ONCOLOGY ISSUES

This publication is a benefit of membership
Association of Community Cancer Centers

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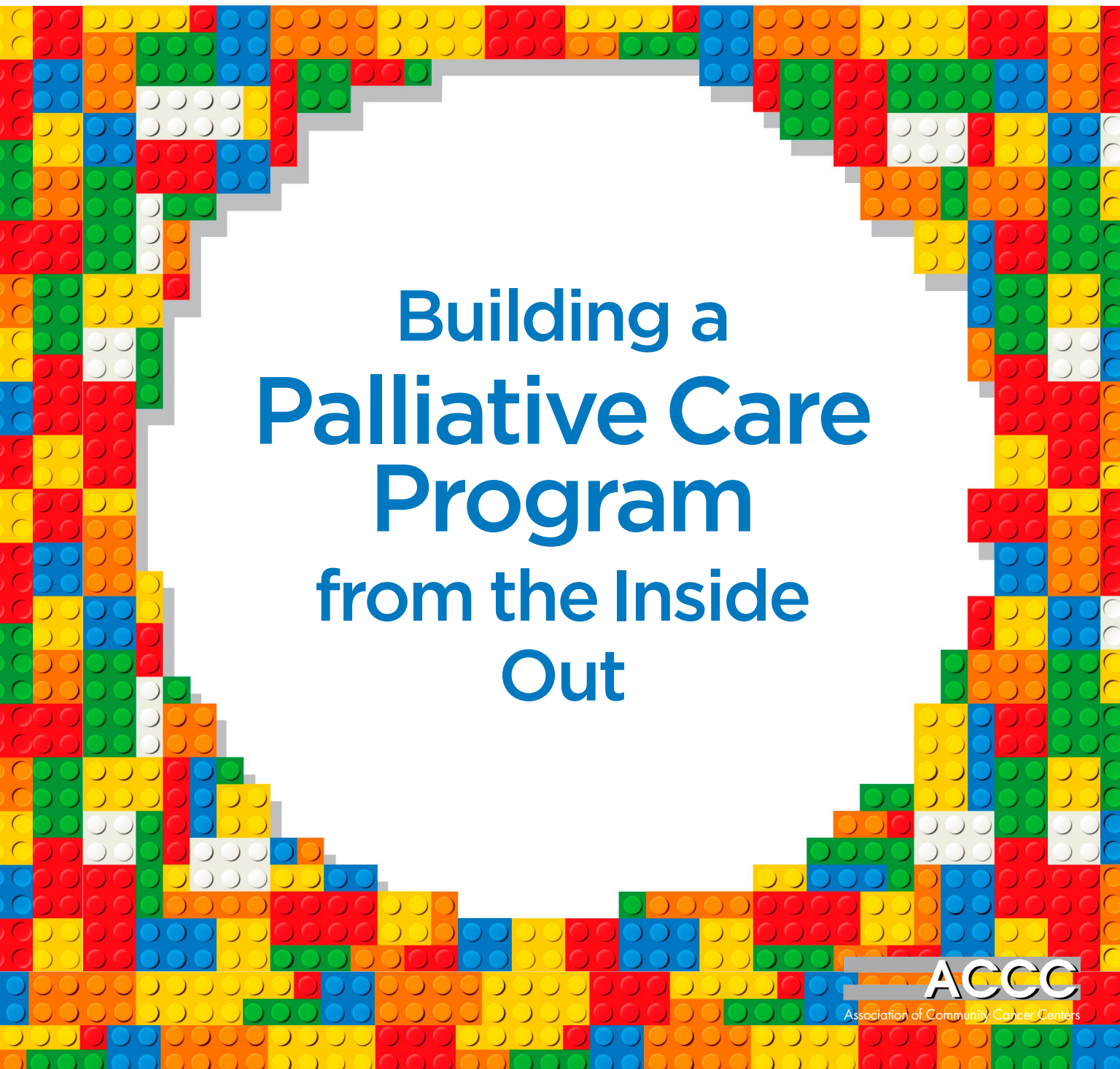

TAGRISSO® (osimertinib): BREAK THROUGH THE T790M RESISTANCE BARRIER

in patients with metastatic EGFR T790M mutation-positive NSCLC, as detected by an FDA-approved test, at progression on or after EGFR TKI therapy

A targeted therapy researched in two clinical trials

- Effective in two separate global, Phase II, single-arm, open-label clinical trials in patients with metastatic EGFR T790M mutation-positive NSCLC who had progressed on or after EGFR TKI therapy[1]
  - A 59% objective response rate (95% CI: 54–64) in patients who progressed with previous EGFR TKI therapy
- In a separate dose-finding part of AURA, 63 patients with centrally confirmed EGFR T790M-positive NSCLC who progressed on prior systemic therapy, including an EGFR TKI, were administered TAGRISSO 80 mg[1]:
  - 51% (32/63) of patients in the 80-mg cohort had a confirmed response by BICR
  - The median DoR was 12.4 months
- Grade 3/4 adverse events occurred at <3.5%[1]
- <6% of patients in a pooled analysis (N=411) had either dose reductions or discontinuations due to adverse events[1]
- 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[1]
- The most common adverse events in a pooled analysis of TAGRISSO patients (N=411) were diarrhea (42%), rash (41%), dry skin (31%) and nail toxicity (25%)[1]

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

Visit **TAGRISSOhcp.com** for more information

IMPORTANT SAFETY INFORMATION (cont.)

- 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%)

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.

Please see Brief Summary of complete Prescribing Information.

Reference: 1. TAGRISSO [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; 2015.

AstraZeneca

TAGRISSO®
osimertinib

TAGRISSO™ (osimertinib) tablets, 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 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 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 60 mL (2 ounces) of non-carbonated water only. Stir until tablet is dispersed into small pieces (the tablet will not completely dissolve) and swallow immediately. Do not crush, heat, or ultrasonicate during preparation. Rinse the container with 120 mL to 240 mL (4 to 8 ounces of) water and immediately drink.

If administration via naso-gastric tube is required, disperse the tablet as above in 15 mL of noncarbonated water, and then use an additional 15 mL of water to transfer any residues to the syringe. The resulting 30 mL liquid should be administered as per the nasogastric tube instructions with appropriate water flushes (approximately 30 mL).

Dosage Modification

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

Drug Interactions

Strong CYP3A4 Inducers

If concurrent use is unavoidable, increase TAGRISSO dosage to 160 mg daily when coadministering with a strong CYP3A inducer. Resume TAGRISSO at 80 mg 3 weeks after discontinuation of the strong CYP3A4 inducer *[see Drug Interactions (7), and Clinical Pharmacology (12.3) in full Prescribing Information]*.

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 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 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 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 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 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 full Prescribing Information]*

QTc Interval Prolongation *[see Warnings and Precautions (5.2) in 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 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

Effect of Other Drugs on Osimertinib

Strong CYP3A Inducers

Coadministering TAGRISSO with a strong CYP3A4 inducer decreased the exposure of osimertinib compared to administering TAGRISSO alone *[see Clinical Pharmacology (12.3) in full Prescribing Information]*. Decreased osimertinib exposure may lead to reduced efficacy.

Avoid coadministering TAGRISSO with strong CYP3A inducers (e.g., phenytoin, rifampin, carbamazepine, St. John's Wort) [note: effect of St. John's Wort varies widely and is preparation-dependent]. Increase the TAGRISSO dosage when coadministering with a strong CYP3A4 inducer if concurrent use is unavoidable *[see Dosage and Administration (2.4) in full Prescribing Information]*. No dose adjustments are required when TAGRISSO is used with moderate and/or weak CYP3A inducers.

Effect of Osimertinib on Other Drugs

Coadministering TAGRISSO with a BCRP substrate increased the exposure of the BCRP substrate compared to administering the BCRP substrate alone *[see Clinical Pharmacology (12.3) in full Prescribing Information]*. Increased BCRP substrate exposure may increase the risk of exposure-related toxicity.

Monitor for adverse reactions of the BCRP substrate (e.g., rosuvastatin, sulfasalazine, topotecan), unless otherwise instructed in its approved labeling, when coadministered with TAGRISSO.

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 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 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 full Prescribing Information]*.

Infertility

Based on animal studies, TAGRISSO may impair fertility in females and males of reproductive potential. The effects on female fertility showed a trend toward reversibility. It is not known whether the effects on male fertility are reversible *[see Nonclinical Toxicology (13.1) in 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 suggests 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 dose adjustment is recommended in patients with mild [creatinine clearance (CLcr) 60-89 mL/min, as estimated by the Cockcroft Gault method (C-G)] or moderate (CLcr 30-59 mL/min, as estimated by C-G) 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 full Prescribing Information]*.

Hepatic Impairment

No dose adjustment is recommended in patients with mild hepatic impairment [total bilirubin less than or equal to upper limit of normal (ULN) and AST greater than 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 full Prescribing Information]*.

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DEPARTMENTS

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Association of Community Cancer Centers

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Oncology Issues serves the multidisciplinary specialty of oncology care and cancer program management.

Archived editions of *Oncology Issues* are available to members at: mynetwork.accc-cancer.org.

FROM THE EDITOR

Construction Zone Ahead: Hard Hats Required!

BY CHRISTIAN DOWNS, JD, MHA

My boys love to go and watch the construction of the super structures being built here in the Washington, D.C., area. From the massive "The Wharf" project that seeks to revitalize the old southwest D.C. waterfront to the area's first casino at the National Harbor, there is so much to see—cranes, bulldozers, welders, and masons. It's easy to get overwhelmed in all of the action and to lose sight of the magnitude of what you're actually seeing, specifically the conceptualization, financing, planning, and engineering behind the construction.

Similar to the construction projects in our nation's capital, many cancer programs around the country are also in a construction mode. Maybe not bricks and mortar, but working on their programs to improve the delivery of care to their patients. In this edition of *Oncology Issues*, we focus on the building, bridging, connecting, and engaging "construction" elements at four 2016 ACCC Innovator Award-winning programs.

First, in "Building a Palliative Care Program from the Inside Out," read, step-by-step, the approach Kaufman Cancer Center employed to grow and enhance existing services to offer early palliative care at their program, including holding weekly palliative care case conferences and developing in-house palliative care specialists.

Next, in "Telehealth—Connecting Patients with Nutrition Services," Baton Rouge General Medical Center Pennington Cancer Center shares how it uses telehealth technology to ensure that patients at multiple clinic locations have seamless access to nutrition services, removing barriers to care, such as transportation and multiple appointments.

In our third feature article, Outer Banks Hospital outlines its successful HPV outreach and education campaign in "HPV Vaccination—Engaging Community Partners for Success." Those in the oncology community understand that HPV vaccination of our children is an important cancer prevention opportunity, but the issue is now becoming a public health priority. As always, we find ACCC member programs at the forefront of these efforts, with this 2016 ACCC Innovator Award winner sharing the "how to's" of its strategic approach, which led to improved HPV vaccination rates in local schools.

Finally, in "Bridging the Gap—Early Detection of Cancer for the Medically Underserved," learn how Mary Bird Perkins Cancer Center's innovative early detection and prevention education program is working to reduce cancer mortality and improve health equity among vulnerable patient populations. Key to this community-based program: patient navigators that connect at-risk patients to resources and support, ensuring follow-up for all patients with abnormal findings.

New construction—and all the change it brings—can be a challenge. And right now, with the election of President Trump and the move to a Republican-led Congress, we are facing four years of possible new construction (or even "deconstruction") on the Affordable Care Act (ACA). Will this landmark legislation be abolished entirely? Or will it merely undergo a major renovation? Learn the latest at the ACCC Annual Meeting, CANCERSCAPE, March 29-31, 2017, in Washington, D.C. Register today at accc-cancer.org/CANCERSCAPE. OI

Advocacy Now!

BY JENNIE R. CREWS, MD, MMM, FACP

As we head into a New Year with a new Administration in the White House, we can be certain that now more than ever the oncology community must continue to be the strong, clear voice for access to quality cancer care delivery in all settings of care.

Looking back over the past months, we can feel proud of the Association of Community Cancers Centers' role in advocating for cancer care providers, their patients, and cancer programs—small and large—serving communities across the nation. As we continue to face the emerging challenges of transitioning to new payment models, ACCC advocacy is there. Among our advocacy successes in 2016:

- Launching the ACCC Oncology Care Model (OCM) Collaborative online community, helping practices and programs through the initial challenges of participating in CMMI's Oncology Care Model.
- Meeting with elected officials on Capitol Hill, as well as CMS staff, to voice serious concerns about the agency's proposed Medicare Part B Drug Demonstration, including sharing data with policy makers on the likely impact of the ill-conceived model on oncology care. In December 2016, CMS announced it would not go forward with the proposal.
- Submitting insightful and substantive comments on MACRA, as well as the hospital Outpatient Prospective Payment System (OPPS) and Physician Fee Schedule (PFS) proposed rules for 2017.
- Ensuring that the voice of community oncology was heard as part of Vice President Biden's Cancer Moonshot initiative. As ACCC President, not only did I have the privilege of participating in the Washington, D.C., Moonshot Summit in June, but also on a panel at the White House announcement of the Cancer Moonshot Blue Ribbon Panel Report recommendations.
- And on Jan. 11, ACCC participated in the Cancer Moonshot healthcare forum, Making Healthcare Better.
- In December 2016, the 21st Century Cures Act was signed into law, bipartisan legislation that allocates $6.3 billion to spur the development of new drugs and devices, and fund the Precision Medicine Initiative, as well as the Cancer Moonshot initiative to speed cancer research—all critical to advancing cancer care.
- Advocating for appropriate payment rates in response to Congressional efforts to equalize payments between physician offices and hospital outpatient departments.

As we move into 2017, we face a host of unknowns. What changes are ahead for cancer care? The ACA? The shift to a value-based healthcare system? At the same time, there are certainties that we can depend on—we can be certain that advocacy on behalf of community cancer care and the patients and families we serve is more critical than ever before.

As we've seen over the past months, our advocacy efforts can effect change. I urge you to take action and join us in Washington, D.C., on March 29, 2017, for ACCC Capitol Hill Day. ACCC offers training and support to help you share your cancer program's story with lawmakers so that they understand how policy is impacting those on the frontlines of cancer care delivery in their home communities. Then plan to attend the ACCC 43rd Annual Meeting, CANCERSCAPE, where you will gain an insider's perspective on policy changes likely to impact your cancer program's future. It looks to be an exciting year ahead, and I urge our members to stay engaged on the policy front so that ACCC—and its members—remain at the forefront of healthcare reform. OI

Coming in Your 2017 *ONCOLOGY ISSUES*

- The Study of High Cost Oncology Patients to Improve Care & Curb Costs
- Enhancing Survivorship through Improved Provider Communication, Care Coordination & Professional Education
- Establishing Personal Pain Goals in Oncology Patients to Improve Care & Decrease Costs
- Expanding Access to Immunotherapy in the Community Setting
- Developing a Nurse Practitioner Productivity Measurement Tool
- Advancing Breast Cancer Care & Survivorship Through a Peer Mentor Program
- Developing a Pathway to Identify Women at Increased Risk for Breast Cancer & Provide Personalized Management & Risk Reduction
- Incorporating Telephone Triage Guidelines into Nursing Workflow
- Spiritual Care of Cancer Patients Across the Continuum: A Pilot Study

more online @ accc-cancer.org

MEETING

ACCC Annual Meeting, CANCERSCAPE

Register today for sessions on The State of Healthcare Under the New Administration—A Democrat and Republican Point/Counterpoint; The Advisory Board Presents the State of Today's Cancer Programs; What Cancer Programs Can Do Thrive — Not Just Survive — MACRA; Drug Pricing Under the Trump Administration; The ACA: What's Going, What's Staying, and What About Those State Health Exchanges? accc-cancer.org/CANCERSCAPE.

PUBLICATION

Trends in Cancer Programs

Key findings from this year's survey include top challenges and concerns, the potential impact of Medicare's site-neutral payment policy, financial education for patients, and much more! accc-cancer.org/trends2016.

RESOURCES

Metastatic Breast Cancer Resources & Tools

A workbook featuring three model community cancer programs that have exhibited consistent, thorough, and integrated support for this patient population, links to the Cancer Experience Registry,® and more. accc-cancer.org/metastaticbreastcancer.

WEBINAR

How to Model Your Emergency Response to Triage Immunotherapy Patients

Strategies to help respond to—and triage—immunotherapy patients. Learn how one cancer program instituted a model to address immuno-oncology symptom management, staff training, and patient education needs, resulting in greater access to coordinated care, a reduction in hospital and ED admissions, and cost savings. accc-iclio.org.

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fast

What Are We Paying Our C-Suite Physician Leaders?

(Median compensation 2016 vs. 2013)

- Emerging Roles, C-Suite—$499,000 vs. $469,000, **up 6%**
- Chief Executive Officer/President—$437,500 vs. $410,000, **up 7%**
- Chief Medical Officer—$388,000 vs. $365,000, **up 6%**
- Chief Information Officer/Chief Medical Information Officer—$372,500 vs. $315,000, **up 18%**
- Chief Quality/Patient Safety Officer—$375,000 vs. $375,000

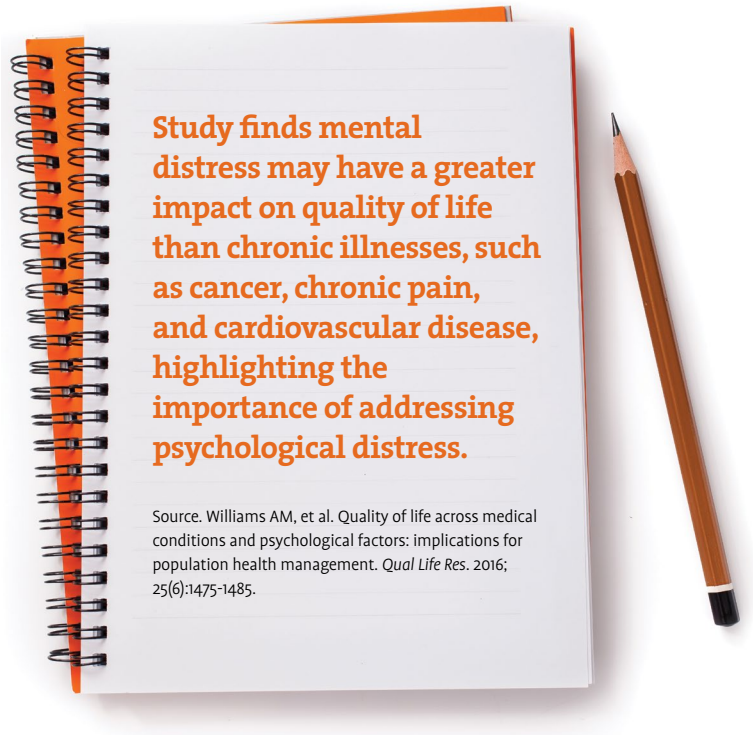
Source. 10th Biennial Physician Leadership Compensation Survey. cejkaexecutivesearch.com/2016-physician-leadership-compensation-survey.

4 Drivers of Physician Leadership Compensation

1. The growing role of "big data" drives up compensation.
2. Working at the corporate level and holding higher degrees and certifications opens the door to higher pay.
3. Physician leaders whose compensation is most aligned with organizational goals earn more.
4. Outside of the C-suite, pay goes up as focus on clinical initiatives increases.

Source. Rosin T. What drives highest physician leadership compensation? 4 findings. *Becker's Hospital Review*. beckershospitalreview.com/compensation-issues/what-drives-highest-physician-leadership-compensation-4-findings.html.

facts



Study finds mental distress may have a greater impact on quality of life than chronic illnesses, such as cancer, chronic pain, and cardiovascular disease, highlighting the importance of addressing psychological distress.

Source. Williams AM, et al. Quality of life across medical conditions and psychological factors: implications for population health management. *Qual Life Res*. 2016; 25(6):1475-1485.

survey

Improvement Needed!

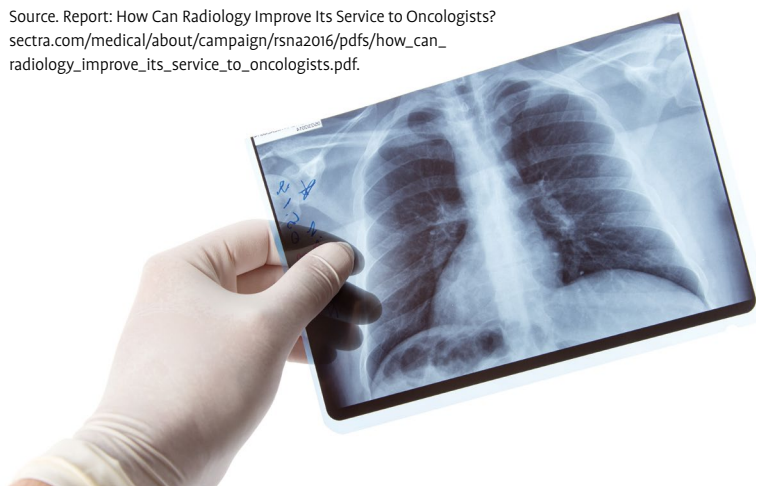
While a majority of healthcare professionals say they discuss steps their patients can take to lower their risk of cancer, less than **1/3** of patients say those discussions have taken place, according to a WebMD/Medscape survey. The survey found that only **27%** of consumers could recall their healthcare professional broaching a cancer prevention discussion, even though more than **70%** of healthcare professionals say that they do. This gap is particularly wide with respect to discussions on family history and vaccinations for hepatitis B and human papillomavirus (HPV), which are known to prevent liver and cervical cancer, respectively.

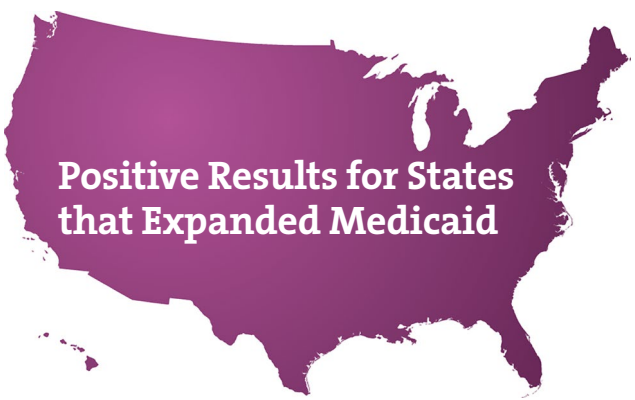
Source. WebMD. Survey: Doctor/Patient Gap On Cancer Prevention. webmd.com/cancer/news/20161025/webmd-cancer-prevention-survey#1.

How Can Radiology Improve Its Service to Oncology?

- Rich reports including images, measurements, annotations, etc.—**23%** of survey respondents
- The ability to deliver a summary report for complex cases with multiple exams—**22%** of survey respondents
- Image-based lesion tracking to show treatment response—**20%** of survey respondents
- Improved communication—**17%** of survey respondents
- Structured reports following pre-defined templates—**10%** of survey respondents

Source. Report: How Can Radiology Improve Its Service to Oncologists? sectra.com/medical/about/campaign/rsna2016/pdfs/how_can_radiology_improve_its_service_to_oncologists.pdf.





Hospitals located in the **19 states** that implemented the Medicaid expansion had significantly increased Medicaid revenue, decreased uncompensated care costs, and improvements in profit margins compared with hospitals located in the 25 states that did not expand Medicaid.

Source. Blavin F. Association between the 2014 Medicaid expansion & hospital finances. *JAMA*. 2016;316(14):1475-1483.

Fasten Your Seat Belts...

BY LEAH RALPH

As we head into the New Year, 2016 is rapidly receding in the rear view mirror. Still, it was quite a year. We saw the Obama Administration finalize regulations around sweeping physician payment reform in Medicare, oncology practices nationwide navigate the first year of the Oncology Care Model (OCM), policymakers try—and fail—to push through drug pricing reform with a national mandatory demonstration program, the 21st Century Cures Act signed into law, and the drug pricing debate hit a fever pitch. More, the surprise election of Donald Trump and transition to a Republican President and Congress that has prioritized repealing the Affordable Care Act (ACA) in early 2017 marks the beginning of an uncertain and tumultuous period in health policy. And fasten your seat belts because it may happen fast: the first 18 months of a new presidency and congress is the most active period of policymaking in the U.S.

With respect to the ACA, while the health reform law is far more than the insurance exchanges, the public debate to date has been focused on the coverage mandate and subsidies in the individual marketplace. President-Elect Trump has signaled he favors politically popular consumer protections in the ACA, such as banning insurers from discriminating against people with preexisting conditions and allowing children to remain on their parents' health plan until age 26. However, the path to achieve this remains unclear. And while there's no agreed-upon replacement plan, Congressional Republicans have also supported allowing the sale of health insurance across state lines, expanding the use of health savings accounts (HSAs), replacing the ACA's health insurance subsidies with tax credits, and establishing high-risk pools. Yet none of these proposals would meaningfully restore access to insurance coverage for the more than 20 million people who have gained coverage under the ACA.

What will these changes mean for cancer patients and providers? While the scope and details remain unclear, generally, under the proposals put forward to date, cancer providers may see an increased number of patients who are under- or uninsured, and higher uncompensated care costs. For the exchange population, benefits and cost-sharing assistance will likely be less generous, which could pose significant access barriers to care. At the same time it's important to note that the ACA overpromised and underperformed—while patients without access to subsidies are seeing out-of-pocket costs spike, concurrently providers' expectations of gaining fully insured patients under the ACA have not necessarily been realized. Patients with exchange coverage have generally been sicker and more expensive to treat and, on top of that, some providers are starting to see their Disproportionate Share Hospital (DSH) payments evaporate, as agreed to under the law. Fixes to the ACA—beyond what Republicans are proposing—are needed to shore up the long-term viability of our healthcare system for both patients and providers.

As the New Year rings in the changes in Washington, D.C., there will undoubtedly be a significant impact on the direction of federal policy with respect to access and coverage in 2017. Still, we expect that key market trends, such as value-based purchasing will continue. The fate of the Center for Medicare and Medicaid Innovation (CMMI), which was created by the ACA, remains in limbo, but we suspect that Medicare's push towards value-based payment is inherently non-partisan and the movement to test different ways to pay providers based on cost and quality is here to stay. Despite the election, Medicare is moving forward with a fundamental shift in physician payment, from fee-for-service (FFS) to value-based purchasing as required under the Medicare Access and CHIP Reauthorization Act (MACRA). The private sector, too, will continue to push towards value; the pharmaceutical industry is engaged in value-based purchasing as they're increasingly pursuing outcomes-based contracts with private plans.

In 2017, ACCC members will need to consider how value-based payments will increasingly shift responsibility for managing cost and quality to providers, and how your cancer program is positioned to engage in a risk-based reimbursement structure. Providers should also prepare for a shift in coverage for patients, and anticipate how to respond to changes in access to care.

Now more than ever is the time for providers' voices to be heard—join us in Washington, D.C., March 29-31, 2017, for our annual policy meeting, CANCERSCAPE, to understand how policy changes will impact your program and patients, engage in policy discussions with your colleagues, and help shape the future of healthcare policy in 2017 and beyond. So buckle up, check out the agenda (accc-cancer.org/CANCERSCAPE), and register today. OI

Supporting Patients Through Their Journey on Jakafi® (ruxolitinib)

IncyteCARES (**C**onnecting to **A**ccess, **R**eimbursement, **E**ducation and **S**upport) provides a single point of contact through a registered nurse, OCN®, to assist eligible patients and healthcare providers in obtaining access to Jakafi® (ruxolitinib) and to connect them with continuing support and resources. The program offers:

REIMBURSEMENT SUPPORT

- Insurance benefit verification
- Information about prior authorizations
- Guidance with appealing insurance denials or coverage restrictions

ACCESS ASSISTANCE

- Copay/Coinsurance assistance
- Free medication program
- Temporary access for insurance coverage delays
- Referrals to independent nonprofit organizations and foundations

EDUCATION & SUPPORT

- Access to a registered nurse, OCN®
- Educational information for your patients about their condition and Jakafi
- Patient Welcome Kit

CONNECTION TO SUPPORT SERVICES

- Referrals for transportation assistance
- Access to patient advocacy organizations for counseling and emotional support resources

Connect with IncyteCARES

For full program terms and eligibility,
visit IncyteCARES.com or call 1-855-4-Jakafi (1-855-452-5234).

IncyteCARES Connecting to Access, Reimbursement, Education and Support | Jakafi® ruxolitinib (tablets)

spotlight

Schneck Cancer Center
Seymour, Indiana

Located one hour north of Louisville, Kentucky, and one hour south of Indianapolis, Schneck Cancer Center treats a large and ever-growing cancer patient population in the south-central portion of Indiana. First certified in 1991 by the American College of Surgeons Commission on Cancer, Schneck Cancer Center has since received the Outstanding Achievement Award for cancer care in its last two surveys. But perhaps what is most noteworthy about Schneck is the story of how the cancer center came to fruition.

Meeting Community Needs

Prior to the construction of the freestanding Schneck Cancer Center, cancer services were housed at Schneck Medical Center. The medical center is a Magnet Hospital and in 2011 received the Malcolm Baldrige National Quality Award. To date, Schneck is the only organization in Indiana to achieve this prestigious award from the President of the United States.

