ONCOLOGY ISSUES

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January | February 2016

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contents

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ACCC
Association of Community Cancer Centers

ONCOLOGY ISSUES
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FROM THE EDITOR

Patients First

BY CHRISTIAN DOWNS, JD, MHA

I'm always amazed by some of the marketing material that comes across my desk—*Are You Ready for Oncology 2.0?*, *NextGen Cancer Delivery*, and *How to Destroy Your Competition and Take All of Their Imaging Business*. Okay, I admit to taking some liberty with that last one, but you get the idea. What I find most interesting about this type of marketing collateral is not what it focuses on, but what it does *not* focus on—patients.

In December, ACCC convened a Supportive Care Summit to discuss the value of patient navigation, psychosocial distress screening, and survivorship care. Summit goals:

- Provide a forum for healthcare leaders and healthcare providers to discuss the current state of value as it relates to these patient-centered services and to identify future actions needed.
- Provide an opportunity for healthcare providers and participants to present existing and/or planned tools and resources.
- Build a collaborative dialogue among stakeholders interested in patient-centered care.

In 2016, ACCC, along with a few key partners, will launch a new program on patient-centric care. As part of this education initiative, we're going to work to define patient-centric care, showcase member programs and practices that do a stellar job of delivering patient-centric care, and then give you tools and resources to measure and improve patient-centric services at *your* cancer program.

In the meantime, this edition of *Oncology Issues* offers some great real-world examples of patient-centric cancer care. First, Paulette Zinkann and Linda Corrigan show how two cancer centers used their registrars to fill a critical role in each facility's lung cancer screening program. At one cancer center, the registrar is able to get out from behind her computer and interact directly with patients in the role of lung screening navigator. This article showcases patient-centered care that also delivers higher job satisfaction for the two registrars who find it "enormously rewarding" to be a part of a cancer care team that helps patients detect (and get treated for) lung cancer earlier!

Next, Chad Schaeffer gives us the charge to improve our cancer programs by improving patient engagement. To help us fully embrace the concept of patient engagement—and be successful at it—Schaeffer shares practical strategies to improve communication between providers and patients. Patients have a choice on where to go for treatment, and cancer programs that offer strong patient-centric services are often the number one choice of patients and family members.

In her article, Mandi Pratt-Chapman answers the question—what does a patient navigator do? Navigation is a core component of patient-centered care, and Pratt-Chapman details GW Cancer Institute's efforts to develop national, consensus-based core competencies for oncology patient navigators, including a corresponding online training module to equip these professionals with the knowledge and skills necessary to perform their role effectively and efficiently.

Finally, in our last feature article, Tricia Strusowski and Jeremy Stapp identify metrics to help cancer programs communicate how navigation programs positively impact patients and healthcare organizations as a whole. I think we can all agree that patient navigation is not only a patient-centered service—it is the right thing to do. The challenge is how to afford these non-reimbursed services. While we wait for public and private payers to catch up to the thinking of credentialing bodies, such as the American College of Surgeons Commission on Cancer, and esteemed organizations like the Institute of Medicine, and create payment codes for these patient-centric services, what a great tool for making the argument to key stakeholders and hospital leadership that patient navigation is needed *now*. OI

5 Reasons to Come to Capitol Hill

BY STEVEN L. D'AMATO, BSPharm, BCOP

ACCC is the leading *education* and *advocacy* organization for the multidisciplinary cancer team. In this column, I'd like to focus on the advocacy piece. In broadest terms, ACCC advocates for quality cancer care. ACCC also empowers you—the membership—to speak out on issues of importance to your programs, patients, and community. One the most powerful ways ACCC does this is through our annual Capitol Hill Day. For most of you, Congress and the White House may seem far removed from what you do on a daily basis—caring for patients with cancer. So why should you take time out from your busy program or practice to join us for Capitol Hill Day 2016? Here are five compelling reasons:

1. ***You can help ensure the financial viability of your cancer program.*** To treat our patients, we must first be able to keep our doors open. That means adequate reimbursement for the life-saving services we provide. There is a paradigm shift happening in healthcare as we move from a fee-for-service model to value-based care. Shortly after last year's ACCC Hill Day, Congress voted to repeal the SGR and enacted MACRA. We must be a part of the discussion as these new models evolve to ensure that we continue to be adequately reimbursed for the services we provide. Everyone loses if a cancer program or oncology practice is forced to close its doors.
2. ***We are in a unique position to advocate for our patients and programs.*** Cancer care providers are the frontline in the fight against this devastating disease, and our representatives want to hear from us. Cancer is a disease that touches everyone. Whether or not someone has experienced cancer firsthand, chances are that someone close to them or someone they know has been affected by cancer. Capitol Hill Day allows you the opportunity to talk with your elected representatives about the challenges and successes your patients and your cancer programs face daily.
3. ***Access. Access. Access.*** The first step in the fight against cancer is the ability to access treatment, yet too many of our patients continue to struggle with this issue. Whether the barrier to care is related to financial toxicity—a patient's ability to pay for treatment—or patients living in rural areas who must travel far from home to receive care or patients who are having difficulty navigating a fragmented and complex healthcare system, as cancer care providers we must do everything we can to ensure all Americans have equal access to care. Often Congressional action is required. Where would we be without legislation that mandated reimbursement for off-label drug use? More recently, we've had great success with legislation related to oral parity. Yet legislative action does not happen in a vacuum. If we don't share our challenges—and our solutions—with those who can create change, then change will not happen.
4. ***Empowerment.*** Anecdotally, every ACCC member who has participated in Capitol Hill Day has talked about what a positive and rewarding experience it has been. Having your voice be heard—alongside those of your colleagues from around the country—and knowing that in some small way you are contributing to improving the care of cancer patients is a powerful feeling. And this year's Capitol Hill Day promises to surpass the successes we've experienced in the past. Learn more about these changes and how ACCC continues to improve Capitol Hill Day on page 11.
5. ***ACCC makes it easy.*** Participants in this year's Capitol Hill Day will receive an orientation and hands-on training so that you'll know what to expect and be well-prepared for your scheduled visits with legislators.

If you cannot attend this year's Capitol Hill Day, I urge you to pass this on to a colleague who can, and I look forward to seeing you on March 1-2, 2016. OI

Coming in Your 2016 *ONCOLOGY ISSUES*

- The Cancer Care Collaborative—Where Patients are an Active Member of the Cancer Care Team
- Building Bridges, Breaking-down Barriers: One Psycho-Oncology Program's Approach to Quality Patient-Centered Psychosocial Care
- A Support Program for Providers that Prevents Burnout and Improves Care
- The Oncology Nursing Fellowship Program: A Pipeline for the Future
- Health Info on the Go: Community Outreach at the Farmer's Market
- Developing an Oncology IT Strategy
- New Technology: The Racetrack Microtron
- Community Health Needs Assessments: How Your Cancer Program Can Prepare
- *2015 ACCC Innovator Award Winner.* Engaging Patients & Assisting PCPs in Lung Cancer Screening

more online @ accc-cancer.org

INFO

Lung Cancer Resources

ACCC member programs share tools and resources related to lung cancer screening. Sample letters to patients and referring providers, patient risk questionnaires, lung cancer screening assessment forms, process flowcharts, and more. accc-cancer.org/lung.

TOOL

ACCC Oncology Drug Database Updated

Newly-approved drugs, ICD-10 codes, and more. The most recent coding and reimbursement information at your fingertips: accc-cancer.org/drugdatabase.

PODCAST

Missed the ICLIO 1st Annual Conference?

Access on-demand presentations and audio podcasts from the groundbreaking conference. Learn at your leisure and enhance your immuno-oncology IQ today! Sessions include: Positioning Your Program to Tackle Immuno-Oncology Integration Challenges and Evolving Indications in Cancer Immunotherapy. accc-iclio.org/resources/iclio-conference-presentation-slides.

EVENT

Experience Capitol Hill Day!

Join your state delegation and make your voice heard on Capitol Hill, Wed., March 2, 2016. Meet one–on–one with legislators to advocate on key issues impacting access to quality cancer care. Use your voice to positively influence the future of community oncology. Learn more about Capitol Hill Day at: accc-cancer.org/HillDay.

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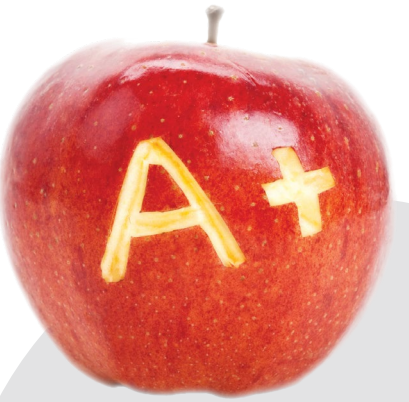
Healthcare spending grew 3.4% in 2014, with more dollars going to brand drugs; healthcare spending averaged $4,967 per individual in 2014—up $163 from 2015.

Source. Health Care Cost Institute. 2014 Health Care Cost and Utilization Report. healthcostinstitute.org/2014-health-care-cost-and-utilization-report.

The CAPC Palliative Care Report Card

- The number of hospital palliative care teams in the U.S. continues to increase.
- For-profit hospitals are less likely to provide palliative care services than nonprofit hospitals. Only **23%** of for-profit hospitals have palliative care; not-for-profit hospitals are **7** times more likely to have a palliative care team than for-profits.
- While the overall 2015 grade was a **B**—unchanged from 2011—**1/3** of hospitals with 50+ beds report no palliative care services, and **1/3** of states received a grade of **C** or **D**.
- Availability of palliative care services varies widely by region. Less than **1/3** of hospitals in AK, MS, and AL reported a palliative care team; in contrast, persons in the NE and mountain regions have almost universal access to hospital palliative care.



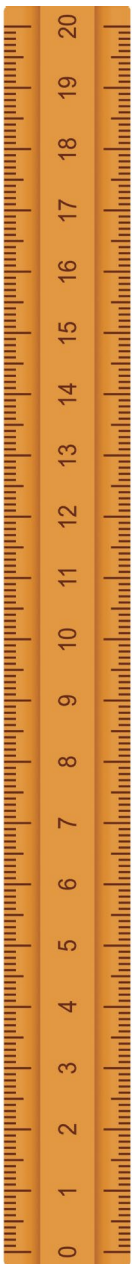
Source. CAPC. America's Care of Serious Illness: 2015 State-by-State Report Card on Access to Palliative Care in Our Nation's Hospitals. reportcard.capc.org.

facts

4 Staffing Tips for Oncology Practices

- Hire right, the first time.
- Let staff work to the level of their license.
- Find the right number of staff, for the right role.
- Employ advanced practitioners.

Source. Sprey E. Staffing Your Medical Practice for the Future. Physicianpractice.com.



How Does *Your* State Measure Up?

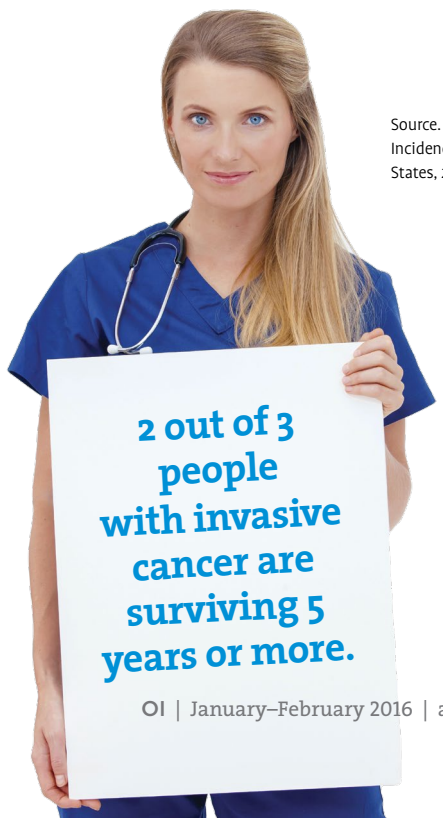
Key findings from a progress report on state legislative activity to reduce cancer incidence and mortality:

- Since August 2014, **Nevada** is the **only state** to significantly increase its tobacco taxes.
- **Not one state** has implemented a comprehensive, statewide smoke-free law covering all workplaces, including bars and restaurants, since 2012.
- States are currently spending **less than 2%** of tobacco tax revenue and Master Settlement Agreement payments on programs to reduce tobacco use.
- **Only 9 states**—CT, IN, MA, ME, MN, ND, OH, PA, and VT—provide comprehensive tobacco cessation coverage under Medicaid that includes individual and group counseling and all 7 FDA-approved tobacco cessation medications.
- States should strengthen **physical education** requirements in schools and implement critical **nutrition standards** for school meals to reduce cancer burden.
- Laws prohibiting indoor tanning devices for everyone under the age of 18 reduce skin cancer incidence and mortality rates.

Source. The American Cancer Society Cancer Action Network. acscan.org/content/wp-content/uploads/2015/08/HDYMU-2015.pdf.

Since 2006, the RAC program has saved Medicare more than $10 Billion

Source: *BNA Health Care Daily Report*. Aug. 5, 2015.



Source. CDC. Invasive Cancer Incidence and Survival – United States, 2011. cdc.gov/mmwr.

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An Easy—and Empowering—New Year's Resolution

BY LEAH RALPH

New Year's resolutions are the very definition of trope: a common or overused theme. But they don't have to be. Today I'm asking you to set aside the old standbys of weight loss or more exercise or less spending on ridiculously over-priced boots, and look at the bigger picture—specifically what you can do to improve the lives of the cancer patients you treat each and every day.

Last year ACCC mobilized members from 23 states and held more than 80 meetings with legislators on Capitol Hill about issues of importance to the oncology community. We effected real change. Just one month after our visits, Congress passed a permanent repeal to the Sustainable Growth Rate (SGR) formula, guaranteeing predictable physician payment rates and setting in motion a wave of Medicare reimbursement reforms. Our voices made a difference!

This year, we're growing our program and making important improvements: more comprehensive training, more face-time with legislators, and, most importantly, less prescriptive dialogue. In other words, we're not going to ask you to repeat by rote messages that you may (or may not) understand. Why should we tell you what to say—when your stories are the ones that legislators most want to hear? What's going on in your community? What's keeping you up at night? What are the stressors that are having a negative impact on your cancer patients?

These changes are part of my New Year's Resolution to improve the engagement of ACCC members on advocacy issues. So whether you've attended one of our Capitol Hill Days or you're an "advocacy newbie," here are three solid reasons to make the ACCC 2016 Capitol Hill Day your New Year's resolution:

1. ***More comprehensive training.*** ACCC's policy team will host webinars and conference calls to prepare you for your congressional meetings. A comprehensive training and cocktail reception will be held Tuesday, March 1, with an additional advocacy review the morning of Wednesday, March 2. Come share your stories with colleagues and practice with staff.
2. ***More face-time with legislators.*** Gather for lunch with your ACCC colleagues and congressional members to discuss key issues that impact your program, such as reimbursement for supportive care services, drug costs, staffing shortages, and how excessive data collection and reporting is cutting into the time you can spend on direct patient care.
3. ***Less focus on specific bill numbers.*** You don't need to be a "policy expert" or familiar with specific legislation in 2016. It's a chance to share *your story* so lawmakers understand how policy impacts oncology care in *your community*. (Now, if you want bill numbers, we'll have those too.)

Policymakers rely on healthcare providers—not policy staff—to provide real-world perspectives on policy issues that matter. As the leading national multi-site, multidisciplinary organization, ACCC is uniquely positioned to serve as a resource. This is our value to legislators. The diversity and sophistication of our membership requires a nuanced, balanced approach to policy challenges—and we stand ready to offer insights on how cancer care is delivered today.

As our experts, we invite you to come to Washington, D.C., to do what you do best. Talk about your programs, your processes, and most importantly your patients. ACCC staff is standing by if you need assistance developing your story, and will handle all of the legwork—scheduling meetings, arming you with background materials and talking points, and even accompanying you to congressional offices. Our annual Capitol Hill Day is an important, and rewarding, opportunity to advocate for policy change. So consider making it your New Year's Resolution and help to put the voice of the cancer care team and cancer patient at the center of policy decisions. Learn more at accc-cancer.org/HillDay.

Leah Ralph is ACCC director of Health Policy.

Oncology Reimbursement Update 2016

BY CINDY PARMAN, CPC, CPC-H, RCC

There is a popular song by Demi Lovato called *Here We Go Again* that includes the lyrics "You think that by now I'd know, 'cause here we go go go again." True words in many settings, but especially with the 2016 final regulations, code updates, and other reimbursement changes. Again this year oncology practices and cancer programs scramble to update their respective chargemasters, fee schedules, and other reimbursement documents to ensure compliance with coding and billing guidelines. To help ACCC members with this arduous task, here is a concise coding update, followed immediately by regulatory updates for both the hospital and practice setting. Be sure to pass this critical information on to all of your billers and coders. And—if they are not receiving *Oncology Issues* as part of their membership benefit—email membership@accc-cancer.org today to ensure that all of your billers and coders receive critical coding, billing, and compliance information year round.

New and Revised Procedure Codes

Each year there are new Current Procedural Terminology (CPT) codes, revised CPT codes, and updates to coding guidelines. For calendar year (CY) 2016, two new codes have been created for prolonged clinical staff services performed under the direct supervision of a physician or qualified non-physician healthcare professional in a non-facility setting:

- **+99415**: Prolonged clinical staff service (the service beyond the typical service time) during an evaluation and management service in the office or outpatient setting, direct patient contact with physician supervision; first hour (List separately in addition to code for outpatient E/M service).
- **+99416**: Each additional 30 minutes (List separately in addition to code for primary procedure).

These codes cannot be reported by facilities (e.g., hospitals, skilled nursing facilities), and the time spent performing separately reportable services is not counted toward the prolonged services time. Prolonged staff time of less than 45 minutes total duration on a given date is not separately reported and these codes cannot be reported for more than two simultaneous patients.

There are also two new codes for soft tissue marker placement:

- **10035**: Placement of soft tissue localization device(s) (e.g., clip, metallic pellet, wire/needle, radioactive seeds), percutaneous, including imaging guidance; first lesion.
- **+10036**: Each additional lesion (List separately in addition to code for primary procedure).

If a more specific site descriptor than soft tissue is applicable (e.g., breast), use the site-specific codes for marker placement at that site. Procedure codes **10035** and **+10036** are reported only once per target, regardless of the number of markers used to define the target.

Once again there are a number of code changes for radiation oncology, many of which consolidate basic dosimetry calculations into other procedure codes. There is an update to the notes in the *CPT® Manual*, that states calculations (code **77300**) is not reported separately with codes **77306**, **77307**, **77316**, **77317**, **77318**, **77321**, **77767**, **77768**, **77770**, **77771**, **77772**, **0394T**, or **0395T**.

High-dose rate brachytherapy procedure codes **77785**, **77786**, and **77787** have been deleted effective Jan. 1, 2016, and replaced with the following codes:

- **77770**: Remote afterloading high-dose rate radionuclide interstitial or intracavitary brachytherapy, includes basic dosimetry, when performed; 1 channel.
- **77771**: 2-12 channels.
- **77772**: Over 12 channels.

As part of the revised definitions, all of these brachytherapy administration codes include basic dosimetry calculations. This means that code **77300** (basic radiation dosimetry calculation) will not be reported on the same day as the HDR brachytherapy codes. The following codes are new for CY 2016 and also include basic calculations:

- **77767**: Remote afterloading high-dose rate radionuclide skin surface brachytherapy, includes basic dosimetry, when performed; lesion diameter up to 2.0 cm or 1 channel.
- **77768**: Lesion diameter over 2.0 cm and 2 or more channels or multiple lesions.

In addition to the new and revised codes for radionuclide HDR, procedure code **0182T** has been deleted and replaced by the following codes for electronic brachytherapy:

- **0394T**: High-dose rate electronic brachytherapy, skin surface application,

per fraction, includes basic dosimetry, when performed.
- **0395T**: High-dose rate electronic brachytherapy, interstitial or intracavitary treatment, per fraction, includes basic dosimetry, when performed.

In the same manner as the other brachytherapy procedure codes, these electronic brachytherapy treatments include the charge for basic calculations. There have also been coding changes relating to the interstitial brachytherapy services. Procedure codes **77776** (simple interstitial brachytherapy) and **77777** (intermediate interstitial brachytherapy) have been deleted. For CY 2016, unlisted procedure code **77799** (unlisted procedure, clinical brachytherapy) will be reported when the service constitutes simple or intermediate interstitial brachytherapy.

The procedure code for complex interstitial brachytherapy has been revised to include supervision, handling, and loading of the radiation source:
- **77778**: Interstitial radiation source application, complex, includes supervision, handling, and loading of radiation source, when performed.

This means that procedure code **77790** (supervision, handling, loading of radiation source) will not be reported when a complex interstitial brachytherapy procedure is performed. Last, procedure code **77417** has received an updated definition: Therapeutic radiology port image(s). This code, which stated "port films" in the past, has been clarified as reporting either film or electronic imaging.

HCPCS Level II Code Updates

There are several new HCPCS modifiers, some of which are discussed in more detail in other sections of this article:
- **Modifier CP**: Adjunctive service related to a procedure assigned to a comprehensive ambulatory payment classification (C-APC) procedure, but reported on a different claim.
- **Modifier CT**: Computed tomography (CT) services furnished using equipment that does not meet each of the attributes of the National Electrical Manufacturers Association (NEMA) XR-29-2013 standard.
- **Modifier EX**: Expatriate beneficiary.
- **Modifier ZA**: Novartis/Sandoz.

A biosimilar product has no clinically meaningful differences from a previously-approved reference product, only minor differences in clinically inactive components. The first biosimilar approved by the Food and Drug Administration (FDA) is Zarxio, which is a biosimilar version of filgrastim. HCPCS modifier ZA will be appended to the following HCPCS Level II drug code to identify Zarxio. For CY 2016, the definition of the code for filgrastim is:
- **J1442**: Injection, filgrastim (G-CSF), 1 microgram.

A new code for TBO-filgrastim (Granix) has been created: **J1447**: Injection, TBO-filgrastim, 1 microgram; prior code **J1446**: Injection, TBO-filgrastim, 5 micrograms has been deleted. Also, a new Q-code was added in July 2015 for biosimilar versions of filgrastim. It appears that code **Q5101**: Injection, filgrastim (G-CSF), biosimilar, 1 microgram, will be reported for any filgrastim biosimilar, and a modifier such as ZA will be added to show which particular biosimilar was administered. Additional instructions will be forthcoming from CMS to clarify these billing requirements.

Compounded drugs are made to order for a specific patient; for example, to provide a combination of drugs that is not available commercially or a liquid version of a drug that is only available in pill form. Compounded drugs were reported with **modifier JF** between April 2015 and July 2015; this modifier was subsequently deleted. The following code update was effective Jan. 1, 2016, for compound drugs: **J7999**: Compounded drug, not otherwise classified; code **Q9977**: Compounded drug, not otherwise classified, has also been deleted.

In 2016 there are again new and revised codes for clotting factors. CPT code **J7205**: Injection, factor VIII FC fusion (recombinant), per IU, has replaced these two deleted codes: **C9136**: Injection, factor VIII, FC fusion protein (recombinant), per IU, and **Q9975**: Injection, factor VIII FC fusion (recombinant), per IU.

There is also a new 2016 code for the netupitant/palonosetron combination. CPT code **J8655**: Netupitant 300 mg and palonosetron, replaces deleted codes **C9448**: Netupitant 300 mg and palonosetron 0.5 mg, oral, and **Q9978**: Netupitant 300 mg and palonosetron 0.5 mg.

Table 1, page 14 identifies CY 2016 replacement codes for chemotherapy drugs. Other drugs with replacement codes for CY 2016 include those shown in Table 2, page 14.

Tacrolimus is an immunosuppressive drug; a new code has been created and the existing code has been revised to distinguish between the two brands:
- **J7508**: Tacrolimus, extended release, (Astragraf XL), oral, 0.1 mg.
- **J7503**: Tacrolimus, extended release, (Envarsus XR), oral, 0.25 mg.

Alemtuzumab (Lemtrada) is used to treat multiple sclerosis; there is a single replacement code **J0202**: Injection, alemtuzumab, 1 mg, for the two deleted HCPCS codes: **J9010**: Injection, alemtuzumab, 10 mg and **Q9979**: Injection, alemtuzumab, 1 mg.

New drug HCPCS codes effective Jan. 1, 2016, include:
- **J7121**: 5% dextrose in lactated Ringer's infusion, up to 1,000 cc.
- **J1575**: Injection, immune globulin/hyaluronidase (Hyqvia), 100 mg immune globulin.

HCPCS codes that were deleted on Jan. 1, 2016, include:
- **J0886**: Injection, epoetin alfa, 1,000 units (for ESRD on dialysis).
- **S3721**: Prostate cancer antigen 3 (PCA3) testing.
- **S3854**: Gene expression profiling panel for use in the management of breast cancer treatment.
- **S3890**: DNA analysis, fecal, for colorectal cancer screening.

- **S5011**: 5% dextrose in lactated ringer's, 1,000 ml.

Effective Oct. 1, 2015, CMS authorized the use of the following HCPCS Level II code:

- **C9743**: Injection/implantation of bulking or spacer material (any type) with or without imaging guidance (not to be used if more specific code applies).

This code may apply when a gel or other substance is inserted into a space created by pushing the prostate away from the rectum (performed prior to radiation treatment in some facilities).

There is also a new HCPCS code, effective Jan. 1, 2016, for Pd-103 brachytherapy sources:

- **C2645**: Brachytherapy planar source, palladium-103, per square millimeter.

Effective Jan. 1, 2016 CMS will bundle basic dosimetry calculations (code **77300**) into 3D computer planning (code **77295**). These new bundling instructions are included in Chapter 9 of the National Correct Coding Policy Manual located at: cms.gov/Medicare/Coding/NationalCorrectCodInitEd/index.html?redirect=/nationalcorrectcodinited. This means that both professional and technical charges for a 3D plan will include basic dosimetry calculations; as a result, this instruction applies to hospitals, freestanding treatment centers, and physician charges. Therefore, when code **77295** is billed after Jan. 1, 2016, the facility or physician practice will continue to report treatment devices, but will not also report basic calculations.

In addition to the codes listed in this article, there are a number of changes to HCPCS quality measure codes, diagnostic imaging agents, and other medical supplies. Remember that the existence of a procedure or supply code *does not* guarantee reimbursement; payment for a service depends on the patient's insurance policy, medical necessity, and other determining factors. OI

Table 1. CY 2016 Replacement CPT Codes for Chemotherapy Drugs

2016 CODES		DELETED 2015 CODES	
J9271	Injection, pembrolizumab, 1 mg	C9027	Injection, pembrolizumab, 1 mg
J9308	Injection, ramucirumab, 5 mg	C9025	Injection, ramucirumab, 5 mg
J9032	Injection, belinostat, 10 mg	C9442	Injection, belinostat, 10 mg
J9039	Injection, blinatumomab, 1 mcg	C9449	Injection, blinatumomab, 1 mcg
J9299	Injection, nivolumab, 1 mg	C9453	Injection, nivolumab, 1 mg
J2860	Injection, situximab, 10 mg	C9455	Injection, situximab, 10 mg

Table 2. Select Drugs with Replacement Codes for CY 2016

2016 CODES		DELETED 2015 CODES	
J1443	Injection, ferric pyrophosphate citrate solution, 0.1 mg of iron	Q9976	Injection, ferric pyrophosphate citrate solution, 0.1 mg of iron
J0596	Injection, C1 esterase inhibitor (recombinant), Ruconest, 10 units	C9445	Injection, C-1 esterase inhibitor (recombinant), Ruconest, 10 units
J7512	Prednisone, immediate release or delayed release, oral, 1 mg	J7506	Prednisone, oral, per 5 mg
J3380	Injection, vedolizumab, 1 mg	C9026	Injection, vedolizumab, 1 mg
J2502	Injection, pasireotide long acting, 1 mg	C9454	Injection, pasireotide long acting, 1 mg

Hospital Regulatory Update

BY CINDY PARMAN, CPC, CPC-H, RCC

The Hospital Outpatient Prospective Payment System (HOPPS or OPPS) is not intended to be a fee schedule, in which separate payment is made for each coded line item. Instead, the OPPS is currently a prospective payment system that packages some items and services, but not others. The overarching goal of the Centers for Medicare & Medicaid Services (CMS) is to make payments for all services covered under the OPPS more consistent with those of a prospective payment system and less like those of a per-service fee schedule. For CY 2016, CMS will continue to base payments on geometric mean costs.

In the 2016 OPPS Final Rule, CMS estimates that total payments, including the beneficiary cost share, to the approximately 4,000 facilities paid under OPPS will decrease by approximately $133 million compared to CY 2015 payments. Outpatient hospital payment rates will decrease by -0.3 percent and CMS will continue the statutory 2.0 percentage point reduction in payments for hospitals that fail to meet the hospital outpatient quality reporting requirements. The CY 2015 conversion factor of $74.173 decreases to $73.725 in 2016, but for hospitals that fail to meet the OQR (Outpatient Quality Reporting) requirements, the conversion factor will drop to $72.251.

CMS will also continue the policy of providing additional payments to the 11 designated cancer hospitals so that the hospitals' payment-to-cost ratio, with the adjustment, is equal to the weighted average for the other OPPS hospitals.

And last, CMS will continue to make an outlier payment that equals 50 percent of the amount by which the cost of furnishing the service exceeds 1.75 times the APC (ambulatory payment classification) payment amount when both the 1.75 multiple threshold and the final fixed dollar threshold of $3,250 are met.

New Code Process Changes

In the 2015 OPPS Proposed Rule, CMS outlined plans for changing the way it handles new procedure codes and this plan was adopted as proposed. Beginning with the 2016 rulemaking process, CMS published APC assignments for new codes as part of the Proposed Rule, because the codes and code descriptors were available in a timely fashion.

