know* webcast on Wednesday, November 29<sup>th</sup> at 12PM PST. Register at <https://register.gotowebinar.com/register/3246328258799617539>.

The *Medicare Quality Payment Program (QPP)*, established by the *Medicare Access and CHIP Reauthorization Act (MACRA)*, began on January 1<sup>st</sup>. This year is a transition year meaning you can "pick your pace" when implementing QPP in your practice. CMS has posted new resources to

the QPP website to help clinicians successfully participate in the first year of the QPP. The new resources focus on support for small practices and alternative payment models (APMs). Visit [qpp.cms.gov](http://qpp.cms.gov) for more information. In addition, CMS is now accepting hardship exceptions from the QPP for the 2017 reporting year based on insufficient internet connectivity, extreme and uncontrollable circumstances, and lack of control over the availability of certified EHR technology. Learn more at [qpp.cms.gov/about/hardship-exception](http://qpp.cms.gov/about/hardship-exception).

**ASCO's Quality Oncology Practice Initiative (QOPI) Qualified Clinical Data Registry (QCDR) is available for CMS MIPS reporting.** By using the QOPI QCDR for MIPS reporting, practices will be able to report in 2017 and 2018 to avoid cuts to Medicare reimbursements in 2019 and 2020. Express your interest in participating in the QOPI QCDR by e-mailing [qopi@asoc.org](mailto:qopi@asoc.org). Practices will be contacted regarding the necessary steps to begin their on-boarding process. For more information, please visit [www.instituteforquality.org/qopi/about/quality-reporting](http://www.instituteforquality.org/qopi/about/quality-reporting).

**ASCO's series of webinars to guide oncology practices to successful quality reporting** are available at [www.asco.org/macra](http://www.asco.org/macra) > MACRA Webinar Series. **ASCO has developed a MACRA decision tree tool to help oncology practices find precise information on their QPP participation status** at [www.asco.org/practice-guidelines/billing-coding-reporting/macra-quality-payment-program/macra-practice-tools/determine-status](http://www.asco.org/practice-guidelines/billing-coding-reporting/macra-quality-payment-program/macra-practice-tools/determine-status). For more information and access to ASCO's revamped QPP/MACRA toolkit, educational materials, and resources, go to [www.asco.org/macra](http://www.asco.org/macra). ASH's updated MACRA webpage is at [www.hematology.org/Clinicians/7427.aspx](http://www.hematology.org/Clinicians/7427.aspx). **ASH members can now sign up to report data for the Medicare MIPS through Healthmonix's MIPSPRO, a 2017 Qualified MIPS Registry.** Learn more at [healthmonix.com/mips-pro/](http://healthmonix.com/mips-pro/).

**The American Medical Association (AMA) has produced a new short video entitled *One Patient, One Measure, No Penalty: How to avoid a Medicare payment penalty with basic reporting.*** The video and other AMA resources are available at [www.ama-assn.org/qpp-reporting](http://www.ama-assn.org/qpp-reporting). **CMA's Center for Economic Services (CES) has published an update to its MACRA preparation checklist entitled *MACRA: What Should I Do Now to Prepare?*** available at [www.cmanet.org/macra](http://www.cmanet.org/macra). **Physicians in practices with 15 or fewer can receive free assistance to prepare and participate in the QPP through the California Health Information Partnership & Services Organization (CalHIPSO).** Contact CalHIPSO at [www.hsag.com/calhipso](http://www.hsag.com/calhipso) (and see the supplement to this edition of the *ANCO FAX News*.)