Every three years, the medical center's marketing department conducts a community needs assessment. In the hospital's 2005 assessment, the community identified local radiation oncology services as a need. At that time, patients had to travel a minimum of 30 minutes to reach the nearest radiation oncology facility.

"It's very tiring just to receive radiation. The community made it very clear that we needed to be offering radiation oncology services here at home," said Sally Acton, RN, BSN, MSM, OCN, director, Cancer and Palliative Care Services at Schneck Cancer Center.

Instead of building a radiation oncology wing into the existing hospital structure, hospital leadership decided to build a free-standing cancer center on the hospital campus that would bring both medical and radiation oncology services under one roof. The hospital foundation took this plan out into the community, and the community responded with $4.5 million in funds for the new cancer center.

"From the larger donors down to the lemonade stands, they [community members] feel like they're part of the cancer center," said Acton. "One woman told us she was driving by the cancer center and her child said, 'Look Mom, there's my cancer center!' because she had held a lemonade stand to raise money for it."

Today the Schneck Cancer Center is located on the Schneck Medical Center campus, across from the hospital on a street owned by the hospital. The cancer center is connected to the pharmacy and lab by a tube system. For those drugs that cannot travel by tube, the pharmacy technicians personally transport them to the center.

The one-story cancer center's lobby features warm, green tones in both the art and design with a large, welcoming fireplace in the middle. The lobby separates the two sides of the building, with medical oncology services located to the right, and radiation oncology services to the left.

When the building of the new infusion space was underway, Ms. Acton served as the voice for her patients. "In many larger centers, chairs are separated into cubby holes with a TV in each cubby hole. Our patients did not want that. Our culture is very open here, so our chemotherapy room is very open and everybody talks to everyone. My patients have told me it's like a big support group. They wanted one TV so they could all talk about what was on, so I think our cancer center reflects our culture," said Acton.

In addition to the 10 chairs in the open infusion space, there is also one private room available if a patient prefers.

Across the entire cancer center, staff includes one medical oncologist, one radiation oncologist, and six registered nurses (RNs). The nurses are required to obtain their oncology certification. One of the RNs is the nurse navigator, one is the radiation oncology nurse, one is the medical oncology nurse, two are stationed in the chemotherapy room, and Ms. Acton assists in all areas.

The palliative care program, housed in the cancer center, also includes two nurse practitioners (NPs), one of whom is an oncology certified nurse who also sees follow-up and survivorship patients. The other NP also sees inpatients for other chronic diseases and the radiation oncology nurse also participates in palliative care activities.

The palliative care program received certification by The Joint Commission in December 2015. While historically palliative care was seen as an equivalent of hospice care, Schneck Cancer Center promotes their program as a symptom management clinic. Even if patients are going to be cured of their disease, they will still experience treatment-related side effects and

symptoms. "Many of our patients are seeing the palliative care team because they've been in treatment and are getting symptoms from either the treatment, disease, or both," said Acton.

Navigating the System

Schneck Cancer Center uses the National Comprehensive Cancer Network (NCCN) Distress Tool to measure patient distress. The clinic nurse will administer the tool to patients prior to the physician appointment. The nurse documents the results in the electronic health record (EHR) and the physician is able to review the patient's responses before the clinic visit.

The documented distress tool allows the cancer treatment team to see what each patient may be distressed about; whether they are concerned mentally, financially, or with a day-to-day need, such as a lack of transportation to and from appointments. Through the EHR, patients can be automatically referred to a psychologist, social worker, chaplain, or the palliative care team, depending on the patient's supportive care needs. Plus, an interdisciplinary supportive care team meets every week to discuss individual patient cases as a group.

Once a patient has been diagnosed with cancer, nurse navigator Lynda Richey, RN, BSN, steps in. She contacts patients prior to their first appointment at Schneck Cancer Center to make sure they are aware of their diagnosis, and then gauges how much navigation they prefer. Should patients desire it, Richey is available to accompany them to doctors' offices, coordinate diagnostic appointments, and help the oncologist write the plan of care to make sure the patient, family, and physician are all on the same page.

In her initial consultation with patients, Richey provides education materials and sits with patients to go through the cancer diagnosis and answer questions. Once a patient has completed their treatment, Richey initiates the Journey Forward (survivorship care plan), which is given to patients at their next follow-up visit.

Continuous Community Assessment

Schneck Cancer Center finds value in surveying its community for evolving needs. A 2015 community needs assessment focused on the state, national, and regional statistics of cancer incidence.

One important finding was the higher incidence of lung cancer and death from lung cancer in the region. "If you look at the statistics, 26 percent of adults smoke in our county. We now have the pulmonologist hold clinic several days a week, and also increased our lung screening program using CT scans," said Acton. Schneck Cancer Center also partners with the State Health Department to offer smoking cessation.

With the high number of smokers in its patient catchment area, Schneck Cancer Center holds a monthly tumor board for lung and breast cases. This tumor board began as a breast cancer-specific board, but with the increase in the number of lung patients and with a pulmonologist on-site, staff has affectionately dubbed this tumor board "all things chest."

This past year, Schneck joined Indiana University in a lung cancer screening research study, "Measuring Stigma and Health Beliefs about Lung Cancer Screening in Long-Term Smokers."

"I think it's key that we use our registry statistics and our community needs assessment to come up with what we need to center on," said Acton. Statistics are also retrieved from the Indiana Cancer Consortium (ICC), as Acton is on the steering committee.

Schneck goes out into the community often—both to engage the public and to promote prevention and early detection. With money raised through philanthropy and community donations, the cancer center is often able to pay for diagnostic testing resulting from their many community screenings; since many of the people attending these free screenings are often without insurance coverage. OI

Select Supportive Care Services

- Chaplain
- Dietitian
- Hospice
- Social worker
- *Look Good, Feel Better*
- *Road to Recovery*

Number of new analytic cases seen in 2015: 264.

tools

Approved Drugs

• Genentech (gene.com) announced that the U.S. Food and Drug Administration (FDA) has approved **Avastin® (bevacizumab)**, either in combination with carboplatin and paclitaxel or in combination with carboplatin and gemcitabine chemotherapy, followed by Avastin alone, for the treatment of patients with platinum-sensitive recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer.

• The FDA has approved Janssen Biotech's (janssen.com) **Darzalex® (daratumumab)** in combination with lenalidomide and dexamethasone, or bortezomib and dexamethasone, for the treatment of patients with multiple myeloma who have received at least one prior therapy.

• Merck & Co., Inc. (merck.com) announced that the FDA has approved **Keytruda® (pembrolizumab)** for the treatment of patients with metastatic non-small cell lung cancer (NSCLC) whose tumors express PD-L1 as determined by an FDA-approved test. This approval also expands the indication in second-line treatment of lung cancer to include all patients with PD-L1-expressing NSCLC.

• The FDA has approved Eli Lilly and Company's (lillyoncology.com) **Lartruvo™ (olaratumab injection, 10 mg/mL)**, in combination with doxorubicin, for the treatment of adults with soft tissue sarcoma with a histologic subtype for which an anthracycline-containing regimen is appropriate and which is not amenable to curative treatment with radiotherapy or surgery.

• The FDA has granted accelerated approval to Clovis Oncology's (clovisoncology.com) **Rubraca® (rucaparib)** for women with advanced ovarian cancer who have been treated with two or more chemotherapies and whose tumors have a specific gene mutation (deleterious BRCA) as identified by an FDA-approved companion diagnostic test.

• Genentech (gene.com) announced that the FDA has approved **Tecentriq® (atezolizumab)** for the treatment of people with metastatic NSCLC who have disease progression during or following platinum-containing chemotherapy, and have progressed on an appropriate FDA-approved targeted therapy if their tumor has EGFR or ALK gene abnormalities.

Drugs in the News

• The FDA has granted orphan drug designation to Ability Pharmaceuticals' (abilitypharma.com) **ABTL0812** for the treatment of pancreatic cancer. ABTL0812 is an oral targeted anticancer compound that inhibits the PI3K/Akt/mTOR pathway.

• EMD Serono Inc. (emdserono.com) announced that the FDA has accepted for priority review the biologics license application (BLA) for the anti-PD-L1 IgG1 monoclonal antibody **avelumab**. This review relates to avelumab's proposed use in patients with metastatic Merkel cell carcinoma, based on tumor response results from the JAVELIN Merkel 200 trial.

• The FDA has accepted for review the new drug application (NDA) for ARIAD Pharmaceuticals' (ariad.com) investigational oral anaplastic lymphoma kinase (ALK) inhibitor, **brigatinib**, in patients with metastatic ALK-positive (ALK+) NSCLC who have progressed on crizotinib.

• Arog Pharmaceuticals, Inc. (arogpharma.com) announced that the FDA has granted fast track designation for **crenolanib** for the treatment of patients with unresectable or metastatic gastrointestinal stromal tumors (GIST) harboring a platelet-derived growth factor receptor alpha (PDGFRα) D842V mutation.

• The FDA has granted fast track designation to Daiichi Sankyo Company's (daiichisankyo.com) investigational HER2-targeting antibody drug conjugate, **DS-8201**, for the treatment of HER2-positive unresectable and/or metastatic breast cancer in patients who have progressed after prior treatment with HER2-targeted therapies including ado-trastuzumab emtansine (T-DM1).

• Pfizer Inc. (pfizer.com) announced that the FDA has accepted for review a supplemental NDA for its CDK 4/6 inhibitor, **Ibrance® (palbociclib)**. The supplemental NDA supports the conversion of the accelerated approval of Ibrance in combination

with letrozole to regular approval and includes data from the Phase III PALOMA-2 trial, which evaluated Ibrance as initial therapy in combination with letrozole for postmenopausal women with estrogen receptor-positive, human epidermal growth factor receptor 2-negative (ER+, HER2-) metastatic breast cancer.

• Merck (merck.com) announced that the FDA accepted for review the supplemental biologics license application (BLA) for **Keytruda® (pembrolizumab)** for the treatment of previously treated patients with advanced microsatellite instability-high cancer.

• The FDA has granted priority review to **LEE011 (ribociclib)** (Novartis, novartis.com) as first-line treatment of postmenopausal women with hormone-receptor positive, human epidermal growth factor receptor-2 negative (HR+/HER2-) advanced or metastatic breast cancer in combination with letrozole.

• Mylan (mylan.com) and Biocon Ltd. (biocon.com) announced submission of Mylan's BLA for **MYL-1401O**, a proposed biosimilar to trastuzumab, which is indicated to treat certain HER2-positive breast and gastric cancers.

• The FDA has granted orphan drug designation to Boston Biomedical's (bostonbiomedical.com) lead investigational compound, **napabucasin**, for the treatment of pancreatic cancer.

• Boehringer Ingelheim (boehringer-ingelheim.us) announced that the FDA has granted orphan drug designation to **nintedanib** for the treatment of mesothelioma.

• The FDA has granted priority review for Tesaro, Inc.'s (tesarobio.com) NDA for **Niraparib**. Niraparib, formerly known as MK-4827, is an orally active and potent poly (ADP-ribose) polymerase, or PARP, inhibitor that is being evaluated as a potential new treatment option for patients with recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer following response to platinum-based chemotherapy.

• Novartis (novartis.com) announced that the FDA has granted priority review to the NDA for **PKC412 (midostaurin)** for the treatment of acute myeloid leukemia in newly-diagnosed adults with an FMS-like tyrosine kinase-3 (FLT3) mutation, as well as for the treatment of advanced systemic mastocytosis.

• Bayer (bayer.us) has submitted a supplemental NDA to the FDA for **Stivarga® (regorafenib) tablets** for the second-line systemic treatment of patients with unresectable hepatocellular carcinoma.

• The FDA has granted orphan drug designation to AbbVie's (abbvieoncology.com) **veliparib**, an oral PARP inhibitor, being investigated in combination with chemotherapies, such as carboplatin and paclitaxel, or radiation for the treatment of advanced NSCLC.

• Astellas Pharma Inc. (astellas.com/en) and Pfizer Inc. (pfizer.com) announced that the FDA has approved a supplemental NDA to update the U.S. product labeling for **Xtandi® (enzalutamide) capsules** to include new clinical data versus bicalutamide from the TERRAIN study. The data demonstrate improvement in radiographic progression-free survival in patients with metastatic castration-resistant prostate cancer who were treated with enzalutamide compared to patients who were treated with bicalutamide.

Approved Devices

• Exact Imaging (exactimaging.com) has received FDA 510(k) clearance for its **ExactVu™ micro-ultrasound system**, which performs targeted prostate biopsies.

• The FDA had approved ZDi Solutions' (zdirad.com) **Z-System™** patient positioning device for proton therapy and conventional radiation therapy. The system is comprised of the Z-Box™, Z-Square™, and Z-Tilt™.

• Biostage, Inc. (biostage.com) announced that its **Cellspan™ Esophageal Implant** was granted FDA orphan drug designation to restore the structure and function of the esophagus subsequent to esophageal damage due to cancer, injury, or congenital abnormalities.

Approved Genetic Tests & Assays

• Roche (roche.com) announced FDA approval of the **Ventana ALK (D5F3) CDx Assay** for use on the Ventana BenchMark ULTRA automated slide stainer. The assay is a companion diagnostic to aid in the identification of ALK-positive lung cancer patients who are eligible for treatment with Pfizer's FDA-approved therapy Xalkori® (crizotinib).

The FDA has also approved Roche's **Ventana PD-L1 (SP142) Assay** as a complementary diagnostic to identify PD-L1 expression levels in patients considering treatment with the FDA-approved Roche cancer immunotherapy Tecentriq® (atezolizumab) for previously treated metastatic NSCLC. The PD-L1 (SP142) assay is also indicated to identify patients with urothelial cancer who may benefit from treatment with Tecentriq. OI

Label Change for Tarceva®

The FDA modified the indication for **Tarceva (erlotinib)** (Astellas Pharm Global Development Inc., astellas.com/en) for treatment of NSCLC to limit use to patients whose tumors have specific EGFR mutations. The labeling change applies to patients with NSCLC receiving maintenance or second or greater line treatment. These indications will be limited to those patients whose tumors have EGFR exon 19 deletions or exon 21 L858R substitution mutations as detected by an FDA-approved test. The first-line indication previously was limited to patients with EGFR exon 19 deletions or exon 21 substitution mutations.

Oncology Reimbursement Coding Update 2017

BY CINDY PARMAN, CPC, CPC-H, RCC

There is a saying that "a change is as good as a rest," which may indeed be true. However, the 2017 final regulations, code updates, and other reimbursement changes once again bring challenges to oncology coding and billing. To help you update your respective chargemasters, fee schedules, and other reimbursement documents to ensure compliance with coding and billing guidelines, we've compiled all of the oncology-specific information you need to know going into 2017.

New & Revised Procedure Codes

Each year there are new codes, revised codes, and updates to coding guidelines. For calendar year (CY) 2017, a new procedure code has been created for the application of an on-body injector:

- **96377**: Application of on-body injector (includes cannula insertion) for timed subcutaneous injection.

According to code definition, code **96377** differs from code **96372** (therapeutic subcutaneous or intramuscular injection) because it describes the work of preparing and applying the on-body injector, rather than the manual injection of a drug.

The 2016 codes for moderate sedation were deleted, and replaced with these redefined codes:

- **99151**: Moderate sedation services provided by the same physician or other qualified healthcare professional performing the diagnostic or therapeutic service that the sedation supports, requiring the presence of an independent trained observer to assist in the monitoring of the patient's level of consciousness and physiological status; initial 15 minutes of intraservice time, patient younger than 5 years of age.
- **99152**: Patient age 5 years or older.
- **+99153**: Each additional 15 minutes intraservice time. (List separately in addition to code for primary service.)
- **99155**: Moderate sedation services provided by a physician or other qualified healthcare professional other than the physician or other qualified healthcare professional performing the diagnostic or therapeutic service that the sedation supports; initial 15 minutes of intraservice time, patient younger than 5 years of age.
- **99156**: Patient age 5 years or older.
- **+99157**: Each additional 15 minutes intraservice time. (List separately in addition to code for primary service.)

In addition, moderate sedation has been included by definition in a number of surgical and procedure codes in the *CPT*© *Manual*. This means that sedation will not be coded and charged separately for an increasing number of services.

In addition to the CPT procedure codes for moderate sedation, there is a new HCPCS code for gastrointestinal endoscopic services:

- **G0500**: Moderate sedation services provided by the same physician or other qualified healthcare professional performing a gastrointestinal endoscopic service (excluding biliary procedures) that the sedation supports, requiring the presence of an independent trained observer to assist in the monitoring of the patient's level of consciousness and physiological status; initial 15 minutes of intraservice time, patient age 5 years or older.

HCPCS Level II Code Updates

In addition to changes in procedure codes, there are new and updated HCPCS modifiers, some of which are discussed in more detail in other sections of this article. **Modifier L1** (Provider attestation that the hospital laboratory test is not packaged under the Hospital OPPS) is the only HCPCS modifier deleted for CY 2017.

As a result of changes to payments for off-campus provider-based departments, below are one new and one updated modifier for billing under the Outpatient Prospective Payment System (OPPS):

- **Modifier PN**: Non-excepted service provided at an off-campus, outpatient, provider-based department of a hospital.
- **Modifier PO**: Excepted service provided at an off-campus, outpatient, provider-based department of a hospital.

Additional new HCPCS Level II modifiers include:

- **Modifier FX**: X-ray taken using film
- **Modifier Q2**: Demonstration procedure/service (Note: this is an existing modifier with revised definition)
- **Modifier V1**: Demonstration modifier 1
- **Modifier V2**: Demonstration modifier 2
- **Modifier V3**: Demonstration modifier 3
- **Modifier ZB**: Pfizer/Hospira.

Modifier JW

Although not part of the year-end coding changes, CMS issued an update to the requirement for reporting **modifier JW** (drug amount discarded/not administered to any patient). Effective Jan. 1, 2017, all providers (hospitals, freestanding centers, and physician offices) will be required to use **modifier JW**, and they will continue to be required to document the amount of discarded drug in the individual patient's medical record. This policy change was announced in Transmittal 3538 (Change Request 9603), learn more at: cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/MM9603.pdf.

Medicare's discarded drug policy is located in Chapter 17 of the Medicare Claims Processing Manual. Briefly, it states that when a provider administers part of a single-use vial or other single-use package to a Medicare patient, and the rest of the container must be discarded, Medicare will pay both for the amount that was administered and the amount that was discarded. Note that this policy applies only to single-use containers or single-use vials. If part of a multi-use container is discarded, the provider may bill only for the amount that was actually administered to the patient.

The provider must report the drug on the claim as two separate charges: one claim line for the amount administered (with no modifier), and one claim line for the discarded drug amount, with **modifier JW**. For example, code **J9035** represents Avastin (bevacizumab), 1 unit per 10 mg. If a patient is given 980 mg from single use vials that total 1,000 mg, and the remainder of the last vial is discarded (20 mg), the provider should report the following:

- **J9035** x 98 units (administered 980 mg)
- **J9035-JW** x 2 units (wasted 20 mg).

Remember to price each line appropriately as well; the charge for the drug administered and the charge for the drug amount wasted should equal the total dollar amount of drug billed. Providers will be paid for both claim lines; CMS simply wants to track the amount Medicare pays for wasted drugs.

CMS states that **modifier JW** should not be used "if the billing unit is equal to or greater than the total actual dose and the amount discarded." For example, 2 mcg of sincalide is administered to a patient from a 5 mcg single use vial, and the remainder is discarded. Sincalide is reported with code **J2805** (Injection, sincalide, 5 micrograms). Since 1 unit of the code is equal to the total amount administered plus the amount discarded, the provider will report 1 unit of code **J2805** and **modifier JW** will not be applied.

Modifier JW is reported with drugs and biologicals (preparations made from living organisms, such as vaccines, antigens, antitoxins, etc.), with the exception of drugs provided under the Competitive Acquisition Program (CAP). Unless your contractor instructs otherwise, this modifier should not be applied to codes for radiopharmaceuticals, which are in a separate category.

Drugs Administered in Portable Pumps

MLN Matters published a special edition April 26, 2016, to clarify charging for prolonged drug and biological infusions started incident-to a physician's service using an external pump. Learn more at: cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/SE1609.pdf.

In some situations, a hospital outpatient department or physician office may:

- Purchase a drug for a medically reasonable and necessary prolonged drug infusion;
- Begin the drug infusion in the outpatient department or physician office using a portable pump;
- Send the patient home for a portion of the infusion; and
- Have the patient return at the end of the infusion period.

According to these clarified instructions, the drug or biological is billable to the Medicare Administrative Contractor (MAC), even though the entire administration of the drug or biological did not occur in the physician's office or the hospital outpatient department. According to CMS, the drug or biological continues to meet the requirements for the incident-to benefit as the physician or hospital incurred a cost for the drug or biological and the administration of the drug began in the physician's office or hospital outpatient department incident-to a physician's services.

Medicare's payment for the administration of the drug or biological billed to the MAC also includes payment for all equipment used in furnishing the service. This means that equipment, such as the portable

Table 1. Current Biosimilar Codes and Modifiers

HCPCS CODE	DESCRIPTOR	SI	APC	EFFECTIVE DATE	MODIFIER
Q5101	Injection, filgrastim (G-CSF), biosimilar, 1 mcg	G	1822	03/06/2015	ZA – Novartis/Sandoz
Q5102	Injection, infliximab, biosimilar, 10 mg	K	1761	04/05/2016	ZB – Pfizer/Hospira

infusion pump used to begin administration of the drug or biological that the patient takes home to complete the infusion is not separately billable as durable medical equipment for a drug or biological paid under the incident-to benefit. This information was updated in *MLN Matters* (cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/MM9749.pdf) to provide the following HCPCS code that will be used to report the administration charge:

- **G0498**: Chemotherapy administration, intravenous infusion technique; initiation of infusion in the office/other outpatient setting using office/other outpatient setting pump/supplies, with continuation of the infusion in the community setting (e.g., home, domiciliary, rest home or assisted living) using a portable pump provided by the office/other outpatient setting, includes follow-up office/other outpatient visit at the conclusion of the infusion.

The full amount drug or biological administered via pump will also be billed to the MAC. HCPCS Level II code **G0498** is reported by the physician office or outpatient hospital department that fills and initiates the portable pump. Last, Medicare states that this code is effective Jan. 1, 2016, so it may be necessary to retroactively file corrected claims.

Biosimilar Products

A biosimilar product has no clinically meaningful differences from a previously-approved reference product, only minor differences in clinically inactive components. CMS updates coding and billing information under the OPPS on a quarterly basis. The information effective July 1, 2016, included a reminder that OPPS claims for separately paid biosimilar biological products are required to include a modifier that identifies the manufacturer of the product. Current biosimilars codes and modifiers are shown in Table 1, above.

Biodegradable Material

This same quarterly updated document states that effective June 30, 2016, the following HCPCS Level II code was deleted:

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

Code **C9743** was replaced with a Category III CPT code, effective July 1, 2016:

- **0438T**: Transperineal placement of biodegradable material, peri-prostatic (via needle), single or multiple, includes image guidance.

This new code will be reported by the hospital for the technical service and by the physician for the professional service. Remember that Category III temporary procedure codes may not be reimbursed by all insurers, so check local payer policies for coverage.

Spacer material separates the anterior rectal wall from the prostate by injecting an absorbable hydrogel- or saline-filled balloon that naturally biodegrades within six months after implantation. The goal of utilizing spacer material is to reduce the radiation dose to the rectum. These materials generally maintain shape and position during treatment, and then degrade or break down within 6 months after implantation, after treatment has completed.

The full text of *MLN Matters MM9658* is located at: cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/MM9658.pdf.

Smoking Cessation

According to CMS, effective Sept. 30, 2016, HCPCS codes **G0436** (Smoking and tobacco use cessation counseling visit; intermediate, greater than 3 minutes up to 10 minutes) and **G0437** (Smoking and tobacco use cessation counseling visit; intensive, greater than 10 minutes) are deleted. The services previously represented by HCPCS codes **G0436** and **G0437** should be billed under existing CPT codes **99406** (Smoking and tobacco use cessation counseling visit; intermediate, greater than 3 minutes up to 10 minutes) and **99407** (Smoking and tobacco use cessation counseling visit; intensive, greater than 10 minutes)

Table 2. Select Deleted Drug Codes & Their CY 2017 Code Replacements

2017 CODE		DELETED 2016 CODE	
J9325	Injection, talimogene laherparepvec, per 1 million plaque forming units	**C9472**	Injection, talimogene laherparepvec, 1 million plaque forming units (PFU)
J9205	Injection, irinotecan liposome, 1 mg	**C9474**	Injection, irinotecan liposome, 1 mg
J9295	Injection, necitumumab, 1 mg	**C9475**	Injection, necitumumab, 1 mg
J9145	Injection, daratumumab, 10 mg	**C9476**	Injection, daratumumab, 10 mg
J9176	Injection, elotuzumab, 1 mg	**C9477**	Injection, elotuzumab, 1 mg
J9352	Injection, trabectedin, 0.1 mg	**C9480**	Injection, trabectedin, 0.1 mg
J8670	Rolapitant, oral, 1 mg	**Q9981**	Rolapitant, oral, 1 mg
J0883	Injection, argatroban, 1 mg (for non-ESRD use)	**C9121**	Injection argatroban, per 5 mg
J0884	Injection, argatroban, 1 mg (for ESRD on dialysis)		
J1942	Injection, aripiprazole lauroxil, I mg	**C9470**	Injection, aripiprazole lauroxil, 1 mg
J7320	Hyaluronan or derivative, Genvisc 850, for intra-articular injection 1 mg	**Q9980**	Hyaluronan or derivative, Genvisc 850, for intra-articular injection 1 mg
J7322	Hyaluronan or derivative, Hymovis, for intra-articular injection 1 mg	**C9471**	Hyaluronan or derivative, Hymovis, for intra-articular injection 1 mg
J2182	Injection, mepolizumab, 1 mg	**C9473**	Injection, mepolizumab, 1 mg
J2840	Injection, sebelipase alfa, 1 mg	**C9478**	Injection, sebelipase alfa, 1 mg
J7342	Instillation, ciprofloxacin otic suspension, 6 mg	**C9479**	Instillation, ciprofloxacin otic suspension, 6 mg
J2786	Injection, reslizumab, 1 mg	**C9481**	Injection, reslizumab, 1 mg

respectively. The full text of *MLN Matters* MM9768 is located at: cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/MM9768.pdf.

Advanced Illness

The second quarter 2016 issue of *Coding Clinic for HCPCS*, included the following new codes:

- **S0311**: Comprehensive management and care coordination for advanced illness, per calendar month
- **S3854**: Gene expression profiling panel for use in the management of breast cancer treatment.

HCPCS codes that begin with the letter "S" are not accepted by Medicare, but may be reimbursed by other insurers, such as Blue Cross Blue Shield.

Telehealth

Effective Jan. 1, 2017, there are two new HCPCS codes for critical care telehealth:

- **G0508**: Telehealth consultation, critical care, initial, physicians typically spend 60 minutes communicating with the patient and providers via telehealth
- **G0509**: Telehealth consultation, critical care, subsequent, physicians typically spend 50 minutes communicating with the patient and providers via telehealth.

Mobility Assistance & Care Planning

There is an add-on HCPCS code that will be reported in addition to a patient office visit for patients that use special mobility equipment and an add-on code for comprehensive care planning:

- **G0501**: Resource-intensive services for patients for whom the use of specialized mobility-assistive technology (such as adjustable height chairs or tables, patient

Table 3. Replacement HCPCS Codes & Definitions for Select Drugs for CY 2017

2017 CODE	2017 DEFINITION	2016 CODE	2016 DEFINITION
J7201	Injection, factor IX, fc fusion protein, (recombinant), Alprolix, 1 IU	**J7201**	Injection, factor IX, fc fusion protein, (recombinant), 1 IU
J0573	Buprenorphine/naloxone, oral greater than 3 mg, but less than or equal to 6 mg	**J0573**	Buprenorphine/naloxone, oral greater than 3 mg, but less than or equal to 3.1 to 6 mg
J0570	Buprenorphine implant, 74.2 mg	**N/A**	
J1745	Injection, infliximab, excludes biosimilar, 10 mg	**J1745**	Injection, infliximab, 10 mg
J3357	Ustekinumab, for subcutaneous injection, 1 mg	**J3357**	Injection, ustekinumab, 1 mg
J7340	Carbidopa 5 mg/levodopa 20 mg enteral suspension, 100 ml	**J7340**	Carbidopa 5 mg/ levodopa 20 mg enteral suspension
P9072	Platelets, pheresis, pathogen reduced or rapid bacterial tested, each unit	**P9072**	Platelets, pheresis, pathogen reduced, each unit

lift, and adjustable padded leg supports) is medically necessary and used during the provision of an office/outpatient, evaluation and management visit (list separately in addition to primary service).

- **G0506**: Comprehensive assessment of and care planning by the physician or other qualified healthcare professional for patients requiring chronic care management services, including assessment during the provision of a face-to-face service (billed separately from monthly care management services). (Add-on code, list separately in addition to primary service.)