Packaged Services

For CY 2016, CMS will continue to unconditionally or conditionally package drugs and biologicals that function as supplies when used in a surgical procedure or a diagnostic test. In addition, CMS will continue to package image guidance, including guidance performed during radiation therapy treatment delivery.

Under current policy, certain clinical laboratory tests listed on the Clinical Laboratory Fee Schedule (CLFS) are packaged into the payment of the primary service performed the same outpatient stay. This means that laboratory tests are only separately paid under the OPPS when the lab test is the only service provided to the patient during that outpatient encounter, or the test is performed on the same date as the primary procedure but for a different diagnosis than the other outpatient hospital services. CMS has clarified that some hospital outpatient stays span more than a single date of service (such as observation); laboratory services provided during this outpatient stay are considered to be integral, supporting, dependent, or adjunctive to the primary service (unless they meet one of the documented exceptions).

The 2016 OPPS Final Rule states that the hospital should continue to append **modifier L1** (separately payable laboratory test) on the clinical laboratory procedure code to indicate when the specified billing exceptions are met. Of importance to oncology programs, all molecular pathology tests will be excluded from this packaging policy for CY 2016.

CMS has continued to review categories of integral, ancillary, supportive, dependent, or adjunctive items and services for which payment would be appropriately packaged into the payment of the primary service they support. For CY 2015, CMS conditionally packaged payment for ancillary services with a geometric mean cost of less than or equal to $100 (primarily minor diagnostic tests and procedures). In the 2016 OPPS Final Rule, CMS states that the $100 cost target was a basis for selecting the initial set of APCs for conditional packaging. For CY 2016, CMS will not limit conditional or unconditional packaging to APCs with a geometric mean cost of $100 or less.

After consideration of all comments received on the 2016 OPPS Proposed Rule, CMS will conditionally package ancillary

services assigned to APCs **5734** (Level 4 minor procedures), **5673** (Level 3 pathology), and **5674** (Level 4 pathology) beginning Jan. 1, 2016. Of importance to oncology departments, **APC 5674** includes procedure codes for the collection of blood from a vascular access device (CPT codes **36591**, **36592**).

Radiosurgery Comprehensive APC

With the advent of C-APCs (Comprehensive-APCs), the Outpatient Prospective Payment System now includes of a wide array of payment methodologies. A comprehensive-APC, by definition, will provide a single payment that includes the primary service and all adjunct services performed to support the delivery of the primary service. For services that trigger a comprehensive-APC payment, the comprehensive-APC will treat all individually reported codes on the claim as representing components of the comprehensive service, resulting in a single prospective payment for the comprehensive service. This means that hospitals will continue to report procedure codes for all services performed, but will receive a single payment for the total service and collect a single beneficiary co-payment for the procedure.

Effective Jan. 1, 2015, CMS implemented a C-APC for single fraction stereotactic radiosurgery (SRS). The intent of this reimbursement change was to ensure that all services performed in connection with SRS were billed on the same hospital claim form, even if the related services (such as patient visit and computer planning) occurred on different service dates. In the 2016 OPPS Final Rule, CMS states that it is aware that certain "planning and preparation" services that are integrally associated with the direct provision of SRS have been incorrectly billed on separate claim forms. This generally occurred because of the different billing patterns when services are performed on Cobalt-60 treatment equipment as opposed to linear accelerator SRS. Cobalt-60 Gamma Knife® treatments typically included all services on a single claim form, while facilities performing SRS on linear accelerators tended to charge simulation, patient visits, and planning services on separate claim forms. CMS stated that payment for these pre-procedure services performed prior to treatment administration was included in the C-APC allowance, and should not have been separately billed and separately paid. As a result of the SRS claims data findings, CMS will remove the following services from the C-APC payment calculation:

- CT and/or MRI localization
- Simulation
- 3D computer planning
- Continuing physics.

These services, represented by CPT codes **77014**, **77011**, **70551**, **70552**, **70553**, **77280**, **77285**, **77290**, and **77295** are the *only* codes CMS plans to remove from the C-APC bundle. Other services, such as the immobilization device, calculations, and beam-shaping devices are still included in the C-APC reimbursement (when performed within one month of treatment delivery). For CY 2016 and CY 2017, these codes will not be included in the C-APC payment for SRS even if they are furnished on the same date of service. The 2016 OPPS Final Rule states, in part:

"However, we remind hospitals that procedure codes related to the primary SRS service should either be reported on the same claim, or, if furnished on a different date than the primary service, must include modifier 'CP' that we are adopting in this Final Rule with comment period."

This means that any service that is integral, ancillary, supportive, dependent, and adjunctive to the primary service identified by HCPCS codes **77371** or **77372** and that is reported on a different claim than the primary service must be billed with this HCPCS modifier:

- **Modifier CP**: Adjunctive service related to a procedure assigned to a comprehensive ambulatory payment classification (C-APC) procedure, but reported on a different claim.

CMS expects providers to identify all adjunctive services provided during the 30-day period prior to SRS. This means the hospital has two choices when billing services for outpatient cranial radiosurgery:

1. All services related to the SRS procedure are billed on one claim submission, regardless of the date of service. This includes all preparatory and planning services that occur in the 30-day period leading up to treatment—from the initial patient visit through the delivery of radiosurgery.
2. The hospital can report preparatory and planning services on separate claims, as they occur, appending modifier CP to each procedure code that constitutes a service related to the SRS procedure. Every service that occurs up to 30 days prior to treatment related to the single-fraction SRS procedure billed on a separate claim must have this modifier.

CMS will then allow separate payment for the 10 procedure codes considered to be "unbundled" from the C-APC and include all other services in the C-APC reimbursement. CMS intends to issue further subregulatory guidance on use of the modifier CP with respect to SRS services prior to Jan. 1, 2016.

Radiation Oncology Services

Section 1833(t)(2)(A) of the Social Security Act requires CMS to develop a classification system for covered outpatient department (OPD) services. In accordance with these provisions, CMS developed a grouping classification system, referred to as Ambulatory Payment Classifications (APCs). The APCs are organized so that each group is homogenous—both clinically and in terms of resource use. As part of its continuing review of the structure of APC families, CMS reviewed and is restructuring nine APC clinical families for CY 2016. This includes renumbering some APCs so that the levels in each family have consecutive APC numbers. In some cases, CMS also consolidated procedures into a smaller number of APCs.

The APCs for radiation oncology services have been significantly impacted in CY 2016 by this restructuring. There will be a four-level configuration for Therapeutic Radiation Treatment Preparation APCs:

- **APC 5611**: Level 1 Therapeutic Radiation Treatment Preparation.
- **APC 5612**: Level 2 Therapeutic Radiation Treatment Preparation.
- **APC 5613**: Level 3 Therapeutic Radiation Treatment Preparation.
- **APC 5614**: Level 4 Therapeutic Radiation Treatment Preparation.

As a result of comments received regarding planning resources expended, CMS has agreed to assign procedure code **77307** (teletherapy isodose plan; complex) to new **APC 5613** and code **77306** (teletherapy isodose plan; simple) to new **APC 5612**.

CMS also took an opportunity to address simulation services performed prior to IMRT planning in the 2016 OPPS Final Rule. The IMRT computer planning code (**77301**) will be assigned to the highest level APC in the group, **APC 5614**. CMS reminded hospitals that the Medicare Claims Processing Manual, Chapter 4, Section 200.3.2, includes the following directive (effective Jan. 1, 2008):

"Payment for the services identified by CPT® codes ***77014***, ***77280***-***77295***, ***77305***-***77321***, ***77331***, ***77336***, *and* ***77370*** *is included in the APC payment for IMRT planning when these services are performed as part of developing an IMRT plan that is reported using CPT code* ***77301****. Under those circumstances, these codes should not be billed in addition to CPT code* ***77301*** *for IMRT planning."*

In addition to the CMS Manual guidance, there is National Correct Coding Initiative (NCCI) guidance in the NCCI Policy Manual for Medicare Services, Chapter 9, Page IX-17, which states:

"Intensity modulated radiotherapy (IMRT) plan (CPT® code ***77301****) includes therapeutic radiology simulation-aided field settings. Simulation field settings for IMRT should not be reported separately with CPT® codes* ***77280*** *through* ***77295****. Although procedure-to-procedure edits based on this principal exist in NCCI for procedures performed on the same date of service, these edits should not be circumvented by performing the two procedures described by a code pair edit on different dates of service."*

While the hospital guidance was implemented Jan. 1, 2008, the NCCI guidance added the same criteria for physicians and freestanding centers effective Jan. 1, 2014. CMS also indicated its intent to clarify this coding guidance going forward as follows:

"Payment for services identified by CPT codes ***77014***, ***77280*** *through* ***77295***, ***77305*** *through* ***77321***, ***77331***, *and* ***77370*** *is included in the APC payment for CPT code* ***77301*** *(IMRT planning). These codes should not be reported in addition to CPT code* ***77301*** *(on either the same or a different date of service) unless these services are being performed in support of a separate and distinct non-IMRT radiation therapy for a different tumor."*

This clarification means that the provider of service will *not* charge for an initial simulation or a verification simulation associated with an IMRT plan. It appears that this coding guidance will be included in the 2016 edition of the National Correct Coding Policy Manual; as a result, it will apply universally to hospitals, freestanding radiation treatment centers, and physicians.

There were a number of comments and CMS responses concerning the resources expended for specific radiation therapy procedures. For CY 2016, there will be seven levels for Radiation Therapy APCs and final APC code assignments to these complexity levels (Table 3, below).

For CY 2016, CMS will maintain intraoperative radiation therapy (IORT) codes **77424** and **77425** in newly renamed and renumbered **C-APC 5093** (Level 3 Breast/Lymphatic

Table 3. CY 2016 Radiation Therapy APCs & Final APC Code Assignments

2016 APC	TITLE	CODES ASSIGNED TO APC
5621	Level 1 Radiation Therapy	77401, 77402, 77407, 77789, 77799
5622	Level 2 Radiation Therapy	0394T, 77412, 77422, 77600, 77750, 77767, 77768
5623	Level 3 Radiation Therapy	77385, 77386, 77423, 77470, 77520, 77610, 77615, 77620, 77761, 77762
5624	Level 4 Radiation Therapy	0395T, 77605, 77763, 77770, 77771, 77772, 77778
5625	Level 5 Radiation Therapy	77522, 77523, 77525
5626	Level 6 Radiation Therapy	77373
5627	Level 7 Radiation Therapy	77371, 77372

Surgery & Related Procedures). CMS will also continue paying for low-dose rate prostate brachytherapy using composite **APC 8001**. In order for the hospital to receive the higher composite APC reimbursement, both code **77778** (Interstitial radiation source application; complex) and **55875** (Transperineal placement of needles or catheters into prostate for interstitial radioelement application with or without cystoscopy) must be billed on the same claim.

Medical Oncology & Hematology Services

For CY 2016, payment for the acquisition and pharmacy overhead costs of separately payable drugs and biologicals that do not have pass-through status will continue to be set at the statutory default of average sales price (ASP)+6 percent. In addition, CMS will pay for biosimilar biological products based on the payment allowance for the product as determined under section 1847A of the Social Security Act. CMS will also extend pass-through payment eligibility to biosimilar biological products and set payment at the difference between the payment amount of the product as determined under section 1847A of the Act, and otherwise applicable Hospital Outpatient Department fee schedule amount.

Again for CY 2016, CMS finalized the proposed policy to continue to establish payment rates for blood and blood products using a blood-specific cost-to-charge methodology. In addition, CMS will pay for blood clotting factors at ASP+6 percent, consistent with the payment for other non-pass-through, separately payable drugs and biologicals and to continue the policy of paying a furnishing fee using an updated amount (to be announced at a later date).

Effective Jan. 1, 2016, the HCPCS Workgroup established three new HCPCS codes for pathogen-reduced blood products:

- **P9070**: Plasma, pooled multiple donor, pathogen reduced, frozen, each unit.
- **P9071**: Plasma (single donor), pathogen reduced, frozen, each unit.
- **P9072**: Platelets, pheresis, pathogen reduced, each unit.

CMS clarified the definition of "pathogen reduction" as describing various techniques (including treatment with Amotosalen and UVA light) used on blood products to eliminate certain pathogens and reduce the risk of transfusion-associated infections.

Section 1833 of the Social Security Act permits CMS to make pass-through payments for a period of at least two, but not more than three years after the product's first payment as a hospital outpatient service under Medicare Part B. The long-standing practice has been to provide pass-through payment for a period of two to three years, with expiration of pass-through status proposed and finalized through the annual rulemaking process. CMS included a list of the drugs for which pass-through status will expire on Dec. 31, 2015, in Table 43 of the Final Rule. These drugs are identified in Table 4, right.

Other medications and substances remain approved for pass-through during CY 2016. Payment for drugs and biologicals with pass-through status under the OPPS is currently made at the rate of ASP+6 percent. In the 2016 Final Rule CMS states:

"Therefore, for CY 2016, we proposed to pay for pass-through drugs and biologicals at ASP+6 percent, equivalent to the rate these drugs and biologicals would receive in the physician's office setting in CY 2016. We proposed that a $0.00 pass-thorough payment amount would be paid for most pass-through drugs and biologicals under the CY 2016 OPPS because the difference between the amount authorized under section 1842(o) of the Act, which was proposed at ASP+6 percent, and the portion of the otherwise applicable OPD fee schedule that the Secretary determines is appropriate, which was proposed at ASP+6 percent, is $0.

In the case of policy-packaged drugs (which include the following: contrast agents; diagnostic radiopharmaceuticals; anesthesia drugs; drugs, biological, and radiopharmaceuticals that function as supplies when used in a surgical procedure), we proposed that their pass-through payment amount would be equal to ASP+6 percent for CY 2016, because if not for their pass through status, payment for these products would be packaged into the associated procedure."

CMS finalized its proposal to continue to set the associated co-payment amount for pass-through diagnostic radiopharmaceuticals, contrast agents, and anesthesia drugs to zero for CY 2016 and future years. Table 5, page 20, identifies the drugs and biologicals that will continue or have been granted pass-through status as of Jan. 1, 2016.

Drugs and therapeutic radiopharmaceuticals without pass-through status are paid separately only if the average per diem cost is greater than that year's packaging threshold. For CY 2016, the threshold is $100, up from $95 in CY 2015. CMS adds that packaging costs into a single aggregate payment for a service, procedure, or episode-of-care is a fundamental principle that distinguishes a prospective payment system from a fee schedule.

The 2016 OPPS Final Rule also included a technical correction related to verbiage associated with self-administered drugs, according to CMS:

"Specifically, we proposed to delete the phrase 'any drug or biological that can be self-administered' and replace it with the phrase 'any drug or biological which is usually self-administered by the patient.' We did not receive any public comments on this proposal. Therefore, we are finalizing our proposed technical correction to § 410.29 to amend the description of self-administered drugs and biologicals to more appropriately reflect the statutory language."

OPPS Payment for Biosimilar Biological Products

The Affordable Care Act (ACA) authorized an abbreviated pathway for the licensing of biosimilar biological products. Under this abbreviated pathway, a proposed biological product that is demonstrated to be

Table 4. Drugs & Biologicals for Which Pass-Through Status Will Expire Dec. 31, 2015

CY 2016 HCPCS CODE	CY 2016 LONG DESCRIPTOR	FINAL CY 2016 SI	FINAL CY 2016 APC
A9520	Technetium Tc 99m tilmanocept, diagnostic, up to 0.5 millicuries	N	N/A
C9132	Prothrombin complex concentrate (human), Kcentra, per IU of Factor IX activity	K	9132
J1556	Injection, immune globulin (Bivigam), 500 mg	K	9130
J3060	Injection, taliglucerase alfa, 10 units	K	9294
J7315	Mitomycin, ophthalmic, 0.2 mg	N	N/A
J7316	Injection, Ocriplasmin, 0.125 mg	K	9298
J9047	Injection, carfilzomib, 1 mg	K	9295
J9262	Injection, omacetaxine mepesuccinate, 0.01 mg	K	9297
J9354	Injection, ado-trastuzumab emtansine, 1 mg	K	9131
J9400	Injection, Ziv-Aflibercept, 1 mg	K	9296
Q4122	Dermacell, per square centimeter	N	N/A
Q4127	Talymed, per square centimeter	N	N/A

biosimilar to a reference product can rely on certain existing scientific knowledge about the safety, purity, and potency of the reference product to support licensure. Section 3139 of the ACA amended section 1847 of the Social Security Act to add the definition of a biosimilar biological product and set forth a payment methodology for biosimilar biological products.

The HCPCS codes and modifiers for biosimilar biological products will be established based on policy documented in the Medicare Physician Fee Schedule (MPFS) Final Rule with comment period. CMS refers readers to the CY 2016 MPFS Final Rule (also reviewed on pages 22-26) for additional detail. Under the OPPS, CMS will assign pass-through status to the first eligible biosimilar biological for each reference product. Subsequent biosimilars for that same reference product will not receive pass-through status.

OPPS Payment for Hospital Outpatient Visits

Since April 7, 2000, CMS has instructed hospitals to report facility resources for clinic and emergency department (ED) hospital outpatient visits. As part of the 2014 OPPS Final Rule, CMS finalized a policy that created HCPCS code **G0463** (hospital outpatient clinic visit for assessment and management of a patient) to report all hospital clinic visits under the OPPS. For CY 2016, HCPCS code **G0463** will be reassigned to **APC 5012** (Level 2 Examinations and Related Services) and CY 2014 claims data will be used to develop the 2016 OPPS payment rate for this service. CMS will also continue the policy of recognizing existing CPT procedure codes for critical care services and payment for these services will be established based on historical claims data.

One commenter recommended that CMS return to a tiered payment structure for clinic visits, citing that providers such as cancer hospitals were unfairly penalized since they provide care for more severely ill Medicare beneficiaries. CMS stated that it continues to believe that the spectrum of hospital resources provided during an outpatient hospital clinic visit is appropriately captured and reflected in the single level of payment.

Advanced care planning services (codes **99497**, **99498**) will be payable under the OPPS with a status change to **Q1** (conditionally packaged) effective Jan. 1, 2016. This means that advance care planning will be paid to the hospital when it is the only service provided that day. Add-on code **99498** will be unconditionally packaged and not separately reimbursed. CMS adds:

"Therefore, based on the code descriptors, we expect that physicians or qualified non-physician practitioners (as defined by 42

(*continued on page 21*)

Table 5. Drugs & Biologicals with Pass-Through Status in CY 2016

CY 2015 HCPCS CODE	CY 2016 HCPCS CODE	CY 2016 LONG DESCRIPTOR	CY 2016 SI	CY 2016 APC
A9586	A9586	Florbetapir fl8, diagnostic, per study dose, up to 10 mci	G	1664
C9025	J9035	Injection, ramucirumab, 5 mg	G	1488
C9026	J3380	Injection, vedolizumab, 1 mg	G	1489
C9027	C9027	Injection, pembrolizumab, 1 mg	G	1490
C9349	C9349	PuraPly, and PuraPly Antimicrobial, any type, per sq cm	G	1657
C9442	J9032	Injection, belinostat, 10 mg	G	1658
C9443	J0875	Injection, dalbavancin, 5 mg	G	1659
C9444	J2407	Injection, oritavancin, 10 mg	G	1660
C9445	J0596	Injection, c-1 esterase inhibitor (human), Ruconest, 10 units	G	9445
C9446	J3090	Injection, tedizolid phosphate, 1 mg	G	1662
C9447	C9447	Injection, phenylephrine and ketorolac, 4 ml vial	G	1663
C9449	J9039	Injection, blinatumomab, 1 mcg	G	9449
C9450	J7313	Injection fluocinolone acetonide intravitreal implant, 0.01 mg	G	9450
C9451	J2547	Injection peramivir, 1 mg	G	9451
C9452	J0695	Injection, ceftolozane, 50 mg and tazobactam, 25 mg	G	9452
C9453	J9299	Injection, nivolumab, 1 mg	G	9453
C9454	J2502	Injection, pasireotide long acting, 1 mg	G	9454
C9455	J2860	Injection, siltuximab, 10 mg	G	9455
C9497	C9497	Loxapine, inhalation powder, 10 mg	G	9497
C9022	J1322	Injection, elosulfase alfa, 1 mg	G	1480
Q9970	J1439	Injection, ferric carboxymaltose, 1 mg	G	9441
J1446	J1446	Injection, TBO-Filgrastim, 5 mcg	G	1477
C9023	J3145	Injection, testosterone undecanoate, 1 mg	G	1487
C9134	J7181	Factor XIII (antihemophilic factor, recombinant), Tretten, per IU	G	1746
C9133	J7200	Factor IX (antihemophilic factor, recombinant), Rixubus, per IU	G	1467
C9135	J7201	Factor IX (antihemophilic factor, recombinant), Alprolix, per IU	G	1486
J7508	J7508	Tacrolimus, extended release, oral, 0.1 mg	G	1465
C9021	J9301	Injection, obinutuzumab, 10 mg	G	1476
J9371	J9371	Injection, vincristine sulfate liposome, 1 mg	G	1466
Q4121	Q4121	Theraskin, per square centimeter	G	1479
Q9975	J7205	Injection factor VIII, fc fusion protein, (recombinant), per IU	G	1656
Q9978	J8655	Netupitant (300 mg) and palonosetron (0.5 mg)	G	9448
C9456	J1833	Injection, isavuconazonium sulfate, 1 mg	G	9456
C9457	Q9950	Injection, sulfur hexafluoride lipid microsphere, per ml	G	9457
N/A	C9458	Florbetan F18, diagnostic, per study dose, up to 8.1 mci	G	9458
N/A	C9459	Flutemetamol F18, diagnostic, per study dose, up to 5 mci	G	9459
N/A	C9460	Injection, cangrelor, 1 mg	G	9460
Q5101	Q5101	Injection, Filgrastim (G-CSF), biosimilar, 1 mcg	G	1822

(*continued from page 19*)
CFR 410.27(g)) will be involved (beyond just providing direct supervision of hospital staff) in providing these services to patients in the outpatient setting."

Lung Cancer Screening with Low-Dose Computed Tomography

On Feb. 5, 2015, CMS issued a National Coverage Determination (NCD) for Medicare coverage of a lung cancer screening counseling and shared decision-making visit, and for appropriate beneficiaries, annual screening with low-dose computed tomography (LDCT) as an additional preventive benefit. There are new HCPCS Level II codes for these covered services listed in the 2016 HOPPS Final Rule:

- **G0296**: Counseling visit to discuss need for lung cancer screening (LDCT) using low-dose CT scan (service is for eligibility determination and shared decision making).
- **G0297**: Low-dose CT scan (LDCT) for lung cancer screening.

Because the counseling visit and LDCT are covered as preventive benefits, there is no patient co-payment or deductible for these services. These new codes and APC assignments are effective Feb. 5, 2015, (the date the NCD was finalized) and may be billed under the OPPS beginning Jan. 1, 2016. Of importance, CMS states that it is in the process of developing claims processing, coding, and billing instructions for those services performed in CY 2015 that must be billed retroactively. CMS recently issued an *MLN Matters* to update coverage and charging requirements for lung cancer screening with LDCT. Learn more at: cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/MM9246.pdf.

Off-Campus Provider-Based Departments

While this issue was not in the 2016 OPPS Final Rule, it is included because the PO HCPCS modifier remains active for CY 2016. According to CMS, research literature and popular press have documented the increased trend toward hospital acquisition of physician practices, integration of those practices as a department of the hospital, and the resulting increase in the delivery of physician services in a hospital setting. When a Medicare beneficiary receives outpatient services in a hospital, the total payment amount for outpatient services made by Medicare is generally higher than the total payment amount made by Medicare when a physician furnishes those same services in a freestanding clinic or in a physician's office.

For physician/practitioner professional claims, CMS has implemented new and revised place of service (POS) codes rather than a modifier. For hospital claims, CMS established the following modifier; reporting of the modifier is voluntary until Jan. 1, 2016, at which point it became mandatory.

- **Modifier PO**: Services, procedures, and/or surgeries provided at off-campus provider-based outpatient departments.

Hospitals will append the modifier to *every* code for all outpatient hospital services furnished in an off-campus provider-based department of a hospital. CMS defines the campus as *"the physical area immediately adjacent to the provider's main buildings, other areas, and structures that are not strictly contiguous to the main buildings but are located within 250 yards of the main buildings, and any other areas determined on an individual case basis, by the CMS regional office, to be part of the provider's campus."*

The modifier should *not* be used on services performed at remote locations of the hospital, satellite facilities of the hospital, or emergency departments. A remote location is defined as *"a facility or an organization that is either created by, or acquired by, a hospital that is a main provider for the purpose of furnishing inpatient hospital services under the name, ownership, and financial and administrative control of the main provider."* CMS states that questions about whether a particular location requires the modifier should be referred to the CMS regional offices.

While not part of the 2016 OPPS Final Rule, the Bipartisan Budget Act of 2015 was signed into law on Nov. 2, 2015 and includes the following:

SEC. 603. Treatment of New Off-Campus Outpatient Departments of a Provider. Section 603 would codify the CMS definition of provider-based (PBD) off-campus hospital outpatient departments (HOPDs) as those locations that are not on the main campus of a hospital and are located more 250 yards from the main campus. The section defines a "new" PBD HOPD as an entity that executed a CMS provider agreement [after the date of enactment]. Any PBD HOPD executing a provider agreement after the date of enactment would not be eligible for reimbursements from CMS' Outpatient Prospective Payment System. New PBD HOPDs, as defined by this section, would be eligible for reimbursements from either the Ambulatory Surgical Center (ASC PPS) or the Medicare Physician Fee Schedule. OI

Physician & Freestanding Center Regulatory Update

BY CINDY PARMAN, CPC, CPC-H, RCC

Since 1992, Medicare has paid for the services of physicians, non-physician practitioners, and certain other suppliers under the Medicare Physician Fee Schedule (MPFS). For reimbursement purposes, relative values are assigned to more than 7,000 services to reflect the amount of work, the direct and indirect (overhead) practice expenses, and the malpractice expenses typically involved in furnishing that specific service. After applying a geographic practice cost indicator, the resulting relative value units (RVUs) are summed for each service and multiplied by a fixed-dollar conversion factor to establish the payment amount for each visit or procedure.

The CY 2016 conversion factor is estimated to be $35.8279, which reflects the budget neutrality adjustment, the 0.5 percent update adjustment factor specified under MACRA (Medicare Access and CHIP Reauthorization Act of 2015), and the 0.77 percent target recapture adjustment required by statute. CMS notes that "several specialties, including gastroenterology and radiation oncology, will experience significant decreases to payments to services that they frequently furnish as a result of widespread revisions to the structure and inputs used to develop RVUs for the codes that describe particular services." Table 6, right, shows the estimated impact of projected payment increases or decreases by specialty (without considering the potential conversion factor change).

Terminology Update

This year, CMS states that throughout the 2016 MPFS Final Rule with comment period and unless otherwise noted, the term "practitioner" is used to describe both physicians and those non-physician practitioners (NPPs) who are permitted to separately bill Medicare under the Physician Fee Schedule.

Radiation Treatment & Image Guidance Codes

While the new CPT procedure codes for brachytherapy services will be used in all practice settings (hospitals, freestanding cancer treatment centers, and physician offices), there remain different treatment delivery and image guidance codes for the hospital and freestanding radiation centers for CY 2016. The 2016 MPFS Final Rule includes a lengthy discussion of issues and challenges involved in setting RVUs for the new CPT procedure codes. As a result, CMS has decided not to implement these new procedure codes for MPFS reimbursement; the G-codes will continue to be reported during CY 2016. CMS states that "significant changes" are required to the codes themselves before CMS can develop accurate payment rates. These changes would include:

- Developing a code set that recognizes the differences in costs between kinds of imaging modalities.
- Making sure that this code set facilitates valuation that incorporates the cost of imaging based on how frequently it is actually provided.
- Developing treatment delivery codes that are structured to differentiate payment based on equipment resources used.

Equipment Utilization Rate for Linear Accelerators

The 2016 MPFS Final Rule states that: *"The cost of the capital equipment is the primary determining factor in the payment rates for these services."* For each procedure code, the equipment costs are estimated based on multiplying the assumed number of minutes the linear accelerator is used for each treatment by the per-minute cost of the specific piece of equipment. CMS currently uses two default equipment usage assumptions when allocating capital equipment costs to practice expense (PE) RVUs:

1. The equipment is available to be used during what are assumed to be regular business hours for a physician's office: 10 hours per day, 5 days per week (50 hours per week), and 50 weeks per year.
2. The equipment is in use only 50 percent of the time it is available for use. This translates to 25 hours per week out of a 50-hour work week.

Based on RUC (Relative Value Update Committee) recommendations for the new and revised radiation treatment delivery and image guidance codes, CMS believes that a usage assumption of 50 percent is inaccurate for the linear accelerator used in radiation treatment services. Further review indicates a 45 percent increase in the amount of time a treatment machine is used (a total of 95 percent of equipment

usage time). As a result, CMS proposed to use a 70 percent assumption rate for the amount of time a linear accelerator is used on a daily basis, phased in over two years. This means that the equipment utilization rate for CY 2016 will be 60 percent and for CY 2017 it will be 70 percent. The more frequently a piece of equipment is used, the lower the reimbursement for each individual treatment. As a result, treatment delivery payments could see a reduction in both CY 2016 and CY 2017.

Superficial Radiation Treatment Delivery

In the CY MPFS 2015 Final Rule with comment period, CMS requested additional information on the physician work involved in superficial radiation therapy (code **77401**), and which services should be considered inclusive in this service. Conflicting comments were received, and CMS is considering the development of a new code that would include all work associated with the delivery of superficial radiation.