**ASCO has met with the FDA and other stakeholders to discuss recent drug shortages and some temporary solutions to help alleviate the situation.** *Baxter Healthcare Corporation* in conjunction with FDA has initiated temporary importation of some intravenous drug products from its facilities in other countries (e.g., Canada). Visit FDA's dedicated webpage at [www.accessdata.fda.gov/scripts/drugshortages/dsp\\_ActiveIngredientDetails.cfm?AI=Sodium%20Chloride%200.9per%20Injection%20Bags&st=c](http://www.accessdata.fda.gov/scripts/drugshortages/dsp_ActiveIngredientDetails.cfm?AI=Sodium%20Chloride%200.9per%20Injection%20Bags&st=c) for the latest information; see the Dear Healthcare Professional letter at [www.fda.gov/downloads/Drugs/DrugSafety/DrugShortages/UCM581644.pdf](http://www.fda.gov/downloads/Drugs/DrugSafety/DrugShortages/UCM581644.pdf). *The American Society of Health-System Pharmacists* and the *University of Utah Drug Information Service* have developed a document with suggestions for management and conservation of small-volume parenteral solutions (SVPs) at [www.fda.gov/downloads/Drugs/DrugSafety/DrugShortages/UCM582461.pdf](http://www.fda.gov/downloads/Drugs/DrugSafety/DrugShortages/UCM582461.pdf). In addition, **ASCO signed onto a joint letter to the House Energy and Commerce Subcommittee on Oversight and Investigations asking Congress to raise awareness about the persistent shortages of critical medications and resulting public health crises.** Read the letter at [www.ashp.org/](http://www.ashp.org/)

/media/assets/advocacy-issues/docs/GRD-Letter-to-EC-on-SVP-Shortages.

**USP has announced that it will postpone the official date of General Chapter 800 (i.e., USP800) to December 1<sup>st</sup>, 2019.** USP800 was originally scheduled to become official on July 1<sup>st</sup>, 2018. USP now plans to align the official date of USP800 with the release of the final version of USP797. However, some state and national enforcement agencies and other entities may require adherence to USP800 before its official implementation date.

### ***CMA, MOASC, and State Legislative & Regulatory Issues***

Sacramento can be a dangerous place for doctors. Many bills impacting medicine wind their way through the *Capitol* on their journey to the *Governor's* desk. And, many of these bills threaten the medical profession with the backing of powerful lobbyists and PACs. It's critical that **physicians have an advocate at work for them every day and who knows how to speak on their behalf. That advocate is the *California Medical Association* (CMA).** While physicians keep a close eye on their patients, CMA is keeping a close eye on those bills...and more. **Got payment delays? Feeling victimized by payers and overwhelmed by the process? Don't let the health plans mistreat you. The CMA's *Center for Economic Services* (CES) has a team of reimbursement specialists available to assist ANCO's CMA members experiencing payment problems with third-party payers.** For membership, please call (916) 551-2042; for reimbursement assistance, please call CMA's *Reimbursement Helpline* at (888) 401-5911.

***CMA Practice Resources* (CPR) is a monthly e-mail bulletin from CMA's *Center for Economic Services* that is full of tips and tools to help physicians and their office staff improve practice efficiency and viability. Subscribing to CPR is free and open to anyone, but CMA membership is necessary to access the resources, toolkits, forms, and tools that are located on the members-**

only CMA website. Please visit [www.cmanet.org/cpr](http://www.cmanet.org/cpr) to subscribe. The November 2017 edition includes:

- Anthem Blue Cross announces plans to significantly cut reimbursement on E/M services with modifier 24
- Be prepared for Covered California changes in 2018
- Do you know if non-contracted payors are complying with AB72 interim payment rules?
- Remember: Don't hesitate to revalidate or Medicare will deactivate
- Blue Shield to required electronic claim submission
- Anthem Blue Cross to alter member ID cards
- Remember: TRICARE transitions to HNFS on January 1
- Act now to avoid 4 percent Medicare penalty in 2018 (Spoiler alert: It's easy!)
- Anthem Blue Cross to discontinue ProviderAccess effective December 8
- CMS extends Physician Compare preview period
- Reminder: Blue Shield Fee schedule changes effective December 1
- Last day to change your Medicare participation status for 2018 is December 31
- The Coding Corner: E/M services with same-day immunization administration

### ***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](http://med.noridianmedicare.com/web/jeb). Recent**

updates include:

- MLN Connects Provider eNews *Announcements*—CMS Offers Medicare Enrollment Relief for Americans Affected by Recent Disasters; Physician Fee Schedule Final Policy, Payment, and Quality Provisions for CY2018; Hospital OPPS and ASC Payment System and Quality Reporting Programs Changes for 2018; HHAs: Payment Changes for 2018; Quality Payment Program Rule for Year 2; New Medicare Card: Help Notify Your Patients; Hospital Value-Based Purchasing Program Results for FY2018; Quality Payment Program Resources in New Location; New Medicare Card: New Webpage Information; Physician Compare: How to Update Your Listing *Claims, Pricers, and Codes*—Evaluation and Management: Correct Coding-Reminder
- Events*—Quality Payment Program Year 2 Final Rule Call-November 30;
- Publications*—Quality Payment Program in 2017: Advanced Alternative Payment Models Web-Based Training Course-New; Transition to New Medicare Numbers and Cards Fact Sheet-Revised; Remittance Advance Information: An Overview Booklet-Reminder; Medicare and Medicaid Basics Booklet-Revised
- Reporting a Non-Covered Test Performed in Preparation for a Non-Covered Procedure
- Chemotherapy Administration-R10
- Non-Covered Services-R18
- November Webinars-Register Now
- Observation and Inpatient E/M Common Denial Resolution Options
- Medicare B News JE October 2017 Bulletin-Now Available

- Open Enrollment Participation Program for 2018
- Eligibility Details Expanded in Portal
- New Waived Tests CR10321
- Medicare Secondary Payer Payment Calculator Now Offers Enhanced Details
- MolDX: Bladder Tumor Marker FISH Billing and Coding Guidelines-R2
- DecisionDX-UM Billing Guidelines Article Retirement-Effective September 22, 2017
- MolDX: AlloSure Donor-Derived Cell-Free DNA Test Final LCD-Effective December 1, 2017

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

- Modifier 59, NCCI and MUE Webinar (November 29)
- Preventive and Screening Services Webinar (December 6)
- Modifier 59, NCCI and MUE Webinar (December 13)

Visit [med.noridianmedicare.com/web/job/education/training-events](http://med.noridianmedicare.com/web/job/education/training-events) for more information and to register.

**CMS has published a MLN Matters article entitled *Medicare Fee-for-Service (FFS) Response to the 2017 California Wildfires* at [www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/SE17035.pdf](http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/SE17035.pdf).** CMS has a webpage dedicated to the 2017 California wildfires at [www.cms.gov/About-CMS/Agency-Information/Emergency/Wildfires.html](http://www.cms.gov/About-CMS/Agency-Information/Emergency/Wildfires.html).

***UnitedHealthcare* recently made changes that may affect coverage or reimbursement for genetic and molecular testing.** Effective November 1<sup>st</sup>, *UnitedHealthcare* is implementing an online Prior Authorization program for genetic and molecular testing. Additional information is available at

[www.uhcprovider.com/en/prior-auth-advance-notification/genetic-molecular-lab.html](http://www.uhcprovider.com/en/prior-auth-advance-notification/genetic-molecular-lab.html).

## EDUCATION

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

### **ANCO's Medicare Reimbursement for Oncology 2017**

ANCO will host its annual *Medicare* update programs entitled *Medicare Reimbursement for Oncology in 2018* on January 3<sup>rd</sup> in San José and January 4<sup>th</sup> in Sacramento. Roberta Buell, M.B.A., *onPoint Oncology*, will provide the latest information impacting Medicare's reimbursement for oncology in 2018 as well as a *Revenue Cycle State of the State* with northern California data on denial rates, days to pay, and days to file. The latter presentation will be a unique opportunity to get benchmarks that you can use for billing and appeals at your practice. Download the meeting announcement at [www.anco-online.org/MedicareUpdate2018.pdf](http://www.anco-online.org/MedicareUpdate2018.pdf).

### **18<sup>th</sup> Multidisciplinary Management of Cancers: A Case-based Approach**

The *18<sup>th</sup> Multidisciplinary Management of Cancers: A Case-based Approach* returns to the *Silverado Resort and Spa* in Napa on March 16-18<sup>th</sup>. The meeting is sponsored by the *Association of Northern California Oncologists*, *Stanford Cancer Institute*, *UC Davis Comprehensive Cancer Center*, and the *UCSF Helen Diller Family Comprehensive Cancer Center*. Go to [www.multicancers.org](http://www.multicancers.org) for more information including registration and housing.