Drug Codes

Effective Jan. 1, 2017, there are new codes, revised codes, and replaced codes for drugs, biologicals, and substances. Following are new drug HCPCS codes not impacted by code definition changes:

- **C9482**: Injection, sotalol hydrochloride, 1 mg
- **C9483**: Injection, atezolizumab, 10 mg
- **J1130**: Injection, diclofenac sodium, 0.5 mg.

Bendamustine is a chemotherapy drug used for lymphoma and leukemia. For CY 2017, there is a new code for Bendeka™ (**J9034**, Injection Bendamustine HCl [Bendeka], 1 mg) and the existing code has been revised to apply only to Treanda™ (**J9033**, Injection, bendamustine HCl [Treanda], 1 mg).

New drug HCPCS codes for clotting factors effective Jan. 1, 2017, include:

- **C9140**: Injection, factor VIII (antihemophilic factor, recombinant), (Afstyla), 1 IU
- **J7179**: Injection, von Willebrand factor (recombinant), (Vonvendi), 1 IU vwf:rco
- **J7202**: Injection, factor IX, albumin fusion protein, (recombinant), Idelvion, 1 IU
- **J7207**: Injection, factor VIII, (antihemolytic factor, recombinant), pegylated, 1 IU
- **J7209**: Injection, factor VIII, (antihemolytic factor, recombinant), (Nuwiq), 1 IU
- **J7175**: Injection, factor X, (human) 1 IU.

HCPCS codes that will be deleted on Jan. 2017, include:

- **C9139**: Injection factor IX, albumin fusion protein (recombinant), Idelvion, 1 IU
- **C9137**: Injection, factor VIII, (antihemolytic factor, recombinant), pegylated, 1 IU
- **C9138**: Injection, factor VIII, (antihemolytic factor, recombinant), (Nuwiq), 1 IU.

Table 2, page 19, shows select deleted codes and their replace codes for CY 2017. Table 3, above, lists replacement HCPCS codes and definitions for select drugs for CY 2017.

Effective Jan.1, 2017, the following HCPCS codes have been deleted and not replaced:

- **J0760:** Injection, colchicine, per 1 mg
- **J1590**: Injection, gatifloxacin, 10 mg.

Update: National Correct Coding Initiative Policy Manual

The 2017 edition of the NCCI Policy Manual includes the following instruction:

- CPT codes **77280–77290** (simulation-aided field settings) should not be reported for verification of the treatment field during a course of intensity modulated radiotherapy (IMRT) treatment.

This policy will be effective Jan. 1, 2017, and will impact physicians, freestanding radiation treatment centers, and hospital outpatient departments. OI

Hospital Regulatory Update

BY CINDY PARMAN, CPC, CPC-H, RCC

The Hospital Outpatient Prospective Payment System (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. CMS' overarching goal 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.

In CY 2017, outpatient hospital payment rates will increase by 1.7 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 Program requirements. The CY 2016 conversion factor of $73.725 increases to $75.001 for CY 2017, but for hospitals that fail to meet the OQR (Outpatient Quality Reporting) requirements, the conversion factor will drop to $73.411. CMS will once again continue the policy of providing additional payments to the 11 designated cancer hospitals so that the hospital's payment-to-cost ratio, with the adjustment, is equal to the weighted average for the other OPPS hospitals. In addition, outlier payments will be triggered when the hospital's cost for furnishing a service exceeds two thresholds:

- Multiplier threshold: The cost must be at least 1.75 times the Ambulatory Payment Classification (APC) payment amount (no change from CY 2016); and
- Fixed-dollar threshold: The cost must also exceed the APC payment amount by at least $3,825; up from $3,250 last year.

Off-Campus Provider-Based Departments

CMS finalized policies to implement Section 603 of the Bipartisan Budget Act of 2015, which requires that certain items and services furnished by specific off-campus hospital outpatient departments will no longer be paid under the OPPS reimbursement mechanism beginning Jan. 1, 2017. Currently, Medicare pays for the same services at a higher rate if those services are provided in a hospital outpatient department rather than a physician's office. This payment differential has provided an incentive for hospitals to acquire physician offices in order to receive the higher rates. This acquisition trend and difference in payment has been highlighted as a long-standing issue of concern by Congress, the Medicare Payment Advisory Commission, and the Department of Health and Human Services Office of Inspector General (OIG). This difference in payment also increases costs for the Medicare program and raises the cost-sharing liability for beneficiaries.

Therefore, CMS is issuing an interim final rule with comment period (IFC) in conjunction with the OPPS final rule to establish new payment rates under the Medicare Physician Fee Schedule (MPFS) for items and services provided by certain off-campus provider-based departments (PBDs) in CY 2017. These new interim final rates adopted in the IFC will permit hospitals to be paid for furnishing items and services that may no longer be paid under the OPPS, and CMS believes this will reduce incentives for hospitals to acquire independent physician practices and convert them into more highly paid outpatient facilities. Physicians furnishing professional services in this setting will continue to be paid on the CMS1500 claim form and will be paid at the facility rate under the MPFS, in the same manner as all physicians practicing in an outpatient facility setting.

Hospitals will be paid under the MPFS at these newly established MPFS rates for non-excepted items and services, which will be billed on the UB04 claim (institutional claim) with a new claim line modifier:

- **Modifier PN**: Non-excepted service provided at an off-campus, outpatient, provider-based department of a hospital.

CMS states that non-excepted off-campus PBDs must report **modifier PN** on each UB04 claim line to indicate a non-excepted item or service. *All* non-excepted items and services billed by a hospital on an institutional claim with **modifier PN** will be paid under the MPFS at the rate established in this final rule. For CY 2017, the payment rate for these services will generally be 50 percent of the OPPS rate (with limited exceptions, such as separately payable drugs). Other OPPS policies, such as packaging of integral services, will continue to apply. CMS continues to seek comments on these new payment mechanisms and payment rates, and will make adjustments as necessary through future rulemaking.

CMS also finalized several policies regarding which off-campus PBDs and which items and services are "excepted" from the payment changes, and will therefore continue to be paid under OPPS

reimbursement. Excepted items and services furnished after Jan. 1, 2017, include:

- Services rendered by a dedicated emergency department;
- Items and services performed in an off-campus PBD that was billing for covered outpatient department services furnished prior to Nov. 2, 2015, and has not impermissibly relocated or changed ownership; or
- Services performed in a PBD that is "on the campus" (within 250 yards) of the hospital or a remote location of the hospital.

With respect to the relocation of an excepted off-campus PBD, CMS finalized the proposal that items and services must continue to be furnished and billed at the same physical address of the off-campus PBD to be considered excepted from Section 603 requirements. The final relocation policy includes a notable change from the proposed rule to allow these off-campus PBDs to relocate temporarily or permanently without loss of excepted status due to extraordinary circumstances outside the hospital's control, such as natural disasters. However, these exceptions for extraordinary circumstances will be reviewed by the CMS Regional Office and are expected to be rare and unusual.

In the CY 2017 OPPS proposed rule, CMS noted that it had received questions from some hospitals regarding whether an excepted off-campus PBD could expand the number or type of services the department furnished and still maintain excepted status. In response to public comments regarding the expansion of services performed in an excepted off-campus PBD, CMS is not finalizing its original proposal. Instead, CMS will monitor the expansion of clinical service lines by off-campus PBDs and continue to consider whether a potential limitation of service line expansion should be adopted in the future.

It is important to remember that the site-neutral rates only apply to facilities that began billing Medicare after Nov. 2, 2015. For those off-campus provider-based departments that were billing Medicare prior to this date, CMS will continue to require the following modifier on all excepted services:

- **Modifier PO**: Excepted service provided at an off-campus, outpatient, provider-based department of a hospital.

As a result, hospitals will append either the **PN** or **PO modifier** to every code for all outpatient hospital services furnished in an off-campus PBD of the hospital. These modifiers 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 reporting of these modifiers should be referred to CMS Regional Offices.

Packaged Services

The OPPS currently packages many categories of items and services that are typically provided as part of the primary hospital outpatient service. According to CMS, packaging encourages hospital efficiency, flexibility, and long-term cost containment, as well as promoting the stability of payment for services over time. For CY 2017, CMS will continue to refine packaging policies under the OPPS. Updates to packaging include:

- CMS finalized its proposal to align the packaging logic for all of the conditionally packaged services so that packaging occurs at the claim level, rather than date of service. According to CMS, this promotes consistency and ensures that items and services provided during a hospital stay are packaged even when the care spans more than a single service date.
- CMS previously adopted a policy to exclude molecular pathology tests from the laboratory packaging policy because these tests may have a different pattern of clinical use than more common and routine laboratory tests. As part of this final rule, CMS finalized the proposal to expand this laboratory test packaging exclusion to advanced diagnostic laboratory tests (ADLTs) that meet the same criteria.
- In CY 2014, CMS implemented **modifier L1** to allow for separate payment of laboratory tests when these tests were the only services on the claim or when the laboratory tests were unrelated to the other services on the claim. For CY 2017, CMS will discontinue separate payment for unrelated laboratory tests, and as a result the following modifier will be discontinued:
  - **Modifer L1**: Provider attestation that the hospital laboratory test(s) is not packaged under the hospital OPPS.

Comprehensive APCs

A comprehensive APC (C-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, on one claim submission regardless of service date, and will receive a single payment for the total service and collect a single beneficiary copayment for the procedure and related services and supplies.

Effective Jan. 1, 2015, CMS implemented C-APCs for single fraction stereotactic radiosurgery (SRS, procedure codes **77371** and **77372**) and intraoperative radiation therapy (IORT), although CMS has reassigned intraoperative radiation therapy codes **77424** and **77425** from a breast surgery C-APC to the Level 7 Radiation

Therapy C-APC. Table 4, right, identifies brachytherapy catheter or needle insertion codes and their related procedures that are designated as C-APCs effective Jan. 1, 2017.

CMS finalized a proposal to create 25 additional C-APCs, bringing the total to 62; most of these represent major surgical procedures, but one new C-APC involves allogeneic hematopoietic stem cell transplantation. Allogeneic hematopoietic stem cell transplantation (HSCT) involves the intravenous infusion of hematopoietic stem cells derived from the bone marrow, umbilical cord blood, or peripheral blood of a donor to a recipient. As provided in the Medicare Claims Processing Manual, donor acquisition charges for allogeneic HSCT include charges for the costs of several services. These services include, but are not necessarily limited to:

- National Marrow Donor Program fees
- Tissue typing of donor and recipient
- Donor evaluation
- Physician pre-procedure donor evaluation services
- Costs associated with the collection procedure (for example, general routine and special care services, procedure/operating room and other ancillary services, apheresis services, among others)
- Post-operative and post-procedure evaluation of donor
- The preparation and processing of stem cells.

When the allogeneic stem cell transplant occurs in the hospital outpatient setting, providers are instructed to report stem cell donor acquisition charges for allogeneic HSCT separately in Field 42 on Form CMS-1450 (or UB-04) by using revenue code **0819** (Organ Acquisition: Other Donor). Revenue code **0819** charges should include all services required to acquire hematopoietic stem cells from a donor, as defined earlier, and should be reported on the same date of service as the transplant procedure in order to be appropriately packaged for payment purposes.

Based on current analysis of several longstanding issues and stakeholder input, CMS proposed to create a new **C-APC 5244** (Level 4 Blood Product Exchange and Related Services) and to assign procedures described by CPT code **38240** (hematopoietic progenitor cell [HPC]; allogeneic transplantation per donor) to this C-APC. The creation of a new C-APC for allogeneic HSCT would allow for the costs for all covered outpatient services, including donor acquisition services, listed on the claim to be packaged into the C-APC payment rate. CMS will analyze these costs using its comprehensive cost accounting methodology to establish future C-APC payment rates.

After consideration of the public comments received, CMS **established C-APC 5244** (Level 4 Blood Product Exchange and Related Services), with the modification to exclude claims that do not include donor acquisition costs reported with revenue code

Table 4. Brachytherapy Catheter or Needle Insertion Codes and Related Procedures Designated as C-APCs, Effective Jan. 1, 2017

2017 C-APC	CODES ASSIGNED TO APC
5091	**19499**: Unlisted breast procedure
5092	**19298**: Breast brachytherapy button & tube catheter placement
5093	**19296**: Breast brachytherapy balloon catheter placement
5113	**20555**: Placement of needles/catheters into muscle and/or soft tissue for subsequent interstitial radioelement application
5153	**31643**: Diagnostic bronchoscope, catheter placement
5165	**41019**: Placement of needles/catheters into head and/or neck region for radioelement application
5302	**43241**: Upper GI endoscopy, catheter placement
5341	**55920**: Placement of needles/catheters into pelvic organs and/or genitalia (except prostate) for radioelement application
5414	**57155**: Insertion of uterine tandem and/or vaginal ovoids **58346**: Insertion of Heyman capsules for clinical brachytherapy

Table 5. CY 2017 Radiation Therapy APCs & Final APC Code Assignments

2017 C-APC	TITLE	CODES ASSIGNED TO APC
5621	Level 1 Radiation Therapy	77401, 77402, 77407, 77789, 77799
5622	Level 2 Radiation Therapy	0394T, 77412, 77600, 77750, 77767, 77768
5623	Level 3 Radiation Therapy	77385, 77386, **77422**, 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, **77424**, **77425**

0819 from rate setting. CMS also established a final payment rate for new **C-APC 5244** of $27,752 for CY 2017.

Pain Management

Physicians and other healthcare providers have expressed concern that patient safety questions about pain management in the Hospital Value-Based Purchasing program may influence prescribing practices. While there is no empirical evidence of such an effect, CMS finalized the removal of the pain management dimension of the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) Survey to eliminate any financial pressure clinicians may feel to overprescribe medications. CMS will continue the development of alternative questions related to provider communications and pain, and will solicit comments in future rulemaking.

Radiation Oncology Services

Section 1833(t)(2)(A) of the Social Security Act requires CMS to develop a classification system for covered outpatient department 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 finalized the proposal to reduce the number of clinical APCs for Therapeutic Radiation Treatment Preparation from 4 levels to 3 levels:

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

Essentially, CMS consolidated prior Level 1 & Level 2 procedure codes into Clinical **APC 5611** (Level 1), with the exception of code **77306** (teletherapy isodose plan; simple), which remains in **APC 5612**. All codes previously listed in Level 3 have been assigned to Level 2, and all codes previously listed in Level 4 are now included in Level 3. With regard to reimbursement, the following procedures that will now be reimbursed at the Level 1 payment are expected to decrease approximately 29.5 percent:

- **77280**: Therapeutic radiology simulation-aided field setting; simple
- **77333**: Treatment devices, design and construction; intermediate.
- **77370**: Special medical radiation physics consultation.

In addition to these APC changes, code **77422** and intraoperative radiation treatment delivery codes **77424** and **77425** were also reassigned to different APC categories (see bold text in Table 5, above).

Once again, CMS will continue paying for low-dose rate prostate brachytherapy using composite **APC 8001**. In order for hospitals to receive the higher composite APC reimbursement, both code **77778** (Interstitial radiation source application, complex, includes supervision, handling, loading of radiation source, when performed) 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. The Medicare Prescription Drug Improvement and Modernization Act of 2003 requires CMS to continue to separate payment for brachytherapy sources in CY 2017 and subsequent years. These sources

are reimbursed on a prospective basis, with 2017 payment rates set using the 2015 geometric mean unit codes for each source. CMS assigned new **status indicator E2** (Items and services for which pricing information and claims data are not available) to HCPCS code **C2644** (Brachytherapy source, cesium-131 chloride solution, per millicurie) because this code was not reported on CY 2015 claims.

Medical Oncology & Hematology Services

CMS assigned new CY 2017 CPT code **96377** (Application of on-body injector [includes cannula insertion] for timed subcutaneous injection) to **status indicator N** (Items and Services Packaged into APC Rates) to indicate that the service is paid under the OPPS; however, its payment is packaged into the payment for other services. Some commenters disagreed with the proposed status indicator assignment of N for code **96377**, and indicated that this is a primary service, not an add-on procedure, that represents a complete and unique drug administration service that a hospital performs for the subcutaneous administration of Neulasta® with the on-body injector. The commenters stated that the service is similar to the drug administration service described by procedure code **96372** (Therapeutic, prophylactic, or diagnostic injection [specify substance or drug]; subcutaneous or intramuscular), which is assigned to **APC 5692** (Level 2 Drug Administration) with a proposed payment rate of approximately $53. CMS stated they do not believe that the resources necessary to deliver the Neulasta service warrants separate payment under the OPPS. Because payment for CPT code **96377** will be packaged, the payment for use of the on-body injector will be included in the payment for the primary service (for example, chemotherapy administration or a clinic visit) that is reported on the same service date as code **96377**.

(*continued on page 28*)

Table 6. Pass-Through Status for Drugs & Biologicals that will Expire Dec. 31, 2016

CY 2017 HCPCS CODE	CY 2017 LONG DESCRIPTOR	FINAL CY 2017 SI	FINAL CY 2017 APC
C9497	Loxapine, inhalation powder, 10 mg	K	**9497**
J1322	Injection, elosulfase alfa, 1mg	K	**1480**
J1439	Injection, ferric carboxymaltose, 1 mg	N	**N/A**
J1447	Injection, TBO-Filgrastim, 1 microgram	N	**N/A**
J3145	Injection, testosterone undecanoate, 1 mg	N	**N/A**
J3380	Injection, vedolizumab, 1 mg	K	**1489**
J7181	Injection, factor XIII a-subunit, (recombinant), per IU	N	**N/A**
J7200	Factor IX (antihemophilic factor, recombinant), Rixubus, per IU	N	**N/A**
J7201	Injection, factor IX, fc fusion protein (recombinant), per IU	N	**N/A**
J7205	Injection, factor VIII fc fusion (recombinant), per IU	K	**1656**
J7508	Tacrolimus, extended release, (Astragraf xl), oral, 0.1 mg	N	**N/A**
J9301	Injection, obinutuzumab, 10 mg	N	**N/A**
J9308	Injection, ramucirumab, 5 mg	K	**1488**
J9371	Injection, Vincristine Sulfate Liposome, 1 mg	K	**1466**
Q4121	Theraskin, per square centimeter	N	**N/A**

Table 7. Drugs & Biologicals With Pass-Through Status in CY 2017

CY 2016 HCPCS CODE	CY 2017 HCPCS CODE	CY 2017 LONG DESCRIPTOR	CY 2017 SI	CY 2017 APC
A9586	**A9586**	Florbetapir f18, diagnostic, per study dose, up to 10 mci	G	**1664**
N/A	**A9588**	Fluciclovine f-18, diagnostic, 0.1 mCi	G	**9052**
N/A	**A9587**	Gallium Ga-68, dotatate, diagnostic, 1 mCi	G	**9056**
N/A	**C9140**	Injection, Factor VIII (antihemophilic factor, recombinant) (Afstyla), 1 IU	G	**9043**
C9137	**J7207**	Injection, Factor VIII (antihemophilic factor, recombinant) PEGylated, 1 IU	G	**1844**
C9138	**J7209**	Injection, Factor VIII (antihemophilic factor, recombinant) (Nuwiq), per IU	G	**1846**
C9139	**J7202**	Injection, Factor IX, albumin fusion protein (recombinant), Idelvion, 1 IU	G	**9171**
C9349	**Q4172**	PuraPly, and PuraPly Antimicrobial, any type, per sq cm	G	**1657**
C9447	**C9447**	Injection, phenylephrine and ketorolac, 4 ml vial	G	**1663**
C9460	**C9460**	Injection, cangrelor, 1 mg	G	**9460**
C9461	**A9515**	Choline C 11, diagnostic, per study dose	G	**9461**
C9470	**J1942**	Injection, aripiprazole lauroxil, 1 mg	G	**9470**
C9471	**J7322**	Hyaluronan or derivative, Hymovis, for intra-articular injection, 1 mg	G	**9471**
C9472	**J9325**	Injection, talimogene laherparepvec, 1 million plaque forming units (PFU)	G	**9472**
C9473	**J2182**	Injection, mepolizumab, 1 mg	G	**9473**
C9474	**J9205**	Injection, irinotecan liposome, 1 mg	G	**9474**
C9475	**J9295**	Injection, necitumumab, 1 mg	G	**9475**
C9476	**J9145**	Injection, daratumumab, 10 mg	G	**9476**
C9477	**J9176**	Injection, elotuzumab, 1 mg	G	**9477**
C9478	**J2840**	Injection, sebelipase alfa, 1 mg	G	**9478**
C9479	**J7342**	Instillation, ciprofloxacin, otic suspension, 6 mg	G	**9479**
C9480	**J9352**	Injection, trabectedin, 0.1 mg	G	**9480**
C9481	**J2786**	Injection, reslizumab, 1 mg	G	**9481**
C9482	**C9482**	Injection, sotalol hydrochloride, 1 mg	G	**9482**
C9483	**C9483**	Injection, atezolizumab, 10 mg	G	**9483**
N/A	**J0570**	Buprenorphine implant, 74.2 mg	G	**9058**
J0596	**J0596**	Injection, c-1 esterase inhibitor (human), Ruconest, 10 units	G	**9445**

Table 7. Drugs & Biologicals With Pass-Through Status in CY 2017 (*continued*)

CY 2016 HCPCS CODE	CY 2017 HCPCS CODE	CY 2017 LONG DESCRIPTOR	CY 2017 SI	CY 2017 APC
J0695	**J0695**	Injection, ceftolozane 50 mg and tazobactam 25 mg	G	**9452**
J0875	**J0875**	Injection, dalbavancin, 5 mg	G	**1823**
J1833	**J1833**	Injection, isavuconazonium sulfate, 1 mg	G	**9456**
J2407	**J2407**	Injection, oritavancin, 10 mg	G	**1660**
J2502	**J2502**	Injection, pasireotide long acting, 1 mg	G	**9454**
J2547	**J2547**	Injection, peramivir, 1 mg	G	**9451**
J2860	**J2860**	Injection, siltuximab, 10 mg	G	**9455**
J3090	**J3090**	Injection, tedizolid phosphate, 1 mg	G	**1662**
N/A	**J7179**	Injection, von Willebrand factor (recombinant), (Vonvendi), 1 IU vwf:rco	G	**9059**
J7313	**J7313**	Injection, fluocinolone acetonide intravitreal implant, 0.01 mg	G	**9450**
J7503	**J7503**	Tacrolimus, extended release, (Envarsus xr), oral, 0.25 mg	G	**1845**
J8655	**J8655**	Netupitant (300mg) and palonosetron (0.5 mg)	G	**9448**
J9032	**J9032**	Injection, belinostat, 10 mg	G	**1658**
J9039	**J9039**	Injection, blinatumomab, 1 mcg	G	**9449**
J9271	**J9271**	Injection, pembrolizumab, 1 mg	G	**1490**
J9299	**J9299**	Injection, nivolumab, 1 mg	G	**9453**
Q5101	**Q5101**	Injection, Filgrastim (G-CSF), Biosimilar, 1 microgram	G	**1822**
Q9950	**Q9950**	Injection, sulfur hexafluoride lipid microsphere, per ml	G	**9457**
C9459	**Q9982**	Flutemetamol F18, diagnostic, per study dose, up to 5 mci	G	**9459**
C9458	**Q9983**	Florbetaben F18, diagnostic, per study dose, up to 8.1 mci	G	**9458**

(*continued from page 25*)

Blood & Blood Products

In the CY 2017 OPPS proposed rule, CMS recommended continuing to establish payment rates for blood and blood products using the current blood-specific cost-to-charge ratio (CCR) methodology. After consideration of the public comments received, CMS finalized this proposal.

As discussed in the CY 2016 OPPS final rule, CMS is in the process of examining the current set of HCPCS P-codes for blood products. Because these codes were created many years ago, CMS is considering whether this code set would benefit from some code descriptor revisions, updating, and/or consolidation to make these codes properly reflect current product descriptions and utilization while minimizing redundancy and eliminating potentially outdated descriptors.

In the CY 2017 OPPS proposed rule, public comments were requested and CMS asked the blood product stakeholder community whether the current blood product HCPCS P-code descriptors with the associated granularity best describe the state of the current technology for blood products that hospitals currently provide to hospital outpatients. A number of detailed responses were received, and these comments will be taken into consideration in the development of proposals to update codes that describe blood products.

Pass-Through Drug Payments

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 longstanding 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 currently accepts applications for pass-through status on a quarterly basis, but this status expires on an annual basis. Beginning in CY 2017, pass-through status will expire on a quarterly basis so that the biological will receive pass-through status for as close to three full years as possible.

CMS included a list of the drugs for which pass-through status will expire on Dec. 31, 2016, in the final rule (see Table 6, page 25).

Payment for drugs and biologicals with pass-through status under the OPPS in CY 2017 will be made at the rate of ASP+6 percent. However, hospitals will actually receive no extra payment for most of these pass-through drugs because they would receive the difference between the regular OPPS drug payment and the pass-through payment. At this time, both of these payment amounts are ASP+6 percent, so the difference is $0. Hospitals will receive payment for pass-through drugs that are classified as "policy-packaged," such as diagnostic radiopharmaceuticals, contrast agents, and anesthesia drugs, since the regular OPPS drug payment for these biologicals is $0. The drugs and biological listed in Table 7, pages 26-27, will continue or have been granted pass-through status for CY 2017.

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 2017, the threshold is $110, up from $100 in CY 2016. 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. CMS is also continuing its policy of making a single packaging decision for all dosages of a drug that is available in multiple dosages that have separate HCPCS codes.

Other Provisions

In addition to the major provisions listed above, the 2017 OPPS final rule addresses restructuring of the imaging APCs, the Ambulatory Surgical Center (ASC) payment update, the hospital Value-Based Purchasing Program, the hospital Outpatient Quality Reporting (OQR) Program, Medicare Conditions of Participation for Organ Transplant programs, and the Electronic Health Record (EHR) Incentive Program. 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 2017 conversion factor is estimated to be $35.8887, which is slightly higher than the 2016 conversion factor of $35.8043. Table 8, below, shows the estimated impact that projects payment increases or decreases by specialty (without considering the potential conversion factor change).

Primary Care

Historically, care management and cognitive work has been bundled into the evaluation and management visit codes used by all specialties. This has meant that payment for these services has been distributed equally among all specialties that report visit codes, instead of being targeted toward practitioners who manage care or primarily

Table 8. Estimated Impact of Projected Payment Increases or Decreases by Specialty*

SPECIALTY	ALLOWED CHARGES (MIL)	IMPACT OF WORK RVU CHANGES	IMPACT OF PE RVU CHANGES	IMPACT OF MP RVU CHANGES	COMBINED IMPACT
Hematology/Oncology	$1,751	0%	0%	0%	0%
Radiation Oncology	$1,726	0%	0%	0%	0%
Radiation Therapy Centers	$44	0%	0%	0%	0%

LEGEND

Specialty: The Medicare specialty code as reflected in the physician/supplier enrollment files.
Allowed Charges: The aggregate estimated PFS allowed charges for the specialty based on CY 2015 utilization and CY 2016 rates.
Impact of Work RVU Changes: This column shows the estimated CY 2017 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: This column shows the estimated CY 2017 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: This column shows the estimated CY 2017 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: This column shows the estimated CY 2017 combined impact on total allowed charges of all the changes in the previous columns.

* Without considering the potential conversion factor change.

provide cognitive services. CMS believes the focus of the healthcare system has shifted to delivery system reforms, such as patient-centered medical homes, clinical practice improvement, and increased investment in primary and comprehensive care management and coordination services for chronic and other conditions. This shift requires more centralized management of patient needs and extensive care coordination among practitioners and providers, often on a non-face-to-face basis across an extended period of time.

For CY 2017, CMS finalized a variety of coding and payment changes as part of an ongoing effort to improve payment for primary care services. These updates include:

- Separate payment for codes describing non-face-to-face prolonged evaluation and management services
- Existing procedure codes that are revalued to describe prolonged face-to-face services
- Separate reimbursement for new codes that describe comprehensive assessment and care planning for patients with cognitive impairment, mobility-related impairment, and patients with behavioral health conditions.

Last, CMS will make separate payments for codes describing chronic care management for patients with greater complexity (refer to HCPCS codes **G0501** and **G0506**). CMS believes that these coding and payment changes will improve healthcare delivery for the types of services holding the most promise for healthier people and smarter spending and advance the agency's health equity goals.

Telehealth Services

CMS finalized the addition of ESRD-related services, advance care planning services, and critical care consultation codes to the current telehealth services list. CMS states that although the agency expects these changes to increase access to care in rural areas, based on recent utilization of similar services already on the telehealth list, there will not be a significant impact on PFS expenditures.

CMS also finalized a payment policy regarding the use of a new place of service code (**02 – Telehealth**), with telehealth defined as the location where health services and health-related services are provided or received, through telecommunications technology. Of note, the originating site will not use this place of service code. In addition, place of service code **02** will be used in addition to—not instead of—**modifiers GT** (Via interactive audio and video telecommunications) and **GQ** (Via asynchronous telecommunications system). The 2017 fee for code **Q3014** (Telehealth originating site facility fee) will be $25.40, up from $25.10 in CY 2016.