Lung Cancer Screening

On Feb. 5, 2015, CMS issued an NCD for Medicare coverage of a lung cancer screening counseling and shared decision-making visit, and for appropriate beneficiaries, annual screening with low dose computed tomography (LDCT) as an additional preventive benefit. The new HCPCS Level II codes for these services include:

- **G0296**: Counseling visit to discuss need for lung cancer screening (LDCT) using low dose CT scan (service is for eligibility determination and shared decision making).
- **G0297**: Low dose CT scan (LDCT) for lung cancer screening.

CMS added that as long as the NCD requirements for the counseling and shared decision-making visit are met, the counseling visit may be billed on the same day as a medically necessary E/M service or with an annual wellness visit. **Modifier 25** (significant, separately identifiable service) would be required on code **G0296**, as well as separate documentation for the counseling visit. Because the counseling visit and LDCT are covered as preventive benefits, there is no patient co-payment or deductible for these services. These new codes and APC assignments are effective Feb. 5, 2015, (the date the NCD was finalized) and may be billed under the MPFS beginning Jan. 1, 2016. Of importance, CMS states that it is in the process of developing claims processing, coding, and billing instructions for those services performed in CY 2015.

Incident-To Update

The 2016 MPFS Final Rule includes yet another clarification that the physician or non-physician practitioner who bills for incident-to services (i.e., the individual listed on the claim form as the performing provider) must be the individual who provided direct supervision of the auxiliary personnel who performed the services. This means that although the physician of record for an individual patient may have ordered a particular service, the practitioner who provides the direct supervision in the office is the provider name that is billed on the claim form.

In addition, CMS explicitly prohibits the provision of incident-to services by auxiliary personnel who have been excluded from federal health programs or who have had their enrollment revoked. There were no changes to the definition of an incident-to service or to the list of non-physician

Table 6. Estimated Impact of Projected Payment Increases or Decreases by Specialty*

SPECIALTY	Allowed Charges (millions)	Impact of Work RVU Changes	Impact of PE RVU Changes	Impact of MP RVU Changes	Combined Impact
Hematology/Oncology	$1,788	0%	0%	0%	0%
Radiation Oncology	$1,766	0%	-2%	0%	-2%
Radiation Therapy Centers	$52	0%	-2%	0%	-1%

Specialty: The Medicare specialty code as reflected in the physician/supplier enrollment files.

Allowed Charges: The aggregate estimated MPFS allowed charges for the specialty based on CY 2013 utilization and CY 2014 rates.

Impact of Work RVU Changes: The estimated CY 2015 impact on total allowed charges of the changes in the work RVUs, including the impact of changes due to new, revised, and misvalued codes.

Impact of Practice Expense RVU Changes: The estimated CY 2015 impact on total allowed charges of the changes in PE RVUs, including the impact due to new, revised, and misvalued codes and miscellaneous minor provisions.

Impact of Malpractice RVU Changes: The estimated CY 2015 impact on total allowed charges of the changes in the MP RVUs, which are primarily driven by the required five year review and update of MP RVUs.

Combined Impact: The estimated CY 2015 combined impact on total allowed charges of all the changes in the previous columns.

*Without consideration of the potential conversion factor change.

practitioners who can perform services that are billed incident-to by a physician. CMS provided the following definitions in the MPFS Final Rule:

"Consistent with this terminology, when referring in this discussion to the physician or other practitioner furnishing the service, we are referring to the physician or other practitioner who is billing for the incident-to service. When we refer to the "auxiliary personnel" or the person who "provides" the service, we are referring to an individual who is personally performing the service or some aspect of it as distinguished from the physician or other practitioner who bills for the incident-to service.

As described in this Final Rule with comment period, incident-to a physician's or other practitioner's professional services means that the services or supplies are furnished as an integral, although incidental, part of the physician's or other practitioner's personal professional services in the course of diagnosis or treatment of an injury or illness."

Off-Campus Provider-Based Departments

Although not included in the 2016 MPFS Final Rule with comment period, CMS announced in *MLN Matters* MM9231 (Aug. 6, 2015) that there would be two place of service codes billed by physicians on CMS1500 claim form when services are performed in the outpatient hospital setting:

1. **POS Code 19**: A portion of an *off-campus hospital provider-based department,* which provides diagnostic, therapeutic (both surgical and nonsurgical), and rehabilitation services to sick or injured persons who do not require hospitalization or institutionalization.
2. **POS Code 22**: A portion of a *hospital's main campus,* which provides diagnostic, therapeutic (both surgical and nonsurgical), and rehabilitation services to sick or injured persons who do not require hospitalization or institutionalization.

These place of service codes were effective Jan. 1, 2016, and are required on all Medicare professional claims for outpatient hospital services. Other insurers may or may not require this level of outpatient facility differentiation.

Potentially Misvalued Codes

In the CY 2015 MPFS Final Rule with comment period, CMS finalized the proposal to transition and revalue all 10- and 90-day global surgery services with 0-day global periods, beginning with the 10-day global services in CY 2017 and following with the 90-day global services in CY 2018. However, MACRA was enacted into law on April 16, 2015, and included a paragraph that prohibits CMS from implementing this global surgery policy change. This same Act requires CMS to develop, through rulemaking, a process to gather information needed to value surgical services and requires that this data collection shall begin no later than Jan. 1, 2017.

Consistent with amendments made by the ACA, CMS has been engaged in a vigorous effort over the past several years to identify and review potentially misvalued codes and make adjustments where appropriate. CMS and the RUC have taken several steps to improve the review process, examining potentially misvalued services in several categories. In the 2016 MPFS Final Rule, CMS stated that it intended to proceed with a review of the high expenditure screen for 2016, while excluding codes with a 10-day or 90-day global period. The top 20 codes by specialty were identified, with patient visits excluded from review, as well as any codes that have already been reviewed since calendar year 2010. Table 7, right, shows the final list of potentially misvalued codes identified through the high expenditure specialty screen, specific to services that may be performed by medical or radiation oncologists.

Part B Drugs

Section 3139 of the ACA amended the Act to define a biosimilar biological product and a reference biological product and to provide for Medicare payment of biosimilar biological products using ASP methodology. A biosimilar biological product is defined as a biological product approved under an abbreviated application for another biological product licensed under section 351 of the Public Health Service Act (PHSA). A reference biological product for a biosimilar biological product is defined as the biological product licensed under section 351 of the PHSA that is referred to in the application of the biosimilar biological product.

CMS stated that because of the degree of similarity that biosimilars share with their reference products, it is appropriate to price biosimilar products in groups in a manner similar to how multiple source or generic drugs are currently priced. After considering all comments, CMS stated that the payment amount for a biosimilar biological product is based on the ASP of all NDCs (National Drug Codes) assigned to the biosimilar biological products included within the same billing and payment code.

Appropriate Use Criteria for Advanced Diagnostic Imaging Services

The Protecting Access to Medicare Act of 2014 (PAMA) requires CMS to establish a program to promote utilization of appropriate use criteria (AUC) for advanced diagnostic imaging services. Advanced diagnostic imaging services include diagnostic imaging exams performed using CT, MR, and nuclear medicine (including PET). AUC are criteria that help professionals who order and furnish imaging services to make the most appropriate treatment decision for a specific clinical condition for an individual patient. CMS can only approve AUC that are developed or endorsed by provider-led entities (PLEs), such as national professional medical specialty societies. In most cases the AUC will be evidence-based, and CMS can approve more than one set of AUC for a given imaging service.

An ordering physician/practitioner (including hematologists, medical oncologists, and radiation oncologists) will access AUC through a clinical decision support (CDS) tool, such as a CDS module in an electronic health record (EHR) or a web-based system. The ordering professional will enter patient information into the CDS tool, and it will provide immediate feedback about the appropriateness of the proposed imaging exam. Under PAMA, ordering physicians/practitioners will be required to consult AUC and to communicate the results of this consultation to the entity that furnishes the imaging study. When the imaging provider bills Medicare, it will then be required to include information on the claim about the ordering physician's consultation with AUC. This requirement applies to imaging studies billed under the Physician Fee Schedule, the Outpatient Prospective Payment System, and the Ambulatory Surgical Center Payment System. It does not apply to inpatient studies billed under Part A, to certain emergency studies, or to ordering physicians/practitioners who qualify for a hardship exception.

CMS will initially pay for the imaging study regardless of whether it was recommended by the AUC. Eventually, however, CMS will identify those ordering professionals who are consistently failing to follow AUC recommendations, and these "outliers" will be required to obtain prior authorization for advanced imaging studies they wish to order. PAMA called for CMS to meet the following deadlines:

- Establish AUC by Nov. 15, 2015.
- Establish CDS by April 1, 2016.
- Implement AUC consultation by ordering physicians/practitioners by Jan. 1, 2017.
- Identify "outlier" ordering professionals for services furnished after Jan. 1, 2017.

Due to the timing of the PAMA legislation, CMS was unable to meet the November 2015 deadline for establishing AUC, and this will in turn delay the other steps. In the 2016 MPFS Final Rule, CMS stated that it expects to establish rules and requirements for CDS mechanisms (including the process for communicating the AUC consultation information between providers and on the claim) during 2016 for the 2017 rulemaking cycle. Approved CDS mechanisms should be in place in summer of 2017.

Advance Care Planning

For CY 2015, the CPT Editorial Panel created two new codes describing advance care planning services:

- **99497**: Advance care planning, including the explanation and discussion of advance directives such as standard forms (with completion of such forms, when performed), by the physician or

Table 7. Potentially Misvalued Codes Performed by Medical and/or Radiation Oncologists

CODE	DESCRIPTION
31575	Laryngoscopy, flexible fiberoptic; diagnostic
38221	Bone marrow; biopsy, needle or trocar
51720	Bladder instillation of anticarcinogenic agent (including retention time)
77263	Therapeutic radiology treatment planning; complex
77334	Treatment devices, design and construction; complex
77470	Special treatment procedure
96360	Intravenous infusion, hydration; initial, 31 minutes to 1 hour
96372	Therapeutic, prophylactic or diagnostic injection; subcutaneous or intramuscular
96374	Therapeutic, prophylactic or diagnostic injection; IV push, single or initial drug
96375	Therapeutic, prophylactic or diagnostic injection; each additional sequential IV push of a new substance/drug
96401	Chemotherapy administration, subcutaneous or intramuscular; non-hormonal antineoplastic
96402	Chemotherapy administration, subcutaneous or intramuscular; hormonal antineoplastic
96409	Chemotherapy administration; IV push, single or initial substance/drug
96411	Chemotherapy administration; IV push, each additional substance/drug

other qualified health professional; first 30 minutes, face-to-face with the patient, family member(s), and/or surrogate.

- **+99498:** Each additional 30 minutes. (List separately in addition to code for primary procedure).

In the CY 2016 MPFS Final Rule, these services were assigned a status indicator of "I" (Not valid for Medicare purposes. Medicare uses another code for the reporting and payment of these services). For CY 2016, CMS will provide reimbursement for these services, and the agency recommends that when a beneficiary elects to receive advance care planning, the practitioner should notify the patient that Part B cost sharing (e.g., co-payment and/or deductible) will apply for this optional, voluntary service in the same manner as for other physician services. CMS also states that it will monitor utilization over time to ensure that these codes are used appropriately. This means, in part, that only one physician member of the patient's multispecialty care team will be permitted to bill for advance care planning within a reasonable time period.

Last, CMS clarified that a number of comments were received on existing or recommended practice patterns for the provision of advance care planning services, including recommendations for individuals who could perform this service as part of a global care team. CMS states in the MPFS Final Rule:

"We note that the CPT code descriptors describe the services as furnished by physicians and other qualified health professionals, which for Medicare purposes is consistent with allowing these codes to be billed by the physicians and NPPs whose scope of practice and Medicare benefit category include the services described by the CPT codes and who are authorized to independently bill Medicare for those services. Therefore, only these practitioners may report CPT codes ***99497*** *or* ***99498****.*

We agree with commenters that advance care planning as described by the proposed CPT codes is primarily the provenance of patients and physicians. Accordingly, we expect the billing physician or NPP to manage, participate and meaningfully contribute to the provision of the services, in addition to providing a minimum of direct supervision."

CMS added that these codes will be separately payable to the billing physician or practitioner in both facility and non-facility settings and are not limited to particular physician specialties. In response to specific comments, CMS agreed that advance care planning can be separately reimbursed when performed at the same time as an annual wellness visit. **Modifier 33** (preventive services) would be reported on the advance care planning charge in this scenario, and the patient would not have a co-payment or deductible.

Other Issues

In addition to the specific topics listed above, CMS also provided details on the Physician Compare Website, the Electronic Health Record Incentive Program, the Medicare Shared Savings Program, the Value-Based Modifier, Physician Self-Referral Updates, and Physician Quality Reporting Systems. CMS also received a number of comments in response to the request for recommendations on how to improve Medicare compensation mechanisms for primary care services and collaborative care. Many commenters complained specifically about the administrative burden associated with billing for transitional care and chronic care. These comments will be considered during future rulemaking.

Bipartisan Budget Act of 2015

While not part of the MPFS Final Rule, the Bipartisan Budget Act of 2015 was signed into law on Nov. 2, 2015, and includes the following:

Sec. 101. Amendments to the Balanced Budget and Emergency Deficit Control Act of 1985. Subsection 101(b) provides for the implementation of the sequester of direct spending as if the amendments in subsection 101(a) had not been made. The President is required by law to implement the sequester of direct spending ordered on February 2, 2015 and the one in the Sequestration Preview Report for Fiscal Year 2017 as if the amendments in subsection 101(a) had not been made. 2 Subsection 101(c) reduces spending by $14 billion in fiscal year 2025 by requiring the President to sequester the same percentage of direct spending in 2025 as will be sequestered in 2021. It also replaces the arbitrary dips and increases in the Medicare sequester percentages in 2023 and 2024 with a flat two-percent rate as applies under current law in fiscal years 2016 through 2022.

This means that Congress extended the annual 2 percent sequestration reduction of Medicare provider reimbursement one more year, into 2025. This pay cut, created by the sequestration provisions of the Budget Control Act of 2011, was supposed to expire in 2021, but Congress has now added additional years to this reimbursement reduction. OI

TAGRISSO™
osimertinib

A NEW TREATMENT OPTION

FOR PATIENTS WITH METASTATIC EGFR T790M MUTATION-POSITIVE NSCLC, AS DETECTED BY AN FDA-APPROVED TEST, WHO HAVE PROGRESSED ON OR AFTER EGFR TKI THERAPY

INDICATION

TAGRISSO is indicated for the treatment of patients with metastatic epidermal growth factor receptor (EGFR) T790M mutation-positive non-small cell lung cancer (NSCLC), as detected by an FDA-approved test, who have progressed on or after EGFR tyrosine kinase inhibitor therapy.

This indication is approved under accelerated approval based on tumor response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

IMPORTANT SAFETY INFORMATION

- There are no contraindications for TAGRISSO
- Interstitial Lung Disease (ILD)/Pneumonitis occurred in 3.3% and was fatal in 0.5% of 813 TAGRISSO patients. Withhold TAGRISSO and promptly investigate for ILD in any patient presenting with worsening of respiratory symptoms indicative of ILD (e.g., dyspnea, cough and fever). Permanently discontinue TAGRISSO if ILD is confirmed
- QTc interval prolongation occurred in TAGRISSO patients. Of the 411 patients in two Phase II studies, 0.2% were found to have a QTc greater than 500 msec, and 2.7% had an increase from baseline QTc greater than 60 msec. Conduct periodic monitoring with ECGs and electrolytes in patients with congenital long QTc syndrome, congestive heart failure, electrolyte abnormalities, or those who are taking medications known to prolong the QTc interval. Permanently discontinue TAGRISSO in patients who develop QTc interval prolongation with signs/symptoms of life threatening arrhythmia
- Cardiomyopathy occurred in 1.4% and was fatal in 0.2% of 813 TAGRISSO patients. Left Ventricular Ejection Fraction (LVEF) decline >10% and a drop to <50% occurred in 2.4% of (9/375) TAGRISSO patients. Assess LVEF before initiation and then at 3 month intervals of TAGRISSO treatment. Withhold TAGRISSO if ejection fraction decreases by 10% from pretreatment values and is less than 50%. For symptomatic congestive heart failure or persistent asymptomatic LV dysfunction that does not resolve within 4 weeks, permanently discontinue TAGRISSO
- Advise pregnant women of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during TAGRISSO treatment and for 6 weeks after the final dose. Advise males with female partners of reproductive potential to use effective contraception for 4 months after the final dose
- The most common adverse reactions (>20%) observed in TAGRISSO patients were diarrhea (42%), rash (41%), dry skin (31%) and nail toxicity (25%)

Please see Brief Summary of complete Prescribing Information.

Visit TAGRISSOhcp.com for more information

AstraZeneca

TAGRISSO™ (osimertinib) tablet, for oral use

Brief Summary of Prescribing Information.
For complete prescribing information consult official package insert

INDICATIONS AND USAGE

TAGRISSO is indicated for the treatment of patients with metastatic epidermal growth factor receptor (EGFR) T790M mutation-positive non-small cell lung cancer (NSCLC), as detected by an FDA-approved test, who have progressed on or after EGFR tyrosine kinase inhibitor (TKI) therapy.

This indication is approved under accelerated approval based on tumor response rate and duration of response *[see Clinical Studies (14) in the full Prescribing Information]*. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

DOSAGE AND ADMINISTRATION

Patient Selection

Confirm the presence of a T790M EGFR mutation in tumor specimens prior to initiation of treatment with TAGRISSO *[see Indications and Usage (1) and Clinical Studies (14) in the full Prescribing Information]*. Information on FDA-approved tests for the detection of T790M mutations is available at http://www.fda.gov/companiondiagnostics.

Recommended Dosage Regimen

The recommended dose of TAGRISSO is 80 mg tablet once a day until disease progression or unacceptable toxicity. TAGRISSO can be taken with or without food.

If a dose of TAGRISSO is missed, do not make up the missed dose and take the next dose as scheduled.

Administration to Patients Who Have Difficulty Swallowing Solids

Disperse tablet in 4 tablespoons (approximately 50 mL) of non-carbonated water only. Stir until tablet is completely dispersed and swallow or administer through naso-gastric tube immediately. Do not crush, heat, or ultrasonicate during preparation. Rinse the container with 4 to 8 ounces of water and immediately drink or administer through the naso-gastric tube *[see Clinical Pharmacology (12.3) in the full Prescribing Information]*.

Dose Modification for Adverse Reactions

Table 1 Recommended Dose Modifications for TAGRISSO

Target Organ	Adverse Reaction[a]	Dose Modification
Pulmonary	Interstitial lung disease (ILD)/Pneumonitis	Permanently discontinue TAGRISSO.
Cardiac	QTc[†] interval greater than 500 msec on at least 2 separate ECGs[b]	Withhold TAGRISSO until QTc interval is less than 481 msec or recovery to baseline if baseline QTc is greater than or equal to 481 msec, then resume at 40 mg dose.
	QTc interval prolongation with signs/ symptoms of life threatening arrhythmia	Permanently discontinue TAGRISSO.
	Asymptomatic, absolute decrease in LVEF[c] of 10% from baseline and below 50%	Withhold TAGRISSO for up to 4 weeks. • If improved to baseline LVEF, resume. • If not improved to baseline, permanently discontinue.
	Symptomatic congestive heart failure	Permanently discontinue TAGRISSO.
Other	Grade 3 or higher adverse reaction	Withhold TAGRISSO for up to 3 weeks.
	If improvement to Grade 0-2 within 3 weeks	Resume at 80 mg or 40 mg daily.
	If no improvement within 3 weeks	Permanently discontinue TAGRISSO.

[a] Adverse reactions graded by the National Cancer Institute Common Terminology Criteria for Adverse Events version 4.0 (NCI CTCAE v4.0).
[b] ECGs = Electrocardiograms
[c] LVEF = Left Ventricular Ejection Fraction
[†] QTc = QT interval corrected for heart rate

CONTRAINDICATIONS

None.

WARNINGS AND PRECAUTIONS

Interstitial Lung Disease/Pneumonitis

Across clinical trials, interstitial lung disease (ILD)/pneumonitis occurred in 3.3% (n=27) of TAGRISSO treated patients (n=813); 0.5% (n=4) were fatal.

Withhold TAGRISSO and promptly investigate for ILD in any patient who presents with worsening of respiratory symptoms which may be indicative of ILD (e.g., dyspnea, cough and fever). Permanently discontinue TAGRISSO if ILD is confirmed *[see Dosage and Administration (2.4) and Adverse Reactions (6) in the full Prescribing Information]*.

QTc Interval Prolongation

The heart rate-corrected QT (QTc) interval prolongation occurs in patients treated with TAGRISSO. Of the 411 patients in Study 1 and Study 2, one patient (0.2%) was found to have a QTc greater than 500 msec, and 11 patients (2.7%) had an increase from baseline QTc greater than 60 msec *[see Clinical Pharmacology (12.2) in the full Prescribing Information]*.

In Study 1 and 2, patients with baseline QTc of 470 msec or greater were excluded. Conduct periodic monitoring with ECGs and electrolytes in patients with congenital long QTc syndrome, congestive heart failure, electrolyte abnormalities, or those who are taking medications known to prolong the QTc interval. Permanently discontinue TAGRISSO in patients who develop QTc interval prolongation with signs/symptoms of life threatening arrhythmia *[see Dosage and Administration (2.4) in the full Prescribing Information]*.

Cardiomyopathy

Across clinical trials, cardiomyopathy (defined as cardiac failure, pulmonary edema, ejection fraction decreased or stress cardiomyopathy) occurred in 1.4% (n=11) of TAGRISSO treated patients (n=813); 0.2% (n=2) were fatal.

In Study 1 and Study 2, Left Ventricular Ejection Fraction (LVEF) decline >10% and a drop to <50% occurred in 2.4% (9/375) of patients who had baseline and at least one follow up LVEF assessment. Assess LVEF by echocardiogram or multigated acquisition (MUGA) scan before initiation of TAGRISSO and then at 3 month intervals while on treatment. Withhold treatment with TAGRISSO if ejection fraction decreases by 10% from pretreatment values and is less than 50%. For symptomatic congestive heart failure or persistent, asymptomatic LV dysfunction that does not resolve within 4 weeks, permanently discontinue TAGRISSO *[see Dosage and Administration (2.4) in the full Prescribing Information]*.

Embryo-Fetal Toxicity

Based on data from animal studies and its mechanism of action, TAGRISSO can cause fetal harm when administered to a pregnant woman. In animal reproduction studies, osimertinib caused post-implantation fetal loss when administered during early development at a dose exposure 1.5 times the exposure at the recommended human dose. When males were treated prior to mating with untreated females, there was an increase in preimplantation embryonic loss at plasma exposures of approximately 0.5-times those observed in patients at the 80 mg dose level.

Advise pregnant women of the potential risk to a fetus.

Advise females of reproductive potential to use effective contraception during treatment with TAGRISSO and for 6 weeks after the final dose. Advise males with female partners of reproductive potential to use effective contraception for 4 months after the final dose *[see Use in Specific Populations (8.1), (8.3) and Clinical Pharmacology (12.3) in the full Prescribing Information]*.

ADVERSE REACTIONS

The following adverse reactions are discussed in greater detail in other sections of the labeling:

Interstitial Lung Disease/Pneumonitis *[see Warnings and Precautions (5.1) in the full Prescribing Information]*

QTc Interval Prolongation *[see Warnings and Precautions (5.2) in the full Prescribing Information]*

Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

The data described below reflect exposure to TAGRISSO (80 mg daily) in 411 patients with EGFR T790M mutation-positive non-small cell lung cancer who received prior EGFR TKI therapy, in two single arm studies, Study 1 and Study 2. Patients with a past medical history of ILD or radiation pneumonitis that required steroid treatment, serious arrhythmia or baseline QTc interval greater than 470 ms were excluded from Study 1 and Study 2. Baseline patient and disease characteristics were: median age 63 years, 13% of patients were ≥75 years old, female (68%), White (36%), Asian (60%), metastatic (96%), sites of brain metastases (39%), World Health Organization (WHO) performance status of 0 (37%) or 1 (63%), 1 prior line of therapy [EGFR-TKI treatment only, second line, chemotherapy-naïve (31%)], 2 or more prior lines of therapy (69%). Of the 411 patients, 333 patients were exposed to TAGRISSO for at least 6 months; 97 patients were exposed for at least 9 months; however no patient was exposed to TAGRISSO for 12 months.

In Studies 1 and 2, the most common (>20%) adverse reactions (all grades) observed in TAGRISSO-treated patients were diarrhea (42%), rash (41%), dry skin (31%), and nail toxicity (25%). Dose reductions occurred in 4.4% of patients treated with TAGRISSO. The most frequent adverse reactions that led to dose reductions or interruptions were: electrocardiogram QTc prolonged (2.2%) and neutropenia (1.9%). Serious adverse reactions reported in 2% or more patients were pneumonia and pulmonary embolus. There were 4 patients (1%) treated with TAGRISSO who developed fatal adverse reactions of ILD/pneumonitis. Other fatal adverse reactions occurring in more than 1 patient included pneumonia (4 patients) and CVA/cerebral hemorrhage (2 patients). Discontinuation of therapy due to adverse reactions occurred in 5.6% of patients treated with TAGRISSO. The most frequent adverse reactions that led to discontinuation were ILD/pneumonitis and cerebrovascular accidents/infarctions.

Tables 2 and 3 summarize the common adverse reactions and laboratory abnormalities observed in TAGRISSO-treated patients.

Table 2 Adverse Reactions (>10% for all NCI CTCAE* Grades or >2% for Grades 3-4) in Study 1 and Study 2

Adverse Reaction	TAGRISSO N=411	
	All Grades	Grade 3-4[f]
	%	%
Gastrointestinal disorders		
Diarrhea	42	1.0
Nausea	17	0.5
Decreased appetite	16	0.7
Constipation	15	0.2
Stomatitis	12	0
Skin disorders		
Rash[a]	41	0.5
Dry skin[b]	31	0
Nail toxicity[c]	25	0
Pruritus	14	0
Eye Disorders[d]	18	0.2
Respiratory		
Cough	14	0.2
General		
Fatigue	14	0.5
Musculoskeletal		
Back pain	13	0.7
Central Nervous System		
Headache	10	0.2
Infections		
Pneumonia	4	2.2
Vascular events		
Venous thromboembolism[e]	7	2.4

* NCI CTCAE v4.0.

[a] Includes cases reported within the clustered terms for rash adverse events: Rash, rash generalized, rash erythematous, rash macular, rash maculo-papular, rash papular, rash pustular, erythema, folliculitis, acne, dermatitis and acneform dermatitis.
[b] Includes dry skin, eczema, skin fissures, xerosis.
[c] Includes nail disorders, nail bed disorders, nail bed inflammation, nail bed tenderness, nail discoloration, nail disorder, nail dystrophy, nail infection, nail ridging, onychoclasis, onycholysis, onychomadesis, paronychia.
[d] Includes dry eye, vision blurred, keratitis, cataract, eye irritation, blepharitis, eye pain, lacrimation increased, vitreous floaters. Other ocular toxicities occurred in <1% of patients.
[e] Includes deep vein thrombosis, jugular venous thrombosis, and pulmonary embolism.
[f] No grade 4 events have been reported.

Additional clinically significant adverse reactions occurring in 2% or more of patients treated with TAGRISSO included cerebrovascular accident (2.7%).

Table 3 Common Laboratory Abnormalities (≥20% for all NCI CTCAE Grades) in Study 1 and Study 2

Laboratory Abnormality	TAGRISSO N=411	
	Change from Baseline All Grades (%)	Change from Baseline to Grade 3 or Grade 4 (%)[a]
Clinical Chemistry		
Hyponatremia	26	3.4
Hypermagnesemia	20	0.7
Hematologic		
Lymphopenia	63	3.3
Thrombocytopenia	54	1.2[a]
Anemia	44	0.2
Neutropenia	33	3.4

[a] The only grade 4 laboratory abnormality was 1 patient with grade 4 thrombocytopenia.

DRUG INTERACTIONS

Drug interaction studies with inhibitors, inducers or substrates of CYP enzymes and transporters have not been conducted with TAGRISSO.

Effect of Other Drugs on Osimertinib

Strong CYP3A Inhibitors

Avoid concomitant administration of TAGRISSO with strong CYP3A inhibitors, including macrolide antibiotics (e.g., telithromycin), antifungals (e.g., itraconazole), antivirals (e.g., ritonavir), nefazodone, as concomitant use of strong CYP3A inhibitors may increase osimertinib plasma concentrations. If no other alternative exists, monitor patients more closely for adverse reactions of TAGRISSO *[see Dosage and Administrations (2.4) and Clinical Pharmacology (12.3) in the full Prescribing Information]*.

Strong CYP3A Inducers

Avoid concomitant administration of TAGRISSO with strong CYP3A inducers (e.g., phenytoin, rifampicin, carbamazepine, St. John's Wort) as strong CYP3A inducers may decrease osimertinib plasma concentrations *[see Clinical Pharmacology (12.3) in the full Prescribing Information]*.

Effect of Osimertinib on Other Drugs

Avoid concomitant administration of TAGRISSO with drugs that are sensitive substrates of CYP3A, breast cancer resistance protein (BCRP), or CYP1A2 with narrow therapeutic indices, including but not limited to fentanyl, cyclosporine, quinidine, ergot alkaloids, phenytoin, carbamazepine, as osimertinib may increase or decrease plasma concentrations of these drugs *[see Clinical Pharmacology (12.3) in the full Prescribing Information]*.

USE IN SPECIFIC POPULATIONS

Pregnancy

Risk Summary

Based on data from animal studies and its mechanism of action, TAGRISSO can cause fetal harm when administered to a pregnant woman. There are no available data on TAGRISSO use in pregnant women. Administration of osimertinib to pregnant rats was associated with embryolethality and reduced fetal growth at plasma exposures 1.5 times the exposure at the recommended human dose *[see Data]*. Advise pregnant women of the potential risk to a fetus.