### **Additional Education Meetings**

November 29<sup>th</sup>

*Advances in the Treatment of Triple Negative Breast Cancer (Part I of Living with Triple Negative Breast Cancer)*

CancerCare Connect Education Workshop ([www.cancercare.org/connect\\_workshops](http://www.cancercare.org/connect_workshops))

November 30<sup>th</sup>

*Coping with the Stresses of Caregiving When Your Loved One Has Triple Negative Breast Cancer (Part II of Living with Triple Negative Breast Cancer)*

CancerCare Connect Education Workshop ([www.cancercare.org/connect\\_workshops](http://www.cancercare.org/connect_workshops))

December 14<sup>th</sup>

*Update on Chronic Lymphocytic Leukemia (CLL)*

CancerCare Connect Education Workshop ([www.cancercare.org/connect\\_workshops](http://www.cancercare.org/connect_workshops))

December 20<sup>th</sup>

*Update on Clinical Trials & Triple Negative Breast Cancer (Part III of Living with Triple Negative Breast Cancer)*

CancerCare Connect Education Workshop ([www.cancercare.org/connect\\_workshops](http://www.cancercare.org/connect_workshops))

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

## ASSOCIATION & MEMBERSHIP NEWS, RESOURCES, & BENEFITS

[Editor's Note: All ANCO members are also eligible for several tangible 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 meeting is scheduled for December 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**

**ASCO seeks applications for volunteers at its ASCO Volunteer Portal**

(<https://volunteer.asco.org/>?). Your application will be used for all upcoming Volunteer Corps opportunities and 2018 committee consideration. Apply by January 31<sup>st</sup> for 2018 committee consideration.

The ASCO *Nominating Committee* has selected 16 distinguished ASCO members as candidates for open leadership positions within the *Society*. Detailed information on candidates for open positions, including a community oncology seat, is now available at [www.asco.org/about-asco/asco-overview/asco-election?](http://www.asco.org/about-asco/asco-overview/asco-election?). Eligible ASCO members may vote through December 4<sup>th</sup>.

A current *Directory of Members* is available online at [www.anco-online.org/pubs.html](http://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](mailto: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 *Diablo Valley Oncology & Hematology Medical Group*, *EPIC Care*, *Marin Cancer Care*, *Pacific Cancer Care*, and *Palo Alto Medical Foundation* 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*

James M. Ford, M.D., *Stanford Cancer Institute*, is the *Editor* of ASCO's new on-line journal entitled *JCO: Precision Oncology* (JCO PO). Learn more at <http://po.jco.org>.

Albert Koong, M.D., Ph.D., *Stanford Cancer Institute*, has been named a *Fellow* of the *American Society for Radiation Oncology* (ASTRO).

### **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* • *Agendia* • *Agios Pharmaceuticals*  
*Alexion Pharmaceuticals*  
*AMGEN* • *ARIAD Pharmaceuticals*  
*Astellas Oncology* • *AstraZeneca*  
*Bayer Healthcare Pharmaceuticals*  
*bioTheranostics*  
*Boehringer Ingelheim Pharmaceuticals*  
*Bristol-Myers Squibb Oncology*  
*Cardinal Health Specialty Solutions*  
*Celgene* • *Clovis Oncology* • *Daiichi Sankyo*  
*Eisai* • *EMD Serono* • *Exelixis*  
*Foundation Medicine* • *Genentech BioOncology*  
*Genomic Health* • *Gilead Sciences*  
*Guardant Health* • *Helsinn Oncology*  
*Heron Therapeutics* • *Incyte*  
*Janssen Oncology* • *Jazz Pharmaceuticals*  
*Kite Pharmaceuticals* • *Lilly Oncology* • *Merck*  
*nanoString* • *Novartis Oncology*  
*Oncology Supply/ION* • *Pfizer Oncology*  
*Pfizer US Biosimilars* • *Pharmacyclics*  
*Puma Biotechnology* • *Sandoz Biopharmaceuticals*  
*Sanofi Genzyme* • *Seattle Genetics*  
*Taiho Oncology* • *Takeda Oncology*  
*TerSera Therapeutics* • *Tesaro*  
*TEVA Oncology*