Physician Self-Referral Update

Section 6204 of the Omnibus Budget Reconciliation Act of 1989 (OBRA 1989), enacted on Dec. 19, 1989, added section 1877 to the Social Security Act. Section 1877, also known as the physician self-referral law:

1. Prohibits a physician from making referrals for certain designated health services payable by Medicare to an entity with which he or she (or an immediate family member) has a financial relationship (ownership or compensation), unless an exception applies; and
2. Prohibits the entity from filing claims with Medicare (or billing another individual, entity, or third party payer) for those referred services.

CMS has reissued regulatory provisions prohibiting certain per-unit-of-service compensation formulas for determining rental charges in the exceptions for the rental of office space, rental of equipment, fair market value compensation, and indirect compensation arrangements. These provisions are necessary to protect against potential abuses, such as overutilization, steering patient choice, the potential reduction in quality of care and patient outcomes. CMS believes that most parties comply with these regulatory provisions since they originally became effective on Oct. 1, 2009, and the reissued regulation text is identical to the existing regulation text.

Qualified Medicare Beneficiaries

Federal law prohibits providers from collecting Medicare Part A and B deductibles, coinsurance, or copayments from beneficiaries enrolled in the Qualified Medicare Beneficiaries (QMB) Program. The QMB program is a Medicaid program that helps low-income individuals with Medicare cost-sharing liability. Under QMB, state Medicaid programs are supposed to pay these patients' Medicare cost-sharing, but Federal law allows the states to limit their payment to the difference between the Medicare payment and the Medicaid rate. Since Medicaid generally reimburses at a lower rate than Medicare, this usually means the provider does not receive any additional payment beyond the Medicare allowance.

Providers are required to accept the Medicare reimbursement (and Medicaid allowance, if any) as payment in full and may not bill the patients for any balance. The same rules apply to dual eligible beneficiaries who are enrolled in both Medicaid and Medicare Advantage plans. In July 2015 CMS released a study finding that confusion and inappropriate balance billing persisted, even in the presence of laws that prohibit these collections.

Some commenters noted that it can be difficult for providers to identify these beneficiaries, and CMS stated it is actively exploring additional mechanisms for Medicare providers to readily identify the QMB status of these patients. Regardless, CMS states that Medicare providers who violate these billing prohibitions are violating their Medicare Provider Agreement and may be subject to sanctions. CMS further recommends that providers take steps to educate themselves and their staff about QMBs to ensure that cost-share is not inappropriately collected prior to

treatment or billed to the patient after services are rendered.

Global Surgical Period

Since the inception of the MPFS, CMS has valued and paid for certain services, such as surgery, as part of global packages that include the procedure and the services typically provided during the period immediately before and after the procedure. There are three primary categories of global packages that are defined based on the number of post-operative days included in the global period: 0-day, 10-day, and 90-day.

In the CY 2015 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. MACRA 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.

As part of the 2017 MPFS final rule, CMS also set forth guidelines for data collection regarding resources used when furnishing global services. The claim-based collection strategy reduces the burden on practitioners by requiring reporting only on high-volume/high-cost procedures, using an existing procedure code (**99024**, Postoperative follow-up visit, normally included in the surgical package), allowing some provider groups to report voluntarily while mandating larger practices in designated states to comply with reporting. Practitioners are encouraged to begin reporting post-operative visits for procedures furnished on or after Jan. 1, 2017, but the requirement to report will be effective for services related to global procedures furnished on or after July 1, 2017.

In mid-2017 CMS will also be surveying a large national sample of about 5,000 practitioners. Individuals in this group will be asked to describe 20 postoperative visits furnished to Medicare patients or other patients during the reporting period. Information to be collected includes:

- Procedure codes and dates of service for the global procedure
- Procedure place of service
- Procedural complications
- The level of the visit using existing codes
- Specific activities on the day of the visit
- Total time
- Practice expense items
- Other prior or anticipated care.

CMS will also send monitors to a small number of sites for direct observation, as well as survey Accountable Care Organizations (both Pioneer and Next Generation) about their global services.

CMS has statutory authority to withhold up to 5 percent of the practitioner's Medicare payment for noncompliance with required reporting. The agency does not plan to use this authority in 2017, but will consider using it in future years if claims-based reporting is not acceptable. At this time, the list of procedures that must be reported is not available; CMS will determine the codes for which reporting is required and display the list on the CMS website. Last, if the aggregated data result in proposals to revalue any global packages, that revaluation will be done through notice and comment rulemaking at a future time.

Potentially Misvalued Codes

The Protecting Access to Medicare Act of 2014 (PAMA) establishes an annual target for reductions in MPFS expenditures resulting from adjustments to RVUs of misvalued codes. If the estimated net reduction in expenditures for a year is equal or greater than the target for the year, reduced expenditures attributable to such adjustments shall be redistributed in a budget-neutral manner through an adjustment to the conversion factor. This policy applies to calendar years 2017 through 2020, with a target amount of 0.5 percent of the estimated expenditures under the MPFS for each of those four years.

CMS estimates the 2017 net reduction in expenditures resulting from adjustments to relative values of misvalued codes to be 0.32 percent. Since this amount does not meet the 0.5 percent target established by the Achieving a Better Life Experience (ABLE) Act of 2014, payments under the MPFS must be reduced by the difference between the target for the year and the estimated net reduction in expenditures, known as the target recapture amount. This results in an estimated 0.18 percent decrease in the 2017 conversion factor.

Services Billed With Modifier 25

CMS states that several high volume procedure codes are typically reported with **modifier 25** (Significant, separately identifiable evaluation and management service on the same day of the procedure or other service), which unbundles payment for visits from the procedure; CMS believes that these services may be misvalued. As a result, CMS has identified 19 services that it intends to review as potentially misvalued and indicates that it will investigate this policy further in future rulemaking. None of the surgical procedures identified would be routinely performed by medical oncologists, hematologists, or radiation oncologists.

Valuation of Moderate Sedation Services

In prior rulemaking, CMS noted that practice patterns for certain procedures appear to be changing, with anesthesia increasingly being separately reported for these procedures even though payment for sedation services was included in the payment to the physician furnishing the primary procedure. In response, the American Medical Association (AMA) CPT Editorial Panel created new codes for reporting moderate sedation and the Specialty Society Relative Value Update Committee provided CMS with recom-

mended values for the moderate sedation codes and recommended adjustments to valuation of the procedure codes.

As part of this final rule, CMS is finalizing values for the new moderate sedation codes and adopting a uniform methodology for valuation of the procedural codes that currently include moderate sedation as an inherent part of the procedure. Table 9, right, shows a list of codes related to oncology services that will be impacted.

Phase-In of Significant RVU Reductions

PAMA specified that if the total RVUs for a service would otherwise be decreased by an estimated amount equal to or greater than 20 percent, the adjustments must be phased-in over a two-year period. This requirement applies only to services described by existing codes and not to services described by new or revised codes.

In the 2017 MPFS final rule, CMS finalized the proposal to reconsider in each year whether the total RVUs for the service would otherwise be decreased by an estimated 20 percent or more as compared to the total RVUs for the previous year. Under this policy the 19 percent reduction in total RVUs would continue to be the maximum one-year reduction for all codes (except those considered new or revised), including those codes with phase-in values in the previous year. CMS identified three radiation oncology codes with significant RVU reductions in 2017:

- **77332**: Treatment devices, design and construction; simple
- **77334**: Treatment devices, design and construction; complex
- **77470**: Special treatment procedure.

CMS identified procedure code **77470** through the high expenditures by specialty screen, and proposed the RUC-recommended work RVU of 2.03. However, according to CMS the description of service and vignette describe different and unrelated treatments being performed by the physician and clinical staff for a typical patient, and this presents a disparity between the work RVUs and practice expense (PE) RVUs. CMS solicited comments on information that would clarify this apparent disparity to help determine appropriate PE inputs. In addition, the agency solicited comments to determine if creating two HCPCS G-codes, one that describes the work portion of this service and one that describes the practice expense portion, may be a potentially more accurate method of valuing and paying for the service or services described by this code. CMS states:

According to the description of work provided for this service, the physician performs cognitive work, such as planning, consideration of test results, and therapeutic treatment contingency planning that is in addition to what he or she would typically be performing for most radiation treatments. Meanwhile, the radiation therapist handles the treatment devices, performs tasks such as positioning the patient, and helps facilitate the scan of the patient. We believe that this may describe activities that are fundamentally disconnected. To illustrate our concern, we offer the example that this is akin to a physician removing a mole from a patient's hand while the clinical staff places a cast on the patient's foot; we see no compelling clinical evidence to indicate that the two tasks are related. In addition, the disparate diagnoses described by the vignettes further calls into question the degree to which the work and PE components are interrelated. While we agree that there should not be separate coding for each possible diagnosis for a particular service, in trying to accurately assess relative value, we believe that the work and PE components should be valued under unified assumptions about the typical service. We are finalizing the RUC-recommended work RVU and PE inputs as proposed; however, we continue to have serious concerns about the validity of this coding.

Appropriate Use Criteria for Advanced Diagnostic Imaging Services

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 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, 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.

The 2017 MPFS final rule lists the first eight priority clinical areas for the AUC:

- Coronary artery disease (suspected or diagnosed)
- Suspected pulmonary embolism
- Headache (traumatic and non-traumatic)
- Hip pain
- Low back pain
- Shoulder pain (to include suspected rotator cuff injury
- Cancer of the lung (primary or metastatic, suspected or diagnosed)
- Cervical or neck pain.

Ordering professionals will be required to consult AUC for *all* advanced imaging services, not just those in priority clinical areas, as long as the service is furnished in an applicable setting such as office or outpatient hospital and paid under an applicable payment system like the MPFS or OPPS. However, the priority clinical areas will be used to identify outlier ordering professionals in the future.

Medicare will initially pay for the imaging study regardless of whether it was recommended by the AUC. Eventually, however,

(*continued on page 34*)

Table 9. Codes for Oncology Services Impacted by Sedation Codes

CODE	DESCRIPTION
19298	Placement of radiotherapy afterloading brachytherapy catheters (multiple tube and button type) into the breast for interstitial radioelement application following (at the time or subsequent to) partial mastectomy, includes imaging guidance
31626	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with placement of fiducial markers, single or multiple
32553	Placement of interstitial device(s) for radiation therapy guidance (e.g., fiducial markers, dosimeter), percutaneous, intrathoracic, single or multiple
43241	Esophagogastroduodenoscopy, flexible, transoral; with insertion of intraluminal tube or catheter
43253	Esophagogastroduodenoscopy, flexible, transoral; with transendoscopic ultrasound-guided transmural injection of diagnostic or therapeutic substance(s) (e.g., anesthetic, neurolytic agent) or fiducial marker(s) (including endoscopic ultrasound examination of the esophagus, stomach and either the duodenum or a surgically altered stomach where the jejunum is examined distal to the anastomosis)
49411	Placement of interstitial device(s) for radiation therapy guidance (e.g., fiducial markers, dosimeter), percutaneous, intra-abdominal, intra-pelvic (except prostate), and/or retroperitoneum, single or multiple
49418	Insertion of tunneled intraperitoneal catheter (e.g., dialysis, intraperitoneal chemotherapy instillation, management of ascites), complete procedure, including imaging guidance, catheter placement, contrast injection when performed, and radiological supervision and interpretation, percutaneous
57155	Insertion of uterine tandem and/or vaginal ovoids for clinical brachytherapy
77371	Radiation treatment delivery, stereotactic radiosurgery (SRS), complete course of treatment of cranial lesion(s) consisting of 1 session, multi-source Cobalt 60 based
77600	Hyperthermia, externally generated; superficial (i.e., heating to a depth of 4 cm or less)
77605	Hyperthermia, externally generated; deep (i.e., heating to depths greater than 4 cm)
77610	Hyperthermia generated by interstitial probe(s); 5 or fewer interstitial applicators
77615	Hyperthermia generated by interstitial probe(s); more than 5 interstitial applicators
0301T	Destruction of malignant breast tumor with externally applied focused microwave, including interstitial placement of disposable catheter with combined temperature monitoring probe and microwave focusing sensocatheter and ultrasound thermotherapy guidance

(*continued from page 32*)
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. CMS will address outlier calculations, which may be used to determine whether clinicians will be subject to prior authorization.

The MPFS final rule also addressed clinical decision support mechanism (CDSM) requirements, stating that CDSMs are "electronic tools through which a clinician consults AUC to determine the level of clinical appropriateness for an advanced diagnostic imaging service for that particular patient's clinical scenario." CMS finalized the CDSM application to allow for preliminary qualification or full qualification based on whether the applicant can demonstrate that all requirements are met at the time of application. The application deadline for the first round of preliminary and full qualifying CDSMs is March 1, 2017.

The first list of qualified CDSMs will be posted no later than June 30, 2017, and CMS expects furnishing professionals to be required to begin reporting on Jan. 1, 2018. In addition, CMS is considering the mechanisms for appending AUC consultation information to the Medicare claim and will issue that information as part of the 2018 rulemaking. Among the mechanisms CMS is considering are the use of HCPCS G codes and HCPCS modifiers. Current exceptions to the use of AUC include:

- Patients with emergency medical conditions (including situations where such a condition is suspected but not yet confirmed)
- Inpatients (the Inpatient Prospective Payment System is not an applicable payment system)
- The ordering professional has a hardship exception, such as practicing in a rural area without sufficient Internet access.

CMS recognizes that the number of clinicians impacted by the scope of this program is massive as it will apply to every physician or other practitioner who orders or furnishes applicable imaging services. This crosses almost every medical specialty and could have a particular impact on primary care physicians since their scope of practice can be quite broad.

Other Issues

In addition to the major provisions listed above, the 2017 MPFS final rule addresses the Medicare Shared Savings Program (MSSP), Medicare Advantage provider enrollment, expansion of the Diabetes Prevention Program Model, the value-based payment modifier and physician feedback program, and recoupment or offset payments to providers sharing the same taxpayer identification number. OI

Cindy Parman, CPC, CPC-H, RCC, is a principal at Coding Strategies, Inc., in Powder Springs, Ga.

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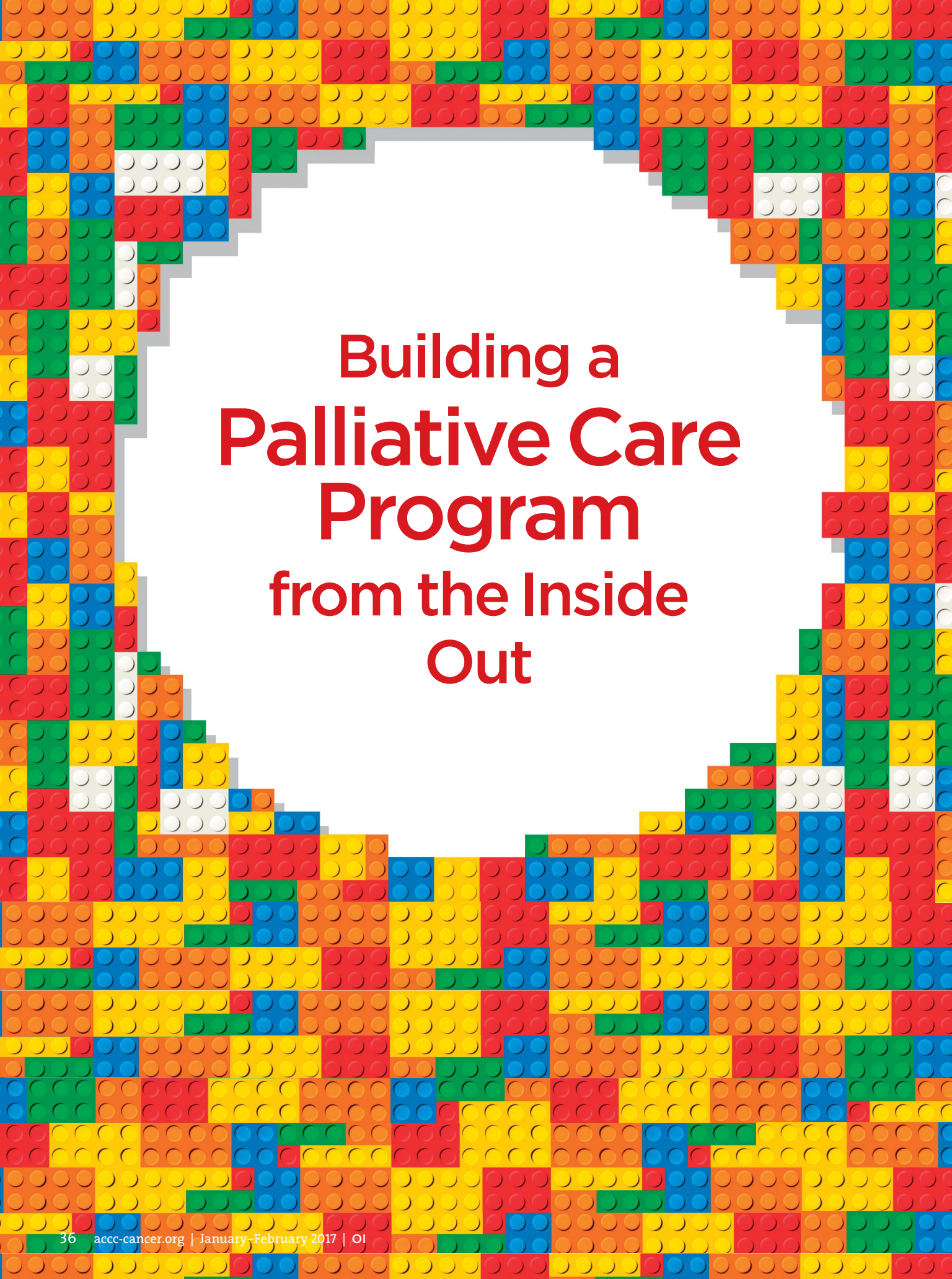


Building a Palliative Care Program from the Inside Out

BY MICHELLE ABRAMOWSKI, CRNP, AND
PATSY ASTARITA, LCSW-C, OSW-C

In the summer of 2014 an important and complex question was asked at the Kaufman Cancer Center: "*How can the palliative care services provided in our center be expanded and enhanced, make a difference for the patients we serve, align with value-based care, and be accomplished utilizing our existing team?*" A tall order indeed. The answer became, "Building a Palliative Care Program from the Inside Out."

In the Beginning

When emerging studies concluded that early palliative intervention with cancer patients leads to better quality of life and reduces cost of care, palliative care became a focus for Kaufman Cancer Center leadership.[1-3] Given the move to value-based healthcare, the rising cost of emerging cancer therapies, and new *Choosing Wisely* recommendations endorsed by the American Society of Clinical Oncology (ASCO) and the American Society for Radiation Oncology (ASTRO), the timing for developing innovative ways to incorporate early palliative care into our center was perfect.

In making the decision to move forward with this initiative, key leaders and team members came together to assess the strengths and challenges of our cancer center. We identified the following strengths, which laid the foundation of our model:

- An existing, strong, mature, inpatient palliative care team that could support this initiative
- An enhanced supportive care services model through the Cancer LifeNet Program
- Increased staff awareness and documentation of the status of advance directives
- Existing leaders and clinicians with a passion for and experience with palliative care, including:
  - An oncologist board certified in oncology and palliative care
  - A medical director of the cancer center and newly appointed director of population health for our hospital
  - An executive director of the cancer center with a background in palliative care and hospice
  - A nurse practitioner (NP) with hospice experience
- A healthcare system transitioning from fee-for-service to a value-based payment model.

Key leaders and team members came together to assess the strengths and challenges of our cancer center.

The team recognized that there were challenges to overcome as well. The challenges described below guided us toward the solutions that became the building blocks of our model:

- No budget
- An existing navigation model focused on newly-diagnosed patients, not on palliative or end-of-life care
- Inadequate communication between departments and treatment team members regarding patients' status
- Lack of in-house educational resources for team members related to palliative care and end-of-life care
- An existing inpatient palliative care team with a central focus on inpatient care and ICU patients
- An existing outpatient palliative care clinic within the Kaufman Cancer Center with limited hours and resources.

Getting Started

After some thoughtful review, a workgroup was established to begin the process of developing and formalizing our palliative care program. We began by identifying key members of our team who were passionate about providing palliative care to our patients, as well as key leaders who supported our efforts. The early planning phase included the hospital's inpatient palliative care physician, one of our medical oncologists who was also

board certified in palliative care, and our medical director who was fully committed to growing this initiative. This phase also included:

- Extensive research of various existing models
- A thorough literature review
- Development and finalization of our model
- A review of the national metrics to determine the outcomes we would use to measure our program.

The Advisory Board Company (advisory.com) has identified five palliative care models:

1. Embedded specialists, including a nurse and physician
2. An inpatient consult service
3. A dedicated palliative care inpatient unit
4. An outpatient clinic
5. A home-based palliative care program.

Already existing within our healthcare system were embedded specialists, including a physician, NPs, and a social worker, which comprised our inpatient palliative consult service. This program also included a limited outpatient palliative care clinic run by our inpatient palliative physician. One of the limitations of the clinic was that our inpatient physician and team were asked to focus mainly on inpatient needs and had limited availability for outpatient services.

Our focus moved to an extensive literature review—determining how we would implement the program to meet the palliative care needs of our patients across the entire disease trajectory. We were able to determine the most effective way to screen our patients, the potential cost-savings, and, finally the impact a palliative care program would have on patient care. After review of a 2011 study from Glare et al., we selected a five-item questionnaire to determine which patients were appropriate for a palliative care referral (see Table 1, below). The tool includes a scoring system of 0-13, with scores greater than or equal to 5 considered high risk and appropriate for a palliative care referral. The questionnaire was formatted for our EHR to allow for ease of documentation.

With an increasing focus on population health and value-based care, our team also considered the economic impact of the palliative care program. A 2015 prospective study by May et al. examined cost savings among inpatients with advanced cancer.

Table 1. Five-Item Palliative Care Screening Tool[2]

SCREENING ITEMS	POINTS
1. Presence of metastatic or locally advanced cancer	2
2. Functional status score, according to ECOG performance status score	0–4
3. Presence of one or more serious complications of advanced cancer usually associated with a prognosis of < 12 months (e.g., brain metastases, hypercalcemia, delirium, spinal cord compression, cachexia)	1
4. Presence or one or more serious comorbid diseases also associated with poor prognosis (e.g., moderate-severe COPD or CHF, dementia, AIDS, end stage renal failure, end stage liver cirrhosis)	1
5. Presence of palliative care problems:	
• Symptoms uncontrolled by standard approaches	1
• Moderate to severe distress in patient or family, related to cancer diagnosis or therapy	1
• Patient and/or family concerns about course of disease and decision-making	1
• Patient and/or family requests palliative care consult	1
• Team needs assistance with complex decision-making or determining goals of care	1
Total Score	0–13

* Abbreviations: CHF, congestive heart failure; COPD, chronic obstructive pulmonary disease; ECOG, Eastern Cooperative Oncology Group

Kaufman Cancer Center's Palliative Care Case Conference.

We learned that early palliative care interventions were associated with larger cost savings. In addition, timely palliative care intervention after hospitalization was also associated with cost savings, suggesting that early palliative care should be more widely implemented.

In determining the framework of our model, we looked at the Advisory Board's hallmarks of an integrated program, which include:

- Oncologists who trust the palliative care team
- Scrupulous care coordination
- A process to ensure that advance care planning is routine for all cancer patients
- A care team who is highly visible in the cancer center
- Clinicians that share responsibility for initiating palliative care
- Oncology clinicians who are trained to provide it.

One of the benefits of utilizing our existing resources was an already established, trusting partnership between the physicians and the cancer center team, as well as existing trust from our patients and families. Our palliative care specialists were not arriving on the scene at the end of life as outsiders. Rather, these providers already had an established relationship with patients and families. We focused our attention on being visible within the cancer center and reaching out to all cancer center team members to refer patients when appropriate. Also, we developed an additional subgroup of multidisciplinary team members that specifically focused on developing palliative care skills and training within the cancer center.

The clinical impact of the palliative care program and the potential benefits for patient care were given careful consideration as well. A 2010 study from the *New England Journal of Medicine* examined the effect of early palliative care for patients with metastatic non-small cell lung cancer (NSCLC).[1] The study found early integration of palliative care in patients with metastatic NSCLC resulted in significant improvement in a patient's mood, mindset, and quality of life (QOL). In fact, this intervention resulted in an approximate two-month longer survival when compared to patients receiving aggressive treatment at the end of life. Earlier data also suggested that a lower QOL and a depressed mood were often associated with shorter survival. We learned that when individuals had early outpatient palliative care, it resulted in earlier documentation of preferences regarding resuscitation in the EHR and less aggressive care at the end of life, including chemotherapy, as well as earlier and longer enrollment in hospice care.

Finally, we looked to national metrics to determine which outcomes we would use to measure the success of our palliative care program. We specifically looked at benchmarks from the Advisory Board's Palliative Care Dashboard (Table 2, page 40), which utilized data from the National Quality Forum, the National Hospice and Palliative Care Organization, and ASCO. We chose

(continued on page 41)

Table 2. Advisory Board's Palliative Care Dashboard

MEASURE	DEFINITION	BENCHMARK	ENDORSED BY
PROCESS—APPROPRIATE UTILIZATION			
New chemotherapy at end-of-life	Percent of patients who died from cancer that started new chemotherapy regimen in the last 30 days of life	Best observed: <2%	
Chemotherapy utilization at end-of-life	Percent of patients who died from cancer that received chemotherapy in the last 14 days of life	National Average: 6% 10th percentile: 4% 50th percentile: 5.9% 90th percentile: 7%	NQF #0210, ASCO
Hospitalizations at end-of-life	Percent of patients who died from cancer with one or more hospitalizations in the last 30 days of life	Best observed: <4%	NQF #0212
ED utilization at end-of-life	Percent of patients who died from cancer with one or more ED visits in last 30 days of life	Estimated typical performance: 8–10% Best observed: 2%	NQF #0211
ICU utilization at end-of-life	Percent of patients who died from cancer admitted to ICU in last 30 days of life	Estimated typical performance: 8–12% Best observed: <4%	NQF #0213
Acute care utilization at end-of-life	Percent of patients who died from cancer within an acute care setting	Best observed: <17%	NQF #0214
Hospice utilization at end-of-life	Percent of patients who died from cancer who were not admitted to hospice	Estimated typical performance: 65–85% Best observed: <55%	NQF #0215
Hospice referral timeliness	Percent of patients who died from cancer, were admitted to hospice, and spent less than 3 days there	Estimated typical performance: 27–35% Best observed: 8%	NQF #0216
Hospice median length of stay	Median length of stay for patients who were admitted to hospice	National median length of stay: 19.7 days	NHPCO

Source: Advisory Board Company, 2013.

(continued from page 39)

to focus our measures on:

1. Chemotherapy utilization at the end of life
2. ED (emergency department) utilization at the end of life
3. ICU (intensive care unit) utilization at the end of life
4. Hospice utilization
5. Hospice referral timeliness.

Developing Our Model

Specific structural and functional components of our model became apparent as our team undertook the development process. The three foundational building blocks for this program were: 1) weekly palliative care case conferences, 2) ongoing proactive goals of care meetings, and 3) the development of in-house palliative care specialists. The key element of this structure is a multidisciplinary team bringing existing and newly acquired skills and knowledge of palliative care to the program (see Figure 1, right). The four primary functions of the model help meet the needs of patients and their families by providing comprehensive support, enhanced communication, meticulous coordination of care, and thorough symptom management (Figure 2, page 42).

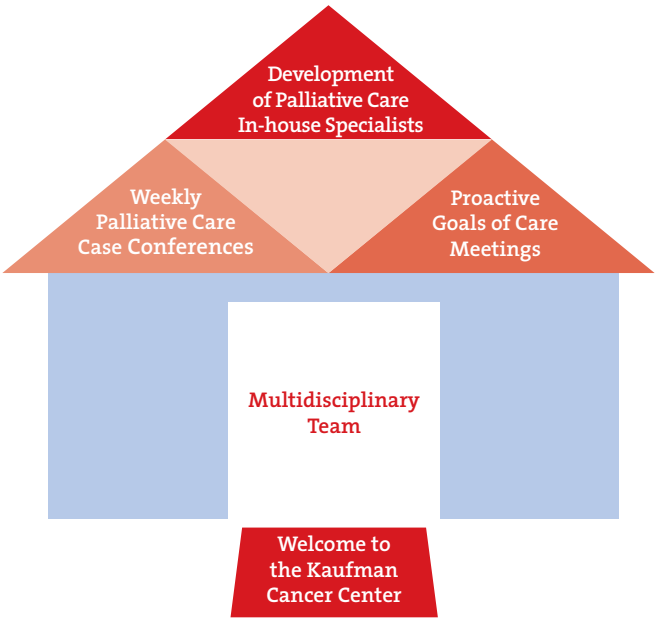
Palliative Care Case Conference

An integral component of the program is the palliative care case conference. These conferences began in October 2014 and continue on a weekly basis. The interdisciplinary conference is open to all members of the cancer center. Prior to conference, a summary sheet is prepared for each patient by one of the palliative care specialists and shared with the team.