In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically-recognized pregnancies is 2% to 4% and 15% to 20%, respectively.

Data

Animal Data

When administered to pregnant rats prior to embryonic implantation through the end of organogenesis (gestation days 2-20) at a dose of 20 mg/kg/day, which produced plasma exposures of approximately 1.5 times the clinical exposure, osimertinib caused post-implantation loss and early embryonic death. When administered to pregnant rats from implantation through the closure of the hard palate (gestation days 6 to 16) at doses of 1 mg/kg/day and above (0.1-times the AUC observed in patients at the recommended dose of 80 mg), an equivocal increase in the rate of fetal malformations and variations was observed in treated litters relative to those of concurrent controls. When administered to pregnant dams at doses of 30 mg/kg/day during organogenesis through lactation Day 6, osimertinib caused an increase in total litter loss and postnatal death. At a dose of 20 mg/kg/day, osimertinib administration during the same period resulted in increased postnatal death as well as a slight reduction in mean pup weight at birth that increased in magnitude between lactation days 4 and 6.

Lactation

Risk Summary

There are no data on the presence of osimertinib in human milk, the effects of osimertinib on the breastfed infant or on milk production. Administration to rats during gestation and early lactation was associated with adverse effects, including reduced growth rates and neonatal death *[see Use in Specific Populations (8.1) in the full Prescribing Information]*. Because of the potential for serious adverse reactions in breastfed infants from osimertinib, advise a lactating woman not to breastfeed during treatment with TAGRISSO and for 2 weeks after the final dose.

Females and Males of Reproductive Potential

Contraception

Females

Advise females of reproductive potential to use effective contraception during treatment with TAGRISSO and for 6 weeks after the final dose *[see Use in Specific Populations (8.1) in the full Prescribing Information]*.

Males

Advise male patients with female partners of reproductive potential to use effective contraception during and for 4 months following the final dose of TAGRISSO *[see Nonclinical Toxicology (13.1) in the full Prescribing Information]*.

Infertility

Based on animal studies, TAGRISSO may impair fertility in females and males of reproductive potential. It is not known if the effects on fertility are reversible *[see Nonclinical Toxicology (13.1) in the full Prescribing Information]*.

Pediatric Use

The safety and effectiveness of TAGRISSO in pediatric patients have not been established.

Geriatric Use

One hundred eighty-seven (45%) of the 411 patients in clinical trials of TAGRISSO were 65 years of age and older, and 54 patients (13%) were 75 years of age and older. No overall differences in effectiveness were observed based on age. Exploratory analysis suggest a higher incidence of Grade 3 and 4 adverse reactions (32% versus 25%) and more frequent dose modifications for adverse reactions (23% versus 17%) in patients 65 years or older as compared to those younger than 65 years.

Renal Impairment

No dedicated clinical studies have been conducted to evaluate the effect of renal impairment on the pharmacokinetics of osimertinib. Based on population pharmacokinetic analysis, no dose adjustment is recommended in patients with mild [creatinine clearance (CLcr) 60-89 mL/min] or moderate (CLcr 30-59 mL/min) renal impairment. There is no recommended dose of TAGRISSO for patients with severe renal impairment (CLcr <30 mL/min) or end-stage-renal disease *[see Clinical Pharmacology (12.3) in the full Prescribing Information]*.

Hepatic Impairment

No dedicated clinical studies have been conducted to evaluate the effect of hepatic impairment on the pharmacokinetics of osimertinib. Based on population pharmacokinetic (PK) analysis, no dose adjustment is recommended in patients with mild hepatic impairment [total bilirubin <upper limit of normal (ULN) and AST between 1 to 1.5 times ULN or total bilirubin between 1.0 to 1.5 times ULN and any AST]. There is no recommended dose for TAGRISSO for patients with moderate or severe hepatic impairment *[see Clinical Pharmacology (12.3) in the full Prescribing Information]*.

17 PATIENT COUNSELING INFORMATION

Advise the patient to read the FDA-approved patient labeling (Patient Information).

Interstitial Lung Disease/Pneumonitis

Inform patients of the risks of severe or fatal ILD, including pneumonitis. Advise patients to contact their healthcare provider immediately to report new or worsening respiratory symptoms *[see Warnings and Precautions (5.1) in the full Prescribing Information]*.

QTc Interval Prolongation

Inform patients of symptoms that may be indicative of significant QTc prolongation including dizziness, lightheadedness, and syncope. Advise patients to report these symptoms and to inform their physician about the use of any heart or blood pressure medications *[see Warnings and Precautions (5.2) in the full Prescribing Information]*.

Cardiomyopathy

- TAGRISSO can cause cardiomyopathy. Advise patients to immediately report any signs or symptoms of heart failure to their healthcare provider *[see Warnings and Precautions (5.3) in the full Prescribing Information]*.

Embryo-Fetal Toxicity

- TAGRISSO can cause fetal harm if taken during pregnancy. Advise pregnant women of the potential risk to a fetus.
- Advise females to inform their healthcare provider if they become pregnant or if pregnancy is suspected, while taking TAGRISSO *[see Warnings and Precautions (5.3) and Use in Specific Populations (8.1) in the full Prescribing Information]*.

Females and Males of Reproductive Potential

- Advise females of reproductive potential to use effective contraception during treatment with TAGRISSO and for 6 weeks after the final dose *[see Use in Specific Populations (8.3) in the full Prescribing Information]*.
- Advise males to use effective contraception during treatment and for 4 months after the final dose of TAGRISSO *[see Use in Specific Populations (8.3) in the full Prescribing Information]*.

Lactation

Advise women not to breastfeed during treatment with TAGRISSO and for 2 weeks after the final dose *[see Use in Specific Populations (8.2) in the full Prescribing Information]*.

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tools

Approved Drugs

• The U.S. Food and Drug Administration (FDA) granted accelerated approval to **Alecensa® (alectinib) capsules** (Genentech, gene.com) for the treatment of patients with anaplastic lymphoma kinase (ALK)-positive metastatic non-small cell lung cancer (NSCLC) who have progressed on or are intolerant to crizotinib. Alecensa is an oral medication that blocks the activity of the ALK protein, which may prevent NSCLC cells from growing and spreading.

• Teva Pharmaceuticals Industries Ltd. (tevausa.com) and Eagle Pharmaceuticals, Inc. (eagleus.com) announced that the FDA has approved **Bendeka™ (bendamustine hydrochloride) injection**, a liquid, low-volume (50 ml) and short-time 10-minute infusion formulation of bendamustine. Bendeka is approved for the treatment of patients with chronic lymphocytic leukemia (CLL) and for the treatment of patients with indolent B-cell non-Hodgkin lymphoma (NHL) that has progressed during or within six months of treatment with rituximab or a rituximab-containing regimen. Efficacy in CLL relative to first-line therapies other than chlorambucil has not been established.

• The FDA has approved Genentech's (gene.com) **Cotellic™ (cobimetinib)** for the treatment of people with BRAF V600E or V600K mutation-positive unresectable or metastatic melanoma in combination with Zelboraf® (vemurafenib). Cotellic and Zelboraf are not used to treat melanoma with a normal BRAF gene.

• Janssen Biotech, Inc. (janssenbiotech.com) announced that the FDA has granted accelerated approval to **Darzalex™ (daratumumab injection)** as a single agent for the treatment of patients with multiple myeloma who have received at least three prior lines of therapy, including a proteasome inhibitor (PI) and an immunomodulatory agent, or who are double-refractory to a PI and an immunomodulatory agent.

• The FDA approved Bristol-Myers Squibb's (bms.com) **Empliciti™ (elotuzumab)** in combination with lenalidomide and dexamethasone for the treatment of patients with multiple myeloma who have received one to three prior therapies.

• Merck (merck.com) announced that the FDA approved an expanded age indication for **Gardasil®9 (Human Papillomavirus 9-valent Vaccine, Recombinant)**, Merck's 9-valent human papillomavirus (HPV) vaccine, to now include use in males 16 through 26 years of age, for the prevention of anal cancer caused by HPV types 16, 18, 31, 33, 45, 52, and 58, precancerous or dysplastic lesions caused by HPV types 6, 11, 16, 18, 31, 33, 45, 52, and 58, and genital warts caused by HPV types 6 and 11.

• The FDA approved the first generic version of **Gleevec® (imatinib mesylate)**. The FDA granted a subsidiary of Indian drug maker Sun Pharmaceutical Industries Ltd. approval to sell generic Gleevec in 100-milligram and 400-milligram pills for chronic myeloid leukemia. Mumbai-based Sun Pharmaceutical will begin selling the once-a-day pill in the U.S. on Feb. 1, 2016.

• Millennium Pharmaceuticals (millennium.com) announced that the FDA has approved **Ninlaro® (ixazomib)** in combination with lenalidomide and dexamethasone for the treatment of patients with multiple myeloma who have received at least one prior therapy. Ixazomib is the first approved oral proteasome inhibitor.

• The FDA approved Bristol-Myers Squibb's (bms.com) **Opdivo® (nivolumab) Injection** for the treatment of advanced renal cell carcinoma in patients who have received prior anti-angiogenic therapy.

• Eli Lilly & Company (lilly.com) announced that the FDA has granted approval to **Portrazza™ (necitumumab)** in combination with gemcitabine and cisplatin for first-line treatment of patients with metastatic NSCLC. Necitumumab is not indicated for treatment of non-squamous NSCLC.

• Novartis (novartis.com) announced that the FDA has granted regular approval for the combination of **Tafinlar® (dabrafenib) + Mekinist® (trametinib)** for the treatment of patients with BRAF V600E/K mutation-positive unresectable or metastatic melanoma as detected by an FDA-approved test.

• The FDA has approved AstraZeneca's (astrazeneca.com) **Tagrisso™ (osimertinib)** 80 mg once-daily tablets for the treatment of patients with metastatic epidermal

growth factor receptor (EGFR) T790M mutation-positive NSCLC, as detected by an FDA-approved test, who have progressed on or after EGFR tyrosine kinase inhibitor (TKI) therapy.

• The FDA has approved Wellstat Therapeutics' (wellstattherapeutics.com) **Vistogard® (uridine triacetate)** for the emergency treatment of adults and children who receive an overdose of the cancer treatment fluorouracil or capecitabine, or who develop certain severe or life-threatening toxicities within four days of receiving these cancer treatments.

Drugs in the News

• ArQule, Inc. (arqule.com) announced FDA orphan drug designation for **ARQ 087** in cholangiocarcinoma. ARQ 087 is a multi-kinase inhibitor designed to preferentially inhibit the fibroblast growth receptor (FGFR) family.

• Daiichi Sankyo, Inc. (dsi.com) and Plexxikon, Inc., a member of the Daiichi Sankyo Group, announced that the FDA has granted breakthrough therapy designation to its investigational oral **CSF-1R inhibitor pexidartinib (formerly PLX3397)** for the treatment of tenosynovial giant cell tumor (TGCT) where surgical removal of the tumor would be associated with potentially worsening functional limitation or severe morbidity.

• The FDA has granted breakthrough therapy designation to Kite Pharma's (kitepharma.com) **KTE-C19** for the treatment of patients with refractory diffuse large B cell lymphoma, primary mediastinal B cell lymphoma, and transformed follicular lymphoma.

Approved Devices

• The FDA has approved EDAP's (edap-tms.com) **Ablatherm® Integrated Imaging High-Intensity Focused Ultrasound (HIFU)** for the ablation of prostate tissue. The Ablatherm Integrated Imaging device precisely targets the tumor through a computer controlled rectal probe. Ultrasound waves destroy the prostate tissue with no damage to the surrounding organs. This treatment option is effective, efficient and adaptable, with early success determination and minimal side effects.

• The FDA cleared for marketing in the U.S. the **DigniCap Cooling System** (Dignitana Inc., dignitana.se/eng/) a cooling cap to reduce hair loss (alopecia) in female breast cancer patients undergoing chemotherapy. The system is indicated to reduce the frequency and severity of alopecia during chemotherapy in breast cancer patients in which alopecia-inducing chemotherapeutic agents and doses are used. It is a computer-controlled system that circulates cooled liquid to a head-worn cooling cap during chemotherapy treatment. The cooling cap is covered by a second cap made from neoprene, which holds the cooling cap in place and acts as an insulation cover to prevent loss of cooling.

Continued Medicare Coverage for PancraGEN™

PDI, Inc. (pdi-inc.com) subsidiary, Interpace Diagnostics, announced that Novitas Solutions, Inc., the Medicare Administrative Contractor (MAC) for Interpace Diagnostics has updated its local coverage determination (LCD) for PancraGEN test, which utilizes the PathFinderTG® platform. The original coverage issued on Nov. 5, 2010, provided "Coverage with Appropriateness Development," which required the company to routinely present updated data to further validate the test's effectiveness. The new policy no longer includes this condition for coverage and was effective Dec. 31, 2015.

Genetic Tests and Assays in the News

• The FDA has approved Roche's (roche.com) **cobas® EGFR Mutation Test v2** for companion diagnostic use. The next-generation test from Roche includes expanded mutation coverage of EGFR gene in DNA derived from tumor tissue. The test can be used to select eligible NSCLC patients who harbor a T790M mutation, for treatment with Tagrisso™ (osimertinib) or for eligible NSCLC patients with exon 19 deletions or L858R mutations for treatment with Tarceva® (erlotinib). OI

spotlight

Fauquier Health Center for Cancer Care

Warrenton, Va.

The Fauquier Health Center for Cancer Care is a hospital-based facility located in Warrenton, Va. The cancer center and the infusion center are located on the main level of Fauquier Hospital. The hospital itself sits at the top of a hill at one of the higher altitudes in Warrenton, making it a visible landmark from anywhere in town. As patients and visitors enter the hospital, they will find the infusion center and medical oncology suite immediately to the left. The infusion center, staffed with oncology certified nurses, has an open design with a total of 11 chairs in separate suites. The open layout has been well-received by patients, though they can also use drapes should they want privacy.

"Patients feel like they are getting a university type of experience with a multidisciplinary consultation but they get it in the luxury and comfort of a community setting," said Syed Salman Ali, MD, medical oncologist at Fauquier Health Center for Cancer Care. Dr. Ali describes Fauquier's patient population as "mixed," with a portion that is truly rural in north Virginia, and a large portion that is suburban, residing just outside Washington, D.C.

The cancer center hospital setting offers an obvious advantage to patients in the event of either an emergency or should inpatient services be required. "Our focus is making sure people are treated on the outpatient side and keeping them in their beds at night. Sometimes you can't do that. Sometimes you have to utilize the hospital," said Dr. Ali.

This built-in advantage allows for a seamless transition to inpatient care. "For example, you don't have to call an ambulance to take someone in. We're able to put patients in a wheelchair and take them ourselves directly to the emergency room, and we will literally take them and hand them off to our emergency room colleagues within a matter of minutes," shared Dr. Ali.

Medical oncology services are located in a suite on the hospital campus. Radiation oncology services are provided offsite in a separate practice located just down the road from the cancer center. The radiation oncology center is owned by a health system partner of Fauquier Health, LifePoint Health.

Between the advanced interventional radiology suite on campus and the radiation oncology services off-site, Fauquier offers a number of cutting-edge therapeutic services, including 3D mammography, RapidArc, and stereotactic radiosurgery (SRS). Dr. Ali hopes that with a new interventional radiologist on staff, the cancer center can begin offering yttrium-90 locally to patients with liver disease.

All other care services are built into the cancer center infrastructure, including pharmacy, nursing, and a lab. On-site supportive care offerings include *Look Good, Feel Better*, cancer support groups, a grief support group, chaplain services, nutrition and exercise counseling, Reiki therapy, and pet therapy.

Patient financial assistance is a team effort handled on a case-by-case basis. The providers, billing department, pharmacy, and patient navigator work together to try and mitigate patients' financial burdens. This includes helping patients access assistance with drugs, co-pays, or obtaining insurance coverage. Fauquier Health is currently developing a formalized relationship with a patient assistance program to identify at-risk patients early during a screening process to capture those who may eventually require help.

The Importance of Navigation

According to Dr. Ali, the cancer center's navigation program has evolved tremendously with the hiring of oncology nurse navigator Richard Shrout, MSN, RN. "The word is out in the community that we have a patient navigator. We will often get referrals from patients themselves or from providers referring patients to our navigator for various cancers," said Dr. Ali. Typically, when new patients with cancer diagnoses come into the cancer center, they will meet with the navigator during their first or second visit, and then the navigator becomes part of the work flow going forward. The oncology nurse navigator helps to facilitate all the necessary appointments and referrals to get patients plugged into the healthcare system and on a path of smooth, coordinated care.

One potential community need Fauquier identified was in regards to time from a suspicious mammogram finding to biopsy. With the navigator as a part of the care team, the radiologist can now alert the oncology nurse navigator to a suspicious finding. "I'm called in to talk to the patient, introduce myself as the nurse navigator, follow them through screening, and if they're diagnosed with cancer, I will get them into the oncology program," said

Opposite: Fauquier Hospital; *Above Left:* Oncologist Dr. Syed Salman Ali and oncology nurse Lois Sutphin, RN, discuss treatment options with a patient in Fauquier Hospital's Infusion Center; *Above Right:* Richard Shrout, MSN, RN, talks with a patient about her cancer care plan.

Shrout, thus helping improve coordination of care.

The addition of the navigator at the start of the treatment journey has had a measurable impact. "It dramatically shortened the amount of time from patients being notified they had a bad finding on a mammogram to actually getting a biopsy. In some cases, patients had been waiting up to a few weeks to meet with a surgeon for a biopsy, and we were able to shorten that time down to one to two days. The net result is that patients are getting a diagnosis and a formalized treatment plan and starting their definitive therapy much faster," said Dr. Ali.

Engaging Patients

Even though clinical trials are not available on-site yet, both Dr. Ali and the oncology nurse navigator screen almost all patients for clinical trial eligibility. By having good working relationships with other cancer centers in the region, such as the Georgetown Lombardi Cancer Center, Fauquier Health Center for Cancer Care is able to refer willing patients to larger systems with robust trial options.

"I will try to identify the best tertiary center for them and get them to those sites as soon as possible for a clinical trial evaluation. That's probably the easiest way to do it as a community site. Because we don't offer trials on-site yet, you don't want to limit your patients' options," said Dr. Ali.

Fauquier Health Center for Cancer Care providers participate in a variety of monthly multidisciplinary tumor boards: breast, GI malignancy, GU malignancy, and head and neck. In addition, a non-specific monthly general tumor board meets for a deeper dive into several additional cases.

Dr. Ali and his colleagues are also currently piloting a monthly tumor board for more complex cases. Currently, one patient per month is invited to meet with the group post-conference. The patient and family meet with the whole multidisciplinary team at once and receive a formal consultation and opinion. Patients are not charged for this visit, which allows them to ask questions and get answers from the entire care team. "This is doctors in our disciplines, taking time out of their day, taking on one complex case, and giving the family an extra hour—sometimes more—of time," said Dr. Ali.

Dr. Ali is hopeful that as the cancer center grows its infrastructure, this type of tumor board can meet more frequently and invite more patients to attend. "We've had some really fantastic feedback. Patients generally bring their families since it's a very unique experience, and we've heard nothing but wonderful reviews about it. What we've heard specifically is that patients felt that all of their potential questions were asked and answered. They were able to talk to all of their participating providers at the same time," he said.

Select Support Services:

- Navigation
- Chaplain
- *Look Good, Feel Better*
- Support groups
- Nutrition counseling

Number of new analytic cases in 2014: 242.

Unlock the Potential of the Cancer Registrar

BY PAULETTE ZINKANN, BS, CTR, AND
LINDA CORRIGAN, MHE, RHIT, CTR

Dual responsibilities—good for staff, better for programs

The cancer registry profession is best known for its data collection and dissemination of cancer incidence, stage, and survival information. Cancer registrars—the backbone of cancer programs—historically have been limited to gleaning information from charts, preparing facility data reports, and conveying this data to the National Cancer Database. This database, jointly sponsored by the American College of Surgeons' Commission on Cancer (CoC) and the American Cancer Society (ACS), receives data from accredited cancer programs (about 30 million historical records) and provides public data on approximately 70 percent of newly diagnosed cancers nationwide.[1]

Registrars prepare abstracts for each cancer patient that include demographic information, cancer identification, treatment, follow-up, and survivorship. The data must be accurate, and registrars are charged by facility, state, and national requirements to ensure that the data are complete. During the case-finding process, registrars review facility records (both inpatient and outpatient cases), diagnostic radiology, pathology, medical, and radiation oncology records. Follow-up tasks include tracking patients from the time of diagnosis through death, using as many reliable sources as possible to ascertain whether or not a cancer patient is still alive, is recurrent, or is disease free.

While this data collection is crucial in understanding cancer incidence rates and to help in the management of a cancer patient's care and treatment, more and more registrars are becoming involved in other aspects of their cancer program. In a day and age when multi-tasking is becoming the norm, cancer registrars are doing far more than case-finding, abstracting, and follow-up.

Other Duties as Assigned

For larger institutions, there are often too many cancer cases for the registrar to move beyond the traditional registry responsibilities discussed above. However, for many community cancer programs (programs that accession more than 100, but less than 500 newly diagnosed cancers each year[2]), a cancer registrar often has the time to become involved with other aspects of the cancer program. This includes, but is not limited to:

- Cancer conference activities
- Oncology committee projects
- Screening and prevention initiatives
- Community outreach programs.

Cancer registrars have a strong working knowledge of the information captured in the cancer registry database. They work with the cancer data on a continuous basis through collection and dissemination of the information, and their attention to detail makes them a natural resource to tap when developing cancer program initiatives. This expertise can prove to be good for staff and even better for the patients and the community served by the cancer program. Here is the story of how Eastside Medical Center, Snellville, Ga., and Atlantic General Hospital, Berlin, Md., are

using their cancer registrars to fill a critical role in each facility's lung cancer screening program.

How LDCT Changed the Landscape

According to the American Cancer Society (ACS), lung cancer is the leading cause of cancer deaths, and it is estimated that there will be a total of 158,040 deaths (both men and women) from lung cancer in the United States in 2015.[3] Until recently, studies for early lung cancer detection were limited to chest X-rays, sputum, and bronchoscopic studies. Unfortunately, these studies did not lead to a reduction in the disease. It was not until the use of low-dose computed tomography (LDCT) and its ability to detect small, early-stage lung cancers that a reduction in mortality occurred. In fact, two clinical trials in the United States and Europe both found a 20 percent reduction in lung cancer deaths in current smokers who used LDCT screening as a diagnostic tool. Based on the results of these studies and others, including the National Lung Screening Trial, the ACS issued guidelines for lung cancer screenings in 2013.[3] In December 2013, the U.S. Preventive Services Task Force (USPSTF) recommended that patients between the ages of 55 and 80 with a history of smoking receive annual screenings for lung cancer with LDCT. Patients who had a 30 pack per year smoking history or those who had quit within the last 15 years were eligible for this screening.[4] On February 5, 2015, the Centers for Medicare & Medicaid Services (CMS) issued a final national coverage determination for LDCT for Medicare beneficiaries who meet established criteria.[5]

The Eastside Medical Center Experience

In 2013, after reviewing its statistics, Eastside Medical Center, a CoC-accredited community cancer program, felt that it should consider LDCT screening as part of its lung cancer detection and prevention program. Eastside Medical Center is a 300-plus bed facility located in the southeastern portion of Gwinnett County, Ga. Lung cancer accounts for approximately 15 percent of the annual accession rate; 35 percent of the cases are Stage 4 disease. After journal reviews, as well as analysis of the National Lung Screening Trial, Eastside felt that it would be in the best interest of the community to implement an LDCT lung cancer screening program.

Under the guidance of its Oncology Committee, Eastside Medical Center established a subcommittee that included the center's administration, cancer registrar, and staff representatives from the medical and radiation oncology, pulmonology, diagnostic radiology, and thoracic surgery departments. The subcommittee developed a lung screening schema and patient-care path (Figure 1, right).

From the time the screening program was initiated, the cancer registrar played a critical role, assisting the oncology director in patient scheduling, order form development, patient follow-up documentation, and the creation of marketing materials. Eastside produced a "self-pay" order form, and members from the hospital's registration department worked with the oncology director and cancer registrar on patient intake and payment. The oncology director took on the role of lung screening patient navigator, with the registrar providing documentation on the screenings to the director, key physicians (diagnostic radiology, primary care, and pulmonology), and patients.

From the time the screening program was initiated, the cancer registrar played a critical role, assisting the oncology director in patient scheduling, order form development, patient follow-up documentation, and the creation of marketing materials.

Eastside Medical Center marketed the program in the Gwinnett County area, and was able to provide a self-pay, low-dose CT lung cancer screening that initially cost $149. At that time, the only other hospitals providing these services were located in the northwest Atlanta corridor, and they were charging $249 per self-pay screening. On the day the LDCT lung cancer screening program was launched, nine patients were screened and the registrar—under the instruction of the oncology director—contacted referring physicians with the patients' results. All nine cases were discussed at a special multidisciplinary lung screening conference, and recommendations from the physicians at the conference were provided to the patients' referring or primary care (PCP) physicians.

As the LDCT lung cancer screening program evolved, the cost was reduced to $99 and the cancer registrar became more involved with the patient navigation role through patient navigation software and related training provided by the Sarah Cannon Cancer Institute. By mid-2014, the cancer registrar had officially assumed the role of lung screening patient navigator. Today, the registrar is the lead staff person managing Eastside Medical Center's LDCT Lung Cancer Screening Program.