We especially wish to thank and welcome *Agendia*, *Agios Pharmaceuticals*, *bioTheranostics*, *EMD Serono*, *Kite Pharmaceuticals*, *Pfizer US*

*Biosimilars, Puma Biotechnology, and TerSera Therapeutics* as new Corporate Members for 2017. *Dendreon, Genoptix Medical Laboratory, GenPath Oncology, Infinity Pharmaceuticals, Ipsen Biopharmaceuticals, Medivation, Merrimack Pharmaceuticals, and Prometheus Laboratories* did not renew their memberships for 2017. Please visit [www.anco-online.org/assistance.html](http://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.

*AstraZeneca* informs ANCO that the *United States Food and Drug Administration* has approved Faslodex, to include use with abemaciclib, a CDK4/6 inhibitor, for the treatment of hormone receptor-positive (HR+), human epidermal growth factor receptor 2 negative (HER2-) advanced or metastatic breast cancer (MBC) in women with disease progression after endocrine therapy.

*Bristol-Myers Squibb Oncology* informs ANCO that the *United States Food and Drug Administration* has approved Sprycel for pediatric patients with chronic phase (CP) Philadelphia chromosome-positive (Ph+) chronic myeloid leukemia (CML).

*Genentech BioOncology* informs ANCO that the *United States Food and Drug Administration* has approved Alecensa for the first-line treatment of patients with anaplastic lymphoma kinase (ALK)-positive metastatic non-small cell lung cancer (NSCLC) as detected by an FDA-approved test.

*Genentech BioOncology* informs ANCO that the *United States Food and Drug Administration* (FDA) has approved **Gazyva** in combination with chemotherapy, followed by Gazyva monotherapy in patients achieving at least a partial remission for the treatment of adult patients with previously treated stage II bulky, III, or IV follicular lymphoma. In addition, CMS has assigned J-code J9022 (10mg) to **Tecentriq** effective for dates of

service on or after January 1<sup>st</sup>. Finally, the FDA has approved **Zelboraf** for patients with Erdheim-Chester disease (ECD) with BRAF V600 mutation. Zelboraf is not indicated for treatment of patients with wild-type BRAF ECD.

*Merck* informs ANCO that the *United States Food and Drug Administration* has approved Prevymis to help prevent CMV (cytomegalovirus) infection and disease in adults who have been exposed to CMV and have received an allogeneic hematopoietic stem cell (bone marrow) transplant (HSCT).

*Pfizer Oncology* has implemented emergency relief protocols at *Pfizer RxPathways* to ensure that patients impacted by the northern California wildfires have continued access to their *Pfizer* medicines. If a medicine provided through a *Pfizer* patient assistance program has been destroyed or lost, or patients who are enrolled are unable to reach their doctors' offices and need their medicine shipped to an alternate location, *Pfizer* can arrange for early refills and/or new shipping addresses. If new patients urgently need a *Pfizer* medicine but have been displaced and are unable to access income documentation and other paperwork needed for enrollment into the program, *Pfizer* is able to waive these requirements so that patients can receive their medication as quickly as possible. Facilities that participate in *Pfizer's* bulk replenishment Institutional Patient Assistance Program can request early replenishment of the *Pfizer* medicines covered or request additional inventory to meet increased demand. For help with *Pfizer's* oncology medicines, call *Pfizer Oncology Together* directly at (877) 744-5675; for help with other *Pfizer* medicines, call *Pfizer RxPathways* at (844) 989-PATH (7284).

*Seattle Genetics* informs ANCO that the *United States Food and Drug Administration* has approved Adcetris for treatment of patients with primary cutaneous anaplastic large cell lymphoma (pcALCL) or CD30-expressing mycosis fungoides (MF) who have received prior systemic therapy.