Referral to the palliative care conference is open to all team members and follows a specific case, including evidence of non-curative disease, and/or a performance status of 2 or greater (ECOG scale) and advanced disease with or without significant co-morbidities. These criteria trigger the completion of the palliative care five-item questionnaire in the EHR before a referral is made to the palliative care team leaders and the patient is added to the conference agenda.

The palliative care case conference follows a specific format beginning with a review of the patient's status, including understanding of the disease process, response to treatment and overall prognosis, presented by the referring team member. The patient's current functional status, patient and family dynamics, the patient's code status, and completion or lack of advance directives are also reviewed. After the initial presentation, reports from each of the disciplines, including physician/NP, nurse navigator, infusion center nurse, social worker, and dietitian are presented. After the reports are completed, discussion is open to all and the patient's status is summarized and recommendations are formulated. The recommendations are documented in the EHR and communicated back to the treating oncologist. If recommended, a goals of care

Figure 1. The Structural Model of Palliative Care in the Kaufman Cancer Center



Members of Kaufman Cancer Center's Palliative Care In-House Specialists Group.

meeting is arranged. This meeting is a billable visit led by the NP and social worker, ensuring a multidisciplinary approach. The results of the goals of care meeting are also documented in the EHR (Figure 3, right).

Proactive Goals of Care Meetings

In the best interest of patient care, we moved to a proactive approach, addressing goals of care with our patients in advance of a crisis. Our strategy involves ongoing monitoring and increased awareness of the status of our patients by our providers and the treatment team to determine the optimal time to discuss a plan of care with both patients and their loved ones. Goals of care meetings are patient and family conferences that facilitate shared decision-making to establish how patients wish to move forward with their care. The meeting—or series of meetings—provide(s) an opportunity to help patients and families understand the patient's current medical status and to summarize the "big picture" issues. They also allow the palliative care team to provide emotional support and to learn about the patient's values, beliefs, and wishes so that the team is best able to support the patient moving forward.

To prepare for goals of care meetings, we utilize the SPIKES protocol, which is a clear and validated protocol for delivering

Figure 2. The Four Primary Functions of the Palliative Care Program in the Kaufman Cancer Center

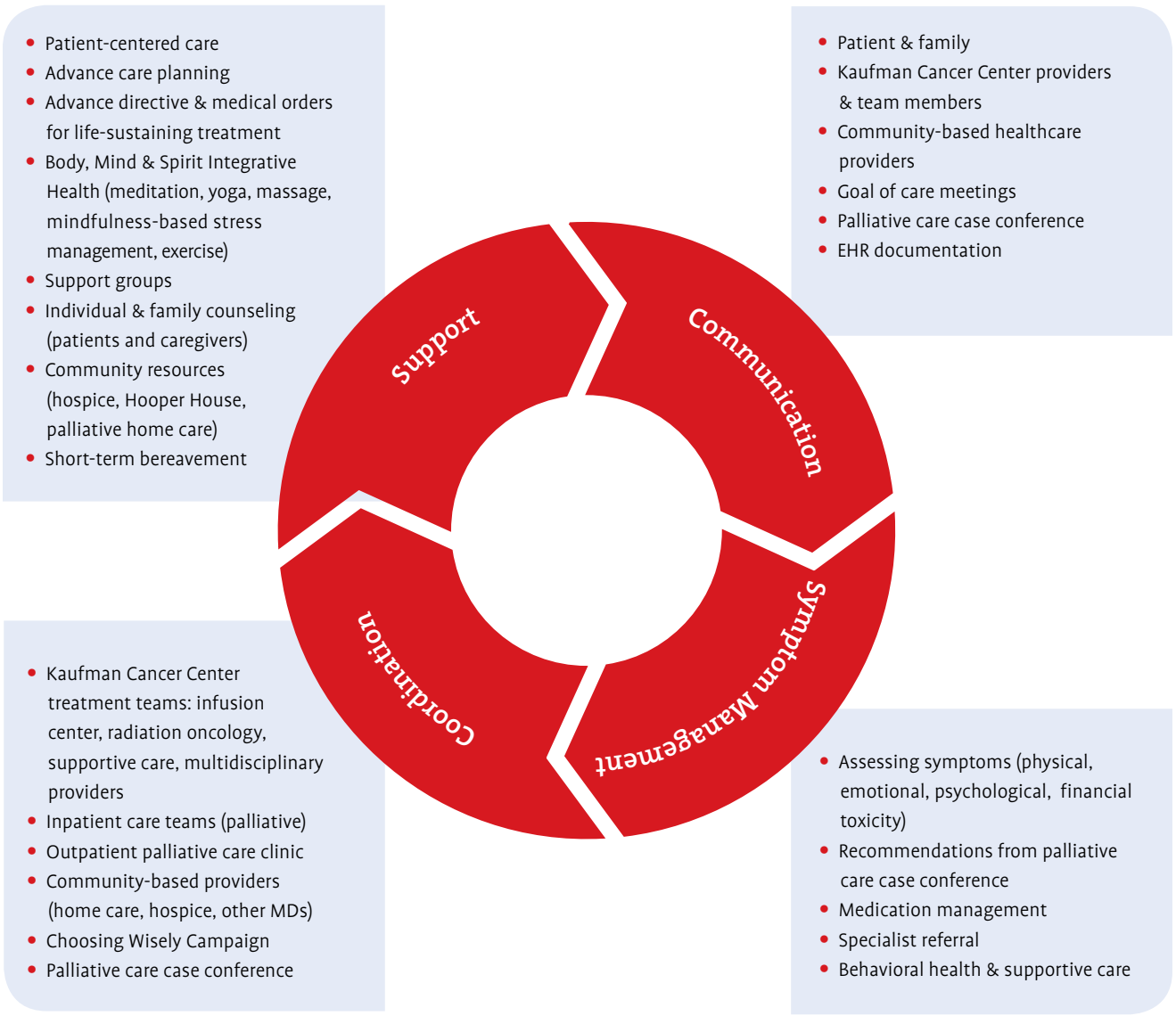
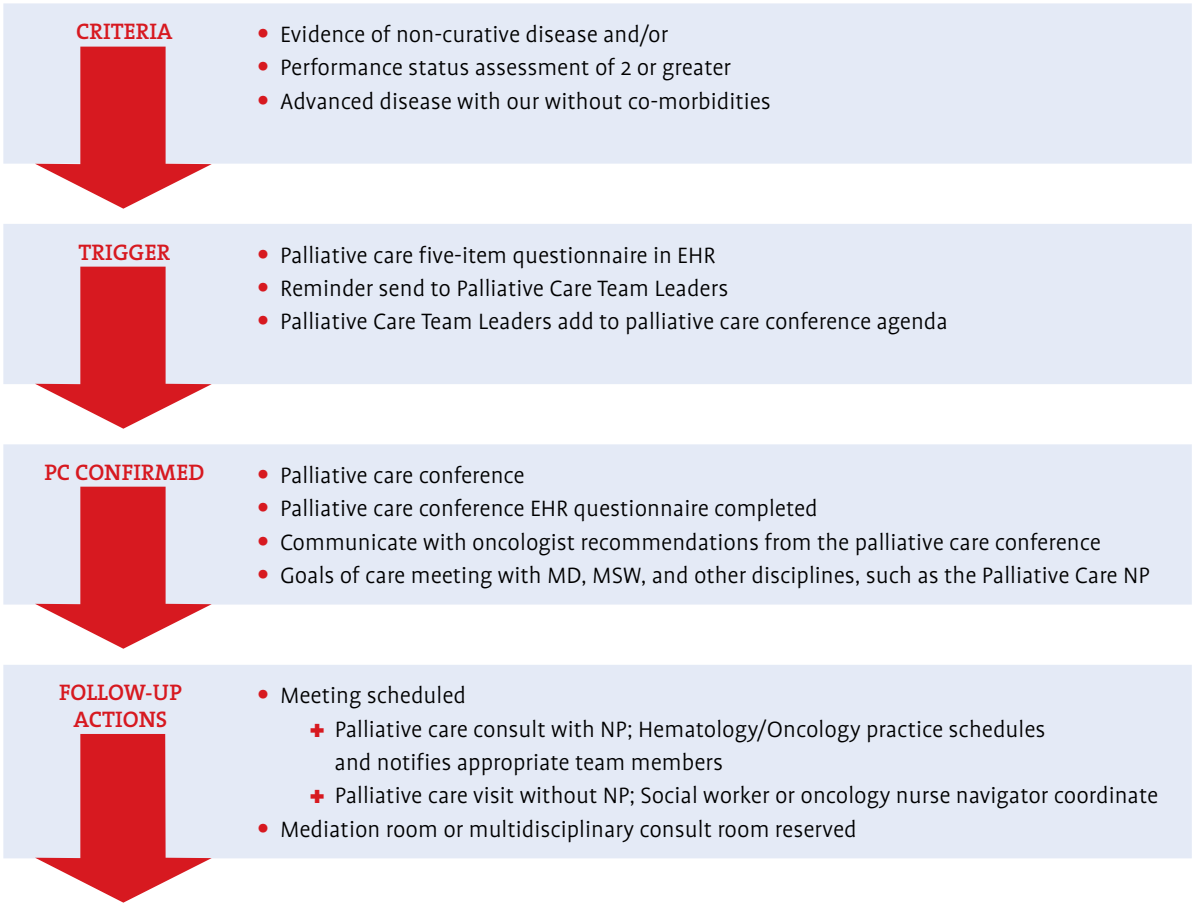


Figure 3. Palliative Care Referral Decision Process



"bad news."[4] This protocol includes:

- Setting up the interview
- Assessing the patient's perception of his or her disease and current medical situation
- Obtaining the invitation from the patient
- Giving knowledge and information to the patient
- Addressing the patient's emotions with empathic responses
- Strategizing and summarizing the discussion and plan.

It is important to arrange for privacy and to involve significant family members and loved ones of the patient's choosing. It is also important that "before you tell, ask." Use open-ended questions to create an accurate picture of how the patient perceives his or her medical situation. From there, determine how much information the patient would like to have. While some patients may want specific details, others may prefer a more general discussion. Before conferring on a treatment plan, ask the patient if he or she is ready for this discussion. Finally, summarize all the decisions that were made and allow time for debriefing with the team.

Palliative Care In-House Specialists

As we began the weekly palliative care case conferences and the proactive goals of care meetings with our patients, providers and team members came together to become part of a professional development group we called our "Palliative Care In-House Specialists." This voluntary group was self-selected and included representation from nursing, social work, administration, pharmacy, and spiritual care. The group met bi-monthly with the purpose of learning new information and palliative care skills, which could then be shared with other members of the multidisciplinary team. As part of this process, group members engaged in a self-assessment exercise—both individually and collectively as a group—using the *Interdisciplinary Team Competency Grid* from the National Hospice and Palliative Care Organization.[5] Group members shared these self-assessments and set personal goals for development. This exercise served as a guide for identifying topics for enhanced learning and external subject experts who were then invited to provide additional palliative care education to the group. The group also discussed their own attitudes

Members of Kaufman Cancer Center's Palliative Care Case Conference.

and beliefs surrounding death and dying. Some of the educational areas explored included:

- Communicating with patients and families
- Learning and sharing the SPIKES protocol
- Implementing language sensitivity and cultivating a culture of such in our center
- Developing religious and cultural sensitivity
- Understanding physician-assisted death
- Managing symptoms, such as terminal restlessness syndrome, respiratory secretions, pain, nausea, anorexia, dyspnea, nutrition, and others.

Presenting subject experts included:

- Palliative care physicians
- Medical director of hospice
- Chaplain
- Hospice and oncology nurses
- Certified pain management nurse
- Certified oncology social workers
- Certified oncology pharmacist
- Administrators with expertise in palliative care.

Two members of the Palliative Care In-House Specialists group became certified in palliative care in their respective professions—nursing and social work. This group has also addressed self-care for themselves and other team members by providing debriefings at the end of palliative care case conferences. In addition, the group was instrumental in instituting an annual remembrance ceremony where Kaufman Cancer Center providers, team members, and volunteers are invited to pay respects to those who have died and to acknowledge the difficult work they do daily.

Programmatic Impact

The palliative care program resulted in a significant culture shift within our cancer center. We became proactive regarding palliative care and end-of-life discussions and moved away from a reactive culture, which often resulted in crisis. Early palliative care has become the mainstay. In addition, we have expanded awareness about language sensitivity and how to deliver bad news to our patients. We avoid phrases such as, "the patient failed chemotherapy" or "we are stopping treatment." The patient did not fail; chemotherapy failed the patient. And we will be continuing to provide treatment to our patients through end-of-life—palliative care and hospice are treatment too. We have worked diligently to move away from the perception that palliative care is hospice

care. Rather, hospice is under the umbrella of palliative care. Any patient can receive palliative care throughout the trajectory of his or her disease, whether receiving curative treatment or not. There is also greater emphasis on completing advance directives, medical orders for life-sustaining treatment (MOLST), and ongoing discussions of advance care planning. Finally, we continue to streamline our palliative care program to meet the growing demands of our population-health initiatives and value-based care.

The palliative care program has also included other community providers and the inpatient palliative care team, resulting in greater partnerships. We have reached out to local hospice and palliative care agencies for input and collaboration concerning mutual patients. We hosted Meet & Greets in December 2014 and March 2016 to increase exposure for our palliative care team members and the community agencies. A local hospice representative joined the weekly palliative case conference in March 2015 and continues to attend, providing valuable information and continuity of care for many of our patients. We also have continuous collaboration with our inpatient palliative care team. This has resulted in a smoother transition for patients in the palliative care program if they are hospitalized and seen by the inpatient palliative care team.

The implementation of this program has had significant effects on patient care, utilization of hospice, goals of care discussions, and implementation of advance care planning (Table 3, below). When compared to national benchmarks, we have seen:

- Fewer ED visits
- Reduced ICU admissions
- Earlier admission to hospice
- Reduction in end-of-life chemotherapy
- Earlier and more frequent "goals of care" meetings
- Improved communication between patients, families, and the treatment team.

Moving Forward

This innovative program is evolving and growing. There is continuous refinement of the weekly palliative care case conference, optimizing the process and the number of patient care issues that can be addressed efficiently. A systematic and expanded identification process of patients who should be presented at weekly case conferences continues to be a focus. Incorporating palliative care consults into multidisciplinary clinics within the cancer center is in the forefront of leadership's attention as well. Continuous data tracking

Table 3. Kaufman Cancer Center Palliative Care Outcome Measures

2014–2016	NATIONAL BENCHMARKS	OCT NOV DEC 2014	JAN FEB MAR 2015	APR MAY JUN 2015	JUL AUG SEPT 2015	OCT NOV DEC 2015	JAN FEB MAR 2016	APR MAY JUN 2016
Proportion receiving chemotherapy in the last 14 days of life	Average: 5.6–6.4%	13%	3%	4%	1%	6%	8%	8%
Proportion with more than one emergency room visit in the last days of life	Average: 8–10% Best observed: 2%	7%	14%	0%	3%	2%	2%	4%
Proportion admitted to the ICU in the last 30 days of life	Average: 8–12% Best observed: <4%	4%	11%	2%	6%	4%	6%	8%
Proportion admitted to hospice for less than 3 days	Average: 27–35% Best observed: <4%	12%	12%	35%	6%	0%	8%	4%
Proportion not admitted to hospice	Estimated typical performance: 65–85% Best observed: <55%	55%	38%	45%	53%	41%	51%	46%
Advance Care Plan	Observed average: 41%	38%	46%	87%	70%	73%	82%	90%

and review is an essential task, along with diving deeper into the data to identify outlying trends and areas for improvement.

The palliative care in-house specialists continue to meet bi-monthly to re-assess their competencies and identify areas for growth. Some recent ongoing initiatives include:

- Exploring how we can record actual goals-of-care meetings (audio or video) to critique and develop professional skills
- Creating a Kaufman Cancer Center pocket resource card to be distributed to all team members
- Implementing a more formally structured resiliency program intended to promote ongoing self-care for all team members.

Additional certifications in palliative care are under pursuit for members of the group and membership remains open to other Kaufman Cancer Center team members. Overall, these initiatives will increase awareness and visibility of our palliative care resources for providers, caregivers, and patients.

Reaching out to our community partners is another area we continue to explore. Keeping our hospice and in-home palliative care providers informed of our model and practices is crucial. Recently some members of the in-house specialist team have joined a newly-formed community group whose members are involved with providing various services to people at end-of-life in our community. Engaging in these relationships and conversations is essential to create an environment where people can receive appropriate and sensitive care at a critical time.

Lessons Learned

What have we learned from this process? To begin with, we have learned that you must start somewhere. Use the valuable resources you already have and tap into people's passions and talent. Be inclusive. Invite everyone on the care team to participate. Multidisciplinary expertise is vital to the success of the program. Each team member has something unique to offer. Secure support from leadership early in the process. This support will provide the strong foundation needed to move processes forward. Early palliative care is vital. It improves patient care and outcomes. Finally, keep at it. It is a fluid, on-going process. Be open to change and be flexible. Ultimately the goal is to improve outcomes for our patients and families. OI

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Our Program At-a-Glance

The Kaufman Cancer Center is in north central Maryland, in Harford County, which is home to approximately 250,000 people who live in a combination of rural and suburban communities. Thanks in part to strong philanthropic support from the community, the Center provides enhanced supportive care services through its Cancer LifeNet program in a state-of-the art community cancer center that is part of the University of Maryland Cancer Network. This community support has been driven largely by the higher than average rates of cancer incidences: 480.6 per 100,000 as compared to 440.7 and 450.6 for Maryland and the entire United States respectively. Learn more at umuch.org/cancer.

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INNOVATE. ACHIEVE. INSPIRE.

ACCC INNOVATOR AWARDS CALL FOR ENTRIES

In its seventh year, the **Association of Community Cancer Centers Innovator Awards** honor Cancer Program Members for their pioneering achievements in oncology.

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

Some suggested areas of focus are:

- Community Outreach
- At-Risk Populations
- Process Improvement
- Supportive Care
- Quality Improvement Initiatives
- Immuno-Oncology Implementation

Past Innovator Award winner topics include:

- Reducing Patient Financial Distress
- HPV Outreach and Education
- Maximizing Tele-Health Technology
- Enhancing Survivorship through Care Coordination
- Outreach for Underserved Communities
- Symptom Management Clinics
- Immunotherapy Access in Rural Settings

Winners will present their innovations at the ACCC 34th National Oncology Conference, October 18–20, 2017, in Nashville, TN, and will be featured in our journal, *Oncology Issues*.

Winners receive regional and national exposure as their innovations are shared with oncology care providers, the broader healthcare community, and national press outlets.

DEADLINE FOR SUBMISSIONS: March 17, 2017

In partnership with the Institute for Clinical Immuno-Oncology (ICLIO), one Innovator Award will be granted to a program demonstrating innovation in the delivery of immunotherapies.

CRITERIA FOR SUBMISSIONS

1. Is your program innovative, creating positive change for your patients and staff?
2. Does this innovation advance patients' access to quality cancer care?
3. Does your program demonstrate value to patients and payers?
4. Can your innovation be replicated in other community-based cancer programs?
5. Does your innovation look to eliminate inefficiencies and reduce cost of care?

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

Telehealth

BY NICOLE ESCO, MPA, RD, LDN

Connecting Patients with Nutrition Services

With nutrition playing an important role before, during, and after cancer treatment, the registered dietitian is an integral member of the multidisciplinary cancer care team. According to the World Health Organization, one-third of all cancers are preventable, and various lifestyle factors, such as tobacco use, alcohol consumption, weight, diet, and physical inactivity are associated with certain types of cancer.[1] On one side of the care continuum oncology dietitians can help educate the public about eating for cancer prevention; further along on the care continuum these professionals can help educate patients diagnosed with cancer on strategies for eating well and managing side effects during treatment.

A Team-Based Approach to Nutrition

At Baton Rouge General Medical Center Pennington Cancer Center, Baton Rouge, La., our nurses, radiation therapists, and physicians work together to keep the dietitian aware of potential at-risk patients, weight changes, or any other nutritional concerns raised by patients or staff. At the initial radiation oncology consult, patients complete two screening forms as part of their new patient paperwork. The functional screen reviews the patient's daily activities, mobility, cognition, and any need for physical therapy, occupational therapy, and/or home health services. Swallowing ability and history of speech therapy are also included in the functional screen. The nutrition screen reviews unintentional weight loss within the past six months and changes in appetite.

> Implementing telehealth technology allows patients to easily address any nutritional concerns with the dietitian, including symptom management, education, and/or diet adherence.

The functional screening form is returned to the nurses; the nutritional screening is returned to the dietitian. The forms are scored and referrals are made as needed. The dietitian's role is to:

- Prepare patients for nutrition-related side effects and symptoms, depending on the treatment regimen.
- Identify at-risk patients, including those with cancers of the head and neck, pancreas, lung, stomach, and bladder.
- Monitor patients on tube feedings or total parenteral nutrition (TPN) and peripheral parenteral nutrition (PPN), and patients experiencing significant weight loss or decreased appetite.

At-risk patients receive an initial nutrition assessment and are assessed weekly in the radiation oncology center. The dietitian follows patients assessed at low nutrition risk as needed. For example, many patients gain weight while being treated for cancer.

Dietitians around the country are now using virtual counseling as a vehicle to provide medical nutrition therapy.

Dietitians can help these patients develop healthy eating strategies to maintain a healthy weight.

Growing Pains

In 2014 Baton Rouge General Medical Center Pennington Cancer Center expanded its services with the opening of a third radiation oncology center. This growth presented a unique challenge to our registered dietitian who was already traveling between the Mid-City and Bluebonnet clinic locations, which are seven miles apart. During the planning process for the new construction, we determined that it was simply not feasible for the dietitian to travel to all three locations (the new site was 16 miles north). However, physicians at the new radiation oncology center wanted their patients to have access to nutrition services. The solution: telehealth technology that would facilitate patient and caregiver access to these critical supportive care services.

A partnership between Baton Rouge General Medical Center and Lane Regional Medical Center to build a state-of-the-art radiation oncology treatment center on Lane's campus in Zachary, La.

Telehealth & Telenutrition Defined

Telehealth services can be a convenient option for patients in rural communities with limited access to medical care services.[2] The Academy of Nutrition and Dietetics defines telehealth and telenutrition as follows:[3]

Telehealth is the use of electronic information and telecommunications technologies to support long-distance clinical healthcare, patient and professional health-related education, public health, and health administration. Telehealth will include both the use of interactive, specialized equipment, for such purposes as health promotion, disease prevention, diagnosis, consultation, therapy, and/or nutrition intervention/plan of care, and non-interactive (or passive) communications, over the internet, video-conferencing, email, or fax lines, and other methods of distance communications, for communication of broad-based nutrition information.

Telenutrition involves the interactive use, by a Registered Dietitian or Registered Dietitian Nutritionist, of electronic information and telecommunications technologies to implement the Nutrition Care Process (nutrition assessment, nutrition diagnosis, nutrition intervention/plan of care, and nutrition monitoring and evaluation) with patients or clients at a remote location, within the provisions of their state licensure as applicable.

This technology has transformed the way registered dietitians provide nutrition counseling. Dietitians around the country are now using virtual counseling as a vehicle to provide medical nutrition therapy. For Pennington Cancer Center, telehealth means that patients at all three clinic locations can access nutrition services and continue to benefit from a multidisciplinary team-based approach to cancer care.

Patient Barriers to Nutrition Consultations

A common barrier for patients needing radiation therapy is coordinating daily transportation to and from treatment appointments. Some patients do not own a vehicle; others are unable to drive or may not have the funds for public transportation. Social services programs, such as Medicaid or the Council on Aging, may provide medical transportation to and from appointments, but patients must be eligible to participate in these programs in order to use services.

The distance from the Zachary, La., location to the Mid-City and Bluebonnet centers presents another challenge for patients who reside in the northern-most part of the region. We frequently find that patients would rather have services close to where they live and/or work, and may decline resources that require significant drive time. Patients often have various medical appointments in addition to their radiation therapy treatments, and often comment on how busy their schedules have become since their cancer diagnosis. Further, those who continue to work during treatment may not always have the extra time to schedule a separate dietitian appointment.

Getting Started

The first step in implementing our telehealth program: setting up a secure transmission to ensure patient privacy. Today our

Baton Rouge General Medical Center Pennington Cancer Center's registered dietitian participates in a nutrition telehealth session.

telehealth program provides free access to patients and clinicians with secure, HIPAA-compliant data transmission for video-conferencing appointments with the registered dietitian.

At each of its locations, Pennington Cancer Center has patient consultation rooms, which are private areas where patients and families can interact with staff with minimal distractions. When implementing our telehealth program, we equipped these patient consultation rooms with 60-inch flat-screen televisions, webcams, headphone sets with microphones, upgraded video telephone systems, and video-secure software. Additional equipment was installed at a work computer in the staff area.

The telehealth program is supported by Google Chrome or Mozilla Firefox. Our IT department was integral in installing Google Chrome and allowing staff access. Today our cancer patients at all three locations can access the dietitian. The dietitian uses two-way real time video-conferencing to conduct nutritional assessments and follow-ups with patients. The dietitian and social worker spend the majority of their time at the Bluebonnet location—the busiest clinic.

Our Initial Telehealth Pilot

In January 2014 we began researching telehealth options. When the new clinic in Zachary opened in March 2014, we initiated our pilot telehealth program, installing and testing a free video-conferencing program at all three clinic locations. A standard operating procedure for use of the telehealth program was developed and staff were trained at each location. The telehealth program was used by our social worker, dietitian, and any other staff member who needed to meet with a patient receiving treatment at a different clinic location. We also used the telehealth program to expand our genetic counseling offerings via our partnership with the Hayward Genetics Center at Tulane University in New Orleans. Prior to the implementation of our pilot telehealth program, the geneticist and genetic counselors commuted to the center one afternoon every six weeks. With telemedicine, we were able to offer more flexible times for patients without a long commute for the genetics team.

Per departmental policy, outpatient nutrition assessments were completed within the first week of treatment and documented in the radiation oncology electronic health record (EHR). (We use

Figure 1. Telehealth Patient Satisfaction Survey

Name (Optional): _____ Date: _____

Did you meet with the dietitian and/or social worker through the video conference? (check 'yes' or 'no')

☐ Yes, continue with the survey below. ☐ No, do not continue with the survey.

Please place a check mark by the appropriate answer.

How satisfied were you with the video-conference meeting in the following areas?	Very Satisfied	Satisfied	Neutral	Dissatisfied	Very Dissatisfied
Quality of the visual image					
Quality of the audio sound					
Your personal comfort using the video system					
Ability to talk freely over the video					
Ability to understand the information presented and any recommendations made					
Your overall video conference experience					

1. Did you find it beneficial to have the video services available? ☐ Yes ☐ No

2. Which would you prefer? ☐ Video conference ☐ On-site visit

MOSAIQ.) All patients undergoing radiation therapy were screened and assessed. In addition to radiation therapy patients, the dietitian saw medical oncology patient referrals face-to-face and community referrals as needed.

The dietitian scheduled patients in MOSAIQ with a note in the patient's treatment schedule for the patient to see the dietitian. For video assessments at the Zachary location, the dietitian scheduled the appointment in MOSAIQ and a flag was placed to "See RD" on the patient's treatment schedule. From the computer, the video icon was selected and the user selected the call location. Once the location was selected, the user selected the video call button to call the secondary location. Each location also had a webcam that could zoom in and around the room. To operate the webcam, the user pressed the microphone button and then the green phone button to see the patient at the secondary location.