Since the program's inception in December 2013, the number of lung cancer screenings has continued to grow, with nine screenings in the first month of the program to more than 15 screenings in July 2015. In 2014 Eastside Medical Center became a member of the national Lung Cancer Alliance (LCA), and was named a Low-Dose Lung Screening Center of Excellence. The facility is

(continued on page 39)

Figure 1. Eastside Medical Center's 2013 Lung Cancer Screening Schema

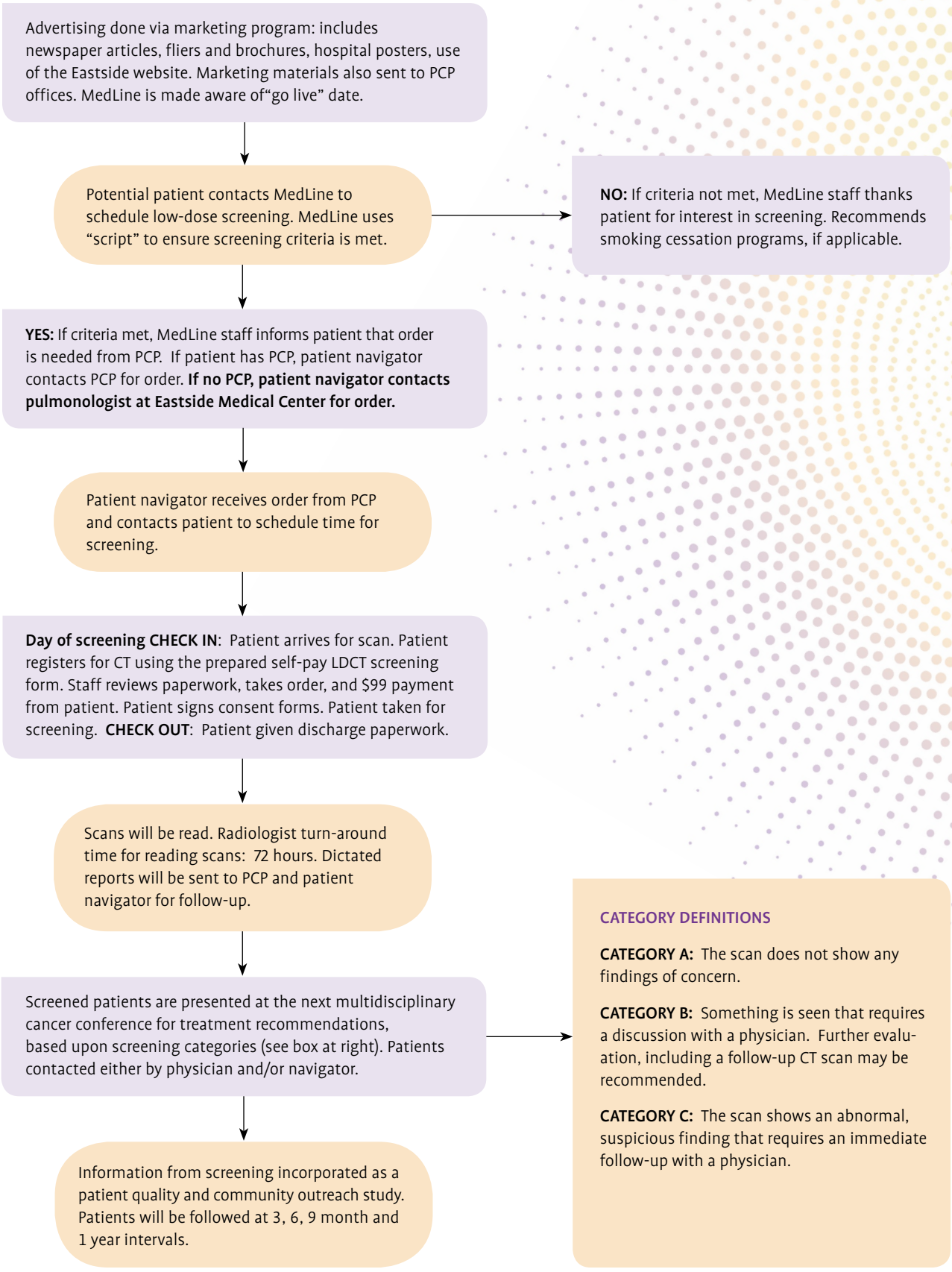
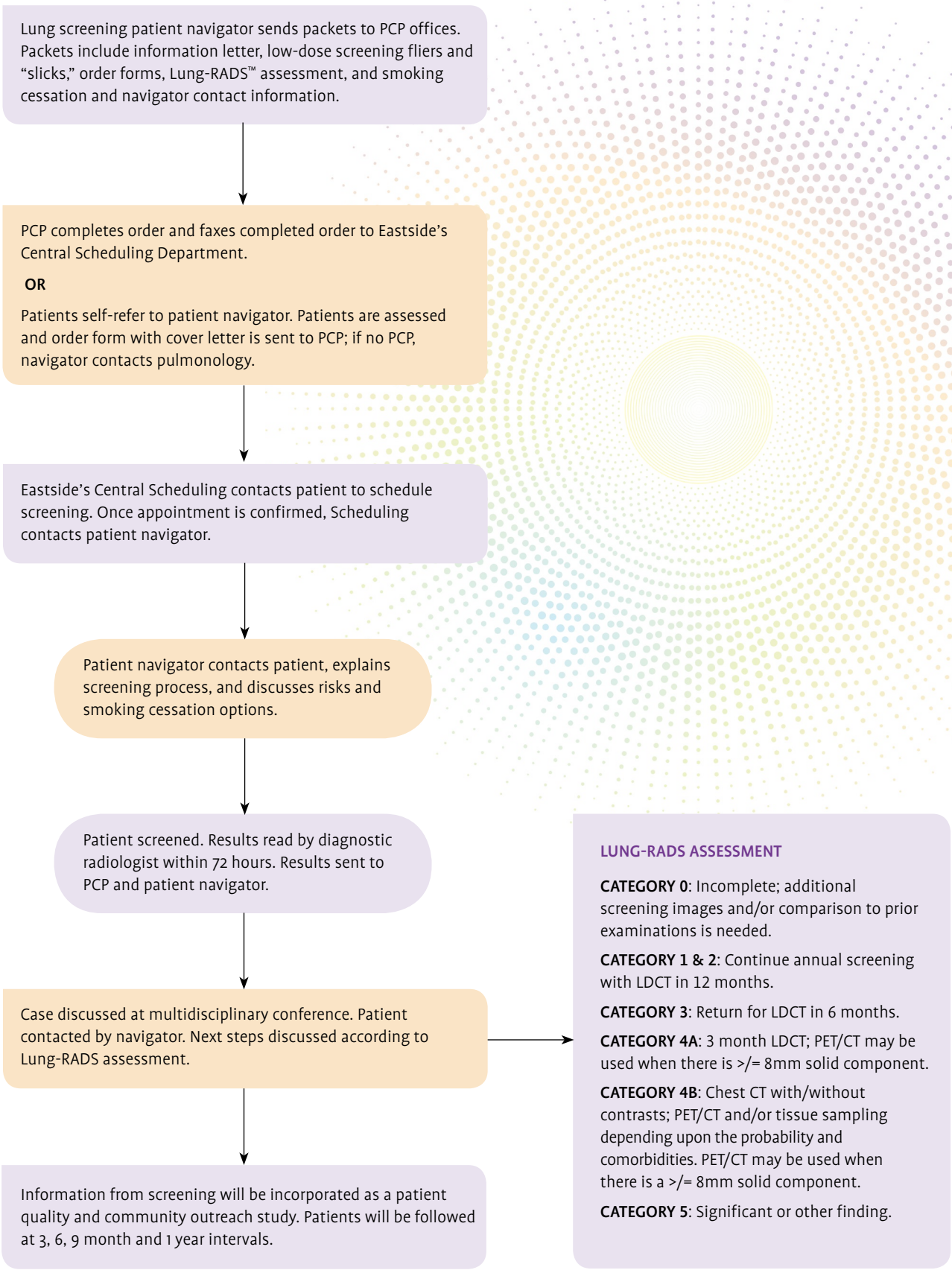


Figure 2. Eastside Medical Center's Current Lung Cancer Screening Schema



(continued from page 36)
listed on the National Lung Cancer Alliance website. As a result, Eastside Medical Center receives many inquiries from other facilities about how to replicate its successful screening program. Eastside promotes its affiliation with Lung Cancer Alliance and its designation as a center of excellence to help educate the community on the importance of low-dose screenings, using many LCA materials to promote lung cancer screening and Lung Cancer Awareness Month in November. (In 2015 ACCC also partnered with LCA to identify lung cancer resources, including member-shared tools that are available at: accc-cancer.org/lung.)

Based on USPSTF recommendations, Eastside Medical Center decided to streamline the processes for its LDCT lung cancer screening program in 2015 (Figure 2, left). To that end, the registrar met with members of the hospital's revenue integrity department, who provided payer codes and details for Medicare billing. Initially, as the Centers for Medicare & Medicaid Services (CMS) had not set a pay scale for Medicare patients, Eastside Medical Center decided to hold for payment all Medicare billings. In April 2015, CMS released coding guidance and a pay scale for screening and the registrar developed a new LDCT lung cancer screening form based on the new guidelines. After hospital approval, the registrar sent copies of the form to registration personnel and the central scheduling department; the registrar also performed an in-service with both departments. Marketing collateral was revised, and these updated fliers and information cards were posted on the hospital's website. The registrar worked with two diagnostic radiologists who would exclusively read the low-dose scans. Using the American College of Radiology's Lung-RADS™(Lung CT Screening Reporting and Data System), patients are now placed into categories according to their results (see Table 3, page 40).

Marketing to physicians has been very beneficial to Eastside Medical Center's LDCT lung cancer screening program. With assistance from the Oncology Committee, marketing, and physician-support representatives, the registrar developed information packets specifically for primary care physicians that contained pertinent information, such as direct phone numbers and screening forms. Working with physician-support representatives, these packets were distributed at quarterly physician meetings, directly to PCP offices, and at a Primary Care Symposium sponsored by Eastside Medical Center in November 2015. The packets were well-received by the physicians and their staff.

These efforts have paid off in a number of ways. Because of the streamlined process, Eastside Medical Center was able to eliminate the use of MedLine, the company that provided the original patient intake services. Now patients can either contact the lung screening patient navigator (i.e., the cancer registrar) directly to schedule an appointment or can be referred directly by their physician to Eastside Medical Center's central scheduling department via the new LDCT lung cancer screening orders. If contacted directly by a potential screening applicant, the lung screening patient navigator can explain the process for qualifying for a LDCT screening. In this scenario, the registrar takes the lead, contacting the patient and ensuring that a low-dose screening order form is completed by the physician and then sent to Eastside Medical Center's central scheduling department. When a screening form is sent directly to the central scheduling department, a daily report is provided to the lung screening patient navigator, who in turn contacts the patient. The lung screening patient navigator calls patients to gauge their understanding of the LDCT screening process. During the conversation, the navigator confirms that patients were informed about the risks of LDCT, discusses smoking cessation programs, and helps allay any patient fears. The one-on-one call affords an excellent time for patients to ask and have questions answered. This process also allows the lung screening patient navigator to further educate patients about the screening process.

To date, Eastside Medical Center has screened nearly 100 patients at its LDCT lung cancer screening program—an impressive number for a community hospital of its size.

Once the LDCT screening is completed and read, the lung screening patient navigator receives the report and contacts the referring physician's office. All recent screening cases are presented at the multidisciplinary conference for discussion and recommendations. Once the case is reviewed, the lung screening patient navigator contacts the patient via phone or letter. Patients are also provided information on the Lung Cancer Alliance and are given literature on the American Cancer Society's *FreshStart*® program (acsworkplacesolutions.com), including current class times, dates, and locations.

To date, Eastside Medical Center has screened nearly 100 patients at its LDCT lung cancer screening program—an impressive number for a community hospital of its size. This is not to say that there have not been challenges. As with all programs, the LDCT lung cancer screening program is a work in progress, and all parties are continuing to make the process more efficient. Some adjustments include the revenue integrity department reviewing each LDCT screening to ensure that Medicare-eligible cases are placed on hold. Registration has become much easier with the new forms, since self-pay is no longer a requirement. The central scheduling department developed and built new

dictionaries and reference lists for ease of scheduling. New schedulers are provided with the specifics for the LDCT screenings and are in contact with the lung screening patient navigator. Most questions relate to use of the proper form. When schedulers call to inform the lung screening patient navigator that an improper screening form was sent by a physician office, the navigator contacts the physician office, sending a copy of the form and asking for completion and resubmission.

But What about the Registry?

The cancer registry at Eastside Medical Center has only one registrar on staff who is responsible for all aspects of the registry. Extra time is required for the LDCT lung screening program, which many might think is an added burden for the registrar, but it is not. Cancer registrars pride themselves on their ability to be self-sufficient and manage their time. Many registrars have an innate capability to juggle many different tasks and responsibilities. Eastside Medical Center averages approximately three LDCT lung cancer screenings per week. With the new process, the

Table 3. Lung-RADS™ Version 1.0 Assessment Categories

CATEGORY DESCRIPTOR	CATEGORY DESCRIPTOR	PRIMARY CATEGORY	MANAGEMENT
Incomplete	N/A	0	Additional lung cancer screening CT images and/or comparison to prior chest CT examinations is needed
Negative	No nodules and definitely benign nodules	1	Continue annual screening with LDCT in 12 months
Benign Appearance or Behavior	Nodules with a very low likelihood of becoming a clinically active cancer due to size or lack of growth	2	
Probably Benign	Probably benign finding(s);short term follow up suggested, includes nodules with a low likelihood of becoming a clinically active cancer	3	6-month LDCT
Suspicious	Findings for which additional diagnostic testing and/or tissue sampling is recommended	4A	3-month LDCT; PET/CT may be used when there is a >/= 8mm solid component
		4B	Chest CT with or without contrast; PET/CT and/or tissue sampling depending on the probability of malignancy and co-morbidities; PET/CT may be used when there a >/= 8mm solid component
Significant-Other		S	
Prior Lung Cancer		C	

registrar receives a daily report of all cancer screenings. After each screening, the registrar is able to document data on each patient through the navigation software, prepare for the next lung screening conference, and perform follow-up on each case. This work averages about 30 minutes per case. With three cases per week, the average is 1.5 hours of registry time—or about the time it would take to perform case-finding on two cases or abstract two cases.

Involving the registrar in screening initiatives benefits both the registrar *and* the cancer program. Registry life revolves around data collection and usage—with little to no interaction with patients. By offering its registrar a dual or multi-faceted role that includes the added responsibilities of a LDCT lung cancer screening program, Eastside Medical Center has given its registrar the opportunity to work directly with patients. Moreover, the registrar has greatly enjoyed the move from a behind-the-scenes environment to actual patient interaction. The registrar is more involved with cancer center patients and now sees them as more than just data in a cancer database. Another benefit is that the registrar becomes more engaged with the cancer program itself. This involvement creates opportunities for professional growth and to advance the cancer registry department as a whole. Collecting cancer data will always be first and foremost for a registrar, but becoming more involved in different levels of patient cancer care is a plus. The cancer program benefits too, because now the registry data has more meaning. The cancer registrar's added responsibilities have brought about an even better understanding of the patient data, leading the registrar to suggest additional studies and other uses of the data to improve screening processes and adjust patient navigation systems. Eastside Medical Center has learned much from its LDCT lung cancer screening program.

The Atlantic General Hospital Experience

Atlantic General Hospital is a not-for-profit 62-bed community hospital in Berlin, Md. With more than 20 community-based physicians; it is part of the larger Atlantic General Health System. As its oncology program grew, Atlantic General began building the case to hire a cancer registrar. According to Ann Bergey, vice president, Quality and Medical Staff Services, Atlantic General Hospital, the decision to include lung cancer screening data collection and patient monitoring in the job description for the new cancer registrar made perfect sense since the cancer registrar would be coordinating the cancer conference where the screening patients would be discussed. Once the registrar was on board and the process to select registry software began, it was clear that the software could also serve a dual purpose. Customizable letters using mail merge, along with user-defined fields in a separate tabbed location, enabled Atlantic General Hospital to actually build the lung cancer screening criteria into OncoLog, the chosen cancer registry software.

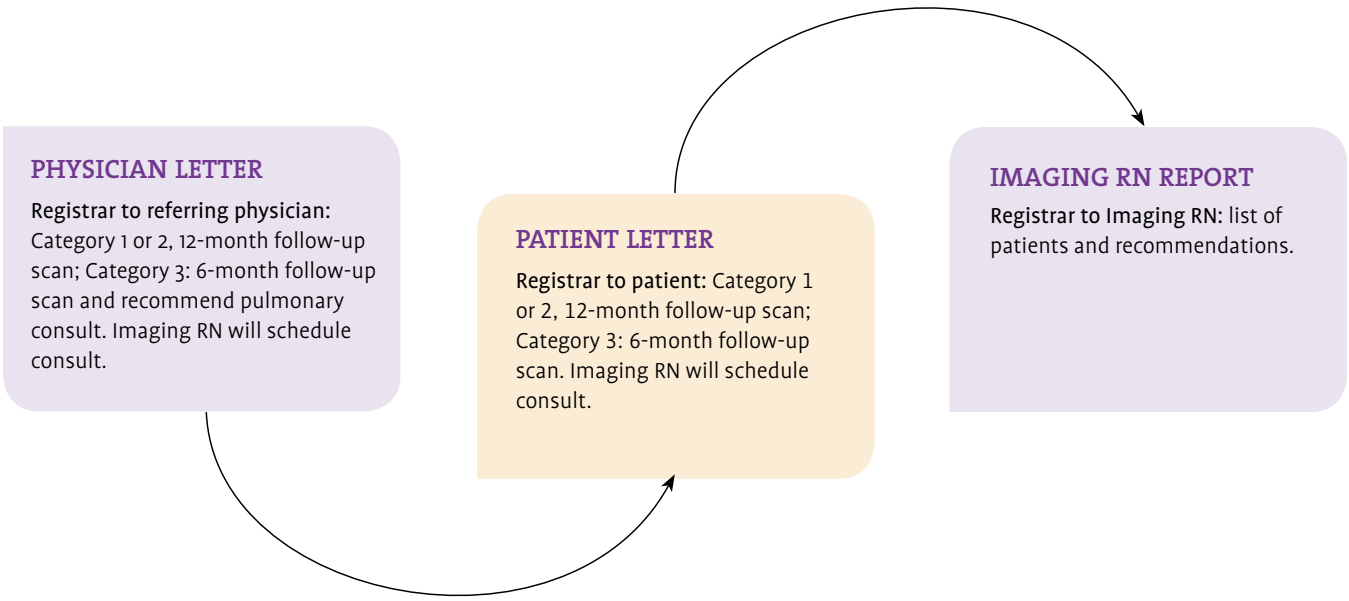
As the lung cancer screening program moves into year two, the hospital looks to measure the impact of smoking cessation counseling and interventions as those fields are now collected by the registrar.

Atlantic General Hospital has only been screening for lung cancer for a little more than a year and continues to make adjustments and refine its patient pathway, as well as the fields collected by the registrar. Registry software programs are rich with standard fields that can be used by a cancer program to analyze a lung screening program's impact on the community and plan for the future. What cities and counties in the hospital's service area have the highest utilization of the lung screening program? Does this utilization match the rate of diagnosed lung cancer for that area? The annual Community Needs Assessment outlines a variety of demographics for a hospital's service area, allowing the registrar to use the software to determine if lung cancer screening patients mirror those demographics. Collecting the insurance payer-type of lung screening patients also provides the marketing department more information on who is utilizing this service.

Additionally, patients' smoking status, along with their pack years, is part of the screening criteria and is assessed at each follow-up exam. As the lung cancer screening program moves into year two, the hospital looks to measure the impact of smoking cessation counseling and interventions as those fields are now collected by the registrar.

Being an American College of Radiology (ACR) Designated Lung Cancer Screening Center, Atlantic General Hospital has also incorporated the ACR Lung-RADS assessment categories into the radiologist's impression on the LDCT report. It is the responsibility of the cancer registrar to review the dictated impression in each report the day after patients have their scan. The pulmonologist and radiologist associated with the lung screening program developed a plan of action based on Lung-RADS and collaborated with the cancer registrar to craft letters specific to each category. Figure 3, page 42, shows the workflow for the cancer registrar for Lung-RADS categories 1, 2, and 3. The workflow for these categories mainly requires reviewing the radiologist's impression on the LDCT, sending letters, and then notifying the imaging nurse. When the radiologist's impression on the lung screen is either a Lung-RADS 4A or 4B, several additional steps are required, and this is where a cancer registrar's

Figure 3. Atlantic General Hospital's LDCT Post-Scan Pathway for Lung-RADS Categories 1, 2, & 3



unique set of skills becomes critical. Attention to detail and follow through are demonstrated on a daily basis in the work of the cancer registrar, so incorporating the registrar into the lung screening workflow can be an effective use of resources.

For patients with Lung-RADS categories 4A and 4B, Atlantic General Hospital decided that a consult with a pulmonologist is warranted. These cases are then presented to the multidisciplinary group at cancer conference. The cancer registrar calls the pulmonologist's office, as a courtesy to the referring physician, and schedules an appointment for the patient. The registrar then calls the referring physician, notifying them of the results of their patient's lung screening, outlining the next steps (including the need for a pulmonologist's evaluation), and offering the courtesy appointment. Referring physicians are responsible for notifying their patients. Following these phone calls, letters are then generated from the cancer registry software and sent to referring physicians and patients, indicating the need for a consult with a pulmonologist. The community-based pulmonologist at Atlantic General Hospital evaluates patients in the office as soon as possible. As a result, the pulmonologist will have first-hand knowledge of patients and their history and is able to present patient cases at the first available cancer conference. The cancer registrar schedules the patient cases to be presented by the pulmonologist at the cancer conference and invites the referring physician to attend. If the referring physician is unable to attend, the pulmonologist will communicate conference recommendations back to the referring physician. In the first year of offering lung cancer screening, Atlantic General Hospital screened 34 patients:

- 73 percent needed a follow-up scan in 1 year
- 12 percent needed a follow-up scan in 6 months
- 15 percent needed a consult with a pulmonologist, resulting in 6 percent being diagnosed with lung cancer.

Expanding the Role of the Registrar

In the ACCC 2015 *Trends in Cancer Programs* survey, 77 percent of respondents reported having a lung cancer screening program in place—up from the 51 percent that reported having such a program in 2014. Interestingly, none of the respondents listed cancer registrars as members of their lung cancer screening team. When cancer programs were asked what they planned to do to increase revenue, 44 percent said they would be increasing screening activities. For cancer programs planning to increase their screening efforts to include lung cancer, expanding the role of cancer registrars to include the dual responsibility of managing the registry and a lung cancer screening program is an option worth considering. The specific job duties of cancer registrars

who help with lung cancer screening programs are as varied as the programs they support. In the case of Eastside Medical Center, the cancer registrar acts as the lung screening navigator to interact directly with patients being screened. This type of personalized service not only distinguishes the center's LDCT lung cancer screening program from others in the area; it has led to higher job satisfaction for the cancer registrar. The cancer registrar at Atlantic General Hospital also reports a higher job satisfaction, noting that analyzing the data for the purpose of supporting the screening program, helping to track patients, and being a part of the team that finds a lung cancer early, is enormously rewarding.

Beyond the cancer registrar having dual responsibilities with the lung cancer screening program, the cancer registry software program can also serve dual functions. As stated earlier, most software programs have a variety of standard and user-defined fields and these can be utilized to gather much needed data for programs with a specific goal of growing their lung cancer screening services. Cancer registrars are familiar with outmigration reports to administration, which highlight or identify procedures and treatments not offered at their hospital. This data is often used to support proposals to purchase new equipment or recruit specialists to the hospital. If specific lung screening data is collected by the registrar, this same process of data reporting could be used to determine if it makes sense for the hospital to add a PET, start offering endobronchial ultrasound procedures, or even recruit a thoracic surgeon. As shown in these two case studies, allowing cancer registrars to assume a greater role in lung cancer screening initiatives can benefit the cancer program and cancer registrars, allowing them to grow professionally and apply their unique, in-depth knowledge of the cancer registry database to enhance services. OI

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BY CHAD SCHAEFFER, MS, FACHE

Talk to Me

Improve patient engagement; improve your cancer program

Patient engagement is a buzz word cancer program administrators are hearing more often as patients become increasingly aware of their ability to choose where they receive healthcare. In most markets, hospitals and physician practices face numerous competitors for healthcare dollars. Cancer care is no different. In fact, because of the acute nature of the disease, more cancer patients are open to seeking second opinions or identifying a specialist who they believe can best take care of their unique needs—even if that means looking for care outside of their community.

By definition, taking care of an individual patient's unique needs requires that healthcare providers actively involve the patient throughout the continuum of care. Today's cancer patients desire more than merely treatment for their disease, they want a cancer program that:

- Includes them in the decision-making process
- Educates them about their treatment options
- Keeps them updated on the progress of their care
- Treats them with a high level of respect and dignity.

The best cancer programs will be those that actively involve patients and their families in all aspects of their care. Indeed, if we are to be successful in competing for these patients, we must fully embrace the concept of patient engagement.

Patient Engagement Defined

The Center for Advancing Health defines patient engagement as "the actions individuals must take to obtain the greatest benefit from the healthcare services available to them."[1] This definition is framed from the patient's perspective. For patients to be "engaged," they must take steps to ensure that they are active participants in their healthcare. Simply put, engagement is an ongoing and mutually beneficial interaction between patients and providers. For this collaboration to occur, the physician and staff at the cancer program must be open and able to spend extra time with patients, as necessary, in order to ensure that patients are truly involved in their care plan. Ultimately, the goal is to develop a shared decision-making approach for each cancer patient and each visit.

Embracing the concept of patient engagement brings many benefits to your cancer program. For example, engaged patients effectively communicate their treatment goals to their providers, which is essential in ensuring that patients' needs are met throughout the course of their therapy. Engaged patients are also more

likely to be compliant with scheduling appointments, and following other instructions properly when they are not in clinic (i.e., their oral chemotherapy medicines, other prescriptions, medication schedules, etc.).

Often cancer programs see improvements in patient safety when patients are actively involved in treatment decision making. Specifically, when providers stop and do a "time out" before a procedure—before giving chemotherapy or radiation oncology—they involve patients, affording them an opportunity to prevent a medical error.

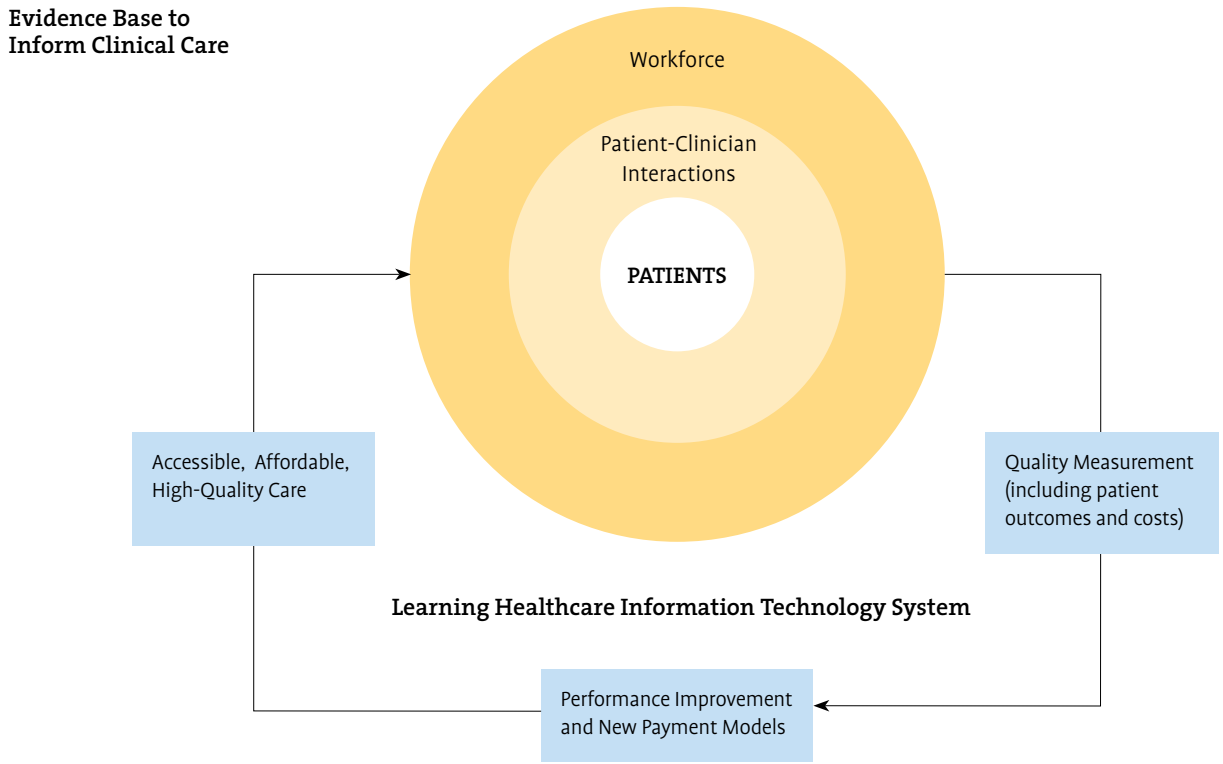
Our Industry's Track Record

Unfortunately, the news is not good when it comes to the healthcare industry's track record for engaging patients. The 2013 Institute of Medicine (IOM) report, Delivering High-Quality Cancer Care: Charting a New Course for a System in Crisis makes two specific recommendations for cancer care providers concerning patient engagement. First, the cancer care team should provide patients and their families with:[2]

- Understandable information on cancer prognosis
- Treatment benefits and harms
- Palliative care
- Psychosocial support
- Estimates of the total and out-of-pocket costs of cancer care.

Second, in the setting of advanced cancer, the cancer care team should provide patients with end-of-life care consistent with their needs, values, and preferences.[2] However, most cancer programs are not meeting these recommendations with a high degree of consistency. Studies cited in the IOM report suggest that clinicians asked about patients' preferences in medical decisions only about 50 percent of the time.[3] Another study found that 70 to 80 percent of cancer patients with a poor prognosis incorrectly believed that their treatments were likely to result in a cure.[4] Unfortunately, if

Figure 1. The IOM Model for a High-Quality Cancer Care Delivery System



Source: The IOM report, Delivering High-Quality Cancer Care (2013)

we were to give a letter grade for the industry's performance as a whole, it would be an "F."

A number of factors contribute to the healthcare industry's poor performance with patient engagement. One is that, historically, third-party payers have been the major source of payment for providers—not patients. However, this situation is rapidly changing in a post-Affordable Care Act (ACA) era that promises more transparency in costs, an increase in pay-for-performance measures, and new technology requirements for providers, such as having electronic health records (EHRs) that meet "Meaningful Use" requirements. That said, it is still difficult for consumers (patients) to find and evaluate quality and cost information on healthcare services.

Getting Started with Patient Engagement

To truly engage your cancer patients, it takes a commitment from everyone in your cancer program. All staff—from the front desk to the C-suite—must share a common vision. This vision must empower staff to always be concerned with providing patient-centered care, making patients the center of all of your daily practices and processes. Figure 1, left, shows the IOM recommendation for a model that has patients in the center with the healthcare workforce surrounding them and patient-staff interaction and communication in the key area in between. Adoption of this model is critical to patient engagement.

The IOM recommendation of this care delivery model is a paradigm shift for many hospitals and physician practices, which often have a physician-centric or staff-centric model. For instance, when establishing a physician clinic, typically the physician has the final say on the schedule, how operations will be staffed, and how services will be provided. In a patient-centered model, completely different choices may be made. In other words, what's convenient for the hospital staff or physician staff might be inconvenient for the patient. Cancer programs that make the decision to stay open later during the week or open on the weekend to accommodate working patients and caregivers are putting patient convenience before provider convenience.

With the understanding that patient engagement is not just a "flavor of the month" strategy, but a real commitment and effort that must be made throughout the cancer program, the following are some steps to help you get started on your journey of increasing patient engagement in your cancer center.

Make patient engagement a major part of your strategic plan. As part of your next strategic planning, take a hard look at your current program and identify opportunities to improve patient engagement. Have patients at the table early and often during the planning process, with a continuous feedback loop post-planning. To kick-start your planning, you might consider having a patient-engagement retreat where physicians, staff, and possibly board members can learn about some of the best practices to engage your cancer patients. During the retreat you might look at your cancer program's vision statement and consider refining it to include patient engagement and/or patient-centered care.

Monica Littlejohn, RN, with a pediatric cancer patient.

Designate a few staff and physicians as "patient engagement champions." In addition to leaders who are well-respected cancer program staff, cancer patients should also serve as champions of the patient engagement initiative. Such champions are important to build support and buy-in from others.

Review IOM recommendations for steps needed to better engage cancer patients. The IOM provides tactics to accomplish stated goals for patient engagement. These include:

- Improving decision aids and making them available through print, electronic, and social media.
- Providing professional educational programs for members of the cancer care team that include comprehensive and formal training in communication. The cancer care team should communicate and personalize this information for patients at key decision points along the continuum of cancer care, using decision aids when available.
- Improving communication with patients with advanced cancer. Clinicians should discuss option with these patients, including conversations about advance care plans, palliative care, psychosocial support, and maximizing quality of life (QOL) by providing timely use of hospice care. The IOM points out that

these difficult conversations do not occur as frequently or in as timely a manner as they should, resulting in care that may not be aligned with patient preferences.
- Ensuring members of the cancer care team receive education and formal training in end-of-life communication.
- Evaluating and potentially improving the current process for handling patients' advance care plans.
- Evaluating and potentially improving the current process for providing cancer patients with palliative care, psychosocial support, and timely referral to hospice care for end-of-life care.

Process mapping the patient (customer) experience. Mapping the steps that patients go through when accessing care at your cancer program helps in understanding not only how patients interact with staff, but also opportunities for improvement. Process mapping also helps you identify current gaps in the patient-engagement "ecosystem" and develop tactics to plug these gaps.