## Clinical Trial News

### **UC San Francisco brings the following oncology clinical trials (not previously listed or changed) to the attention of the ANCO membership:**

- A Phase 2 Study of Abemaciclib in Patients with Brain Metastases Secondary to Hormone Receptor Positive Breast Cancer, Non-small Cell Lung Cancer, or Melanoma (CC#15752). Contact: Michael Assefa, (415) 885-7213, michael.assefa@ucsf.edu.
- A Pilot Study of Pembrolizumab and Liver-Directed Therapy For Patients With Well-Differentiated Neuroendocrine Tumors and Symptomatic and/or Progressive Liver Metastases (CC#17705). Contact: Andrew Chon, (415) 476-2351, andrew.chon@ucsf.edu.
- Open-label, Multicenter, Phase 1b/2 Clinical Study to Evaluate the Safety and Efficacy of CD40 Agonistic Monoclonal Antibody (APX005M) Administered Together with Gemcitabine and Nab-Paclitaxel With or Without PD-1 Blocking Antibody (Nivolumab) in Patients With Previously Untreated Metastatic Pancreatic Adenocarcinoma (CC#17709). Contact: Andrew Chon, (415) 476-2351, andrew.chon@ucsf.edu.
- A Pilot Study of APX005M in Combination With Concurrent Chemoradiation as Neoadjuvant Therapy for Resectable Esophageal and Gastroesophageal Junction Cancers (CC#17701). Contact: Christopher Wong, (415) 476-1044, christopher.wong@ucsf.edu.
- A Phase I Open Label Clinical Trial Evaluating the Safety and Anti-Tumor Activity of Autologous T Cells Expressing Enhanced TCRs Specific for Alpha Fetoprotein (AFP<sup>e332</sup>T) in HLA-A2 Positive Subjects With Advanced Hepatocellular Carcinoma (HCC; CC #16708). Contact: Jeremy Burbanks-Ivey, (415) 502-4727, jeremy.burbanks-ivey@ucsf.edu.
- A Phase I, First-in-Human, Open Label, Dose Escalation Study of MGD009, A Humanized B7-H3 x CD3 Dual-Affinity Re-Targeting (DART) Protein in Patients with Unresectable or Metastatic B7-H3-Expressing Neoplasms and Neoplasms whose Vasculature Expresses B7-H3 (CC#16706). Contact: Jeremy Burbanks-Ivey, (415) 502-4727, jeremy.burbanks-ivey@ucsf.edu.
- A Phase I/Ib, Open-Label, Multicenter, Repeat-Dose, Dose-Selection Study of CPI-444 as Single Agent and in Combination with Atezolizumab in Patients with Selected Incurable Cancers

[CC#16702]. Contact: Katrina Sadang, (415) 476-2958, katrinagrace.sadang@ucsf.edu

- A Phase I, Multicenter, Open-Label Study of Oral Entrectinib (RXDX-101) in Adult Patients with Locally Advanced or Metastatic Cancer Confirmed to be Positive for NTRK1, NTRK2, NTRK3, ROS1 or ALK Molecular Alterations (CC#17951). Contact: Claire Hooker, (415) 885-3724, claire.hooker@ucsf.edu

Further information is available at [cancer.ucsf.edu/trials](http://cancer.ucsf.edu/trials).

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

**ASCO University is having a 2017 Year-End Sale offering discounts on ASCO Annual Meeting or Symposium captured presentations; and, ASCO-SEP, 5<sup>th</sup> Edition Book/eBook.** Discounts are valid through December 4<sup>th</sup> at <https://university.asco.org>.

**ASCO's Clinical Affairs Department provides 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, practice management (staffing, technology), practice transformation, and market analysis are available from the *Department*. For more information, visit [www.asco.org/practice-guidelines/practice-support](http://www.asco.org/practice-guidelines/practice-support).