Our Current Telehealth Process

After using the free video-conferencing program for two years, we began researching other telehealth options in late 2015. In early 2016 we made the switch to doxy.me as we found it to be more user-friendly, HIPAA compliant, and with a more secure data transmission. Doxy.me offers both free and professional versions for its clients. Once clinicians register on the website, doxy.me will send them a personal login along with a link that can be given to patients to check-in on their appointment day. Since patients meet with the dietitian at the radiation oncology treatment center, they do not need the link to check-in. Instead, staff at each location use the link to check-in patients for their session. When patients complete their treatment, a staff person explains to the patient that they will meet with the dietitian via video link at our secondary location. The patient and/or family member is escorted into the private consultation room where the

Table 1. Responses to the Telehealth Patient Satisfaction Survey

QUESTION	n	Very Satisfied	Satisfied	Neutral	Dissatisfied	Very Dissatisfied	Total
Quality of the visual image	17	16	0	1	0	0	100%
Quality of the audio sound	18	17	1	0	0	0	100%
Your personal comfort using the video system	18	14	3	0	1	0	100%
Ability to talk freely over the video	18	15	3	0	0	0	100%
Ability to understand the information presented and any recommendations made	18	15	3	0	0	0	100%
Your overall video conference experience	19	15	3	0	1	0	100%

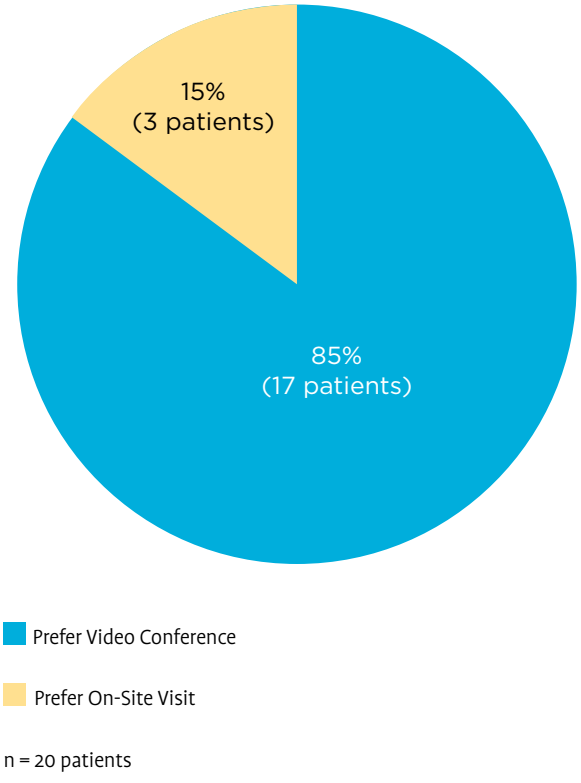
staff person opens the doxy.me link and enters the patient's name to check-in. An alert is sent to the dietitian that the patient is in the waiting room; the dietitian selects the patient's name and both parties can see one another and begin the consultation. Once the session is complete, the dietitian ends the session and the screen returns to the waiting room.

Patient & Staff Interaction

Interpreting a person's tone of voice, facial expressions, and body language are important cues for effective communication. Face-to-face interaction allows the dietitian to actively engage with patients by interpreting non-verbal cues, such as facial expression and body language. At our initial telehealth session, some patients need a few minutes to get comfortable in front of the camera, but they often relax as the session progresses. In one instance, following an initial patient assessment with a patient and caregiver, the dietitian received a follow-up email from the patient thanking her for her guidance and sharing that it helped the caregiver identify and purchase foods of nutritional value. The face-to-face video interaction allows the dietitian to better assess a person's readiness for change and/or comprehension of nutrition information.

Video-conferencing is a new concept for many of our patients, and initially some are more comfortable with this technology than others. The dietitian's role is to engage the patient and help build rapport during each session. There are patients who are very comfortable and open up immediately. Many of our patients appreciate the telehealth nutrition consultation and frequently ask how often they can meet with the dietitian.

Figure 2. Patient Consultation Preferences



Telehealth Challenges

The initial telehealth program we used had its set of challenges. Staff frequently encountered grainy video and low sound quality; some staff found the technology difficult to operate. We were also concerned about the protection of typed data, and so we decided to stop using that particular program. Even with our current telehealth technology (Doxy.me), we occasionally experience video lag time and fading in and out of audio during a patient session.

Patient Satisfaction

We gave satisfaction surveys (Figure 1, page 52) to patients on their final radiation oncology treatment day along with a self-addressed envelope, asking patients to evaluate our telehealth program. This survey is given in addition to our standard survey evaluating the patients' overall treatment experience. Patients are instructed by staff to complete the survey and mail it back in the provided envelope.

We've found that our patients are very satisfied with the quality of the video image (94 percent) and sound (94 percent), and 83 percent were very satisfied with their ability to talk freely over the video, understand the information presented, and the overall video-conferencing experience (see Table 1, page 53). The majority of patients (95 percent) found the telehealth program beneficial and 84 percent of patients preferred the telehealth vists to an on-site visit (Figure 2, page 53).

Convenience

Telehealth nutrition counseling sessions take place while the patient is at the radiation oncology center for treatment. This technology eliminates patients having to schedule additional appointments to see the dietitian. This convenience is a benefit to patients as this patient population tends to have many appointments. As stated previously, transportation to and from daily treatment is another barrier for some patients and the telehealth option means patients do not have to drive or try to find a ride to their nutrition counseling session. The flexibility of telehealth allows the dietitian to work from any location and limits the need for additional travel for this busy staff member.

Closing Thoughts

As a part of the multidisciplinary cancer care team, registered dietitians apply evidenced-based nutrition intervention to improve patient outcomes. Implementing telehealth technology allows patients to easily address any nutritional concerns with the dietitian, including symptom management, education, and/or diet adherence. Further, telehealth options allow for easier and more frequent follow-up with high-risk nutrition patients receiving radiation therapy.

For Pennington Cancer Center, telehealth technology allows us to provide much needed supportive care services to patients who may otherwise have limited access them, including those for whom travel time for additional appointments would have been a barrier to receiving care.

Future use can include on-demand video-conferencing when a patient has a concern that can be addressed while he or she is at the clinic or if a staff person has a nutritional concern and feels that a follow-up would be beneficial. This on-demand feature can potentially improve patient satisfaction scores and increase access to the dietitian. OI

Top: Exterior shot of Baton Rouge General Medical Center's Mid-City campus. Below: Exterior shot of Baton Rouge General Medical Center's Bluebonnet campus.

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3. Academy of Nutrition and Dietetics. Definition of Terms List; Oct. 2016. Available online at: eatrightpro.org/~/media/eatrightpro%20files/practice/scope%20standards%20of%20practice/academydefinitionofterms list.ashx. Last accessed Nov. 18, 2016.

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ACCC
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LATEST AGENDA UPDATES
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HPV Vaccination

Engaging Community Partners For Success

BY ROBIN HEARNE, RN, MS, AND
AMY MONTGOMERY, MAED

"If you could prevent your child from developing a certain type of cancer as an adult later in life, would you do it?"

The question the Outer Banks Hospital Cancer Committee used to frame conversations about increasing the HPV vaccination rate among students enrolled in local public schools.

Human Papillomavirus (HPV) is a very common virus that infects epithelial tissue, including the surfaces of the skin and mucosal surfaces that line cavities of the body, such as the nose, mouth, throat, and genital surfaces. Most HPV types infect cutaneous epithelial cells and cause a benign condition commonly known as warts. However, persistent infections with high-risk, oncogenic HPV types, such as HPV 16 and 18, can cause cancers of the cervix, vulva, vagina, anus, and penis, as well as cancers of the oropharynx, including the back of the throat, base of the tongue, and tonsils. Among women diagnosed with an HPV-related cancer, cervical cancer is the most common. For men diagnosed with an HPV cancer, oropharyngeal cancer is the most common.

Our Call to Action

In early 2014 a Cancer Committee analysis of cancer registry data at Outer Banks Hospital, Nags Head, N.C., revealed that the incidence of HPV-related cancers, particularly head and neck cancers, was on the rise. Although alarming, our local cancer incidence compared consistently with national findings. That same year, during the discussion to select our cancer program's annual prevention goal, one Cancer Committee member, a gynecologist, reported a large percentage of unvaccinated patients presenting for gynecological care. He made a passionate plea for an organized campaign to promote HPV vaccination in our community as our cancer prevention goal for 2014.

Our Cancer Committee chair, a radiation oncologist who has been treating HPV-related cancers for more than 20 years, recalled one of his first patients, a young woman with advanced cancer of the cervix, caused by the HPV virus. Her quality of life was forever changed as a result of this now-preventable disease.

Cancer Committee members shared their personal family experiences with healthcare and discussed concerns about the underutilization of HPV vaccines in our community. Members speculated that barriers to effective vaccination in our community included a lack of awareness of the relationship between certain HPV infections and the incidence of cancer and subsequent missed clinical opportunities for vaccination.

Increasing HPV vaccination is one of the most achievable cancer prevention opportunities and it has recently become a public health priority. The Outer Banks Hospital chose the complex (and somewhat controversial) cancer prevention initiative to improve HPV vaccination rates in our local schools.

Cancer Committee Meeting, Outer Banks Hospital, Nags Head, N.C.

Getting Started

The Outer Banks Hospital Cancer Committee established a multidisciplinary workgroup led by two prominent cancer care team providers who served as project champions. The workgroup reviewed the literature and modeled our HPV vaccination awareness campaign after evidence-based strategies found in the literature. For example, the President's Cancer Panel Annual Report, published in February 2014, explored the underutilization of HPV vaccines and outlined strategies to accelerate vaccination. We set out on a coordinated community education campaign focused on increasing awareness of the cancer prevention benefit of HPV vaccination, gaining parental acceptance, and engaging local providers to promote vaccination to reduce missed opportunities.

Vaccination Recommendations

Ideally, adolescents should be vaccinated before they are exposed to HPV. The Centers for Disease Control and Prevention (CDC) recommends HPV vaccination for girls and boys at ages 11 or 12 years to protect against cancers caused by HPV infections. Currently, HPV vaccines are administered as a three-dose series over six months. Literature widely available through the CDC and the National Cancer Institute (NCI) report a high safety profile for the vaccine, similar to other adolescent vaccines.

Strategies & Action Plan

From the beginning, our Cancer Committee leadership underscored the importance of establishing strategic partnerships with

Table 1. HPV Vaccination Baseline Audits, Rising 9th Graders & Graduates

RISING 9TH GRADERS 2014–2015

YEAR	SCHOOL	TOTAL	BOYS	GIRLS	NORTH CAROLINA IMMUNIZATION REGISTRY (NCIR)	
July 2014	MMS	131	65	66	129	
July 2014	CHSS	46	26	20	45	
July 2014	FFMS	191	85	106	190	

GRADUATES JUNE 2014

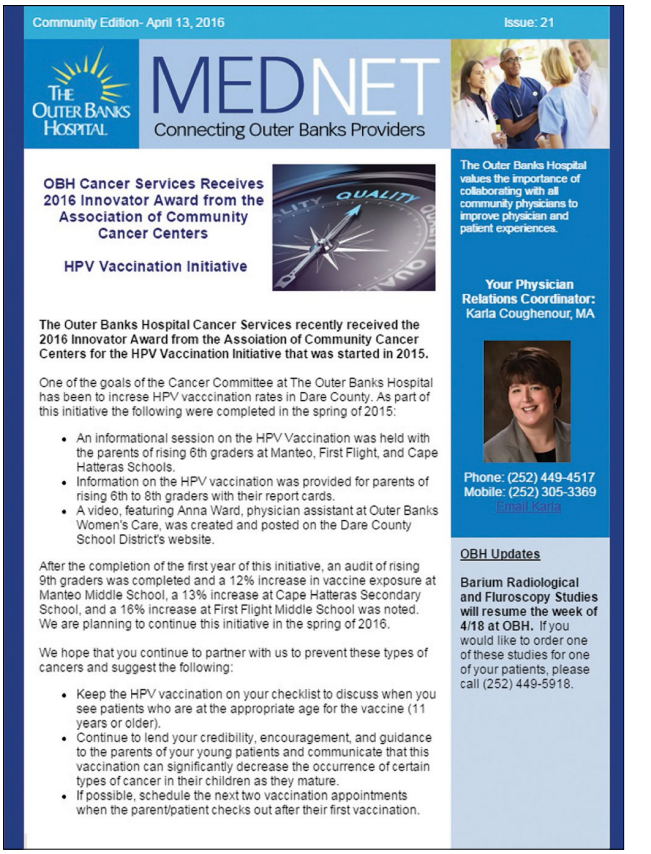
YEAR	SCHOOL	TOTAL	BOYS	GIRLS	NORTH CAROLINA IMMUNIZATION REGISTRY (NCIR)	
July 2014	MMS	111	50	61	100	
July 2014	CHSS	37	17	20	35	
July 2014	FFMS	185	95	90	166	

We now know that HPV vaccination is a powerful tool in our cancer prevention toolkit and this message resonates with parents.

key community leaders to ensure program acceptance and, in the end, programmatic success. With our hospital President's support in hand, the Director of Community Outreach met with leadership from our local health department and the Superintendent of Schools to educate them about our HPV vaccination education initiative and gain their support. The County Lead School Nurse soon became an active member of our workgroup.

Over the summer of 2014, school nurses conducted an audit of student vaccination records for all rising 9th and 12th grade students (Table 1, below). The results of this audit showed alarmingly low rates of vaccination. This baseline data served as both a validation of the work that needed to be done and a baseline metric to monitor the impact of our efforts.

(*continued on page 61*)



Community Edition- April 13, 2016 Issue: 21

THE OUTER BANKS HOSPITAL

MEDNET

Connecting Outer Banks Providers

OBH Cancer Services Receives 2016 Innovator Award from the Association of Community Cancer Centers

HPV Vaccination Initiative

The Outer Banks Hospital Cancer Services recently received the 2016 Innovator Award from the Assoiation of Community Cancer Centers for the HPV Vaccination Initiative that was started in 2015.

One of the goals of the Cancer Committee at The Outer Banks Hospital has been to increse HPV vacccination rates in Dare County. As part of this initiative the following were completed in the spring of 2015:

- An informational session on the HPV Vaccination was held with the parents of rising 6th graders at Manteo, First Flight, and Cape Hatteras Schools.
- Information on the HPV vaccination was provided for parents of rising 6th to 8th graders with their report cards.
- A video, featuring Anna Ward, physician assistant at Outer Banks Women's Care, was created and posted on the Dare County School District's website.

After the completion of the first year of this initiative, an audit of rising 9th graders was completed and a 12% increase in vaccine exposure at Manteo Middle School, a 13% increase at Cape Hatteras Secondary School, and a 16% increase at First Flight Middle School was noted. We are planning to continue this initiative in the spring of 2016.

We hope that you continue to partner with us to prevent these types of cancers and suggest the following:

- Keep the HPV vaccination on your checklist to discuss when you see patients who are at the appropriate age for the vaccine (11 years or older).
- Continue to lend your credibility, encouragement, and guidance to the parents of your young patients and communicate that this vaccination can significantly decrease the occurrence of certain types of cancer in their children as they mature.
- If possible, schedule the next two vaccination appointments when the parent/patient checks out after their first vaccination.

The Outer Banks Hospital values the importance of collaborating with all community physicians to improve physician and patient experiences.

Your Physician Relations Coordinator:
Karla Coughenour, MA

Phone: (252) 449-4517
Mobile: (252) 305-3369
Email Karla

OBH Updates

Barium Radiological and Fluroscopy Studies will resume the week of 4/18 at OBH. If you would like to order one of these studies for one of your patients, please call (252) 449-5918.

Outer Banks Hospital's provider newsletter.

	HPV: 0	%POP	HPV: 1	%POP	HPV: 2	%POP	HPV: 3	%POP	PAST DUE	TOTAL % VACCINE EXPOSURE
	99	76%	11	8%	13	10%	6	5%	14	23%
	35	76%	6	13%	2	4%	2	4%	4	22%
	145	76%	13	7%	20	6%	20	10%	unknown	24%

	HPV: 0	%POP	HPV: 1	%POP	HPV: 2	%POP	HPV: 3	%POP	PAST DUE	TOTAL % VACCINE EXPOSURE
	68	61%	8	7%	2	2%	22	20%	9	29%
	22	59%	5	14%	0	0%	8	22%	1	35%
	107	58%	12	6	16	9%	32	17%	24	32%

Date

First Name, Last Name, Credentials

Practice Name

Mailing Address

City, State, Zip

Dear [Provider's Name]:

The Outer Banks Hospital is working toward accreditation of our Cancer Services Program from the American College of Surgeons' Commission on Cancer. I am currently serving as Chair of the Outer Banks Hospital Cancer Committee, and I am writing this letter on the committee's behalf.

During 2014, the Cancer Committee selected HPV vaccination as our cancer prevention goal. According to the National Cancer Institute (NCI), HPV is the cause of most cervical cancers and HPV vaccination has the potential to decrease cervical cancer deaths by two-thirds worldwide. According to the Centers for Disease Control and Prevention (CDC), infection with HPV also causes 95% of anal cancer in men and women, 65% of vaginal cancer, 60% of oropharyngeal cancer in men and women, 50% of vulva cancer, and 35% of penile cancer. All of these cancers are preventable, if early action is taken.

As part of our initiative, we initially collected primary data among all 8th and 12th grade students in Dare County Schools during the summer of 2014 to establish a baseline. We learned that a mere 8% of all rising 8th graders and rising 12th graders had received all three doses of the vaccine.

Our goal is to increase the percentage of Dare County youth who receive all three doses of the HPV vaccine. We need your help!

The CDC recommends that preteen boys and girls age 11 or 12 should receive all three doses of the vaccine over a six-month time period. Giving the vaccine at this age is important so that children develop an immune response to the virus before they become sexually active later on. Giving the vaccine at this age may also be more comfortable for some parents as they can protect their child from developing some cancers later in life, without the need to talk about the purpose of the vaccine administration; thus, eliminating the parental misperception that the vaccine will encourage early sexual activity. We support the CDC guidelines for cancer prevention and we have therefore adopted its current recommendations.

Sincerely,

[Providers Name]

Program Name

Mailing Address

City, State, Zip

Table 2. 2014–2015 Vaccination Rates Compared

	BASELINE AUDIT JULY 2014	FOLLOW UP AUDIT JULY 2015
8th Graders	6%	16%
12th Graders	20%	23%

(*continued from page 59*)

After reviewing audit results, we collaborated with school leaders to identify educational strategies for success. A common perception shared by many was the fear that a conversation about the HPV vaccine would promote early sexual behavior, an alarming topic for most parents of preteen children. As a result, more often than not, the conversation stopped there and the cancer-prevention benefit was left unexplored.

We now know that HPV vaccination is a powerful tool in our cancer prevention toolkit and this message resonates with parents. Our workgroup identified a key strategic approach to keep the focus on cancer prevention throughout all community education efforts.

Engaging Local Providers

Primary care providers (PCPs) are uniquely influential in promoting vaccination of adolescents. The Outer Banks Hospital Cancer Committee recognized the importance of a strong, consistent vaccination recommendation from patients' trusted PCPs, and so developed strategies centered around:

- Raising PCP awareness of the cancer prevention benefit of the HPV vaccine.
- Communicating cancer prevention benefits to patients and parents at every opportunity.
- Encouraging PCPs to recommend HPV vaccination in the same manner as they recommend other adolescent vaccines.

Our Cancer Committee chair developed a "*Dear Colleague*" letter (left), which was distributed to all local primary care providers. The letter summarized the alarmingly low vaccination rates found in our recent audit and emphasized the cancer prevention benefits of HPV vaccination. This strategy not only highlighted the key aspects of our HPV vaccination initiative but also served to promote collaboration between the hospital Cancer Committee, primary care providers, and local school officials to improve the health of our community.

To keep this concept first and foremost in the minds of our local providers, we followed up with a cover story on our HPV cancer prevention initiative in our provider newsletter, *MEDNET* (page 59).

(*continued on page 64*)

Outer Banks Hospital's community newsletter.

One of the Outer Banks Hospital Health Clips housed on the hospital's YouTube Channel and posted on the County Schools' website.

Table 3. HPV Vaccination Rates, 2014–2016 *

RISING 9TH GRADERS

YEAR	SCHOOL	TOTAL	BOYS	GIRLS	NCIR	HPV: 0	%POP	
July 2016	MMS	132	64	68	132	82	62%	
July 2015		131	65	66	130	83	63%	
July 2014		131			129	99	76%	
July 2016	CHSS	37	17	20	37	20	54%	
July 2015		46	26	20	45	29	63%	
July 2014		46			45	35	76%	
July 2016	FFMS	209	114	95	202	134	64%	
July 2015		191	85	106	190	115	60%	
July 2014		191			190	145	76%	

GRADUATES

YEAR	SCHOOL	TOTAL	BOYS	GIRLS	NCIR	HPV: 0	%POP	
July 2016	MMS	104	58	46	103	53	51%	
July 2015		111	50	61	105	62	56%	
July 2014		111			100	68	61%	
July 2016	CHSS	29	18	11	29	17	59%	
July 2015		37	17	20	45	21	57%	
July 2014		37			45	22	59%	
July 2016	FFMS	163	82	81	153	91	56%	
July 2015		185	95	90	175	103	56%	
July 2014		185			166	107	58%	

* Data Collection and Presentation by M. Coley, R. Winnett, & J. Wyant: DCDHHS School Nurses

	HPV: 1	%POP	HPV: 2	%POP	HPV: 3	%POP	PAST DUE	TOTAL % VACCINE EXPOSURE
	12	9%	10	8%	28	21%	18	38%
	14	11%	12	9%	20	15%	17	35%
	11	8%	13	10%	6	5%	14	23%
Percent Increase in Total Students Exposed to HPV Vaccination—MMS								15%
	11	30%	2	5%	4	11%	12	46%
	2	4%	7	15%	7	15%	8	35%
	6	13%	2	4%	2	4%	4	22%
Percent Increase in Total Students Exposed to HPV Vaccination—CHSS								24%
	19	9%	30	9%	30	14%	31	33%
	21	11%	34	10%	34	18%	26	39%
	13	7%	20	6%	20	10%	unknown	24%
Percent Increase in Total Students Exposed to HPV Vaccination—FFMS								9%

	HPV: 1	%POP	HPV: 2	%POP	HPV: 3	%POP	PAST DUE	TOTAL % VACCINE EXPOSURE
	7	7%	8	8%	35	34%	12	48%
	13	12%	7	6%	23	21%	12	39%
	8	7%	2	12%	22	20%	9	29%
Percent Increase in Total Students Exposed to HPV Vaccination—MMS								**15%**
	3	10%	1	3%	8	28%	12	41%
	4	11%	3	8%	9	24%	4	43%
	5	14%	0	0%	8	22%	1	35%
Percent Increase in Total Students Exposed to HPV Vaccination—CHSS								**6%**
	11	7%	12	7%	39	24%	19	38%
	11	6%	14	8%	47	25%	14	39%
	12	6%	16	9%	32	17%	24	32%
Percent Increase in Total Students Exposed to HPV Vaccination—FFMS								**6%**

(*continued from page 61*)

Increasing Awareness & Gaining Parental Acceptance

While promotional efforts were underway with our local PCPs, Outer Banks Hospital ran a parallel awareness campaign to educate parents. The cover story in our hospital's community newsletter highlighted the cancer prevention benefits of the HPV vaccination—with a call to action for parents to add the HPV vaccine to their back-to-school checklist (see page 61). This community newsletter is distributed bi-monthly as an insert to our local newspapers, with a circulation of approximately 15,000. The newsletter is also distributed to local provider offices.

In conjunction with the community newsletter, Outer Banks Hospital also produced a brief health clip video on HPV vaccination. The video is promoted through the newsletter and housed on the hospital's YouTube channel. The HPV video was also posted on the Dare County Schools' website.

The hospital's Director of Community Outreach and Dare County's Lead School Nurse attended parent meetings of rising 6th grade students at local schools. A flyer (available in both English and Spanish) was inserted into report cards informing parents that the HPV vaccine would be discussed at these parent meetings. The flyer was also used to help create awareness of the importance of the vaccine. The parent meetings were well attended, and the focus of the conversation remained cancer prevention—not premature sexual activity.

Last, but not least, the Dare County school system added an HPV vaccine information sheet (Figure 1, right) to the annual student code of conduct booklet distributed annually to all parents and students.

Results & Future Directions

One year after our HPV Outreach Education Initiative, vaccination rates among 8th grade students increased from 6 percent to 16 percent (Table 2, page 61). Follow-up data after the second year of the HPV vaccination campaign shows continued improvements (Table 3, page 62).

HPV vaccination has the potential to prevent tens of thousands of individuals from certain cancers. It is critical that all stakeholders make HPV vaccination a priority so that prevention of the vast majority of cervical, vaginal, vulvar, anal, penile, and oropharyngeal cancers becomes a reality. Now that organizations such as the American Cancer Society (ACS) have endorsed the U.S. government's HPV vaccination recommendations, healthcare providers can access an array of practical resources readily available to promote the cancer prevention benefits of the HPV vaccine. OI

Robin Hearne, RN, MS, is director of Cancer Services and Amy Montgomery, MAEd, is director of Community Outreach at The Outer Banks Hospital, Nags Head, N.C.

Resources

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Acknowledgements

The Outer Banks Hospital would like to thank Charles Shelton, MD; Daniel Dwyer, MD; Anna Butler-Ward, PA-C; and Debbie Dutton, RN; for their collaboration and support for this project.

Figure 1. HPV Vaccine Information Sheet

HOW DO YOU GET HPV?

HPV is spread through any type of sexual activity and can infect any person who is sexually active. Both males and females can get it and pass it on to their sex partners without even realizing it.

WHAT ARE THE SIGNS AND SYMPTOMS OF HPV INFECTION

The virus lives in the body and usually causes no symptoms. Some people will develop visible growth or bumps in the genital area (genital warts) but most men and women who have HPV do not know they are infected.

HOW IS HPV RELATED TO CANCER?

Some types of HPV can infect a woman's cervix (lower part of the womb) and cause the cells to change. Most of the time, HPV goes away on its own. When HPV is gone, the cervix cells go back to normal. But sometimes, HPV does not go away. Instead, it stays in the body and continues to change the cells on a woman's cervix. These cervical cell changes (also called cervical dysplasia) can lead to cancer over time, if they are not treated. HPV can also cause other types of cancer, such as vulvar, vaginal, penile, anal, and oropharyngeal (cancer of the back of the throat, including the base of the tongue and tonsils).

HOW CAN MY CHILD BE PROTECTED FROM GETTING HPV?

The only sure protection from HPV is lifelong abstinence or a monogamous relationship with an uninfected partner. However vaccines are now available that can protect females and males (ages 9–26) from some of the major types of HPV.

DOES THE HPV VACCINE PREVENT ALL TYPES OF HUMAN PAPILLOMAVIRUS?

No, but the HPV vaccine can prevent most cases of cervical cancer and/or most genital warts. There are currently two HPV vaccines in the United States:

- The quadrivalent HPV vaccine (Gardasil), which protects against the four types of HPV that cause most cervical and anal cancers and genital warts. This vaccine is available for males and females.
- The bivalent HPV vaccine (Cervarix), which protects against the types of HPV that cause most cervical cancers. This vaccine is only available to females at this time.

WHO SHOULD GET THE HPV VACCINE?

Both of the HPV vaccines licensed are safe and effective for females ages 9 through 26 years. The CDC recommends that the following individuals receive the HPV vaccine:

- Routine vaccination is recommended for 11 and 12 year old girls and boys. The vaccines can also be started as early as age 9.
- The vaccine is also recommended for males and females 13–26 years of age who did not receive it when they were younger.

WHY IS THE HPV VACCINE RECOMMENDED FOR SUCH YOUNG GIRLS AND BOYS?

For the HPV vaccine to work best, it is very important to get all three doses (shots) before being exposed to HPV. Someone can be infected with HPV the very first time they have sexual contact with another person. It is also possible to get HPV even if sexual contact only happens one time. Ideally, males and females should get the vaccine before they even consider becoming sexually active.

HOW IS THE VACCINE GIVEN?

The vaccine is given as a series of three shots over six month. The best protection is achieved after all three shots are given.

Bridging the Gap:

Early detection of cancer for the medically underserved

BY RENEA DUFFIN, MPA

About Our Program

Mary Bird Perkins Cancer Center, headquartered in Baton Rouge, La., partners with more hospitals and serves more cancer patients than any other program in the state. Our mission: to improve survivorship and lessen the burden of cancer through expert treatment, compassionate care, early detection, research, and education. To achieve our mission, we collaborate with the state's largest private hospital: Our Lady of the Lake Regional Medical Center in Baton Rouge, as well as with St. Tammany Parish Hospital in Covington and Terrebonne General Medical Center in Houma to deliver comprehensive, quality cancer care.