Creating an Engagement Ecosystem

The following are some potential areas that offer a chance to interact and engage with your patients. To be successful, your cancer program needs to explore every area that provides an opportunity for better communication with your patients.

Adopt a shared decision-making approach. According to the National Cancer Institute (NCI), patient-clinician communication plays an important role in optimizing the health outcomes for people who have or have had cancer. More support for this approach comes from a 2014 IOM report that describes shared decision making as a three-phase process:[5]

1. Information exchange
2. Deliberation
3. Reaching final decision.

The decision often extends beyond medical issues, and includes factors such as finances and the impact on employment and family.[5] Shared decision making may be a shift for many providers that tend to make decisions on behalf of their patients and typically do not take into consideration the patient's own preferences. This "paternal" model of physician-patient interaction is still highly prevalent throughout the U.S. and is clearly a barrier to effective patient engagement. For patients who face a number of treatment choices, use of decision-making tools may help improve patient engagement.

Introduce the entire care team early in the treatment process. For all new patients, establish up-front appointments with a financial counselor, social worker, and patient navigator. Patients should have contact information for these providers to easily reach them when they have questions during their course of therapy. As appropriate, additional appointments with dietitians, palliative care staff, chaplains and/or spiritual counselors, lymphedema therapists, and/or other supportive care services should be made.

Provide effective patient education. Patients get treatment information in a variety of ways. Patients can only absorb so much information during initial visits with their nurse and/or physician. While nothing equals actual face-to-face education, clinicians can use a number of other methods to reinforce the teaching and education that is provided in the clinic setting, including:

- Vetted print materials and online tools
- New patient classes
- Chemotherapy patient classes
- Video orientation
- Family and/or caregiver education classes.

If materials are available on your cancer program's website or on a patient portal, they can be viewed at any time, so patients can revisit the information as needed.

Encourage patient involvement with safety and error prevention. A very basic example of engaging patients in their own safety occurs prior to treatment, when patients are asked to verify their identity prior to treatment. However, you may want to consider involving patients and/or caregivers in other areas.

For example, ask patients for their assistance in monitoring physicians and other staff with hand hygiene practices. Our protocol is for providers to wash hands immediately upon entering exam rooms. If patients are aware of this practice, they can gently remind providers if they forget this safety step. This way, patients are involved in their own safety. Another safety area that patients can help with is a time-out procedure, which is recommended by The Joint Commission's Speak Up™ Program. Time-outs are usually done prior to surgery or certain procedures. The American College of Radiology's radiation oncology accreditation staff recommends that a time-out occur prior to the patient receiving radiation therapy treatments, and that patients be asked what site is to be treated.

Develop an up-front care plan. The American Society of Clinical Oncology's Quality Oncology Practice Initiative (QOPI) encourages a care plan that clearly states the patient's diagnosis, stage, recommended treatment plan, major side-effects of the regimen, and whether or not the regimen is for curative or palliative intent. This plan should be discussed with patients to ensure that they have a good understanding prior to chemotherapy. This information should be also included on the consent form. When developing this care plan, you may want to consider these findings from a national survey of older adults with chronic illness: 74 percent of respondents did not want treatment if it would cause functional impairment, and 88 percent did not want treatment if it would cause cognitive impairment, regardless of the impact on survival.[6]

Implement survivorship program components. Survivorship care planning, which is a service line offering at most cancer programs due to Commission on Cancer (CoC) requirements that went into effect in 2015, can help engage your cancer patients. Two key components of a survivorship program include developing a treatment summary for patients at the end of treatments and developing an ongoing surveillance plan for follow-up care. Both of these can serve to increase patient involvement and knowledge about the care they have received and the importance of returning to the cancer program to monitor for any recurrence of cancer. At some cancer programs, a survivorship coordinator not only provides "new" patient handbooks with information about specific cancers, common treatments, and supportive care services that might be needed during the treatment but also reviews treatment plans. Still other cancer programs have developed survivorship clinics managed by physicians and/or mid-level providers. All of these approaches are excellent for engaging patients.

Offer support and activity groups. Support groups and peer-to-peer programs are important for patients who may benefit from interacting with others going through (or who have gone through) a similar experience. If your cancer program can host or promote these types of programs, they can be very beneficial for patients and possibly lead to better outcomes.

Another area that can be sometimes overlooked is the formation of activity groups. Our cancer program partners with a local museum in a program called Arts in Medicine, whereby, the museum arranges for an art instructor to visit the infusion area for several hours each week. The art instructor provides materials and ideas for patients to do arts and crafts activities while they are receiving treatments. Patient response to this new program has been overwhelmingly positive.

Use technology to engage patients. Many hospitals and practices are already using technology to help patients. Some offer online appointment scheduling; others have patient portals that offer two-way messaging with a patient's care team and/or allow patients to see lab or imaging results. In some cancer programs, patients use hand-held notebooks or pads to register, sign consent forms, receive patient education, or simply access entertainment.

The Arts in Medicine Program is a partnership between ECCC and the Huntington Museum of Art.

Social media can be used to promote cancer screenings, health fairs, support groups, and community events.

Form a Patient and Family Advisory Council. If your cancer program doesn't already have one, a Patient and Family Advisory Council can help guide all aspects of your program. This council can serve as a barometer, helping your cancer program improve and monitor the progress with patient engagement. Our cancer program formed a Patient and Family Advisory Council in 2013, and it has made a tremendous improvement in our patient engagement. Below we share benefits realized through our Patient and Family Advisory Council, including lessons learned from the experience.

A Deeper Dive into a Patient and Family Advisory Council

Our journey to implementing a Patient and Family Advisory Council began in February 2013. Initially our council consisted of eight patients and two cancer center managers. We wanted patients and family members that mirrored our patient population, including representation from pediatric oncology, lung, breast, colon, and GYN oncology—our top disease sites. We also wanted the council to be a mix of patients in various stages of treatment—active and follow-up. Most of the council members were nominated by staff members and voted on by management. One member was recruited from the waiting area because he offered

some good suggestions on improving signage; he turned out to be the council's first Chair.

At our first meeting, we adopted by-laws, which outlined the purpose of the council, membership requirements, meeting frequency, confidentiality issues, and decision and quorum requirements. We found the Institute for Patient and Family-Centered Care (ipfcc.org/) to be an excellent resource for helping a cancer program establish a Patient and Family Advisory Council. Council member responsibilities included:

- Attending scheduled meetings
- Participating to the fullest extent possible during each meeting
- Participating, as time and interest allow, on additional committees and taskforces
- Embracing the Mission, Vision, and Values of the cancer program, the hospital, and the Patient and Family Advisory Council
- Advocating the concepts of patient-family-centered care.

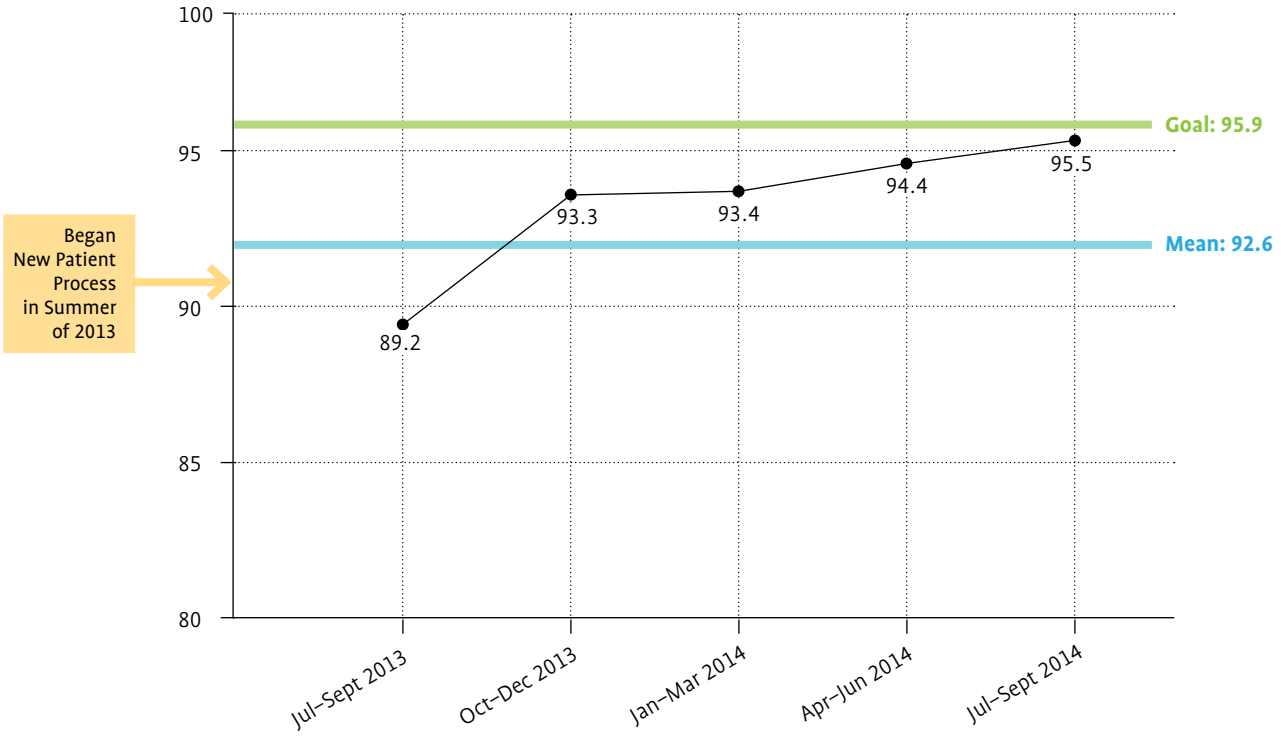
The first time the council met, we structured the meeting as an orientation so that the members learned about our cancer program, including its components, strengths, and opportunities for improvement. We wanted to be sure that the Patient and Family Advisory Council had all the information necessary to help the program improve its patient services.

Once established, the Patient and Family Advisory Council started by evaluating our supportive care offerings, but we soon learned that the Patient and Family Advisory Council had important input on almost every aspect of our program. For example, the council weighed in on what channels are most appropriate for the TV waiting areas, and what kind of food should be available in the chemotherapy infusion area. The cancer program's marketing department met with the Patient and Family Advisory Council to poll members on which marketing messages geared toward cancer screenings would resonate best with the general public. The council helped the cancer program review its educational videos and with planning its annual 5K run/walk fundraiser.

During its first year, the Patient and Family Advisory Council worked with the cancer program on one major goal—improving our patient satisfaction scores. This process involved asking council members to answer Press Ganey survey questions, including providing feedback about each answer. During that meeting, our cancer program made a major finding. Up until that night, we had always thought that we did a great job with our patients, and—for the most part—the Patient and Family Advisory Council confirmed that we did, once a patient was established. We learned, however, that our new patient process was not working. Almost

The Patient and Family Advisory Council at Edwards Comprehensive Cancer Center.

Figure 2. Press Ganey Patient Satisfaction Scores



every single council member agreed and some were even still upset about the new patient on-boarding process. This feedback hit us like a ton of bricks. We knew that our new patient processes had to change, and the Patient and Family Advisory Council was going to help us in this effort.

Based on the council's feedback, our cancer program decided to completely redesign its new patient process. After a deep-dive into every aspect of how new patients are on-boarded, we implemented a more user-friendly process that required pre-registration. Welcome kits were sent to the patient's home, and we also made new patient forms available online. Even before the first visit, our medical assistants and/or nurses now call patients to answer questions and welcome them.

Based on Patient and Family Advisory Council feedback, we added additional dedicated parking for the cancer center. For those patients who use the valet service, we instructed staff to call the valet service for them at the end of an appointment, so that their car would be retrieved while they exited the cancer center.

We created new signage specifically for new patients and, as needed, nurses began to call patients at home after their first visit to follow-up and ask if they had additional questions that were not answered while at the center. We tasked staff to be extra sensitive to patients who came to their first visit without a diagnosis to help ease their anxiety and fears. All of these initiatives really paid off in terms of our Press Ganey scores. We moved immediately in the right direction and reached our goal in about 12 months (Figure 2, above). (The primary goal was to improve our patients' overall experience when visiting our cancer center; our measureable goal was to reach a Press Ganey patient satisfaction score of 95 percent or higher. Prior to the formation of the Patient and Family Advisory Council, our scores were hovering just below 90 percent.)

The Patient and Family Advisory Council is now helping our cancer program monitor our quality improvement (QI) programs, while continuing to work on patient satisfaction. This past month, we installed suggestion/comment boxes throughout the cancer center, inviting patients to contact the Patient and Family Advisory Council directly with any comments, questions, or concerns.

Patient Engagement Key Success Factors

For your cancer program or oncology practice to make significant improvements in patient engagement, you must have a high level of support from everyone in your organization. It is critical that there is institution- or practice-wide commitment from leadership, as well as staff. You must have physician champions who can help to influence the patient engagement behaviors of your medical staff. It is also important to note that the cancer program must properly budget for any proposed or new initiatives. Finally, keep

OUR PROGRAM AT-A-GLANCE

The Edwards Comprehensive Cancer Center (ECCC) at Cabell Huntington Hospital – Huntington, W.Va., is a 70,000-square-foot facility that houses an adult oncology center with infusion stations; medical and surgical oncology exam and consultation rooms; minor procedure rooms; a diagnostic breast center and physician offices; and a children's oncology and hematology treatment center with infusion stations, pediatric oncology clinics, and physician offices. Each year the cancer program sees about 1,000 new cancer cases and has approximately 70,000 patient visits. ECCC offers patients state-of-the-art cancer treatment, including PET/CT scanning, image-guided radiation therapy (IGRT), 3D mammography, stereotactic breast biopsy, and the da Vinci® Surgical System. Services include:

- Breast Oncology
- Cancer Risk Assessment
- Clinical Trials
- Colorectal Cancer Program
- Comprehensive Lung Nodule Program
- Genetic Testing/Board Certified Genetics NP
- Gynecologic Oncology
- Medical Oncology
- Multidisciplinary Lung Cancer Program
- Neuro-Oncology
- Orthopedic Oncology
- Pediatric Oncology
- Radiation Oncology
- Fellowship-Trained Surgical Oncologist
- Survivorship Program
- Urologic Oncology.

On the third floor is the Charles H. McKown, Jr., MD, Translational Genomic Research Institute (TGRI), which allows scientists to work in close proximity to clinicians, fostering collaboration and improving bench to bedside treatments. This facility supports the Marshall University Joan C. Edwards School of Medicine and clinical researchers by enabling them to conduct a greater number of investigator-initiated clinical trials and rapidly translate genome-based laboratory research into clinical applications that will improve patient care.

in mind, that developing a Patient and Family Advisory Council is a long journey—not a quick-fix solution. If done right, the Patient and Family Advisory Council should feel like a permanent culture change and not just the implementation of one or two initiatives.

While the pathway to better patient engagement is not an easy one, the benefits of caring for engaged patients will far outweigh the time and cost. Most important, your patients will thank you! OI

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AstraZeneca

In EGFRm+ advanced NSCLC,

NEARLY 2 OUT OF 3

cases of progression with first-generation EGFR TKIs are related to the T790M mutation[1,2]

NEARLY **2 OUT OF 3**

CASES ARE RELATED TO T790M

T790M is an acquired mutation and has been identified as the most common mechanism of acquired resistance in nearly 2 out of 3 patients with advanced NSCLC.[1,2]

When patients with EGFRm+ status progress, prior to changing therapy, a biopsy is reasonable to identify mechanisms of acquired resistance, as stated in NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®).[3]

Find out how the T790M mutation could affect the future of NSCLC at: EGFRevolution.com.

AstraZeneca is conducting ongoing research to understand the science of the T790M mutation as a driver of resistance.

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What Does a Patient Navigator Do?

Patient navigation core competencies, training & certification

MANDI PRATT-CHAPMAN, MA

Do you feel like your cancer program is scrambling to meet the American College of Surgeons' Commission on Cancer (CoC) Patient Navigation standards? If so, you are not alone. The CoC accredits approximately 1,500 cancer programs, and these institutions provide more than 70 percent of cancer care for newly-diagnosed patients in the U.S.[1] In 2012 the CoC issued three new continuum of care standards to be phased in by accredited cancer programs by 2015: Standard 3.1 (Patient Navigation Process), Standard 3.2 (Psychosocial Distress Screening), and Standard 3.3 (Survivorship Care Plan).[2]

This article describes resources that can help your cancer program keep pace with new patient navigation standards, raise the caliber of your patient navigation services, and protect your cancer program from potential legal liabilities.

A Growing & Evolving Field

Patient navigation is a rapidly growing and evolving healthcare profession—from Dr. Harold Freeman's groundbreaking patient navigation study[3] to the new CoC standards discussed above. While the need for patient navigation has never been greater, the role of the patient navigator and scope of practice has been ill-defined until now. Patient navigation programs have proliferated quickly with no clear standards.[4] A large, unregulated workforce poses obvious legal risks to patient navigators and the organizations that employ them. To support professional development and scope of practice standards for the newest member of the multidisciplinary cancer care team, the George Washington University (GW) Cancer Institute developed national, consensus-based core competencies for oncology patient navigators (sometimes called "lay navigators") and a corresponding online training module to equip oncology patient navigators with the foundational knowledge and skills necessary to perform their role effectively and efficiently.

Oncology Patient Navigator Core Competencies

GW developed these core competencies with input from a steering committee that included representation from the Academy of Oncology Nurse & Patient Navigators (AONN+), the Association of Community Cancer Centers (ACCC), the Association of Oncology Social Work (AOSW), the National Association of Social Workers (NASW), and the Oncology Nursing Society (ONS). The steering committee also included patient navigators from three cancer programs and community health workers (CHWs) from two community-based organizations from a variety of geographic locations across the U.S.

This article describes resources that can help your cancer program keep pace with new patient navigation standards, raise the caliber of your patient navigation services, and protect your cancer program from potential legal liabilities.

Competencies were reviewed by 22 national experts and endorsed by 525 patient navigators, nurse navigators, navigation supervisors, navigation trainers, and navigation researchers through a 272-question survey.[4]

Core competencies are important for healthcare professions to define the basic knowledge, skills, and abilities for a particular profession. Our research resulted in a total of 45 core competency statements that align with the Association of American Medical Colleges' health professions taxonomy[5] and distinguish the oncology role of patient navigators from their nurse navigator and CHW counterparts. The core competencies are provided in Table 1, pages 56-58. For additional information on how patient navigators differ from CHWs and nurse navigators, see prior research from the GW Cancer Institute by Willis et al.[6]

(continued on page 58)

Table 1. Oncology Patient Navigator Core Competencies

DOMAIN 1. PATIENT CARE Facilitate patient-centered care that is compassionate, appropriate, and effective for the treatment of cancer and the promotion of health.	
1.1. Assist patients in accessing cancer care and navigating health-care systems. Assess barriers to care and engage patients and families in creating potential solutions to financial, practical, and social challenges.	**1.4.** Empower patients to communicate their preferences and priorities for treatment to their healthcare team; facilitate shared decision making in the patients' healthcare.
1.2. Identify appropriate and credible resources responsive to patient needs (practical, social, physical, emotional, spiritual), taking into consideration reading level, health literacy, culture, language, and amount of information desired. For physical concerns, emotional needs, or clinical information, refer to licensed clinicians.	**1.5.** Empower patients to participate in their wellness by providing self-management and health promotion resources and referrals.
1.3. Educate patients and caregivers on the multidisciplinary nature of cancer treatment, the roles of team members, and what to expect from the healthcare system. Provide patients and caregivers evidence-based information and refer to clinical staff to answer questions about clinical information, treatment choices, and potential outcomes.	**1.6.** Follow up with patients to support adherence to agreed-upon treatment plan through continued non-clinical barrier assessment and referrals to supportive resources in collaboration with the clinical team.
DOMAIN 2. KNOWLEDGE FOR PRACTICE Demonstrate basic understanding of cancer, healthcare systems, and how patients access care and services across the cancer continuum to support and assist patients. *(NOTE: This domain refers to foundational knowledge applied across other domains.)*	
2.1. Demonstrate basic knowledge of medical and cancer terminology.	**2.4.** Demonstrate basic knowledge of health system operations.
2.2. Demonstrate familiarity with and know how to access and reference evidence-based information regarding cancer screening, diagnosis, treatment, and survivorship.	**2.5** Identify potential physical, psychological, social, and spiritual impacts of cancer and its treatment.
2.3. Demonstrate basic knowledge of cancer, cancer treatment, and supportive care options, including risks and benefits of clinical trials and integrative therapies.	**2.6** Demonstrate general understanding of healthcare payment structure, financing, and where to refer patients for answers regarding insurance coverage, and financial assistance.
DOMAIN 3. PRACTICE-BASED LEARNING AND IMPROVEMENT Improve patient navigation process through continual self-evaluation and quality improvement. Promote and advance the profession.	
3.1. Contribute to patient navigation program development, implementation, and evaluation.	**3.5.** Continually identify, analyze, and use new knowledge to mitigate barriers to care.
3.2. Use evaluation data (barriers to care, patient encounters, resource provision, population health disparities data, and quality indicators) to collaboratively improve navigation process and participate in quality improvement.	**3.6.** Maintain comprehensive, timely, and legible records capturing ongoing patient barriers, patient interactions, barrier resolution, and other evaluation metrics and report data to show value to administrators and funders.
3.3. Incorporate feedback on performance to improve daily work.	**3.7.** Promote navigation role, responsibilities, and value to patients, providers, and the larger community.
3.4. Use information technology to maximize efficiency of patient navigator's time.	

DOMAIN 4. INTERPERSONAL AND COMMUNICATION SKILLS Demonstrate interpersonal and communication skills that result in the effective exchange of information and collaboration with patients, their families, and healthcare professionals.	
4.1. Assess patient capacity to self-advocate; help patients optimize time with their doctors and treatment team (e.g., prioritize questions, clarify information with treatment team).	**4.5.** Communicate effectively with navigator colleagues, health-care professionals, and health-related agencies to promote patient navigation services and leverage community resources to assist patients.
4.2. Communicate effectively with patients, families, and the public to build trusting relationships across a broad range of socioeconomic and cultural backgrounds.	**4.6.** Demonstrate empathy, integrity, honesty, and compassion in difficult conversations.
4.3. Employ active listening and remain solutions-oriented in interactions with patients, families, and members of the healthcare team.	**4.7.** Know and support National Standards for Culturally and Linguistically Appropriate Services (CLAS) in Health and Health-care to advance health equity, improve quality, and reduce health disparities.
4.4. Encourage active communication between patients and/or families and healthcare providers to optimize patient outcomes.	**4.8.** Apply insight and understanding about emotions and human responses to emotions to create and maintain positive interpersonal interactions.
DOMAIN 5. PROFESSIONALISM Demonstrate a commitment to carrying out professional responsibilities and an adherence to ethical principles.	
5.1. Apply knowledge of the difference in roles between clinically licensed and non-licensed professionals and act within professional boundaries.	**5.5.** Know and support patient rights.
5.2. Build trust by being accessible, accurate, supportive, and acting within scope of practice.	**5.6.** Demonstrate sensitivity and responsiveness to a diverse patient population, including but not limited to diversity in gender, age, culture, race, religion, abilities, and sexual orientation.
5.3. Use organization, time management, problem-solving, and critical thinking to assist patients efficiently and effectively.	**5.7.** Demonstrate a commitment to ethical principles pertaining to confidentiality, informed consent, business practices, and compliance with relevant laws, policies, and regulations (e.g., HIPAA, agency abuse reporting rules, Duty to Warn, safety contracting).
5.4. Demonstrate responsiveness to patient needs within scope of practice and professional boundaries.	**5.8.** Perform administrative duties accurately and efficiently.
DOMAIN 6. SYSTEMS-BASED PRACTICE Demonstrate an awareness of and responsiveness to the larger context and system of healthcare, as well as the ability to call effectively on other resources in the system to provide optimal healthcare.	
6.1. Support a smooth transition of patients across screening, diagnosis, active treatment, survivorship, and/or end-of-life care, working with the patient's clinical care team.	**6.3.** Organize and prioritize resources to optimize access to care across the cancer continuum for the most vulnerable patients.
6.2. Advocate for quality patient care and optimal patient care systems.	

(table continued on page 58)

(table continued from page 57)

DOMAIN 7. INTERPROFESSIONAL COLLABORATION Demonstrate ability to engage in an interprofessional team in a manner that optimizes safe, effective patient- and population-centered care.	
7.1. Work with other healthcare professionals to establish and maintain a climate of mutual respect, dignity, diversity, ethical integrity, and trust.	**7.3.** Participate in interprofessional teams to provide patient- and population-centered care that is safe, timely, efficient, effective, and equitable.
7.2. Use knowledge of one's role and the roles of other healthcare professionals to appropriately assess and address the needs of patients and populations served to optimize health and wellness.	
DOMAIN 8. PERSONAL AND PROFESSIONAL DEVELOPMENT Demonstrate qualities required to sustain lifelong personal and professional growth.	
8.1. Set learning and improvement goals; identify and perform learning activities that address one's gaps in knowledge, skills, attitudes, and abilities.	**8.3.** Manage possible and actual conflicts between personal and professional responsibilities.
8.2. Demonstrate healthy coping mechanisms to respond to stress; employ self-care strategies.	**8.4.** Recognize that ambiguity is part of patient care and respond by utilizing appropriate resources in dealing with uncertainty.

(continued from page 55)

Oncology Patient Navigator Training

The GW Cancer Institute developed the Oncology Patient Navigator Training structured around these 45 core competencies to prepare oncology patient navigators with the knowledge and skills to do their job. The Oncology Patient Navigator Training is the first comprehensive course on patient navigation fundamentals using consensus-based competencies provided for free online (see Table 2, right).

The training content covers general information including:

- The history of patient navigation
- Basic medical terminology
- Cancer basics
- The impact of cancer
- The U.S. healthcare system and financing
- Key skills of the oncology patient navigator, including patient assessment, identifying resources, communication, advocacy, and cultural competency.

Finally, the training also discusses ethics, scope of practice, and the importance of ongoing professional development, and quality improvement.

Oncology Patient Navigation Training will help prepare oncology patient navigators for national certification as an Oncology Patient Navigator-Certified Generalist (OPN-CG) through the Academy of Oncology Nurse & Patient Navigators (AONN+), beginning in 2016. To qualify for certification, oncology patient navigators will need to take a proctored examination to demonstrate core competencies, fulfill an experiential requirement, and maintain membership in their professional organization, AONN+. The examination will be beta tested in May 2016 at the AONN+ East Coast Regional Meeting in New Orleans, La., The inaugural certification examination will be held at the 2016 AONN+ annual meeting in Las Vegas.

Additional Resources to Improve Capacity for the New CoC Standards

In summer 2013, the CoC conducted a survey to assess readiness of member organizations to implement the new patient-centered standards. Based on survey results, the CoC determined that Standards 3.1 (patient navigation) and 3.2 (psychosocial distress screening) were required to be implemented by January 1, 2015, as originally planned.[7] However, the CoC revised the Survivorship Care Plan requirement (Standard 3.3) to allow for phase-in between 2015 and 2019.[8] All of these standards have proved challenging for cancer programs who are being asked to provide

most of these services with little to no reimbursement from payers. Additional resources created by the GW Cancer Institute to help cancer programs meet these CoC standards (Figure 1, page 60) include:

- ***The Executive Training on Navigation and Survivorship.*** This training walks you through the nuts and bolts of patient-centered program development and includes brief interactive presentations; supplemental written content that summarizes the latest research; and best practices, case studies, and customizable activities to create a program plan for your institution. Eight free continuing education (CE) hours are available for physicians and nurses. Access the Executive Training on Navigation and Survivorship online at tinyurl.com/GWOnlineAcademy.
- ***The Cancer Survivorship e-Learning Series.*** This free continuing education program educates clinicians to care for cancer survivors. Developed through the National Cancer Survivorship Resource Center, a collaboration between the American Cancer Society (ACS) and the GW Cancer Institute and funded by the Centers for Disease Control and Prevention (CDC), the series was originally intended to improve longitudinal care for cancer survivors in a primary care setting. However, oncology clinicians who participated in the program have demonstrated significant knowledge change. Currently, the series encompasses nine modules that educate clinicians on a wide variety of topics, including physical and psychosocial impacts of cancer treatment, the importance of health promotion and care coordination, and specific guidelines for prostate, colorectal, and breast cancer survivorship. Head and neck guidelines for survivorship care are coming in the spring of 2016. Access the e-learning series at cancersurvivorshipcenter education.org.
- ***Archived webinars.*** This free series covers topics relevant to best practices and new approaches or tools in patient navigation, survivorship, and distress screening. The series can be accessed through the education section of the gwcancerinstitute.org home page.

Future Implications

Given the reach of CoC-accredited programs, these new patient-centered standards are poised to have a significant impact on the way that cancer care is delivered in the U.S. The Oncology Patient Navigator Core Competencies and the Oncology Patient Navigator Training are critical resources to ensure that patient navigators are performing their role efficiently and effectively. Certification from AONN+ for Oncology Patient Navigators – Certified Generalists will document that patient navigators understand functions within their scope of practice. Furthermore, core competencies, standardized training, and certification will support sustainability by setting expectations regarding the

Table 2. Patient Navigation Training Modules & Lessons

MODULE 1. Welcome & Introduction
- Welcome letter and video
- Training overview
- Acknowledgements
- Frequently asked questions (FAQS)

MODULE 2. Overview of Patient Navigation & the Oncology Patient Navigator Training
- An overview of patient navigation and competencies

MODULE 3. The Basics of Healthcare
- Medical terminology
- Cancer basics
- Clinical trials
- Impact of cancer
- U.S. healthcare system
- Healthcare payment financing

MODULE 4. The Basics of Patient Navigation
- The role of the patient navigator
- Navigating patients
- Shared decision-making
- Identifying resources

MODULE 5. Enhancing Communication
- Communicating with patients
- Patient advocacy
- Culturally competent communication

MODULE 6. Professionalism
- Scope of practice
- Ethics and Patient Rights

MODULE 7. Enhancing Practice
- Practicing efficiently and effectively
- Healthcare team collaboration
- Program evaluation and quality improvement
- Personal and professional development

Figure 1. Additional GW Cancer Institute Navigation & Survivorship Resources

duties of the role for payers and, potentially, fulfilling a portion of the care coordination requirements for new value-based payment structures. OI

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INNOVATE. ACHIEVE. INSPIRE.