**ASCO is launching its new Practice Engagement Program to help administrators, physicians, and other members of the care team navigate ASCO tools, programs, and resources available to help oncology practices respond to the changes occurring in the cancer care delivery system.** Building on an array of resources developed to help practices remain viable and thrive during this turbulent period, the new *Practice Engagement Team* will help participating practices learn more about the specific ASCO services and programs that can best support their needs. Learn more at [www.asco.org/advocacy-policy/asco-in-](http://www.asco.org/advocacy-policy/asco-in-)

action/new-practice-engagement-program-connects-practices-specific-resources.

**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. Learn more and enroll at [www.asco.org/practice-guidelines/practice-support/practicenet?et\\_cid=39764896&et\\_rid=933038345&linkid=Enroll+in+PracticeNET](http://www.asco.org/practice-guidelines/practice-support/practicenet?et_cid=39764896&et_rid=933038345&linkid=Enroll+in+PracticeNET).

**ASCO and *Innovative Oncology Business Solutions* (IOBS) have announced a new collaboration, ASCO COME HOME—an oncology medical home program designed to transition community oncology practices from volume-based to value-based care by structuring reimbursement around the full range of services needed by patients with cancer.** ASCO COME HOME will also prepare oncology practices for full implementation of the Quality Payment Program under MACRA. ASCO is currently accepting practices for the fee-based program. For more information, please visit [www.asco.org/practice-guidelines/practice-support/asco-consulting-services/asco-come-home](http://www.asco.org/practice-guidelines/practice-support/asco-consulting-services/asco-come-home).

**The November/December issue of ACCC's *Oncology Issues* includes articles entitled *Access: The First Step Toward Analyzing Precision Medicine Data; Optimizing Your EHR: Real-World Experiences with Electronic Health Records; Challenges to EHR Optimization for Cancer Programs—Workload, Cost, and Interoperability;* and, *An EMR-Driven Approach to Survivorship Care Plans*.** Visit [www.accc-cancer.org/oncology\\_issues](http://www.accc-cancer.org/oncology_issues) to read this issue.

**ACCC's 2017 *Patient Assistance and Reimbursement Guide* (updated September 2017) is an essential tool for cancer program staff to use in helping patients with issues related to the cost**

**of treatment and in meeting reimbursement challenges.** The *Guide* features a list of pharmaceutical and non-pharmaceutical patient assistance programs (PAPs), including directions on how to apply and links to enrollment forms. Visit [www.accc-cancer.org/publications/PatientAssistanceGuide.asp?](http://www.accc-cancer.org/publications/PatientAssistanceGuide.asp?) to access this resource. In addition, ACCC has developed a tool for accessing patient assistance and reimbursement programs for use on a desktop, table, or mobile device. The *Financial Advocacy Network* (FAN) app is available at [accc-fan-app.org](http://accc-fan-app.org). **ASH also has a webpage (at [www.hematology.org/Clinicians/Drugs/Programs/](http://www.hematology.org/Clinicians/Drugs/Programs/)) that provides a consolidated list of resources for hematologists and patients trying to access high cost hematologic drugs.** And, at NCCN's Reimbursement Resource Room ([www.nccn.org/reimbursement\\_resource\\_room/default.asp](http://www.nccn.org/reimbursement_resource_room/default.asp)) you can select a cancer diagnosis or supportive care indication and learn about reimbursement help and services available to you.

NCCN has published and/or updated their *Chemotherapy Order Templates, Clinical Practice Guidelines in Oncology, Drugs & Biologics Compendium, Evidence Blocks, Guidelines for Patients, Imaging Appropriate Use Criteria, and/or Radiation Therapy Compendium* for AIDS-Related Kaposi Sarcoma (V1.2018), B-cell lymphomas (V6.2017), chronic lymphocytic leukemia/small lymphocytic lymphoma (V2.2018), colorectal cancer screening (V2.2017), melanoma (V1.2018), occult primary (cancer of unknown primary; V1.2018), ovarian cancer (V4.2017), primary cutaneous B-cell lymphomas (V1.2018), soft tissue sarcoma (V1.2018), T-cell lymphomas (V1.2018), vulvar cancer (V1.2018). Go to [www.nccn.org](http://www.nccn.org) for more information.