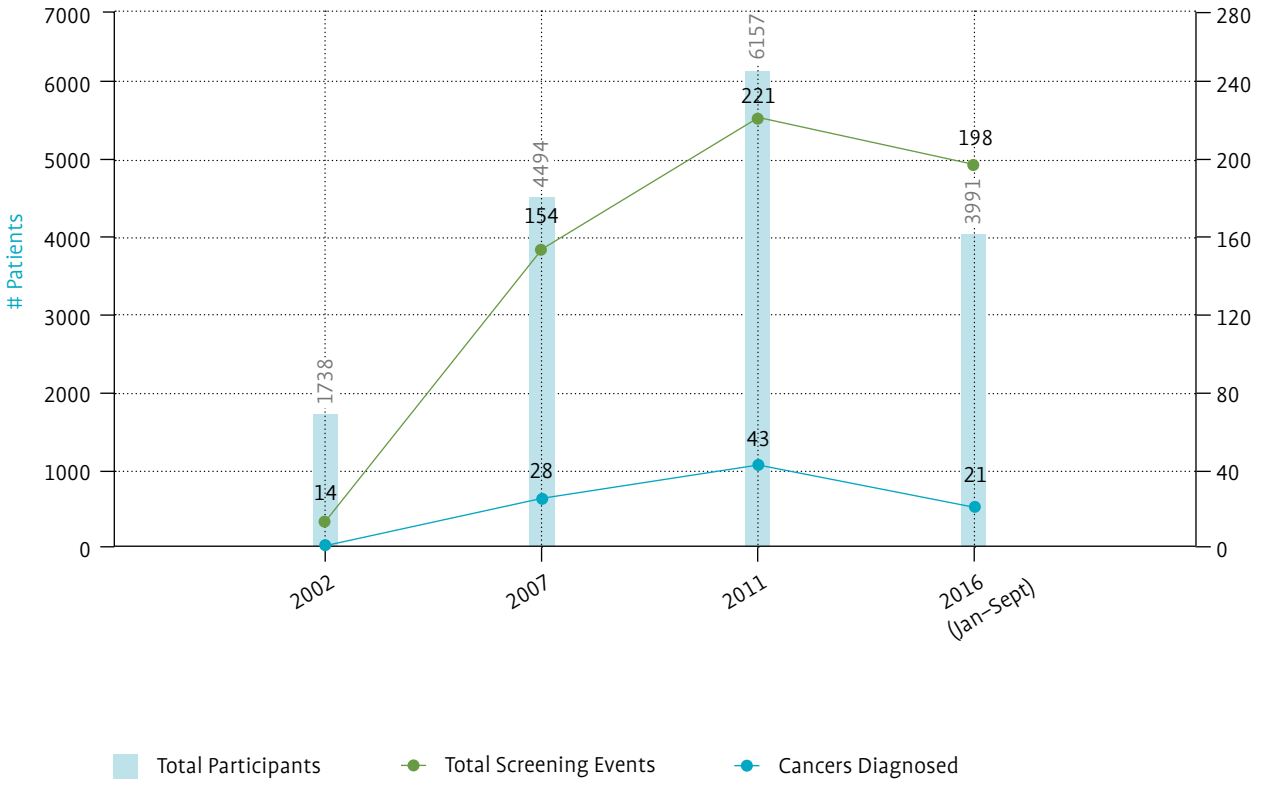
In a state with high cancer mortality rates due to late-stage diagnosis, Mary Bird Perkins has pioneered education, prevention, and early detection programs to deliver these services to communities where they are needed most. Mary Bird Perkins' early detection and education program, established in 2002, is committed to serving members of our community. Over the years, the early detection program has been enhanced and refined to ensure efficient, evidence-based, effective screening for five types of cancer and a broad array of education programs in southeast Louisiana. Through this vital outreach program, the people who live in our community have access to secondary prevention interventions, such as cancer screenings, awareness events, and education services, to help improve the overall health and quality of their lives.

Early detection is the nation's best strategy for decreasing cancer mortality rates.[1] Mary Bird Perkins' early detection and education program was established in 2002, in response to the growing number of patients in our region diagnosed with late-stage tumors. Often, the medically underserved face the greatest challenges in accessing critical early detection services. Accordingly, our early detection and education program focuses on this at-risk population, providing life-saving cancer screening programs for thousands of southeast Louisiana residents who lack access due to insurance status, limited availability of primary care providers (PCPs), or other barriers.

Using two mobile medical clinics, Mary Bird Perkins delivers more than 7,000 free screenings annually for breast, colorectal, prostate, skin, and oral cavity cancers. Each screening participant is also provided with education on cancer risk, screening guidelines, and healthy lifestyles. Participants with abnormal findings are supported by a patient navigator through resolution of the abnormal finding. On average, each year 1,200 screening participants require additional follow-up with about 50 of these individuals receiving a cancer diagnosis.

Since its inception, Mary Bird Perkins' early detection program has provided more than 75,000 free cancer screenings for Louisiana's medically underserved population, continuously working toward our goal of reducing cancer mortality in our state (Figure 1, page 68). From 14 screening events in 2002, the program today has expanded to more than 300 events in 18 parishes (counties) in southeast Louisiana annually. The program is funded by grants, third party events, and the compassionate generosity of the communities we serve.

Figure 1. Screenings & Diagnosis, 2002–2016



Early Detection & Prevention Education

Louisiana's cancer mortality rate is one of the highest in the nation. The Louisiana Tumor Registry reports that high cancer-mortality rates are attributable to residents' lack of education, inadequate access to cancer screening for early detection, and a lack of primary healthcare in some regions.[1] The result is high percentages of late-stage diagnosis—making cancer difficult, if not impossible, to treat successfully. Mary Bird Perkins' early detection program is significant to healthcare and health equity in our region because it works to reduce cancer mortality among a considerable number of medically underserved adults.

With the availability of simple screening procedures for breast, prostate, colorectal, skin, and oral cancers that help detect the disease in asymptomatic adults, we are able to successfully use mobile medical clinics in strategically selected locations and work with grassroots organizations to recruit and serve participants within medically underserved neighborhoods.

While many communities have mobile health clinics or mobile digital mammography, few programs address five different cancer types and provide follow-up until resolution for each participant with an abnormal finding via a patient navigator. In addition to the number of cancer types we address, Mary Bird Perkins' early detection program serves a geographic area that includes more than one-quarter of the state's population. Our early detection program is built on four key elements:

- A community-based, 12-month delivery model
- Patient navigation that streamlines the process for patients and ensures follow-up of findings
- The use of national tools that monitor health outcomes by ZIP Code
- Partnerships that reduce duplication and maximize transitions through the care continuum.

On weekdays, evenings, and weekends, our mobile clinics can be found in the parking lots of barber shops, shopping centers,

Mary Bird Perkins' mobile clinics, the Early Bird I and II, travel throughout southeastern Louisiana providing early detection services to those most in need.

community centers, grocery stores, or at community events across the 18-parish service region. In the simplest terms, we increase access to cancer-related health services that improve community health in our region for low-income and under-resourced families. Of the 18 parishes we serve, 11 are Health Services and Resources Administration (HRSA) Health Professional Shortage Areas. Mary Bird Perkins' early detection and education program efficiently increases both access to cancer screenings and health literacy for thousands of medically underserved adults. We help save and extend the lives of individuals affected by cancer by finding tumors early, which allows those we serve additional time to work, parent, volunteer, and engage in other activities that enrich under-resourced communities. For patients without insurance or facing other barriers to healthcare, an "all clear" health status provides the peace of mind to carry on with their lives.

Measuring Program Effectiveness & Collecting Outcomes Data

Five key questions drive our evaluation of programmatic effectiveness and success:

1. Are we using evidence-based best practices for cancer screening and outreach to medically underserved adults?
2. Are we reaching the targeted population(s)?
3. Are we effective in increasing screening rates and compliance, as well as reducing late-stage diagnosis among the underserved?
4. Is our approach cost effective?
5. Does the program ensure timely follow-up of abnormal findings in order to transition participants quickly into treatment, if diagnosed?

Implementation of evidence-based practices has improved the performance of our early detection program. For example, the Community Preventive Services Task Force promotes reminder

systems to increase breast mammography and colorectal cancer screening.[3] We document three reminder calls for participants to return colorectal kits [fecal immunochemical test (FIT) kits] and two reminder calls for annual mammograms. One of the most preventable among the more common cancers, colon cancer affects Louisiana citizens at particularly high rates, so Mary Bird Perkins enhanced its strategy for colorectal screenings in 2012. Each month, we spend additional time educating those at highest risk for this disease, those with a personal or family history of polyps and colon cancer, and minority patients over age 50 who have never been screened and distributing FIT kits to those at highest and average risk. This additional education and the reminder phone calls increased our return rates from 46 percent to 57 percent from 2012 to 2013.

Our highest priority for data analysis, however, is to ensure we are reaching our goal of serving those patients facing barriers to healthcare. Analyses of aggregated participant demographic profiles demonstrate that we are effective in attracting these at-risk patients, including patients lacking health insurance and those more likely to experience disparate outcomes because of race and/or ethnicity. For example, between January 2010 and September 2016, of patients screened 59 percent (n=45,618) were uninsured and 51 percent were minorities (a group often characterized with worse cancer outcomes). Of the uninsured, 21 percent of those screened required navigation and 214 uninsured individuals were diagnosed with cancer. Approximately 48 percent of the navigated screening participants were minorities and 108 were diagnosed with cancer.

Over the life of the early detection program, we have developed numerous measures of effectiveness, including cost studies. Our average cost per community-based early detection event, during which we routinely screen 35 to 40 adults, is between $4,000 to $9,000. This covers the costs for:

- Personnel
- Outreach and awareness efforts
- Fuel
- Regular clinic maintenance
- Screening exams, such as mammograms, colorectal FIT kits, and PSA tests.

In 2016, the cost per adult screened (which also includes follow-up diagnostic tests) averaged $206, depending on the type of cancer screening and follow-up required. This is less than the cost of an office visit at clinics and physician offices for these same services. Some screening events attract more than 100 participants, which further decreases the cost per participant.

Mary Bird Perkins Cancer Center also monitors compliance with annual cancer screenings by previously screened individuals.

The Center offers free cancer screening for five types of cancer, including skin, breast, colorectal, oral cavity, and prostate.

Table 1. Early Detection Program Outcomes, 2015

	BREAST	SKIN	PROSTATE	COLORECTAL	ORAL	TOTAL
Total Participants	3,858	1,875	850	1,190 (56%*)		8055
Total Events	99	65	30	127	8	329
Participants Never Screened	886 (23%)	1251 (67%)	221 (26%)	686 (58%)	250 (87%)	3294 (41%)
Participants Navigated (abnormal)	1225 (32%)	179 (10%)	62 (7%)	33 (3%)	12 (4%)	1511 (19%)
Participants Uninsured	2663 (69%)	551 (29%)	242 (28%)	492 (41%)	100 (35%)	4048 (50%)
Minority Participants	2283 (59%)	648 (35%)	507 (60%)	600 (50%)	163 (58%)	4201 (52%)
Diagnosis of Cancer	36	32	2	0	0	70

* Percentage in parentheses represents the return rate

Annual compliance demonstrates patients' understanding of recommended screening guidelines (one of our educational goals) and the confidence they have in our program. Since 2010, more than 63 percent of screening participants have been screened by our early detection program more than once. Because of demand and available funding, we are performing more breast cancer screening events and, as a result, finding more breast cancers than other diseases. Over the last six years, 50 percent of these screening participants have returned for a mammogram at least once.

We continue to layer summative and formative measures as effective screening outreach practices emerge. Additionally, we have developed a customized screening-tracking database that allows the cancer center to capture:

- Participant demographics
- Insurance status
- Length of time since last screening
- Abnormal findings
- Documentation of follow-up diagnostics.

At a minimum, we track the numbers of adults served, participant demographics, the number of screenings and communities served, and the types and numbers of cancers diagnosed. Analyses of these data sets ensure we continue to reach the target populations (see Table 1, above).

Improving Health Status Through Convenience

For many of the participants in our early detection program, a key barrier to accessing cancer screenings in a traditional setting is the time it takes to be screened, including time away from work or other obligations. Mary Bird Perkins uses its mobile medical clinics to bring culturally-appropriate best practices for cancer screening and prevention education directly to venues that are strategically and conveniently located in areas that are easily accessible and, at times, outside traditional clinic hours. Using this approach, we remove multiple geographic, structural, and psychological barriers to regular cancer screenings that often result in late-stage diagnosis. For most participants, our screenings are relatively quick and convenient, allowing them to maintain their regular schedule with minimal interruption. To ensure timeliness, we schedule appointments for breast cancer screenings, but work to accommodate walk-ups as our screening locations are often held in high-traffic areas that allow us to engage individuals' onsite. An additional convenience factor is our ability to offer participants more than one type of cancer screening at a single event.

Throughout the year, we offer multiple screenings at a single event, especially in rural areas. Our experience has shown that people are more likely to participate if they have access to multiple services at one time. In addition, for the past 10 years, Mary Bird Perkins–Our Lady of the Lake Cancer Center has hosted Fest for Life, a signature event designed to bring cancer awareness and screening access to the minority community. This event offers a festival-like atmosphere complete with live music, food, activities for children, and door prizes for those screened. This one-day family event, held on the parking lot of a local technology park, delivers more than 600 cancer screenings in a single day and focuses on screening awareness among ethnic minorities. It is a true community event that encourages families to create a culture of wellness. More than 100 community volunteers and partnering nonprofit organizations come together to make the annual Fest for Life event a success.

In addition to providing multiple screening opportunities

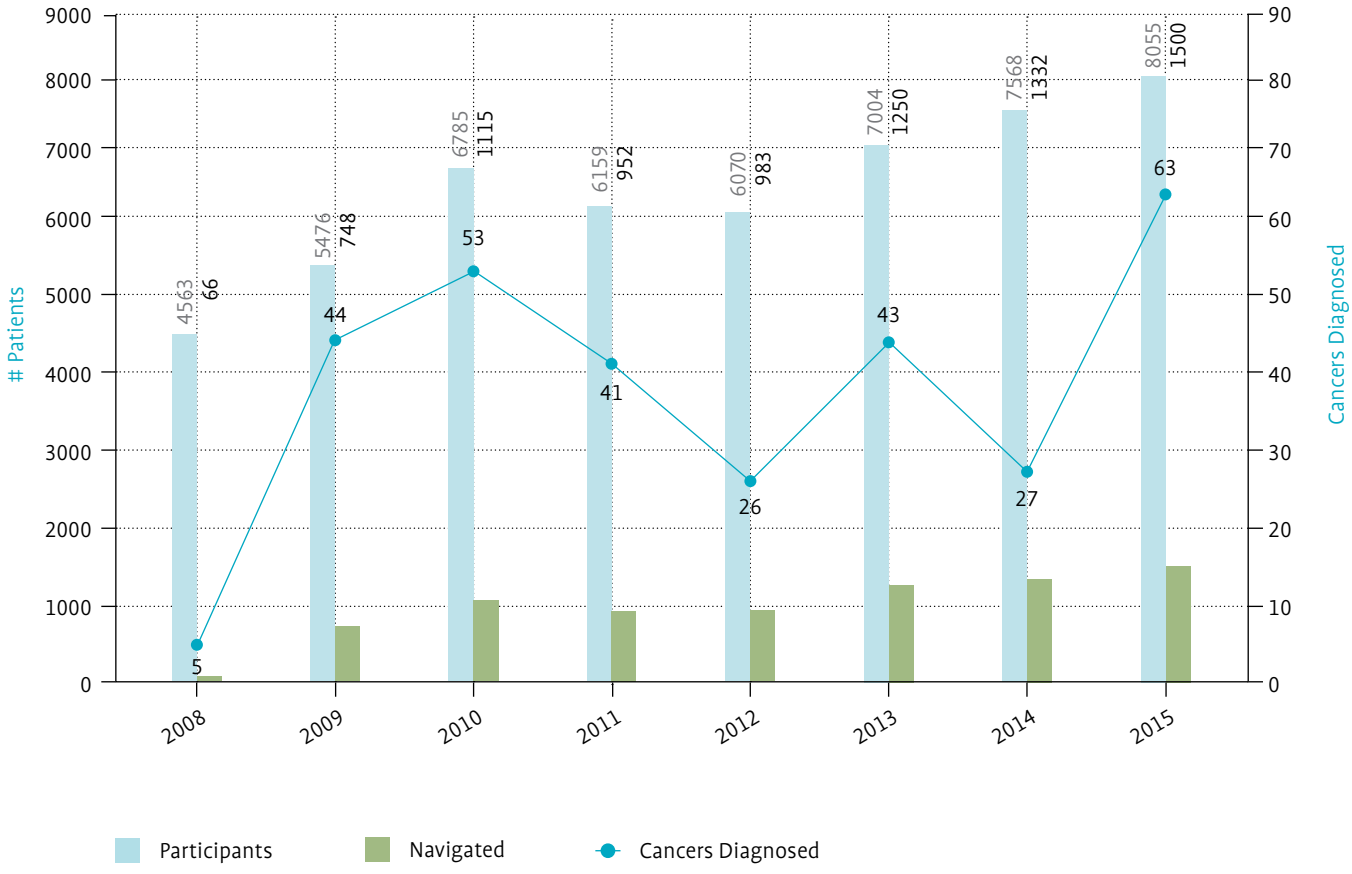
at times and locations that are convenient for our participants, our partnership with other local providers, such as Woman's Hospital in Baton Rouge, ensures that screening and follow-up processes are streamlined, allowing participants to save time and other resources. For example, to avoid duplication with mobile mammography resources, Mary Bird Perkins has a long-standing partnership with Woman's Hospital for breast screening events (99 events in 2015). Although mobile mammography is a common delivery strategy in the U.S., our partnership has provided more than 32,000 free breast screenings since the inception of the early detection program, with follow-up, allowing each organization to maximize resources and areas of strength.

Woman's Hospital's mobile mammography clinic and Mary Bird Perkins' mobile medical clinics park side-by-side at each breast screening. Mary Bird Perkins provides publicity and recruitment, a physician for clinical breast exams, physician orders if mammograms are needed, and patient navigation services. Woman's Hospital delivers on-site screening mammograms and follow-up tests at the hospital. We leverage Woman's Hospital's participation in the Louisiana Breast and Cervical Health Program to cover eligible women (ages 50 to 64 with no insurance) and follow-up diagnostics, along with additional funding administered by both organizations. In 2015, approximately 3,858 women were screened for breast cancer through our partnership, with more than 32 percent navigated for abnormal findings, and 36 individuals diagnosed with breast cancer and transitioned into treatment.

Improving Health Status Through Patient Navigation

Delays along the cancer continuum can have a negative effect on survivorship. Research shows that women without insurance, who are diagnosed with breast cancer often delay treatment, which can compromise outcomes. Our patient navigation model promotes timely diagnosis and treatment and aims to ensure seamless, coordinated care and services. Patients with a screening abnormality are contacted by a patient navigator and supported

Figure 2. Patient Navigation, 2008–2015



Participants are screened by physicians in a mobile clinic environment. Navigation services are provided to patients who receive an abnormal finding to ensure they receive the necessary follow-up care.

until the abnormal finding is resolved in a timely manner. When necessary, the navigator works with other providers, including safety-net hospitals, to assist uninsured and underinsured patients in receiving further follow-up exams. When participants do not qualify for any assistance programs, the early detection program is billed for diagnostic exams, such as breast biopsies and colonoscopies. Our partner hospitals ensure participants diagnosed with cancer are transitioned into treatment, if necessary.

Patient navigators assist patients and their families by guiding them through the complex healthcare systems. On average, approximately 17 percent of all persons screened receive navigation services (Figure 2, left). For example, from 2011 through June 2015, breast screening participants with an abnormal finding in the early detection program have had an average of six days to resolution of any finding, which strongly exceeds national standards. In fact, the CDC recommended performance standard is less than 60 days.[4]

To ensure effective communication between the navigator and the screening participants, Mary Bird Perkins uses an anonymous, mail-back survey for each navigated screening participant. Since 2009, our patient survey results demonstrate that those we serve would recommend our navigation services to others more than 99 percent of the time.

Improving Health Status through Innovation

Peter Drucker's seven opportunities for innovation include "innovation based upon process need—perfecting a process that already exists, replacing a link that is weak, or supplying a link that's missing."[5] To save lives among those patients characterized with disparate cancer outcomes, patients most often affected by a fragmented health system, Mary Bird Perkins continues to innovate to enhance its early detection and education program. In the program's early years, for example, we increased access by moving screening events from federal clinics and community health facilities to grocery stores, food banks, barber shops, and community centers in underserved communities. Our efforts in bringing screening out to communities was enhanced in 2006, when corporate and individual donors supported the purchase of the Early Bird, our mobile medical clinic, a key element in our current program.

ZIP Codes & Health Status

A person's ZIP Code is frequently more important to health status than insurance. Using data sources from Thomson Reuters, we use a tool that identifies the severity of health disparity for every ZIP Code in the U.S. The Community Needs Index (CNI) demonstrates the link between community need, access to care, and preventable hospitalizations, which enables us to pinpoint neighborhoods most in need. The CNI score is an average of five scores that measure socioeconomic factors in the community including, income, cultural, education, insurance, and housing barriers. A score of 1.0 indicates a ZIP Code with the least need while a score of between 4.2 and 5.0 represents a ZIP Code with the highest, most immediate need.

Using the CNI tool, we have identified those ZIP Codes within Mary Bird Perkins' service area as having the highest, most

Pictured are members of 100 Black Men of Metro Baton Rouge, Ltd., a community group that has volunteered at the Center's screening events for many years, encouraging men to come to our annual prostate screening at a local barbershop. Volunteers and donors are critical to the Center's ability to provide free cancer screenings.

immediate need. There are 19 ZIP Codes with a score of 4.5-5, which is deemed the highest need. In 2013, Mary Bird Perkins chose to increase outreach, awareness, and screening locations in these ZIP Codes, especially in areas with significantly high incidence and mortality rates. As a result of our efforts, we experienced a 253 percent increase in the number of persons screened and a 175 percent increase in the number of cancers diagnosed. We achieved these improvements by increasing the number of screening events conducted in these ZIP Codes by 59 percent. We have also experienced an increased number of community partnerships in these regions, which has allowed us to reach even more people.

Moving Forward

For the past 15 years, Mary Bird Perkins has continuously grown its primary (to avert disease) and secondary (to detect illness early and intervene) prevention efforts throughout southeast Louisiana most recently through the use of its mobile medical clinics, the Early Birds I and II.

Going forward we will continue focusing our energies more on primary prevention through providing education and awareness to the community at large. We are also expanding our efforts into the corporate world. We recently launched a pilot focused on employers to provide education and screening services for their employees. The program provides tools to assist in the identification of cancer risk and education on the importance of cancer screening. The program also provides select screenings and navigation services, as well as the design of interventions that address the result of lifestyle choices that increase the risk of developing cancer, i.e., tobacco use, obesity, and physical inactivity.

Mary Bird Perkins remains committed to bridging the gap for those in need, one cancer screening at a time. OI

Renea Duffin, MPA, is vice president, Cancer Support and Outreach, Mary Bird Perkins Cancer Center, Baton Rouge, La.

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careers

RN NAVIGATOR & RN SUPERVISOR
Urbana, Illinois

At the Carle Foundation - Cancer Center, the RN Navigator 1) coordinates the delivery of coordinated care to the Inflammatory Bowel Disease (IBD) or GI Cancer patient population; 2) provides clinical expertise and program management for the inpatients and outpatients; and 3) serves as a liaison and resource to patients and staff members, as well as provides direct patient care.

The RN Supervisor manages nursing, CMA, and MA activities for the cancer center with multiple departments and provides clinical expertise in the nursing process.

Bachelors in Nursing required. RN in the State of Illinois and Basic Life Support. RN Navigator—GI Cancer and RN Supervisor also require ACLS, and Chemotherapy/Biotherapy Certifications. OCN Certification must be obtained within 2 years of start date. Minimum of 2 years in a related field required for RN Navigator; Minimum of 5 years required for RN Supervisor.

Apply online at *carle.org/careers.*

MANAGER, PSYCHO-SOCIAL ONCOLOGY SURVIVORSHIP PROGRAM
Annapolis, Maryland

The Manager, Psycho-Social Oncology oversees the Patient and Family Services program in the Anne Arundel Medical Center DeCesaris Cancer Institute. Responsibilities include:

- Collaborate with a multidisciplinary team to design, implement, and coordinate a viable and vibrant patient and family services program.
- Organize educational sessions for primary care and other community-based providers focused on best practices for psychosocial oncology.
- Develop research or outcomes measurements of our psycho-social programs.
- Provide clinical social work supervision and mentorship.

Requirements: Master's Degree in Social Work (OSW-C preferred); at least 2 years of progressive leadership or management skills in healthcare; certification to provide clinical social work supervision in MD; and minimum of 5 years of experience in medical social work.

Apply online at *aamcrccorp.peoplefluent.com/res_joblist.html.*

EXECUTIVE DIRECTOR, ONCOLOGY CLINICAL SERVICES
Atlanta, Georgia

At Piedmont Cancer, the Executive Director will:

1. Identify and execute on Piedmont Cancer's strategic plan for growth, leveraging Centers of Excellence and regional cancer centers across the Atlanta metropolitan region.
2. Measure and maintain profitability of the cancer program. Oversee the Monthly Operating Report.
3. Direct oversight of the MD Anderson Physician Network relationship.
4. Direct oversight of Facility, Ancillary, and Business staff and functions.
5. Collaborate with the Chief of Oncology Services, Director of Oncology Care Coordination, and Regional Cancer Center dyad leaders to optimize care delivery functions.

Requirements: MBA or MHA; at least 5 years in a position at the level of director or above with track record of success in leading the operations of a cancer program with medical, radiation, surgical, and ancillary components.

Apply online at *piedmontcareers.org/job-post.php?job_id=1605133.*

EXECUTIVE DIRECTOR
Huntington, West Virginia

The Executive Director of the Edwards Comprehensive Cancer Center (ECCC) provides leadership over the cancer services of Cabell Huntington Hospital, including, but not limited to: Breast Diagnostic Center, Breast Imaging Center, Cancer Center, Adult and Pediatric Infusion Centers, Tumor Registry, Clinical Trials, and Radiation Oncology. Accountable for the quality of care and financial performance of the service line, as well as community, employee, and physician engagement. Works closely with the Joan C. Edwards School of Medicine at Marshall University.

Requirements: Bachelor's degree required; Master's degree strongly preferred (equivalent experience may be considered); at least 5 years of progressive experience managing an academic-based cancer program or appropriate service in a hospital setting and 7 years experience with a clinical program; a demonstrated track record as an effective manager with a participatory style experience with building awareness among referring physicians in primary and secondary referral market areas.

Apply online at *chhjobs.com.*

The Healthy Forks Survivorship Series: Fighting cancer one fork at a time

BY JENNIFER FITZGIBBON, MS, RD, CSO, CDN

In the fall of 2014, clinical staff leaders got together at Stony Brook Cancer Center, Stony Brook, N.Y., and decided to develop a nutritional survivorship program for patients and family members. While education is important, the impact of any program is only viable if the material taught easily translates to practical solutions. Our team created the Healthy Forks Survivorship Program. Since inception, we have found the program to be non-intimidating, easy to manage, fun to do, and—most important—one that offers each participant a sense of great accomplishment.

Participant Feedback

"Thank you both so much for the nutrition and fitness seminars. You were so informative, friendly, and professional, and I learned so much from you both!"

"I have been trying to exercise more and sit less, and have incorporated a lot more affordable organic produce into our daily meals."

"You guys are awesome! Keep up the great work! You provide such a valuable service for survivors, thank you! I feel more energetic, not overwhelmed, and uplifted as a result!"

Our Program

The mission of Healthy Forks is to provide participants with resources to understand the necessity of providing healthy meals, at a reasonable cost, for themselves and their families, while increasing their mindfulness of the importance of stress reduction and physical activity and mental stimulation.

Cancer patients must juggle doctors' appointments, combat treatment side effects, and face financial challenges—all while trying to maintain a sense of normalcy. Because Stony Brook is a state-funded healthcare institution, many of our patients have limited resources, while others are unable to access healthcare insurance or subsidies due to their immigrant status. Approximately 40 percent of our patients require some type of financial assistance. It is vital to offer these patients and their families the resources needed to practice a healthy lifestyle.

Most payers do not cover nutritional counseling. Stony Brook offers its Healthy Forks program free of charge to patients and families in the hope that maintaining a better nutritional status will allow patients to experience fewer treatment complications, as well as reduce the incidence of obesity and malnutrition during and after treatment.

The Health Forks program is divided into three one-hour sessions.

Session 1

This session features an overview of nutrition basics and an antioxidant healthy smoothie demonstration by our oncology dietitian who reviews:

- Nutritional influences with diseases
- The importance of eating a plant-based diet
- The role of antioxidants
- Body weight and shape factors
- Simple measuring tools.

The oncology dietitian also reviews healthy goals and helps attendees identify ways to achieve these recommendations. Each participant receives a Healthy Forks Nutrition Survivorship booklet, which is a comprehensive resource for cancer patients and survivors. This physician-reviewed booklet includes American Institute of Cancer Research recommendations, weight issues, food controversies, product labeling, physical activity, healthy meal plans, and more.

Session 2

The second session focuses on mental relaxation, with a discussion by our physical therapist about inflammation in the body. Participants are invited to take part in 5 Minutes of Fitness, an exercise that gets everyone moving while still remaining in their chairs. All movements are non-intimidating and modified for each participant as needed. Each participant receives "crunchy" anti-inflammatory snacks and samples of green tea and water.

Session 3

Led again by our oncology dietitian, this last session provides a tour of the local supermarket to help participants learn how to read product labels and purchase quality ingredients at a reasonable price. We have found that some cancer patients are vulnerable to media-hyped nutritional products and habits, and a simple visit to a local supermarket can help dispel many nutritional myths and optimize eating habits.

Our Participants

We estimate that between 10 to 20 oncology patients (18 years of age and older) and family members attend each session of the Healthy Forks program. The demographics include primarily Caucasian, Hispanic, and African American adults. Following each session, participants are asked to complete surveys, which help us to continually assess the success of our Health Forks program (see box at left). OI

Jennifer Fitzgibbon, MS, RD, CSO, CDN, is a registered oncology dietitian at Stony Brook Cancer Center, Stony Brook, N.Y.