ACCC INNOVATOR AWARDS CALL FOR ENTRIES

Now in its sixth year, the **Association of Community Cancer Centers** Innovator Awards honor Cancer Program Members for their pioneering achievements in oncology. ACCC recognizes programs that have developed and implemented innovative strategies for the effective delivery of cancer care.

Innovations should advance the goals of improving access, quality, and value in cancer care.

Some suggested areas of focus are:

- Community Outreach
- Process Improvement
- New Technologies
- Supportive Care

Winners will present their innovations at the ACCC 33rd National Oncology Conference, October 19–21, 2016, in St. Louis, MO, online, and in our award-winning journal, *Oncology Issues*.

Past Innovator Award winner topics include:

- Distress Screenings: Patient Centered Support
- Prehabilitation Program
- Family Program for Parents with Cancer
- Rural Chemotherapy Project
- Location Technology
- Survivorship Care Plans
- Outpatient Nutrition
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DEADLINE FOR SUBMISSIONS: March 18, 2016

New in 2016! In partnership with the Institute for Clinical Immuno-Oncology (ICLIO), an Innovator Award will be presented to a program demonstrating innovation in the delivery of immunotherapies. Details at accc-iclio.org.

CRITERIA FOR SUBMISSIONS

1. Is your program innovative, with the potential to create positive change?
2. Can your program be replicated in other community-based cancer programs?
3. Does your program demonstrate value?

For details, an application form, and to learn about past Innovator Award winners, please visit accc-cancer.org/innovator

BY TRICIA STRUSOWSKI, MS, RN,
AND JEREMY STAPP, MBA

Patient Navigation Metrics

Measuring the impact of your patient navigation services

The Oncology Nursing Society (ONS), the Association of Oncology Social Work (AOSW), and the National Association of Social Workers (NASW) all take the position that patient navigation—whether provided on-site or in coordination with local agencies or facilities—is an essential component of cancer care. Patient navigation programs have achieved more traction over the last several years, including the release of the 2013 ONS Nurse Navigator Core Competencies and the 2012 Commission on Cancer (CoC) Standard 3.1, Patient Navigation Process, which went into effect in 2015. While these guidelines and standards have provided cancer programs with additional justification to support the navigator role, navigation programs, like many support services, are often not a billable service; hospital executives and/or cancer program administrators tend to heavily scrutinize navigation programs because of this fact. Thus, it is incredibly important for managers and administrators to be able to report the true impact navigation programs have on cancer patients, as well as the cancer program.

What type of reporting is best suited to communicate patient navigator efficacy? The answer is clear: data and metrics. The challenge is that while navigation programs have existed for decades, standardized national metrics to measure programmatic

success have yet to be created. After a comprehensive literature search on the topic of navigation metrics, we identified three main categories of metrics:

1. Business performance/return on investment (ROI)
2. Clinical outcomes
3. Patient experience.

To be able to support continuation or perhaps even expansion of patient navigation services, cancer programs will need to collect quality metrics in all three of these categories. In this article, we outline example metrics to help you best communicate how your navigation program is positively impacting patients and the healthcare organization as a whole.

As the focus on cancer treatment broadens...navigators increasingly have opportunities to enhance patient experience from outreach and screening through survivorship and/or end-of-life care.

Patient Experience Metrics

The "patient experience" is increasingly emerging as a more enhanced method for measuring navigation success. The 2013 Consumer Assessment of Healthcare Providers and Systems (CAHPS) cancer survey identified that patients' expectations were exceeded when they felt their healthcare provider actively listened and incorporated their personal psychosocial goals into the treatment plan. The results of this survey also confirm the importance of navigators and support staff knowing how to provide the appropriate level of education, asking patients about their experience(s), and encouraging patients to actively participate in treatment discussions. These actions lead to increased levels of understanding and satisfaction of the patient and their family.

As the focus on cancer treatment broadens to include the entire continuum of care, navigators increasingly have opportunities to enhance patient experience from outreach and screening through survivorship and/or end-of-life care. Especially as patients complete active treatments, the focus will need to shift to prevention and wellness, as well as implementing a successful surveillance plan in the outpatient setting for the balance of their life. Table 1, right identifies navigation metrics that cancer programs should collect related to patient experience.

Patient experience interventions are not difficult to create for a navigation program, and there may be additional metrics not listed below that are currently in use nationally. However, it is vital to remember that patient-centered care methodology must always be applied in order to create appropriate metrics.

Clinical Outcomes Metrics

Clinical outcomes metrics are much more familiar to healthcare providers as clinicians have always measured success through patient clinical outcomes. Example metrics include distress screening, pathway compliance, and timeliness of care. Table 2, page 66, identifies clinical outcomes metrics related to navigation, including how to measure the metrics and corresponding benchmarks and sources.

Business Performance Metrics

Business performance metrics, unlike patient experience or clinical outcomes, are much less familiar for navigation programs. Yet, this category is becoming increasingly important as cancer program administrators question the return on investment (ROI) for navigation services. Navigators focusing on business performance metrics may require additional training or education on such measures. To fully understand the "what" and "why" of business metrics, navigators should be knowledgeable about business-related cancer topics including:

- Value-based cancer care
- Federal healthcare reform and reimbursement
- Centers for Medicare & Medicaid Services (CMS) quality measures
- Affordable care organizations (ACOs), oncology medical homes, and bundled payments
- Commission on Cancer standards—beyond navigation standards
- NCI Community Oncology Research Program (NCORP) research related to: symptom and treatment-related toxicities, post-treatment surveillance, over- and under-diagnosing, social factors, financing systems, organizational structure, health technologies, and individual behaviors
- Future reimbursement models for medical care based on quality measures rather than fee for service
- Population management and the initiation of penalties for readmission
- Patient-Reported Outcomes Measurement Information System (PROMIS), which standardizes health-related patient-reported outcomes.

Table 3, pages 67-68, identifies business performance metrics that cancer programs should collect to justify ROI on navigation services.

(continued on page 69)

Table 1. Navigation Metrics Related to Patient Experience

METRIC: WHAT TO MEASURE	DEFINITION: HOW TO MEASURE	BENCHMARK AND/OR SOURCE
Quality of life (QOL) survey	• Number of patients that received a QOL survey at pivotal medical visits throughout the continuum of care • Number of interventions provided as a result of QOL survey results	Internal benchmark Source: Ferrell B, et al. Quality of Life, Patient/Cancer Survivor Version, (QOL/CSV); 2012. midss.org/sites/default/files/qol-cs.pdf.
Patient experience survey	Percentage of patients extremely satisfied with the patient experience	Internal benchmark Source: the Consumer Assessment of Healthcare Providers and Systems for Cancer Care (CAHPS for Cancer Care); 2012. For more information on the CAHPS for Cancer Care survey, email CancerCAHPS@air.org.
Discharge experience	Number of patients that received a discharge assessment and educational packet upon discharge (i.e., medication reconciliation, safety tips for home, discharge instructions, navigator contact information, etc.)	Internal benchmark; ideal: 100%
Surgical oncology patient education	Number of patients that received a surgical oncology educational packet (i.e., discharge instructions, incentive spirometer, pain medication prescription, etc.)	Internal benchmark; ideal: 100%
Patient decision aids or tools by disease site or department	Number of patients that received decision aids and/or tools by disease site	Internal benchmark; ideal: 100% Source: O'Connor A, et al. Decision aids for patients facing health treatment or screening decisions: systematic review. *BMJ*. 1999; 319(7212):731-734.
Toolkit for caregiver(s): provides patient and family with education and support	Number of caregivers that received a caregiver resource toolkit and their satisfaction with the toolkit	Internal benchmark; ideal: 100% Source: Hook A, et al. Breast cancer navigation and patient satisfaction: exploring a community based patient navigation model in a rural setting. *Oncol Nurs Forum*. 2012; 39(4): 379-385.
Complementary and alternative therapies and/or outcomes	Number of patients that were referred for complementary and/or alternative therapies and outcomes	Internal benchmark; ideal: 100%
Utilization of decision-aid tools and outcomes for treatment discussions with physicians or healthcare providers	• Number of patients that used decision-aid tools with a successful outcome • Additional metric: survey patients after a decision aid was utilized regarding the level of patient empowerment during discussions with the healthcare provider	Internal benchmark; ideal 100%

Table 2. Navigation Metrics Related to Clinical Outcomes

METRIC: WHAT TO MEASURE	DEFINITION: HOW TO MEASURE	BENCHMARK AND/OR SOURCE
Tumor conference compliance with NCCN guidelines	Percentage of treatment plans that followed the NCCN guidelines and recommendations as discussed in the tumor conference	Internal benchmark; ideal: 100%
Psychosocial distress screening	• Number of patients that received psychosocial distress screening • Additional metrics may include the number of interventions provided to the patient, types of interventions, and outcomes	Internal benchmark; ideal 100% Source: CoC Standard 3.2 Psychosocial Distress Screening: Patients with cancer are offered screening for distress a minimum of one time per patient at a pivotal medical visit (to be determined by the program).
Patient compliance on pathway and guidelines	Percentage of patients that were compliant with their treatment plan	Internal benchmark; ideal: 100% Source: Quality in Health Care Advisory Group. Oncology Quality Improvement Collaborative. info.cecity.com/assets/Oncology_QCDR_Narrative_Specifications.pdf. Source: Case MA. Oncology nurse navigator. *Clin J Oncol Nurs.* 2011;15(1):33-40.
Interventions provided to address patient barriers to care	Number and type of intervention provided to patients based on barriers to care	Internal benchmark Source: Naylor K, et al. Interventions to improve care related to colorectal cancer among racial and ethnic minorities: a systematic review. *J Gen Intern Med.* 2012, 27(8):1033-1046.
Timeliness of care: the time between diagnosis and the patient's first treatment modality	Number of days from the time the patient is diagnosed until the first cancer physician appointment to receive and/or review the treatment plan	Internal benchmark Source: Gilbert JE, et al. Nurses as patient navigators in cancer diagnosis; review, consultation and model design. *Eur J Cancer Care.* 2011; 20(2):228-236. (Article also reviews results related to reduced anxiety and higher satisfaction.)
Clinical trial education: educating patients on clinical trials and reducing patient's barriers to participate	• Number of patients educated regarding clinical trials • Number of patient barriers identified and/or documented and the interventions provided	Internal benchmark; ideal: 100% Source: Holmes DR, et al. Increasing minority patient participation in cancer clinical trials using oncology nurse navigation. *Am J Surg.* 2012;203(4):415-422.

Table 3. Business Performance and ROI Metrics

METRIC: WHAT TO MEASURE	DEFINITION: HOW TO MEASURE	BENCHMARK AND/OR SOURCE
Decreased patient outmigration and increased patient retention rates	Percentage of patients that are diagnosed and treated at your cancer center	Internal benchmark
Referrals to revenue-generating services and downstream revenue	Number of patients referred to revenue generating services, i.e., registered dietitian, health psychologist, palliative care, imaging, etc.	Internal benchmark
30-day readmission rate via emergency department (ED)	Number of patients readmitted through the ED within 30 days	• Average 30-day readmission is 32.5% • Preventable, unexpected, and unplanned 30-day readmission rate is 3.6% Source: Quality in Health Care Advisory Board.
ED admissions per number of chemotherapy patients	Number of ED admissions per 1,000 chemotherapy patients	• National average is 929 ED visits per 1,000 chemotherapy visits • Lowest is 465 ED visits per 1,000 chemotherapy visits Source: Quality in Health Care Advisory Board.
Number of referrals of self-pay patients for financial counseling and/or assessment	Number of self-pay patients referred for financial assessment for Medicaid, Medicare, Social Security Disability, or hospital charitable applications	Internal benchmark; ideal: 100%
Home care for elderly (Medicare) oncology patient	• Amount of money saved by beneficiary for elderly (>65) years old oncology patients that received home care coordination. • Measures could also include number of elderly patients referred to home care and 30-day readmission rate to hospital, skilled nursing facilities, and ED visits	Benchmark: $8,477 less per Medicare beneficiary over 2 years Source: DeJonge K, et al. Effects of home-based primary care on Medicare cost in high risk elders. *J Amer Geriatric Society*. 2014;62:1825-1831.
Adherence to treatment plan	The percentage of patients that received the appropriate treatment as outlined by the treatment plan: • Was the recommended surgery performed? • Was the recommended chemotherapy received? • Was the recommended radiation therapy provided?	Internal benchmark; ideal 100% Source: Fillion L, et al. Professional patient navigation in head and neck cancer. *Semin Oncol Nurs*. 2009;25(3):212-221.
Medication reconciliation program	Number of patients that participate in the medication reconciliation program and what interventions were provided	Internal benchmark Source: The Joint Commission, July 2011, National Patient Safety Goal #3.

(table continued on page 68)

(table continued from page 67)

METRIC: WHAT TO MEASURE	DEFINITION: HOW TO MEASURE	BENCHMARK AND/OR SOURCE
Medication coverage	Number of patients eligible vs. the number of patients that were assisted with pharmaceutical indigent programs and co-pay cards, and/or free drug programs	Internal benchmark; ideal 100% of eligible patients
Follow-up calls post-hospitalization	• Number of patients that received a discharge call 24 hours after being discharged from the hospital and what interventions, if any, were provided • Weekly follow-up calls for 4 weeks • Measures could also include 30-day readmissions and ED visits of those patients receiving follow-up calls after discharge and the 4 weekly follow-up calls	HealthLeaders Media Breakthroughs: Strategic Solutions for the Readmissions Challenge, June 2012. (healthleadersmedia.com/breakthroughs/281599/Strategic-Solutions-for-the-Readmissions-Challenge) The initiative started with heart failure patients. The first year the program was in place, participants saw a drop in inpatient admissions by 44% on the hospital side.
Measurement of and reduction in: 1. Length of stay (LOS) 2. Carve out days 3. Discharge delays	• Average LOS for inpatient oncology unit (medical and surgical) • Partner with the inpatient oncology units	Identify internal benchmark for oncology unit LOS
Proactive discharge planning for home care prior to admissions for surgical procedure	Number of patients that received proactive discharge planning prior to being admitted for a procedure and/or surgery that required home care or infusion services, i.e., PEG tube, Penrose drain, tracheostomy, etc.	Internal benchmark; ideal: 100%
Disease-site specific rehabilitation or prehabilitation programs, including but not limited to: • Cancer-related fatigue • Chemotherapy-induced peripheral neuropathy • Lung cancer • Head and neck cancer • Lymphedema management • Advanced stage cancer rehabilitation	Number of patients referred to rehabilitation or prehabilitation services	Internal benchmark; ideal: 100%
Hospice LOS of less than 3 days	Percentage of patients who died from cancer and were admitted to hospice and had a LOS of <3 days	Average 27% to 35% Source: ASCO, QOPI/EOL measures
Oncology medical home	Number of patients referred to the oncology medical home to prevent avoidable admissions and ED visits.	Internal benchmark

(continued from page 64)

Going Forward

Using metrics such as those referenced in this article provides a level of detail into navigation services not previously available. Regardless of the metrics' focus—be it patient experience, clinical outcomes, or business performance—navigators should be creative and collaborate with other departments within their cancer program to identify areas of greatest impact.

It has been our experience that when establishing metrics, navigation programs should keep in mind a few variables:

1. How easy is the information to collect?
2. Who will collect the data?
3. How often will data be collected?
4. How many metrics should be monitored at a time?

Do not overwhelm your navigators by collecting too much data. When too much data is collected, it becomes diluted, time consuming, and too much information to digest. We would also like to note that the process of selecting metrics to measure and the reporting of those metrics is an iterative process that ultimately leads to better understanding of how navigation services can have the greatest impact on patients and the cancer program. Metrics are the first step towards recognizing what cancer patients need and how the navigation program can be adapted to fit those needs. The ultimate outcome for all metrics is to provide the best possible care for the oncology patient and their caregiver(s). OI

Tricia Strusowski, MSN, RN, is a senior associate, and Jeremy Stapp, MBA, is an analyst at Oncology Solutions LLC, Decatur, Ga., an oncology-specific consulting firm, providing strategic, programmatic, and financial advisory services to help healthcare organizations advance their cancer programs.

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- Experience in oncology setting preferred.

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Why You'll Want to Read the ICLIO White Paper

BY LEE SCHWARTZBERG, MD, FACP
CHAIR, ICLIO ADVISORY COMMITTEE

Along with this *Oncology Issues*, you received "Advancing Immuno-Oncology in the Community Setting," the inaugural white paper from the Institute for Clinical Immuno-Oncology (ICLIO). ICLIO is an institute of the Association of Community Cancer Centers (ACCC), which launched in June 2015.

As members of the oncology community well know, the last five years have brought us thrilling advances in immunotherapy. We've seen the introduction of checkpoint inhibitors and vaccines that are unleashing the power of an individual's immune system to fight cancer. In the past few months, we've witnessed a surge of new FDA indications for immunotherapy agents in a number of disease sites, including melanoma, lung cancer, and renal cell carcinoma.

Immuno-Oncology is now emerging as the fourth pillar of cancer treatment. It is a new field, bringing new promise and new challenges for patients, providers, and payers.

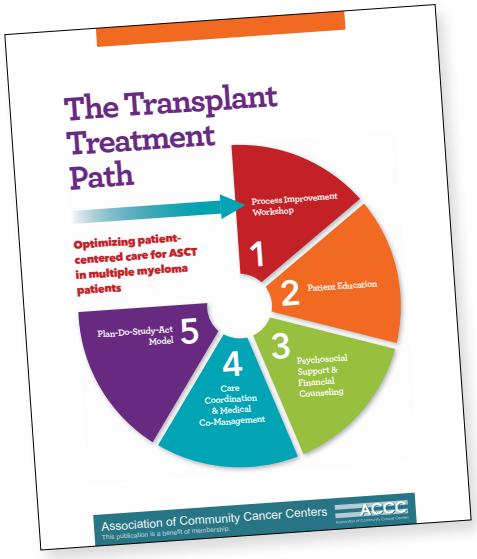
As Chair of the ICLIO Advisory Committee, I urge you to take a few minutes to explore the ICLIO white paper. Whatever your role in cancer care delivery, you'll benefit from learning about the resources ICLIO offers today and those planned for tomorrow. Here are three reasons why:

1. The immunotherapy momentum continues to build. There is a robust pipeline of new immunotherapies in development, as well as emerging combination therapies. Staying up-to-date on advances in this new field is imperative—for your cancer program and your patients.
2. Empowered, informed patients and their families will be asking about (and for) these new immunotherapy options.
3. The challenges of integrating new therapies occur on many fronts—clinical, administrative, programmatic—and across disciplines. ICLIO brings a multidisciplinary approach to addressing these challenges with practical resources that help build a bridge from bench to bedside so that eligible patients in the community can access these new therapies and receive care in an evidence-based way.

Read "Advancing Immuno-Oncology in the Community Setting," and find out how ICLIO is already helping your colleagues to integrate delivery of immunotherapies into practice. The white paper is also available online at accc-iclio.org. Learn about future ICLIO initiatives and join us in a community centered on transformative care.

ADVERTISER'S INDEX

The Transplant Treatment Path:
Optimizing Patient-Centered Care for ASCT in Multiple Myeloma



This ACCC educational initiative is aimed at improving communication among transplant centers, local hematology and oncology practices, and patients with multiple myeloma. The four-phase project explored ways to improve the treatment journey for patients with multiple myeloma who receive autologous stem cell transplant (ASCT) as part of their therapy. By working closely with several cancer programs, ACCC identified specific ways to improve communication and clinical workflow processes. The project was funded by Celgene. The Blood & Marrow Transplant Information Network (BMT InfoNet) served as a key partner in this process improvement initiative.

Members of the project advisory committee are identified in Table 1, page 75.

Phase I: Needs Assessment Survey

To assess the current state of care for patients with multiple myeloma who undergo ASCT, ACCC collaborated with BMT InfoNet to carry out a survey in the early part of 2015. Responses were received from 46 cancer programs throughout the country; 57 percent of those responses came from academic or NCI-designated comprehensive cancer centers and 22 percent came from community cancer programs or outpatient oncology practices.

According to survey results, the #1 rated challenge associated with the treatment and support of patients with multiple myeloma was: "Patient's logistical, financial, and/or personal barriers." Clearly, oncology programs must be prepared to discuss and address practical issues of psychosocial support, insurance coverage, and total cost of treatment.

Phase II: Regional Process Improvement Workshops

To identify key opportunities for process and communication improvements, ACCC conducted regional process improvement workshops at four transplant centers and invited one or two of their referring programs to participate in the discussion. The interactive workshops allowed clinicians, transplant coordinators, and administrators to identify ways to improve communication and clinical workflow processes as patients with multiple myeloma undergo ASCT and return back to their primary oncologist for long-term follow-up care. Table 2, page 75, identifies the cancer programs that participated in these workshops.

Phase III: The Transplant Treatment Path:

Numerous patient education resources about ASCT have been developed by national organizations, but use of these materials varies highly across cancer programs. Furthermore, good and bad information may be found on the Internet as patients do their own research to learn about their condition and treatment options. Since some of the public information may be outdated or erroneous, it becomes critical for members of the cancer care team to guide and educate patients properly. The topic of shared decision making came up during the workshops. Clinicians discussed barriers and concerns associated with the application of shared decision making if staff members are not adequately trained and if patients are misinformed. More time may be required to walk a patient through a decision aid and to explain clinical treatment options that continue to remain somewhat controversial or confusing. Furthermore, when family members and other caregivers are in the room, they may express additional questions that may consume even more time.

Key barriers identified included: time constraints and high workloads, insufficient provider training, and inadequate clinical trial information systems. Workshop participants also shared additional concerns related to patient anxiety, misinformation or lack of information, and an unwillingness or inability to participate.

During the process improvement workshops, representatives from both transplant centers and referring practices agreed that it would be valuable to incorporate the use of the same patient

Table 1. Advisory Committee

Jennifer Bires, LICSW, OSW-C
Program Coordinator
Patient Support Services and Community Outreach
GW Medical Faculty Associates
GW Cancer Institute

Kathleen Burt, RN, BSN, MS
Director
Nanticoke Health Services
Cancer Care Center at Nanticoke Memorial Hospital

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Clinical Nurse Specialist
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Sharron Forsberg, RN
HCT Case Manager
University of Nebraska Medical Center

Sara Hegerle
Patient Family Financial Advocate
St. Luke's Mountain States Tumor Institute

Rodney Jamil, MD
Medical Oncologist
Lancaster General Hospital

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BMT Nurse Practitioner
Barnes-Jewish Hospital

Deborah Russell, BSN, RN
Blood and Marrow Transplant Program
Duke University Hospital

Paul Shaughnessy, MD
Texas Transplant Institute

educational resources and decision aids at referring locations so that patients are presented with similar information when they are referred for ASCT consultation and when they arrive at the transplant center. Based on this insight, several of the transplant centers agreed to develop and distribute a one-page patient resource about ASCT to the surrounding referring oncology practices. This way, when patients with multiple myeloma are referred to a transplant center for an ASCT consultation, the primary oncologist has the opportunity to give the patient a resource developed by that same transplant center.

Information gleaned from these workshops was used to develop The Transplant Treatment Path: Optimizing Patient-Centered Care for ASCT in Multiple Myeloma, a 24-page white paper that mailed with the September-October 2015 *Oncology Issues*. This white paper can also be accessed online at: accc-cancer.org/MultpleMyeloma.

Phase IV: Webinars for the Community Practice

Using content from the process improvement workshops, ACCC hosted a three-part webinar series to educate community practices on improving care for multiple myeloma patients who undergo ASCT. The webinars covered the following topics: 1) Patient Education & Engagement; 2) Psychosocial Support & Financial Counseling; and 3) Coordination of Care & Medical Co-management and featured speakers from cancer programs that participated in this education initiative. All three webinars were recorded and archived on the ACCC website: accc-cancer.org/MultipleMyeloma.

Table 2. Process Improvement Workshop Participants

TRANSPLANT CENTERS

Emory University Bone Marrow and Stem Cell Transplant, Winship Cancer Institute

GW Medical Faculty Associates, Dr. Cyrus and Myrtle Katzen Cancer Research Center

Seattle Cancer Care Alliance

Arthur G. James Cancer Hospital and Richard J. Solove Research Institute at The Ohio State University

REFERRING PROGRAMS

University Cancer & Blood Center

Central Georgia Cancer Care

Oncology/Hematology of Loudoun and Reston

MultiCare Regional Cancer Center

Bend Memorial Clinic

The Mark H. Zangmeister Center

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ACCC Welcomes its Newest Members

Beth Israel Deaconess Medical Center, Hematology/Oncology
Boston, Mass.
Delegate Rep: Jody Blumberg, MBA
Website: bidmc.org

Breastlink Medical Group, Inc.
Orange, Calif.
Delegate Rep: Kristi A. Maya
Website: breastlink.com

El Camino Hospital
El Camino Hospital Oncology Services
Mt. View, Calif.
Delegate Rep: Monica Hite, MSN
Website: elcaminohospital.org

Mobile Infirmary Medical Center
Mobile, Ala.
Delegate Rep: Susan Boudreau, MSHA
Website: infirmaryhealth.org

Theda Care
Theda Care Cancer Center
Appleton, Wisc.
Delegate Rep: Stacy Toyana, BA
Website: thedacare.org

NEW ACCC CHAPTER MEMBER
Oncology Managers of Florida
President: Michelle Smith Flowers
Website: oncologymanagersofflorida.com

Welch Cancer Center
Sheridan, Wyoming
Delegate Rep: Olalekan Ajayi, PharmD
Website: welchcancercenter.org

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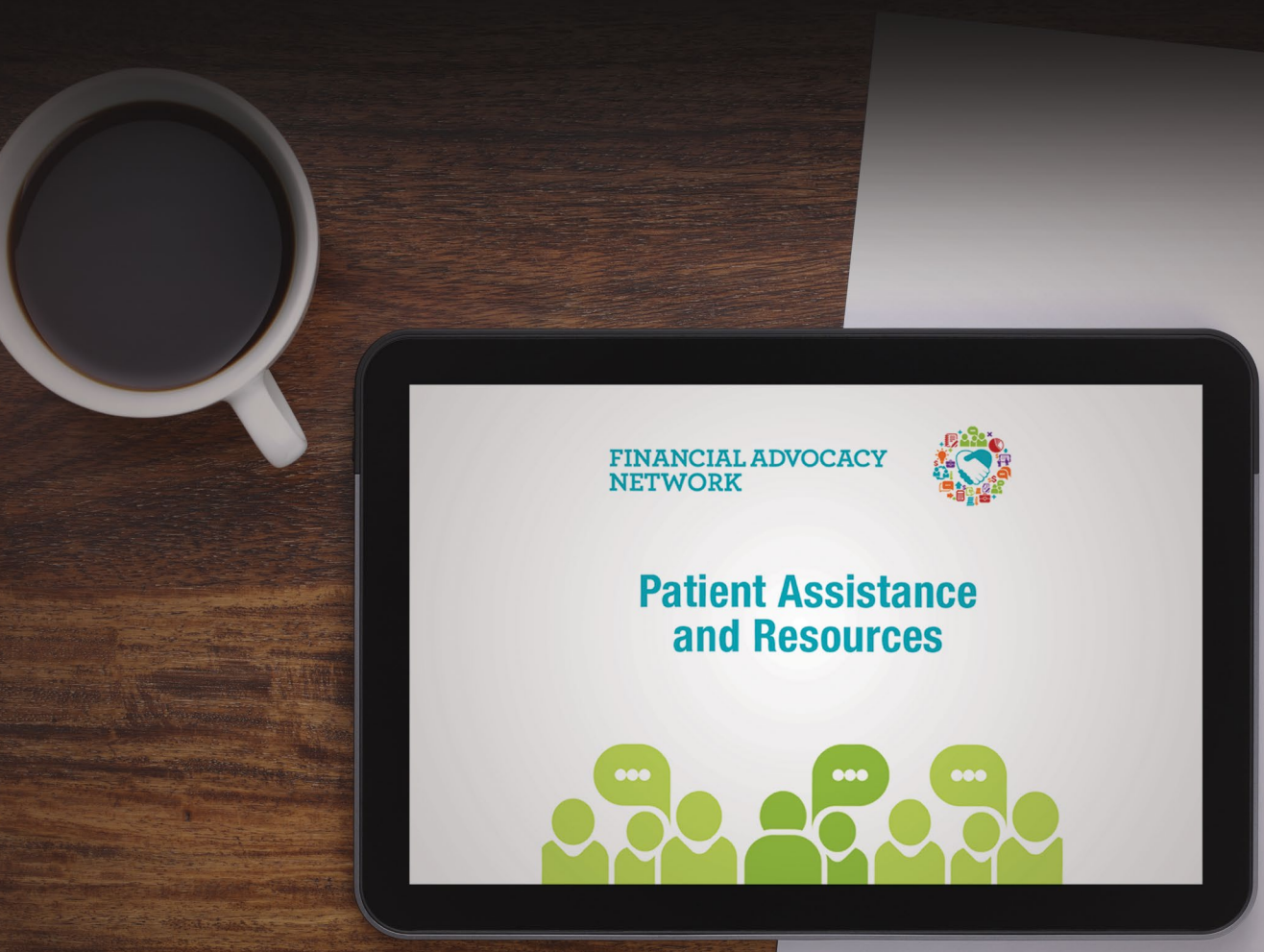
Making patient assistance resources easily accessible to cancer providers.