Engaging the Community

Stony Brook Cancer Center is the only cancer center in Suffolk County and is well known for its community outreach activities. Our professional staff is well versed in educational outreach and highly-trained in their specialties. Our collaboration with community organizations offers Stony Brook Cancer Center the opportunity to present its programs to a wider audience and to engage college students and community members in cancer center activities. Our outreach efforts allow program participants the opportunity to meet individually with various members of the multidisciplinary cancer care team, including a nutritionist, physical therapist, patient advocate, and social worker, all of whom reinforce the educational materials offered. The Healthy Forks program, specifically, provides participants with practical information, healthy recipes, and instructions for easy and quick, hands-on meal preparation—knowledge to last a lifetime.

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All members of the cancer care team who deal with oncology business and reimbursement will benefit from these meetings. Attend the meeting that's most convenient to you for a comprehensive look at oncology reimbursement issues, tools to strengthen your program, and information to help you weather market changes. Gain a full-spectrum perspective in just one day of sessions:

- Hear the latest trends in oncology coding and billing, navigate new regulations in 2017, and gain strategies to overcome reimbursement obstacles.
- Learn how to smoothly transition to new quality data reporting requirements under the Merit-Based Incentive Program System (MIPS).
- Gain practical management how-to's for increasing efficiencies through the proper management of financial data.
- Hear strategies for the practical application of radiation oncology CPT codes in physician office and hospital settings.
- Gain insight to optimize insurance coverage by expanding access and eliminating barriers—helping to save money for your patients and program

Best of all, these essential meetings are free to ACCC members. Non-members are invited to join us at the low registration rate of $69. OI

SAVE THE DATES!

April 13, 2017
Hyatt Regency Minneapolis
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April 25, 2017
The Westin Tampa Harbour Island
Tampa, FL

May 18, 2017
Omaha, Nebraska Embassy Suites by Hilton Omaha Downtown Old Market
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Register for these free meetings at:
accc-cancer.org/reimbursementmeeting.

ACCC Welcomes Its Newest Members

Aurora St. Luke's Medical Center
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Milwaukee, WI
Delegate Rep:
Marija Bjegovich-Weidman, RN, MSN
Website: aurorastlukes.org

Aurora BayCare Medical Center
Aurora Cancer Center
Green Bay, WI
Delegate Rep: Dhimant Patel, MD
Website: aurorabaycare.com

Cayuga Medical Center
Cayuga Cancer Center
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Delegate Rep: Ellen Dugan, MBA
Website: cayugamed.org

Lovelace Medical Center
Lovelace Cancer Care
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Delegate Rep: Christie White, MBA
Website: lovelacecancercare.com

Salish Cancer Center
Fife, WA
Delegate Rep: Ken Rarey
Website: salishcancercenter.com

ACCC Chapter Member
Nebraska Oncology Society
Lincoln, NE
Executive Director: Sarah Dunbar
Website: nebraskaoncology.org

Xtandi® (enzalutamide) 40 mg capsules

XTANDI® (enzalutamide) capsules for oral use
Initial U.S. Approval: 2012
BRIEF SUMMARY OF PRESCRIBING INFORMATION

The following is a brief summary. Please see the package insert for full prescribing information.

INDICATIONS AND USAGE

XTANDI is indicated for the treatment of patients with metastatic castration-resistant prostate cancer (CRPC).

CONTRAINDICATIONS

Pregnancy

XTANDI can cause fetal harm when administered to a pregnant woman based on its mechanism of action and findings in animals. XTANDI is not indicated for use in women. XTANDI is contraindicated in women who are or may become pregnant. If this drug is used during pregnancy, or if the patient becomes pregnant while taking this drug, apprise the patient of the potential hazard to the fetus and the potential risk for pregnancy loss.

WARNINGS AND PRECAUTIONS

Seizure

In Study 1, which enrolled patients who previously received docetaxel, 7 of 800 (0.9%) patients treated with XTANDI experienced a seizure and no patients treated with placebo experienced a seizure. Seizure occurred from 31 to 603 days after initiation of XTANDI. In Study 2, 1 of 871 (0.1%) chemotherapy-naive patients treated with XTANDI and 1 of 844 (0.1%) patients treated with placebo experienced a seizure. Patients experiencing seizure were permanently discontinued from therapy and all seizure events resolved. There is no clinical trial experience re-administering XTANDI to patients who experienced seizure.

Limited safety data are available in patients with predisposing factors for seizure because these patients were generally excluded from the trials. These exclusion criteria included a history of seizure, underlying brain injury with loss of consciousness, transient ischemic attack within the past 12 months, cerebral vascular accident, brain metastases, and brain arteriovenous malformation. Study 1 excluded the use of concomitant medications that may lower the seizure threshold, whereas Study 2 permitted the use of these medications.

Because of the risk of seizure associated with XTANDI use, patients should be advised of the risk of engaging in any activity where sudden loss of consciousness could cause serious harm to themselves or others. Permanently discontinue XTANDI in patients who develop a seizure during treatment.

Posterior Reversible Encephalopathy Syndrome (PRES)

There have been reports of posterior reversible encephalopathy syndrome (PRES) in patients receiving XTANDI. PRES is a neurological disorder which can present with rapidly evolving symptoms including seizure, headache, lethargy, confusion, blindness, and other visual and neurological disturbances, with or without associated hypertension. A diagnosis of PRES requires confirmation by brain imaging, preferably magnetic resonance imaging (MRI). Discontinue XTANDI in patients who develop PRES.

ADVERSE REACTIONS

Clinical Trial 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.

Two randomized clinical trials enrolled patients with metastatic prostate cancer that has progressed on androgen deprivation therapy (GnRH therapy or bilateral orchiectomy), a disease setting that is also defined as metastatic CRPC. In both studies, patients received XTANDI 160 mg orally once daily in the active treatment arm or placebo in the control arm. All patients continued androgen deprivation therapy. Patients were allowed, but not required, to take glucocorticoids.

The most common adverse reactions (≥ 10%) that occurred more commonly (≥ 2% over placebo) in the XTANDI-treated patients from the two randomized clinical trials were asthenia/fatigue, back pain, decreased appetite, constipation, arthralgia, diarrhea, hot flush, upper respiratory tract infection, peripheral edema, dyspnea, musculoskeletal pain, weight decreased, headache, hypertension, and dizziness/vertigo.

Study 1: Metastatic Castration-Resistant Prostate Cancer Following Chemotherapy

Study 1 enrolled 1199 patients with metastatic CRPC who had previously received docetaxel. The median duration of treatment was 8.3 months with XTANDI and 3.0 months with placebo. During the trial, 48% of patients on the XTANDI arm and 46% of patients on the placebo arm received glucocorticoids.

Grade 3 and higher adverse reactions were reported among 47% of XTANDI-treated patients and 53% of placebo-treated patients. Discontinuations due to adverse events were reported for 16% of XTANDI-treated patients and 18% of placebo-treated patients. The most common adverse reaction leading to treatment discontinuation was seizure, which occurred in 0.9% of the XTANDI-treated patients compared to none (0%) of the placebo-treated patients. Table 1 shows adverse reactions reported in Study 1 that occurred at a ≥ 2% higher frequency in the XTANDI arm compared to the placebo arm.

Table 1. Adverse Reactions in Study 1

	XTANDI N = 800		Placebo N = 399	
	Grade 1-4[a] (%)	Grade 3-4 (%)	Grade 1-4 (%)	Grade 3-4 (%)
General Disorders				
Asthenic Conditions[b]	50.6	9.0	44.4	9.3
Peripheral Edema	15.4	1.0	13.3	0.8
Musculoskeletal And Connective Tissue Disorders				
Back Pain	26.4	5.3	24.3	4.0
Arthralgia	20.5	2.5	17.3	1.8
Musculoskeletal Pain	15.0	1.3	11.5	0.3
Muscular Weakness	9.8	1.5	6.8	1.8
Musculoskeletal Stiffness	2.6	0.3	0.3	0.0
Gastrointestinal Disorders				
Diarrhea	21.8	1.1	17.5	0.3
Vascular Disorders				
Hot Flush	20.3	0.0	10.3	0.0
Hypertension	6.4	2.1	2.8	1.3
Nervous System Disorders				
Headache	12.1	0.9	5.5	0.0
Dizziness[c]	9.5	0.5	7.5	0.5
Spinal Cord Compression and Cauda Equina Syndrome	7.4	6.6	4.5	3.8
Paresthesia	6.6	0.0	4.5	0.0
Mental Impairment Disorders[d]	4.3	0.3	1.8	0.0
Hypoesthesia	4.0	0.3	1.8	0.0
Infections And Infestations				
Upper Respiratory Tract Infection[e]	10.9	0.0	6.5	0.3
Lower Respiratory Tract And Lung Infection[f]	8.5	2.4	4.8	1.3
Psychiatric Disorders				
Insomnia	8.8	0.0	6.0	0.5
Anxiety	6.5	0.3	4.0	0.0
Renal And Urinary Disorders				
Hematuria	6.9	1.8	4.5	1.0
Pollakiuria	4.8	0.0	2.5	0.0
Injury, Poisoning And Procedural Complications				
Fall	4.6	0.3	1.3	0.0
Non-pathologic Fractures	4.0	1.4	0.8	0.3
Skin And Subcutaneous Tissue Disorders				
Pruritus	3.8	0.0	1.3	0.0
Dry Skin	3.5	0.0	1.3	0.0

Table 1. Adverse Reactions in Study 1 (cont.)

Respiratory Disorders				
Epistaxis	3.3	0.1	1.3	0.3

a CTCAE v4
b Includes asthenia and fatigue.
c Includes dizziness and vertigo.
d Includes amnesia, memory impairment, cognitive disorder, and disturbance in attention.
e Includes nasopharyngitis, upper respiratory tract infection, sinusitis, rhinitis, pharyngitis, and laryngitis.
f Includes pneumonia, lower respiratory tract infection, bronchitis, and lung infection.

Study 2: Chemotherapy-naive Metastatic Castration-Resistant Prostate Cancer

Study 2 enrolled 1717 patients with metastatic CRPC who had not received prior cytotoxic chemotherapy, of whom 1715 received at least one dose of study drug. The median duration of treatment was 17.5 months with XTANDI and 4.6 months with placebo. Grade 3-4 adverse reactions were reported in 44% of XTANDI-treated patients and 37% of placebo-treated patients. Discontinuations due to adverse events were reported for 6% of XTANDI-treated patients and 6% of placebo-treated patients. The most common adverse reaction leading to treatment discontinuation was fatigue/asthenia, which occurred in 1% of patients on each treatment arm. Table 2 includes adverse reactions reported in Study 2 that occurred at a ≥ 2% higher frequency in the XTANDI arm compared to the placebo arm.

Table 2. Adverse Reactions in Study 2

	XTANDI N = 871		Placebo N = 844	
	Grade 1-4[a] (%)	Grade 3-4 (%)	Grade 1-4 (%)	Grade 3-4 (%)
General Disorders				
Asthenic Conditions[b]	46.9	3.4	33.0	2.8
Peripheral Edema	11.5	0.2	8.2	0.4
Musculoskeletal And Connective Tissue Disorders				
Back Pain	28.6	2.5	22.4	3.0
Arthralgia	21.4	1.6	16.1	1.1
Gastrointestinal Disorders				
Constipation	23.2	0.7	17.3	0.4
Diarrhea	16.8	0.3	14.3	0.4
Vascular Disorders				
Hot Flush	18.0	0.1	7.8	0.0
Hypertension	14.2	7.2	4.1	2.3
Nervous System Disorders				
Dizziness[c]	11.3	0.3	7.1	0.0
Headache	11.0	0.2	7.0	0.4
Dysgeusia	7.6	0.1	3.7	0.0
Mental Impairment Disorders[d]	5.7	0.0	1.3	0.1
Restless Legs Syndrome	2.1	0.1	0.4	0.0
Respiratory Disorders				
Dyspnea[e]	11.0	0.6	8.5	0.6
Infections And Infestations				
Upper Respiratory Tract Infection[f]	16.4	0.0	10.5	0.0
Lower Respiratory Tract And Lung Infection[g]	7.9	1.5	4.7	1.1
Psychiatric Disorders				
Insomnia	8.2	0.1	5.7	0.0
Renal And Urinary Disorders				
Hematuria	8.8	1.3	5.8	1.3
Injury, Poisoning And Procedural Complications				
Fall	12.7	1.6	5.3	0.7
Non-Pathological Fracture	8.8	2.1	3.0	1.1
Metabolism and Nutrition Disorders				
Decreased Appetite	18.9	0.3	16.4	0.7
Investigations				
Weight Decreased	12.4	0.8	8.5	0.2
Reproductive System and Breast Disorders				
Gynecomastia	3.4	0.0	1.4	0.0

Table 2. Adverse Reactions in Study 2 (cont.)

a	CTCAE v4
b	Includes asthenia and fatigue.
c	Includes dizziness and vertigo.
d	Includes amnesia, memory impairment, cognitive disorder, and disturbance in attention.
e	Includes dyspnea, exertional dyspnea, and dyspnea at rest.
f	Includes nasopharyngitis, upper respiratory tract infection, sinusitis, rhinitis, pharyngitis, and laryngitis.
g	Includes pneumonia, lower respiratory tract infection, bronchitis, and lung infection.

Laboratory Abnormalities

In the two randomized clinical trials, Grade 1-4 neutropenia occurred in 15% of patients treated with XTANDI (1% Grade 3-4) and in 6% of patients treated with placebo (0.5% Grade 3-4). The incidence of Grade 1-4 thrombocytopenia was 6% of patients treated with XTANDI (0.3% Grade 3-4) and 5% of patients treated with placebo (0.5% Grade 3-4). Grade 1-4 elevations in ALT occurred in 10% of patients treated with XTANDI (0.2% Grade 3-4) and 16% of patients treated with placebo (0.2% Grade 3-4). Grade 1-4 elevations in bilirubin occurred in 3% of patients treated with XTANDI (0.1% Grade 3-4) and 2% of patients treated with placebo (no Grade 3-4).

Infections

In Study 1, 1% of patients treated with XTANDI compared to 0.3% of patients treated with placebo died from infections or sepsis. In Study 2, 1 patient in each treatment group (0.1%) had an infection resulting in death.

Falls and Fall-related Injuries

In the two randomized clinical trials, falls including fall-related injuries, occurred in 9% of patients treated with XTANDI compared to 4% of patients treated with placebo. Falls were not associated with loss of consciousness or seizure. Fall-related injuries were more severe in patients treated with XTANDI and included non-pathologic fractures, joint injuries, and hematomas.

Hypertension

In the two randomized trials, hypertension was reported in 11% of patients receiving XTANDI and 4% of patients receiving placebo. No patients experienced hypertensive crisis. Medical history of hypertension was balanced between arms. Hypertension led to study discontinuation in < 1% of patients in each arm.

Post-Marketing Experience

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

Neurological Disorders: posterior reversible encephalopathy syndrome (PRES)

DRUG INTERACTIONS

Drugs that Inhibit CYP2C8

Co-administration of a strong CYP2C8 inhibitor (gemfibrozil) increased the composite area under the plasma concentration-time curve (AUC) of enzalutamide plus N-desmethyl enzalutamide by 2.2-fold. Co-administration of XTANDI with strong CYP2C8 inhibitors should be avoided if possible. If co-administration of XTANDI with a strong CYP2C8 inhibitor cannot be avoided, reduce the dose of XTANDI.

Drugs that Induce CYP3A4

Co-administration of rifampin (strong CYP3A4 inducer and moderate CYP2C8 inducer) decreased the composite AUC of enzalutamide plus N-desmethyl enzalutamide by 37%. Co-administration of strong CYP3A4 inducers (e.g., carbamazepine, phenobarbital, phenytoin, rifabutin, rifampin, rifapentine) with XTANDI should be avoided if possible. St John's wort may decrease enzalutamide exposure and should be avoided. If co-administration of a strong CYP3A4 inducer with XTANDI cannot be avoided, increase the dose of XTANDI.

Effect of XTANDI on Drug Metabolizing Enzymes

Enzalutamide is a strong CYP3A4 inducer and a moderate CYP2C9 and CYP2C19 inducer in humans. At steady state, XTANDI reduced the plasma exposure to midazolam (CYP3A4 substrate), warfarin (CYP2C9 substrate), and omeprazole (CYP2C19 substrate). Concomitant use of XTANDI with narrow therapeutic index drugs that are metabolized by CYP3A4 (e.g., alfentanil, cyclosporine, dihydroergotamine, ergotamine, fentanyl, pimozide, quinidine, sirolimus and tacrolimus), CYP2C9 (e.g., phenytoin, warfarin) and CYP2C19 (e.g., S-mephenytoin) should be avoided, as enzalutamide may decrease their exposure. If co-administration with warfarin cannot be avoided, conduct additional INR monitoring.

USE IN SPECIFIC POPULATIONS

Pregnancy– Pregnancy Category X.

Risk Summary

XTANDI can cause fetal harm when administered to a pregnant woman based on its mechanism of action and findings in animals. While there are no human data on the use of XTANDI in pregnancy and XTANDI is not indicated for use in women, it is important to know that maternal use of an androgen receptor inhibitor could affect development of the fetus. Enzalutamide caused embryo-fetal toxicity in mice at exposures that were lower than in patients receiving the recommended dose. XTANDI is contraindicated in women who are or may become pregnant while receiving the drug. If this drug is used during pregnancy, or if the patient becomes pregnant while taking this drug, apprise the patient of the potential hazard to the fetus and the potential risk for pregnancy loss. Advise females of reproductive potential to avoid becoming pregnant during treatment with XTANDI.

Animal Data

In an embryo-fetal developmental toxicity study in mice, enzalutamide caused developmental toxicity when administered at oral doses of 10 or 30 mg/kg/day throughout the period of organogenesis (gestational days 6-15). Findings included embryo-fetal lethality (increased post-implantation loss and resorptions) and decreased anogenital distance at ≥ 10 mg/kg/day, and cleft palate and absent palatine bone at 30 mg/kg/day. Doses of 30 mg/kg/day caused maternal toxicity. The doses tested in mice (1, 10 and 30 mg/kg/day) resulted in systemic exposures (AUC) approximately 0.04, 0.4 and 1.1 times, respectively, the exposures in patients. Enzalutamide did not cause developmental toxicity in rabbits when administered throughout the period of organogenesis (gestational days 6-18) at dose levels up to 10 mg/kg/day (approximately 0.4 times the exposures in patients based on AUC).

Nursing Mothers

XTANDI is not indicated for use in women. It is not known if enzalutamide is excreted in human milk. Because many drugs are excreted in human milk, and because of the potential for serious adverse reactions in nursing infants from XTANDI, a decision should be made to either discontinue nursing, or discontinue the drug taking into account the importance of the drug to the mother.

Pediatric Use

Safety and effectiveness of XTANDI in pediatric patients have not been established.

Geriatric Use

Of 1671 patients who received XTANDI in the two randomized clinical trials, 75% were 65 and over, while 31% were 75 and over. No overall differences in safety or effectiveness were observed between these patients and younger patients. Other reported clinical experience has not identified differences in responses between the elderly and younger patients, but greater sensitivity of some older individuals cannot be ruled out.

Patients with Renal Impairment

A dedicated renal impairment trial for XTANDI has not been conducted. Based on the population pharmacokinetic analysis using data from clinical trials in patients with metastatic CRPC and healthy volunteers, no significant difference in enzalutamide clearance was observed in patients with pre-existing mild to moderate renal impairment (30 mL/min ≤ creatinine clearance [CrCL] ≤ 89 mL/min) compared to patients and volunteers with baseline normal renal function (CrCL ≥ 90 mL/min). No initial dosage adjustment is necessary for patients with mild to moderate renal impairment. Severe renal impairment (CrCL < 30 mL/min) and end-stage renal disease have not been assessed.

Patients with Hepatic Impairment

Dedicated hepatic impairment trials compared the composite systemic exposure of enzalutamide plus N-desmethyl enzalutamide in volunteers with baseline mild, moderate, or severe hepatic impairment (Child-Pugh Class A, B, or C, respectively) versus healthy controls with normal hepatic function. The composite AUC of enzalutamide plus N-desmethyl enzalutamide was similar in volunteers with mild, moderate, or severe baseline hepatic impairment compared to volunteers with normal hepatic function. No initial dosage adjustment is necessary for patients with baseline mild, moderate, or severe hepatic impairment.

OVERDOSAGE

In the event of an overdose, stop treatment with XTANDI and initiate general supportive measures taking into consideration the half-life of 5.8 days. In a dose escalation study, no seizures were reported at ≤ 240 mg daily, whereas 3 seizures were reported, 1 each at 360 mg, 480 mg, and 600 mg daily. Patients may be at increased risk of seizure following an overdose.

NONCLINICAL TOXICOLOGY

Carcinogenesis, Mutagenesis, Impairment of Fertility

Long-term animal studies have not been conducted to evaluate the carcinogenic potential of enzalutamide.

Enzalutamide did not induce mutations in the bacterial reverse mutation (Ames) assay and was not genotoxic in either the *in vitro* mouse lymphoma thymidine kinase (Tk) gene mutation assay or the *in vivo* mouse micronucleus assay.

Based on nonclinical findings in repeat-dose toxicology studies, which were consistent with the pharmacological activity of enzalutamide, male fertility may be impaired by treatment with XTANDI. In a 26-week study in rats, atrophy of the prostate and seminal vesicles was observed at ≥ 30 mg/kg/day (equal to the human exposure based on AUC). In 4-, 13-, and 39-week studies in dogs, hypospermatogenesis and atrophy of the prostate and epididymides were observed at ≥ 4 mg/kg/day (0.3 times the human exposure based on AUC).

Manufactured by: Catalent Pharma Solutions, LLC, St. Petersburg, FL 33716

Manufactured for and Distributed by: Astellas Pharma US, Inc., Northbrook, IL 60062

Marketed by:
Astellas Pharma US, Inc., Northbrook, IL 60062
Medivation, Inc., San Francisco, CA 94105

Revised: October 2015

15C018-XTA

Rx Only

076-1200-PM

Indication and Important Safety Information

Indication

XTANDI (enzalutamide) capsules is indicated for the treatment of patients with metastatic castration-resistant prostate cancer (CRPC).

Important Safety Information

Contraindications XTANDI is not indicated for women and is contraindicated in women who are or may become pregnant. XTANDI can cause fetal harm when administered to a pregnant woman.

Warnings and Precautions

Seizure In Study 1, conducted in patients with metastatic castration-resistant prostate cancer (CRPC) who previously received docetaxel, seizure occurred in 0.9% of XTANDI patients and 0% of placebo patients. In Study 2, conducted in patients with chemotherapy-naive metastatic CRPC, seizure occurred in 0.1% of XTANDI patients and 0.1% of placebo patients. There is no clinical trial experience re-administering XTANDI to patients who experienced a seizure, and limited safety data are available in patients with predisposing factors for seizure. Study 1 excluded the use of concomitant medications that may lower threshold; Study 2 permitted the use of these medications. Because of the risk of seizure associated with XTANDI use, patients should be advised of the risk of engaging in any activity during which sudden loss of consciousness could cause serious harm to themselves or others. Permanently discontinue XTANDI in patients who develop a seizure during treatment.

Posterior Reversible Encephalopathy Syndrome (PRES) In post approval use, there have been reports of PRES in patients receiving XTANDI. PRES is a neurological disorder which can present with rapidly evolving symptoms including seizure, headache, lethargy, confusion, blindness, and other visual and neurological disturbances, with or without associated hypertension. A diagnosis of PRES requires confirmation by brain imaging, preferably MRI. Discontinue XTANDI in patients who develop PRES.

Adverse Reactions

The most common adverse reactions (≥ 10%) reported from two combined clinical studies that occurred more commonly (≥ 2% over placebo) in XTANDI patients were asthenia/fatigue, back pain, decreased appetite, constipation, arthralgia, diarrhea, hot flush, upper respiratory tract infection, peripheral edema, dyspnea, musculoskeletal pain, weight decreased, headache, hypertension, and dizziness/vertigo.

In Study 1, Grade 3 and higher adverse reactions were reported among 47% of XTANDI patients and 53% of placebo patients. Discontinuations due to adverse events were reported for 16% of XTANDI patients and 18% of placebo patients. In Study 2, Grade 3-4 adverse reactions were reported in 44% of XTANDI patients and 37% of placebo patients. Discontinuations due to adverse events were reported for 6% of both study groups.

- Lab Abnormalities: Grade 1-4 neutropenia occurred in 15% of XTANDI patients (1% Grade 3-4) and 6% of placebo patients (0.5% Grade 3-4). Grade 1-4 thrombocytopenia occurred in 6% of XTANDI patients (0.3% Grade 3-4) and 5% of placebo patients (0.5% Grade 3-4). Grade 1-4 elevations in ALT occurred in 10% of XTANDI patients (0.2% Grade 3-4) and 16% of placebo patients (0.2% Grade 3-4). Grade 1-4 elevations in bilirubin occurred in 3% of XTANDI patients (0.1% Grade 3-4) and 2% of placebo patients (no Grade 3-4).
- Infections: In Study 1, 1% of XTANDI patients compared to 0.3% of placebo patients died from infections or sepsis. In Study 2, 1 patient in each treatment group (0.1%) had an infection resulting in death.
- Falls (including fall-related injuries), occurred in 9% of XTANDI patients and 4% of placebo patients. Falls were not associated with loss of consciousness or seizure. Fall-related injuries were more severe in XTANDI patients, and included non-pathologic fractures, joint injuries, and hematomas.
- Hypertension occurred in 11% of XTANDI patients and 4% of placebo patients. No patients experienced hypertensive crisis. Medical history of hypertension was balanced between arms. Hypertension led to study discontinuation in < 1% of all patients.

Drug Interactions

Effect of Other Drugs on XTANDI Avoid strong CYP2C8 inhibitors, as they can increase the plasma exposure to XTANDI. If co-administration is necessary, reduce the dose of XTANDI.

Avoid strong CYP3A4 inducers as they can decrease the plasma exposure to XTANDI. If co-administration is necessary, increase the dose of XTANDI.

Effect of XTANDI on Other Drugs Avoid CYP3A4, CYP2C9, and CYP2C19 substrates with a narrow therapeutic index, as XTANDI may decrease the plasma exposures of these drugs. If XTANDI is co-administered with warfarin (CYP2C9 substrate), conduct additional INR monitoring.

Please see adjacent pages for Brief Summary of Full Prescribing Information.

References: 1. XTANDI [package insert]. Northbrook, IL: Astellas Pharma US, Inc. **2.** Beer TM, Armstrong AJ, Rathkopf DE, et al, for the PREVAIL Investigators. Enzalutamide in metastatic prostate cancer before chemotherapy. *N Engl J Med*. 2014;371(5):424-433.

astellas MEDIVATION

Xtandi® (enzalutamide) 40 mg capsules

XTANDI (enzalutamide) capsules is indicated for the treatment of patients with metastatic castration-resistant prostate cancer (CRPC).

TO EXTEND SURVIVAL[1]

23% reduction in risk of death with XTANDI + GnRH therapy vs placebo + GnRH therapy[†‡1]

- Co-primary endpoint, overall survival: (HR = 0.77 [95% CI, 0.67-0.88])[1]
- Median overall survival was 35.3 months (95% CI, 32.2-NR) with XTANDI + GnRH therapy vs 31.3 months (95% CI, 28.8-34.2) with placebo + GnRH therapy[1]

Co-primary endpoint, radiographic progression or death: (HR = 0.17 [95% CI, 0.14-0.21]; *P* < 0.0001)[1]

CONVENIENT DOSING[1]

Administer XTANDI as 160 mg (four 40 mg capsules) orally, once daily

Each capsule should be swallowed whole and should not be chewed, dissolved, or opened. If a patient experiences a ≥ Grade 3 toxicity or an intolerable side effect, withhold dosing for one week or until symptoms improve to ≤ Grade 2, then resume at the same or a reduced dose (120 mg or 80 mg), if warranted. For additional dosing information, see Drug Interactions and Full Prescribing Information.

Learn more about XTANDI at **StartXtandi.com**

Select Safety Information

XTANDI is not indicated for use in women. XTANDI is contraindicated in women who are or may become pregnant.

Seizure occurred in 0.9% of patients receiving XTANDI who previously received docetaxel and in 0.1% of patients who were chemotherapy-naive. Permanently discontinue XTANDI in patients who develop a seizure during treatment.

There have been post approval reports of **posterior reversible encephalopathy syndrome** (PRES), a neurological disorder which can present with rapidly evolving symptoms and requires confirmation by brain imaging. Discontinue XTANDI in patients who develop PRES.

CI, confidence interval; HR, hazard ratio; NR, not reached.
***Or after bilateral orchiectomy.[1]**
†As seen in the PREVAIL trial (Study 2): a multinational, double-blind, randomized, phase 3 trial that enrolled 1717 patients with metastatic CRPC who progressed on GnRH therapy or after bilateral orchiectomy, and who had not received prior cytotoxic chemotherapy. All patients continued on GnRH therapy.[1,2]
‡An updated survival analysis was conducted when 784 deaths were observed. The median follow-up time was 31 months. Results from this analysis were consistent with those from the prespecified interim analysis.[1]

Please see reverse for Important Safety Information and for Brief Summary of Full Prescribing Information.

Xtandi®
(enzalutamide)
40 mg capsules