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ACCC
Association of Community Cancer Centers

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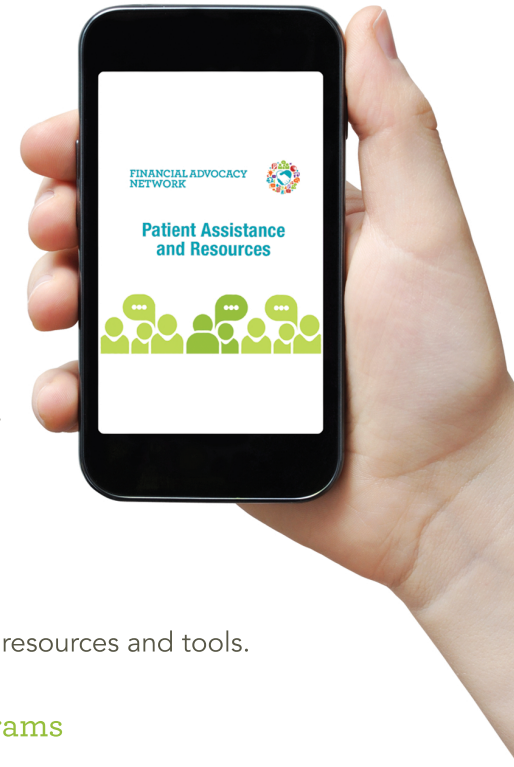

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Plus, links to the ACCC Patient Assistance Guide and Oncology Drug Database appear on each individual drug page.

FINANCIAL ADVOCACY NETWORK
Resources & Tools for the Multidisciplinary Team

To access the app, go to accc-FAN-App.org.
Or, scan the QR code below!

Funding for this project was provided by Amgen, Bristol-Myers Squibb, Celgene, Genentech, Incyte, Lilly Oncology, Merck, Pfizer Oncology, and Teva Oncology.

This tool is a benefit of membership.
Association of Community Cancer Centers

Someone With Group

BY PAULA JAGEMANN-BANE

Michele Paul had been in her job just over a month when she was diagnosed with non-Hodgkin lymphoma. Since she hadn't yet met the 60-day waiting period to qualify for insurance, she was uninsured. The second blow came when her employer stated that her treatment would require too much time away from work, and that Michele would not be able to fulfill her responsibilities. She was let go. Now she was uninsured and unemployed and facing a devastating diagnosis.

Stories like Michele Paul's are all too familiar. And even when patients have health insurance, high out-of-pocket costs and co-pays can be financially crippling. In fact, the number one stressor for patients facing a cancer diagnosis is how they will pay for care.

In 2009 I created *someonewith.com*, an online marketplace that consolidated all the products a woman facing a breast cancer diagnosis would need for treatment. To avoid HIPAA violations, the online registry and "wish-lists" were available only to those individuals—families and friends—identified by patients. Soon after, I had an even better idea: helping patients raise money to pay for the items on their wish-list. Little did I know that my vision to raise money for cancer patients would intersect with the advent of crowdfunding, but it did and Someone With Group was born.

Our first hospital customer was PinnacleHealth System in Harrisburg, Pa., which leads us back to Michele Paul, one of the first participants in the PinnacleHealth HOPE (Helping Others Pay Expenses) Program created using the patented *Someone With Group* crowdfunding platform. Branded to the hospital system, the program features a reloadable debit card that the hospital sponsors on behalf of individual patients. Michele's husband contacted friends, family, and co-workers through Facebook and email; contributions loaded directly onto Michele's HOPE Card. Since the card can only be used with medical-related merchant codes, donors know that funds raised would pay for treatment or to purchase treatment-related items, such as medicine or wigs. After raising $7,500, Michelle was able to pay for expensive treatments she otherwise would not have been able to afford. And PinnacleHealth benefited as well by avoiding lost dollars through bad debt or charity care.

I've observed time and again that when someone is diagnosed with a catastrophic disease, friends and family want to do something—anything—to support that patient. But so often people are unsure exactly how to help. Our *Someone With Group* fundraising coaches encourage patients to gently let others know what will really help: funds to pay for cancer treatment and medical-related expenses. Our How To Help cards make it easy for patients to hand someone the card when asked how they can help. And we know our solution works. The average patient raises more than $2,500 with our program.

Unfortunately, medical costs continue to skyrocket and hospitals face a growing debt problem; U.S. hospital systems had $40 billion in bad debt last year alone. On the patient side of the equation, an alarming 67 percent of personal bankruptcies are caused due to medical expenses—with 75 percent of those individuals having health insurance! *Someone With Group* looks to change this trend.

Based on the success of our Harrisburg program, we are in discussions with other cancer programs and hospital systems across the country. Our dream is to make life significantly better for cancer patients by alleviating some of the tremendous stress they feel about not being able to pay their medical bills. At the same time, we understand that cancer programs and hospitals must remain fiscally solvent or avoid the risk of closing or cutting important services. Help us bridge the gap for our cancer patients and our cancer programs. Learn more at: *someonewithgroup.com*.

Paula Jagemann-Bane is founder and CEO of Someone With Group, hospital-sponsored crowdfunding for patients.

IRESSA® (gefitinib) tablets for oral use

Brief Summary of Prescribing Information.
For complete prescribing information consult official package insert

INDICATIONS AND USAGE

IRESSA is indicated for the first-line treatment of patients with metastatic non-small cell lung cancer (NSCLC) whose tumors have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitution mutations as detected by an FDA-approved test *[see Clinical Studies (14) in the full Prescribing Information].*

Limitation of Use: Safety and efficacy of IRESSA have not been established in patients with metastatic NSCLC whose tumors have EGFR mutations other than exon 19 deletions or exon 21 (L858R) substitution mutations *[see Clinical Studies (14) in the full Prescribing Information].*

DOSAGE AND ADMINISTRATION

Patient Selection

Select patients for the first-line treatment of metastatic NSCLC with IRESSA based on the presence of EGFR exon 19 deletion or exon 21 (L858R) substitution mutations in their tumor *[see Indications and Usage (1)* and *Clinical Studies (14) in the full Prescribing Information].* Information on FDA-approved tests for the detection of EGFR mutations in NSCLC is available at: http://www.fda.gov/CompanionDiagnostics.

Recommended Dose

The recommended dose of IRESSA is 250 mg orally once daily with or without food until disease progression or unacceptable toxicity.

Do not take a missed dose within 12 hours of the next dose.

Administration to Patients Who Have Difficulty Swallowing Solids

Immerse IRESSA tablets in 4 to 8 ounces of water by dropping the tablet in water, and stir for approximately 15 minutes. Immediately drink the liquid or administer through a naso-gastric tube. Rinse the container with 4 to 8 ounces of water and immediately drink or administer through the naso-gastric tube.

Dose Modification

Dose Modifications for Adverse Drug Reactions

Withhold IRESSA (for up to 14 days) for any of the following:

- Acute onset or worsening of pulmonary symptoms (dyspnea, cough, fever) *[see Warnings and Precautions (5.1) in the full Prescribing Information]*
- NCI CTCAE Grade 2 or higher in ALT and/or AST elevations [*see Warnings and Precautions (5.2) in the full Prescribing Information*]
- NCI CTCAE Grade 3 or higher diarrhea *[see Warnings and Precautions (5.4) in the full Prescribing Information]*
- Signs and symptoms of severe or worsening ocular disorders including keratitis *[see Warnings and Precautions (5.5) in the full Prescribing Information]*
- NCI CTCAE Grade 3 or higher skin reactions *[see Warnings and Precautions (5.6) in the full Prescribing Information]*

Resume treatment with IRESSA when the adverse reaction fully resolves or improves to NCI CTCAE Grade 1.

Permanently discontinue IRESSA for:

- Confirmed interstitial lung disease (ILD) *[see Warnings and Precautions (5.1) in the full Prescribing Information]*
- Severe hepatic impairment *[see Warnings and Precautions (5.2) in the full Prescribing Information]*
- Gastrointestinal perforation *[see Warnings and Precautions (5.3) in the full Prescribing Information]*
- Persistent ulcerative keratitis *[see Warnings and Precautions (5.5) in the full Prescribing Information]*

Dose Modifications for Drug Interactions

Strong CYP3A4 Inducers

Increase IRESSA to 500 mg daily in the absence of severe adverse drug reaction, and resume IRESSA at 250 mg seven days after discontinuation of the strong CYP3A4 inducer *[see Drug Interactions (7)* and *Clinical Pharmacology (12.3) in the full Prescribing Information].*

CONTRAINDICATIONS

None.

WARNINGS AND PRECAUTIONS

Interstitial Lung Disease (ILD)

ILD or ILD-like adverse drug reactions (e.g., lung infiltration, pneumonitis, acute respiratory distress syndrome, or pulmonary fibrosis) occurred in 1.3% of the 2462 patients who received IRESSA across clinical trials; of these, 0.7% were Grade 3 or higher and 3 cases were fatal.

Withhold IRESSA and promptly investigate for ILD in any patient who presents with worsening of respiratory symptoms such as dyspnea, cough and fever. Permanently discontinue IRESSA if ILD is confirmed [*see Dosage and Administration (2.4) and Adverse Reactions (6.1) in the full Prescribing Information*].

Hepatotoxicity

In patients who received IRESSA across clinical trials, 11.4% of patients had increased alanine aminotransferase (ALT), 7.9% of patients had increased aspartate aminotransferase (AST), and 2.7% of patients had increased bilirubin. Grade 3 or higher liver test abnormalities occurred in 5.1% (ALT), 3.0% (AST), and 0.7% (bilirubin) of patients. The incidence of fatal hepatotoxicity was 0.04%.

Obtain periodic liver function testing. Withhold IRESSA in patients with worsening liver function and discontinue in patients with severe hepatic impairment *[see Dosage and Administration (2.4)*, *Adverse Reactions (6.1)*, and *Use in Specific Populations (8.7) in the full Prescribing Information].*

Gastrointestinal Perforation

Gastrointestinal perforation occurred in three (0.1%) of the 2462 IRESSA-treated patients across clinical trials [*see Adverse Reactions (6.1) in the full Prescribing Information*]. Permanently discontinue IRESSA in patients who develop gastrointestinal perforation [*see Dosage and Administration (2.4) in the full Prescribing Information*].

Severe or Persistent Diarrhea

Grade 3 or 4 diarrhea occurred in 3% of 2462 IRESSA-treated patients across clinical trials. Withhold IRESSA for severe or persistent (up to 14 days) diarrhea *[see Dosage and Administration (2.4)* and *Adverse Reactions (6.1) in the full Prescribing Information].*

Ocular Disorders including Keratitis

Ocular disorders [keratitis (0.1%), corneal erosion and aberrant eyelash growth (0.2%), conjunctivitis, blephritis and dry eye (6.7%)] occurred in the 2462 IRESSA-treated patients across clinical trials. The incidence of Grade 3 ocular disorders was 0.1% [*see Adverse Reactions (6.1) in the full Prescribing Information*]. Interrupt or discontinue IRESSA for severe, or worsening ocular disorders [*see Dosage and Administration (2.4) in the full Prescribing Information*].

Bullous and Exfoliative Skin Disorders

Bullous conditions including toxic epidermal necrolysis, Stevens Johnson syndrome and erythema multiforme have been reported from treatment with IRESSA. Erythema multiforme and dermatitis bullous have been reported in two patients (0.08%) across NSCLC trials (Study 2, Study 3 and Study 4). IRESSA treatment should be interrupted or discontinued if the patient develops severe bullous, blistering or exfoliating conditions.

Embryo-fetal Toxicity

Based on its mechanism of action and data from animal reproduction studies IRESSA can cause fetal harm when administered to a pregnant woman. In animal reproductive studies, oral administration of gefitinib from organogenesis through weaning resulted in fetotoxicity and neonatal death at doses below the recommended human dose. Advise pregnant women of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment with IRESSA and for at least two weeks following completion of therapy [*see Use in Specific Populations (8.1, 8.3) in the full Prescribing Information*].

ADVERSE REACTIONS

The following adverse drug reactions are discussed in more detail in other sections of the labeling:

- Interstitial Lung Disease *[see Warnings and Precautions (5.1) in the full Prescribing Information]*
- Hepatotoxicity *[see Warnings and Precautions (5.2) in the full Prescribing Information]*
- Gastrointestinal Perforation *[see Warnings and Precautions (5.3) in the full Prescribing Information]*
- Severe or Persistent Diarrhea *[see Warnings and Precautions (5.4) in the full Prescribing Information]*
- Ocular Disorders including Keratitis *[see Warnings and Precautions (5.5) in the full Prescribing Information]*
- Bullous and Exfoliative Skin Disorders *[see Warning and Precautions (5.6) in the full Prescribing Information]*

Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

The safety of IRESSA is based on the data from 2462 patients with NSCLC who received IRESSA 250 mg daily monotherapy in three randomized clinical studies (Study 2, Study 3 and Study 4). Patients with a history of interstitial lung disease, drug-induced interstitial disease, radiation pneumonitis that required steroid treatment or any evidence of clinically active interstitial lung disease were excluded from these studies.

Controlled Studies:

Study 2 was a randomized, multicenter, open-label trial in which 1217 patients were randomized to receive first-line treatment for metastatic NSCLC; 607 patients received IRESSA 250 mg daily and 589 patients received carboplatin/paclitaxel. The median duration of treatment with IRESSA was 5.9 months. The study population characteristics were: median age 57 years, age less than 65 years (73%), female (79%), Asian (100%), NSCLC adenocarcinoma histology (100%), never smoker (94%), light ex-smoker (6%), ECOG PS 0 or 1 (90%).

Study 3 was a randomized, multicenter, double-blind, placebo-controlled trial in which 1692 patients were randomized to receive second- or third-line treatment for metastatic NSCLC; of which 1126 patients received IRESSA 250 mg daily and 562 patients received placebo. The median duration of treatment with IRESSA was 2.9 months. The study population characteristics were: median age 62 years, age less than 65 years (60%), female (33%), Caucasian (75%), Asian (21%), NSCLC adenocarcinoma histology (48%), never smoker (22%), ECOG PS 0 or 1 (65%), PS 2 (29%), PS 3 (5%) and two or more prior therapies (51%).

Study 4 was a randomized, multicenter, open-label trial in which 1466 patients were randomized to receive second-line treatment for metastatic NSCLC; 729 patients received IRESSA 250 mg daily and 715 patients received docetaxel. The median duration of treatment with IRESSA was 2.4 months. The study population characteristics were: median age 61 years, age less than 65 years (61%), female (36%), Caucasian (79%), Asian (21%), NSCLC adenocarcinoma histology (54%), never smoker (20%), ECOG PS 0 or 1 (88%) and two or more prior therapies (16%).

The pooled safety database from the three randomized trials was used to evaluate for serious and uncommon adverse drug reactions. Common adverse reactions were evaluated in Study 3. The most frequent adverse reactions in Study 3 (incidence of >20% and greater than placebo) reported in IRESSA-treated patients were skin reactions (47%) and diarrhea (29%). The most frequent fatal adverse reactions in IRESSA-treated patients were respiratory failure (0.9%), pneumonia (0.8%), and pulmonary embolism (0.5%).

Approximately 5% of IRESSA-treated patients and 2.3% of placebo-treated patients discontinued treatment due to an adverse event. The most frequent adverse reactions that led to discontinuation in patients treated with IRESSA were nausea (0.5%), vomiting (0.5%) and diarrhea (0.4%).

Table 1 – Selected Adverse Drug Reactions Occurring with an Incidence Rate ≥5% and an Increase of >2% of IRESSA-treated Patients in Study 3

	Percentage (%) of patients			
	IRESSA (N=1126)		Placebo (N=562)	
Adverse Reaction	**All Grades**	**Grade 3 and 4**	**All Grades**	**Grade 3 and 4**
Skin and subcutaneous tissue disorders				
Skin reactions[1]	47%	2%	17%	0.4%
Nail disorders[2]	5%	0.1%	0.7%	0%
Gastrointestinal disorders				
Diarrhea[3]	29%	3%	10%	1%
Vomiting	14%	1.2%	10%	0.4%
Stomatitis[4]	7%	0.3%	4%	0.2%
Metabolism and nutrition disorders				
Decreased appetite	17%	2.3%	14%	2.0%

Table 1 – Selected Adverse Drug Reactions Occurring with an Incidence Rate ≥5% and an Increase of >2% of IRESSA-treated Patients in Study 3 (cont'd.)

	Percentage (%) of patients			
	IRESSA (N=1126)		Placebo (N=562)	
Adverse Reaction	**All Grades**	**Grade 3 and 4**	**All Grades**	**Grade 3 and 4**
Eye disorders				
Conjunctivitis/blepharitis/dry eye[5]	6%	0%	3.2%	0%

[1] Includes Acne, Acne pustular, Dermatitis, Dermatitis acneiform, Dermatitis exfoliative, Drug eruption, Dry skin, Erythema, Exfoliative rash, Folliculitis, Pruritus, Pruritus generalized, Rash, Rash erythematous, Rash generalized, Rash macular, Rash maculo-papular, Rash papular, Rash pruritic, Rash pustular, Rash vesicular, Skin exfoliation, Skin toxicity, Xeroderma
[2] Includes Ingrowing nail, Nail bed infection, Nail disorder, Nail infection, Onychoclasis, Onycholysis, Paronychia
[3] Includes Diarrhea, Feces soft, Frequent bowel movements
[4] Includes Aphthous stomatitis, Cheilitis, Glossodynia, Mouth ulceration, Mucosal inflammation, Oral mucosal blistering, Stomatitis, Tongue disorder, Tongue ulceration
[5] Includes Blepharitis, Conjunctival hyperemia, Conjunctivitis, Dry eye, Eye irritation, Eye pruritus, Eye swelling, Eyelid irritation, Eyelid edema, Eyelids pruritus

Table 2 – Treatment Emergent Laboratory Abnormalities Occurring More Frequently in IRESSA-Treated Patients in Study 3

	IRESSA		Placebo	
Adverse Reaction	**All Grades %**	**Grade 3 and 4 %**	**All Grades %**	**Grade 3 and 4 %**
Alanine aminotransferase increased[1]	38%[2]	2.4%	23%[2]	1.4%[4]
Aspartate aminotransferase increased[1]	40%[3]	2.0%	25%[3]	1.3%[5]
Proteinuria	35%	4.7%	31%	3.3%

[1] Patients were allowed to enter the clinical study with lab values of ALT or AST CTCAE grade 1 or 2
[2] 14% gefitinib patients and 10% placebo patients were CTC grade 1 or 2 ALT at baseline
[3] 15% gefitinib patients and 12% placebo patients were CTC grade 1 or 2 AST at baseline
[4] 0.2% of placebo patients were CTC grade 3 at baseline
[5] 0.4% of placebo patients were CTC grade 3 at baseline

The following adverse reactions have been reported with IRESSA across NSCLC trials (Study 2, Study 3 and Study 4) and are not listed elsewhere in Section 6: nausea (18%), asthenia (17%), pyrexia (9%), alopecia (4.7%), hemorrhage (including epistaxis and hematuria) (4.3%), dry mouth (2%), dehydration (1.8%), allergic reactions including angioedema and urticaria (1.1%), elevations in blood creatinine (1.5%), and pancreatitis (0.1%).

Postmarketing Experience

The following adverse reactions have been identified during post-approval use of IRESSA. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

Renal and urinary disorders: cystitis, hemorrhagic cystitis

Skin and subcutaneous tissue disorders: cutaneous vasculitis

DRUG INTERACTIONS

Drugs Affecting Gefitinib Exposure

CYP3A4 Inducer

Drugs that are strong inducers of CYP3A4 increase the metabolism of gefitinib and decrease gefitinib plasma concentrations. Increase IRESSA to 500 mg daily in patients receiving a strong CYP3A4 inducer (e.g., rifampicin, phenytoin, or tricyclic antidepressant) and resume IRESSA at 250 mg 7 days after discontinuation of the strong inducer [*see Dosage and Administration (2.4)* and *Clinical Pharmacology (12.3) in the full Prescribing Information*].

CYP3A4 Inhibitor

Drugs that are strong inhibitors of CYP3A4 (e.g., ketoconazole and itraconazole) decrease gefitinib metabolism and increase gefitinib plasma concentrations. Monitor adverse reactions when administering strong CYP3A4 inhibitors with IRESSA.

Drugs Affecting Gastric pH

Drugs that elevate gastric pH (e.g., proton pump inhibitors, histamine H_2-receptor antagonists, and antacids) may reduce plasma concentrations of gefitinib. Avoid concomitant use of IRESSA with proton pump inhibitors, if possible. If treatment with a proton-pump inhibitor is required, take IRESSA 12 hours after the last dose or 12 hours before the next dose of the proton-pump inhibitor. Take IRESSA 6 hours after or 6 hours before an H_2-receptor antagonist or an antacid [*see Clinical Pharmacology (12.3) in the full Prescribing Information*].

Hemorrhage in Patients taking Warfarin

International Normalized Ratio (INR) elevations and/or hemorrhage have been reported in some patients taking warfarin while on IRESSA therapy. Patients taking warfarin should be monitored regularly for changes in prothrombin time or INR.

USE IN SPECIFIC POPULATIONS

Pregnancy

Risk Summary

Based on its mechanism of action and animal data, IRESSA can cause fetal harm when administered to a pregnant woman. In animal reproductive studies, oral administration of gefitinib from organogenesis through weaning resulted in fetotoxicity and neonatal death at doses below the recommended human dose (*see Animal Data*). Advise pregnant women of the potential hazard to a fetus or potential risk for loss of the pregnancy.

The background risk of major birth defects and miscarriage for the indicated population is unknown; however, the background risk in the U.S. general population of major birth defects is 2-4% and miscarriage is 15-20% of clinically recognized pregnancies.

Data

Animal Data

A single dose study in rats showed that gefitinib crosses the placenta after an oral dose of 5 mg/kg (30 mg/m^2, about 0.2 times the recommended human dose on a mg/m^2 basis). When pregnant rats were treated with 5 mg/kg from the beginning of organogenesis to the end of weaning there was a reduction in the number of offspring born alive. This effect was more severe at 20 mg/kg (approximate the human clinical dose on a mg/m^2 basis) and was accompanied by high neonatal mortality soon after parturition. In rabbits, a dose of 20 mg/kg/day (240 mg/m^2, about twice the recommended dose in humans on a mg/m^2 basis) caused reduced fetal weight.

Lactation

Risk Summary

It is not known whether IRESSA is excreted in human milk. Animal studies indicate the gefitinib and its metabolites are present in rat milk at a concentration higher than those in maternal plasma. Because of the potential for serious adverse reactions in nursing infants from IRESSA, advise women to discontinue breast-feeding during treatment with IRESSA.

Data

Animal Data

Levels of gefitinib and its metabolites were 11-to-19-fold higher in milk than in blood, after oral exposure of lactating rats to a dose of 5 mg/kg.

Females and Males of Reproductive Potential

Contraception

Based on its mechanism of action and animal data, IRESSA can cause fetal harm when administered to a pregnant woman [*see Use in Specific Populations (8.1) in the full Prescribing Information*]. Advise females of reproductive potential to use effective contraception during treatment with IRESSA and for at least two weeks following completion of therapy.

Infertility

IRESSA may result in reduced fertility in females of reproductive potential [*see Nonclinical Toxicology (13.1) in the full Prescribing Information*].

Pediatric Use

The safety and effectiveness of IRESSA in pediatric patients have not been established.

Geriatric Use

Of the 823 patients enrolled in two randomized, active-controlled clinical trials 374 patients (45%) were 65 years and older, and 93 patients (11%) were 75 years and older. No overall differences in safety were observed between patients 65 years and older and those younger than 65 years. There is insufficient information to assess for differences in efficacy between older and younger patients.

Renal Impairment

Less than four percent (<4%) of gefitinib and its metabolites are excreted via the kidney. No clinical studies were conducted with IRESSA in patients with severe renal impairment.

Hepatic Impairment

The systemic exposure of gefitinib was compared in patients with mild, moderate, or severe hepatic impairment due to cirrhosis (according to Child-Pugh classification) and healthy subjects with normal hepatic function (N=10/group). The mean systemic exposure ($AUC_{0-\infty}$) was increased by 40% in patients with mild impairment, 263% in patients with moderate impairment, and 166% in patients with severe hepatic impairment. Monitor adverse reactions when IRESSA is administered to patients with moderate and severe hepatic impairment.

In a study comparing 13 patients with liver metastases and moderate hepatic impairment (addition of CTC grade of baseline AST/SGOT, ALP, and bilirubin equals 3 to 5) to 14 patients with liver metastases and normal hepatic function, the systemic exposure of gefitinib was similar [*see Warnings and Precautions (5.2) in the full Prescribing Information*].

OVERDOSAGE

Twenty three patients were treated weekly with doses from 1500 mg to 3500 mg, and IRESSA exposure did not increase with increasing dose. Adverse events were mostly mild to moderate in severity, and were consistent with the known safety profile of IRESSA. In the event of suspected overdose, interrupt IRESSA, institute supportive care, and observe until clinical stabilization. There are no specific measures/treatments that should be taken following IRESSA overdosing.

PATIENT COUNSELING INFORMATION

Advise the patient to read the FDA-approved patient labelling (Patient Information).

Interstitial Lung Disease: Advise patients to immediately contact their healthcare provider for new onset or worsening of pulmonary symptoms such as dyspnea, cough and fever [*see Warnings and Precautions (5.1) in the full Prescribing Information*].

Hepatotoxicity: Inform patients that they will need to undergo lab tests to monitor for liver function. Advise patients to contact their healthcare provider to report any new symptoms indicating hepatic toxicity [*see Warnings and Precautions (5.2) in the full Prescribing Information*].

Gastrointestinal Perforation: Advise patients that IRESSA can increase the risk of gastrointestinal perforation and to seek immediate medical attention for severe abdominal pain [*see Warnings and Precautions (5.3) in the full Prescribing Information*].

Severe or Persistent Diarrhea: Advise patients to contact their healthcare provider for severe or persistent diarrhea [*see Warnings and Precautions (5.4) in the full Prescribing Information*].

Ocular Disorders including Keratitis: Advise patients promptly to contact their healthcare provider if they develop eye symptoms, lacrimation, light sensitivity, blurred vision, eye pain, red eye or changes in vision *[see Warnings and Precautions (5.5) in the full Prescribing Information].*

Bullous and Exfoliative Skin Disorders: Advise patients that IRESSA can increase the risk of bullous and exfoliative skin disorders and to seek immediately medical attention for severe skin reactions [*see Warnings and Precautions (5.6) in the full Prescribing Information*].

Embryo-fetal Toxicity: Advise pregnant women of the potential risk to a fetus or potential risk for loss of the pregnancy [*see Warnings and Precautions (5.7) and Use in Specific Populations (8.1) in the full Prescribing Information*]. Advise females of reproductive potential to use effective contraception during treatment with IRESSA and for at least two weeks following completion of therapy [*see Use in Specific Populations (8.3) in the full Prescribing Information*].

Lactation: Advise women to discontinue breast-feeding during treatment with IRESSA [*see Use in Specific Populations (8.2) in the full Prescribing Information].*

IRESSA is a trademark of the AstraZeneca group of companies.

Manufactured for:
AstraZeneca Pharmaceuticals LP Wilmington, DE 19850
By: AstraZeneca UK Limited Macclesfield, Cheshire, England Product of Belgium

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For the treatment of metastatic NSCLC

A TKI for first-line use in EGFR mutation–positive patients

whose tumors harbor exon 19 deletions or exon 21 (L858R) substitution mutations

IRESSA®
gefitinib

Indication

IRESSA is indicated for the first-line treatment of patients with metastatic non-small cell lung cancer (NSCLC) whose tumors have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitution mutations as detected by an FDA-approved test.

Limitation of Use: Safety and efficacy of IRESSA have not been established in patients with metastatic NSCLC whose tumors have EGFR mutations other than exon 19 deletions or exon 21 (L858R) substitution mutations.

Select Safety Information

- There are no contraindications for IRESSA
- Interstitial Lung Disease (ILD) or ILD-like reactions (eg, lung infiltration, pneumonitis, acute respiratory distress syndrome, or pulmonary fibrosis) occurred in 1.3% of 2462 IRESSA patients; of these, 0.7% were Grade ≥3 and 3 cases were fatal. Withhold IRESSA and promptly investigate for ILD in any patient who presents with worsening of respiratory symptoms such as dyspnea, cough and fever. Permanently discontinue IRESSA if ILD is confirmed
- In patients who received IRESSA, 11.4% of patients had increased alanine aminotransferase (ALT), 7.9% of patients had increased aspartate aminotransferase (AST), and 2.7% of patients had increased bilirubin. Grade ≥3 liver test abnormalities occurred in 5.1% ALT, 3.0% AST, and 0.7% bilirubin of patients. The incidence of fatal hepatotoxicity was 0.04%. Obtain periodic liver function testing. Withhold IRESSA in patients with worsening liver function and discontinue in patients with severe hepatic impairment
- Gastrointestinal perforation occurred in three (0.1%) of 2462 IRESSA patients. Permanently discontinue IRESSA in patients who develop gastrointestinal perforation
- Grade ≥ 3 diarrhea occurred in 3% of 2462 IRESSA patients. Withhold IRESSA for severe or persistent (up to 14 days) diarrhea
- The most commonly reported adverse drug reactions reported in more than 20% of patients and greater than placebo, were skin reactions (47%) and diarrhea (29%)

Please see Brief Summary of complete Prescribing Information on the next two pages.

Learn more about IRESSA at www.iressa-usa.com.

AstraZeneca